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**Impact and Challenges of
Otorhinolaryngology (ORL)
Services during the COVID-19 Pandemic**

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Malaysian Medical Association
4th Floor, MMA House, 124, Jalan Pahang, 53000 Kuala Lumpur.
Tel: (03) 4042 0617, 4041 8972, 4041 1375 Fax: (03) 4041 8187
E-mail: info@mma.org.my / mjm@mma.org.my
Website: www.mma.org.my

Printed by: Digital Perspective Sdn. Bhd.
42-1, Level 1, Plaza Sinar, Taman Sri Sinar, 51200 Kuala Lumpur. Tel: 03-6272 3767
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Instructions for registration and submission are found on the website. Authors will be able to monitor the progress of their manuscript at all times via the *MJM Editorial Manager*. For authors and reviewers encountering problems with the system, an online Users' Guide and FAQs can be accessed via the "Help" option on the taskbar of the login screen.

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Original Articles are reports on findings from original unpublished research. Preference for publications will be given to high quality original research that make significant contribution to medicine. Original articles shall consist of a structured Abstract and the Main Text. The word count for the structured abstract should not exceed 500 words. The

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Articles describing Original Research should consist of the following sections (IMRAD format): Abstract, Introduction, Materials and Methods, Results, Discussion, Acknowledgment and References. Each section should begin on a fresh page. Scientific names, foreign words and Greek symbols should be in italic.

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A structured abstract is required for Original and Review Articles. It should be limited to 500 words and provided immediately after the title page. Below the abstract provide and identify three (3) to 10 key words or short phrases that will assist indexers in cross-indexing your article. Use terms from the medical subject headings (MeSH) list from Index Medicus for the key words where possible. Key words are not required for Short Communications, CME articles, Case Reports, Commentaries and Letter to Editors.

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Describe your selection of the observational or experimental subjects (patients or experimental animals, including controls) clearly, identify the methods, apparatus (manufacturer's name and address in parenthesis), and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods; provide references and brief descriptions of methods that have been published but are not well-known; describe new or substantially modified methods, give reasons for using them and evaluate their limitations.

Identify precisely all drugs and chemicals used, including generic name(s), dosage(s) and route(s) of administration. Do not use patients' names, initials or hospital numbers. Include numbers of observation and the statistical significance of the findings when appropriate.

When appropriate, particularly in the case of clinical trials, state clearly that the experimental design has received the approval of the relevant ethical committee.

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Present your results in logical sequence in the text, tables and illustrations. Do not repeat in the text all the data in the tables or illustrations, or both: emphasise or summarise only important observations in the text.

Discussion:

Emphasise the new and important aspects of the study and conclusions that follow from them. Do not repeat in detail data given in the Results section. Include in the Discussion the implications of the findings and their limitations and relate the observations to other relevant studies.

Conclusion:

Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not completely supported by your data. Avoid claiming priority and alluding to work that has not been completed. State new hypotheses when warranted, but clearly label them as such. Recommendations, when appropriate, may be included.

Acknowledgements:

Acknowledgements of general support, grants, technical assistance, etc., should be indicated. Authors are responsible for obtaining the consent of those being acknowledged.

Referencing guide:

The Medical Journal of Malaysia, follows the Vancouver numbered referencing style. Citations to someone else's work in the text, should be indicated by the use of a number. In citing more than one article in the same sentence, you will need to include the citation number for each article. A hyphen should be used to link numbers which are inclusive, and a comma used where numbers are not consecutive. The following is an example where works 1,3,4,5, have been cited in the same place in the text.

Several effective drugs are available at fairly low cost for treating patients with hypertension and reducing the risk of its sequelae.^{1,3,5}

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If you are citing the author's name in your text, you must insert the citation number as well. Jewell BL (8) underlined that as focus in the SARS-CoV-2 pandemic shifts to the emergence of new variants of concern (VOC), characterising the differences between new variants and non-VOC lineages will become increasingly important for surveillance and maintaining the effectiveness of both public health and vaccination programme. If you are citing more than one author's name in your text and you want to cite author names in your text, use 'et al.' after the first author. Example: Rampal et al. (9) highlighted that the disregard of the manuscript guidelines and instruction to authors of the journal you submit, is one of the common reasons for 'Rejection' of the article.

Example references Journals:

Standard Journal Article

Rampal L and Liew BS. Coronavirus disease (COVID-19) pandemic. *Med J Malaysia* 2020; 75(2): 95-7.

Rampal L, Liew BS, Choolani M, Ganasegeran K, Pramanick A, Vallibhakara SA, et al. Battling COVID-19 pandemic waves in six South-East Asian countries: A real-time consensus review. *Med J Malaysia* 2020; 75(6): 613-25.

NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in hypertension prevalence and progress in treatment and control from 1990 to 2019: a pooled analysis of 1201 population-representative studies with 104 million participants. *Lancet* 2021; 11; 398(10304): 957-80.

Books and Other Monographs:

Personal Author(s)

Goodman NW, Edwards MB. 2014. *Medical Writing: A Prescription for Clarity*. 4th Edition. Cambridge University Press.

Chapter in Book

McFarland D, Holland JC. Distress, adjustments, and anxiety disorders. In: Watson M, Kissane D, Editors. *Management of clinical depression and anxiety*. Oxford University Press; 2017: 1-22.

Corporate Author

World Health Organization, Geneva. 2019. WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: seventh report of a WHO study group. WHO Technical Report Series, No. 1015.

NCD Risk Factor Collaboration (NCD-RisC). Rising rural body-mass index is the main driver of the global obesity epidemic in adults. *Nature* 2019; 569: 260-64.

World Health Organization. Novel Coronavirus (2019-nCoV) Situation Report 85, April 14, 2020. [cited April 2020] Accessed from: <https://www.who.int/docs/default-source/coronavirus/situationreports/20200414-sitrep-85-covid-19>.

Online articles

Webpage: Webpage are referenced with their URL and access date, and as much other information as is available. Cited date is important as webpage can be updated and URLs change. The "cited" should contain the month and year accessed.

Ministry of Health Malaysia. Press Release: Status of preparedness and response by the ministry of health in and event of outbreak of Ebola in Malaysia 2014 [cited Dec 2014]. Available from: http://www.moh.gov.my/english.php/database_stores/store_view_page/21/437.

Other Articles:

Newspaper Article

Panirchellvum V. 'No outdoor activities if weather too hot'. *the Sun*. 2016; March 18: 9(col. 1-3).

Magazine Article

Rampal L. World No Tobacco Day 2021 - Tobacco Control in Malaysia. *Berita MMA*. 2021; May: 21-22.

Tables:

All tables and figures should have a concise title and should not occupy more than one printed page. The title should concisely and clearly explain the content of the table or figure. They should be numbered consecutively with Arabic numerals (e.g. Table 1), and placed after the sections of the manuscript which they reflect, particularly the results which they describe on separate pages. Cite tables in the text in consecutive order. Indicate table footnotes with lower-case letters in superscript font. Place the information for the footnote beneath the body of the table. If a table will be submitted as a separate document, the filename should contain the surname of the first author and match its label in the manuscript (e.g., SMITH Table 1). Vertical lines should not be used when constructing the tables. All tables and figures should also be sent in electronic format on submission of the manuscript as supplementary files through the journal management platform. Clinical Photographs should conceal the subject's identity. Tables and flow-charts should be submitted as Microsoft Word documents. Images should be submitted as separate JPEG files (minimum resolution of 300 dpi).

Photographs of Patients:

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Use only standard abbreviations. The full-term for which an abbreviation stands should precede its first use in the abstract, article text, tables, and figures, unless it is a standard unit of measurement. Abbreviations shall not be used in the Title. Abbreviations should be kept to a minimum.

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Numbers one to ten in the text are written out in words unless they are used as a unit of measurement, except in tables and figures. Use single hard-returns to separate paragraphs. Do not use tabs or indents to start a paragraph. Do not use the automated formatting of your software, such as hyphenation, endnotes, headers, or footers (especially for references). Submit the Manuscript in plain text only, removed all 'field codes' before submission. Do not include line numbers. Include only page number.

BEST PAPER AWARD

All original papers which are accepted for publication by the MJM, will be considered for the 'Best Paper Award' for the year of publication. No award will be made for any particular year if none of the submitted papers are judged to be of suitable quality.

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Challenges faced by Otorhinolaryngology (ORL) services, Malaysia, in the current pandemic

Philip Rajan, MMed(ORLHNS)

Editor, Medical Journal of Malaysia, Clinical Research Centre, Hospital Raja Permaisuri Bainun, Ipoh, Department of Otorhinolaryngology, Hospital Raja Permaisuri Bainun, Ipoh

The COVID-19 pandemic marked a turning point in almost all fields and in how we conduct, our otherwise, routine activities from the workplace and from our homes. It is not an exaggeration to say that the medical fraternity bore the brunt of carrying the additional burden of dealing directly with COVID-19 infected patients whilst maintaining high standards of service.

The first reported case of COVID-19 in Malaysia was on the 25th of January 2020.¹ As cases began increasing, the Malaysian government introduced a movement control order (MCO) for two weeks from 18 – 31st March 2020, when the total number of cases reached 790.^{1,2} Patients with COVID-19 were managed in designated hospitals throughout Malaysia which had intensive care unit (ICU) facilities. Undeniably, a big challenge was the continued provision of the on-going care to non-COVID-19 patients with other medical conditions. In many instances elective surgical admissions had to give way for emergency and semi-urgent cases. As COVID-19 cases kept increasing, on the 2nd of October 2020, Hospital Sungai Buloh was declared a dedicated hospital to the care of COVID-19 patients.³ Doctors and personnel from all clinical departments, including those from Otorhinolaryngology (ORL) services, were recruited to be part of the COVID-19 patient management teams. Other hospitals with specialty services, termed 'hybrid hospitals' provided dedicated COVID-19 care alongside other specialty services.⁴ Guidelines were issued by the Ministry of Health, Malaysia on otorhinolaryngology (ORL) service provision during this period including specific guidelines for tracheostomy, which is an aerosol generating procedure.^{5,6} New methods and approaches in providing patient care such as telemedicine was explored. Outpatient clinic services were restructured to comply with standard operating procedures (SOP). Travel restrictions made it difficult for patients to access certain centralised services, such as radiotherapy in the Ministry of Health, Malaysia. Outsourcing to private centres was opted for in areas where such services were available.

Although initially a quick solution to the pandemic was hoped for, it became evident that this battle with the unseen enemy would be a more protracted and challenging process. On the 11th of January 2021, the then Prime Minister of Malaysia, Tan Sri Muhyiddin Yasin announced the re-introduction of the MCO from 13 – 26th January for selected states.⁷ The number of new COVID-19 cases surpassed 3000 cases per day during this period.⁸

On the 28th of May, the Prime Minister announced a stricter nationwide restrictions or total lockdown from 1st June to 14th June 2021 due to rising daily cases of COVID-19 above 8000 cases per day.⁹ The third MCO has seen the highest surge of COVID-19 cases in Malaysia and pushed the healthcare capacity of the nation to its limits. The highest number of new cases recorded per day was on the 26th of August 2021 with 24599 cases.¹⁰ The majority of cases were in the greater Klang Valley. More public government hospitals were converted to full COVID-19 hospitals.¹¹ Hospital Ampang and Hospital Selayang was also converted to full COVID-19 hospitals on the 23rd of June and 21st of July respectively.^{12,13} Thus, routine ORL service and elective surgical care was affected in both these hospitals. Patients requiring specialist care were decanted to other government facilities, university hospitals or private hospitals.¹⁴

An additional problem that emerged was the training and teaching of junior doctors. Direct face to face teaching was often not practical due to need of safe social distancing, space and travel restrictions and minimising overcrowding. Online platforms such as zoom were and are being used extensively for teaching, webinars and even conferences.

The number and breadth of surgical cases were also reduced thus resulting in trainees not being able to achieve the required practical experience needed. To minimise the risks of virus transmission, operation theatres also restricted the number of personnel to the minimal need and necessity. Thus, even opportunities for trainees to observe surgical procedures was lost. The conduct of the Conjoint Master's in ORL examinations was another area of needing much adaptation and innovation. The first examination during the pandemic scheduled for May 2020 was postponed to November 2020. For the first time, the exam was decentralised. The written examination was held on the 2nd of November 2020 followed by the clinical exams at the respective universities. The clinical exams were conducted in a hybrid mode where the examiners were present in both physical and online mode. This was to reduce the number of persons within the confines of a clinic and to comply with the national SOP's. Examination candidates were required to wear full personal protective equipment during the clinical sessions. Two final exam diets have successfully been conducted thus far, in November 2020 and May 2021. The intake into the four-year Master's programme was also affected during the 3rd MCO as many medical officers were required to alleviate the manpower constraints faced by

medical teams managing the ever increasing Covid patients and to support the vaccination centres. The academic intake for the year 2021/22 for ORL was postponed from June 2021 to December 2021.¹⁵

The paucity of elective surgical cases also had repercussions on gazettelement of ORL specialists in the Ministry of Health of Malaysia. For specialists unable to fulfil logbook requirements in the stipulated six months, an extension period of three months was allowed.

Every challenge brings an opportunity to improve and innovate. This special issue of the Malaysian Medical Journal describes how the ORL fraternity in Malaysia and elsewhere, dealt with this pandemic thus far. The solutions advocated by the authors in these articles in this special issue are not final. Changes, evolution and innovation will continue to take place. And one day, as we emerge from this pandemic, perhaps, we will look back on our success, achievements and progress rather than our losses and temporary setbacks.

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A preliminary study of the original TIBSIT and its cultural adaptation in Malaysia

Kevin Suresh Doshi, Ms (ORL-Head & Neck Surg)¹, Revadi Govindaraju, Ms (ORL-Head & Neck Surg)¹, Mahmoud Danaee, PhD², Tengku Ahmad Shahrizal, Ms (ORL-Head & Neck Surg)¹, Prepageran Narayanan, FRCS¹

¹Department of Otorhinolaryngology, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia, ²Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia

ABSTRACT

Background: A simple and self-administered 'scratch & sniff' test kit like the TIBSIT smell kit based on the Taiwan Smell Identification Test (TWSIT), provides a safe and quick assessment of olfaction. The original TIBSIT has been validated for use in Taiwan with age specific scores for different age groups and diagnosis. The main aim of this study is to examine if TIBSIT can be applicable for the Malaysian population and perform cultural adaptation as necessary to allow a more accurate assessment using this tool.

Method and Material: A preliminary study of the original TIBSIT (Phase 1) followed by cultural adaption (Phase 2) were carried out on volunteers from various neighbourhoods in Klang Valley, Malaysia comprising of age group 16-80 years. A total of 150 test subjects and 50 test subjects were recruited for Phase 1 and Phase 2 respectively. Cultural adaptation was done with changes to the distractors that were found to be confusing. In addition, modifications included added language translation and visual reinforcement with images of the odour's substance of origin.

Results: 109 out of the 150 responses were accepted for Phase 1. A detection rate of less than 75% was found in three of the odours with the remaining showing an average rate of 87.2% to 97.7%. These three odours were culturally adapted for Phase 2. All 50 responses for Phase 2 were accepted; two of the odours' detection rates improved to 98% but the plum odour was only detected 53% of the time.

Conclusion: TIBSIT provides a quick office-based olfaction testing. The culturally adapted test kit is a potentially useful screening test for the Malaysian population. It is also safe and excludes the need of the clinician to carry out the test. This becomes especially useful in testing any dysosmia (hyposmia/anosmia) cases suspected of SARS-COV-2 virus infection (COVID-19).

KEYWORDS:

Smell test kit, scratch and smell test, anosmia, hyposmia, olfactory dysfunction, olfactory psychophysical test, COVID-19

INTRODUCTION

The sense of smell or olfaction is one of the five basic senses of human being. Smell provides enjoyment of scents and

influences taste of food. It can give information about the surrounding, and act to protect such as warn us of nearby danger/smoke/toxic fumes. Any alteration to it, temporary or permanent, will disrupt the quality of life and can lead to psycho-emotional stress.¹

Olfaction disorders are sometimes overridden by disorders of the other senses like vision and hearing. They can be underdiagnosed by the clinician or not even perceived as an important symptom needing to report by the patient. There are numerous causes that may give rise to dysosmia, and with the pandemic occurrence of SARS-COV-2 virus (COVID-19) as one causative agent, it becomes more relevant to give importance to olfactory testing. However, it is well accepted that smell perception and identification is culturally different and relates closely to memory and familiarity. A reliable test should take into account this important factor apart from being reproducible.

Commercially popular smell test kits such as Sniffin' Sticks and University of Pennsylvania Smell Test (UPSIT) developed in Europe and America are well established psychophysical smell assessment.^{2,3} Both tests have undergone cultural adaption in several countries followed by normative data collection for the specific population to validate its use. The results of validation studies have shown gender and age variations for a healthy population and different cut-off points to differentiate normosmia from hyposmia and anosmia.³ However, in Malaysia, such data is not yet available at our disposal for a routine use, though the cultural adaption for the Sniffin' Sticks has been performed by a team from another institution and by the authors institution.⁴

The Top International Biotech Smell Identification Test (TIBSIT) test kit/booklet is a self-administered 'scratch and sniff' smell test kit from Taiwan. It is a rebranded version of the Taiwan smell identification test (TWSIT) which uses amber jars containing the liquid odorants.⁵ TIBSIT is a sealed booklet questionnaire that has embedded fragrant microcapsule on individual pages.

As the COVID-19 pandemic evolved and dysosmia (anosmia/hyposmia) was recognized as one of the early symptoms, smell testing became important.⁶ However, due to the transmission mode of the infection with SARS-COV-2, administering a face-to-face test that is also time-consuming such as Sniffin' Sticks may not be feasible. A self-

Corresponding Author: Revadi Govindaraju
Email: revadi@um.edu.my

administered test would be the preferred option, and therefore the objective of this study was to validate this new kit. As it was developed in an Asian country it would be suitable as most odorants if not all are likely to be familiar to Malaysians. The original TIBSIT has been validated for use in Taiwan with age specific scores for different age groups and diagnosis.⁷ We study the applicability of the original TIBSIT test kit and after being culturally adapted for the Malaysian population, for the objective assessment of smell deficits.

MATERIAL AND METHODS

A cross sectional study of asymptomatic volunteers from various neighbourhoods of the Klang Valley, Malaysia was conducted from July 2020 to April 2021. A convenient sampling of the general public was the chosen method, comprising from the age group of 16 to 80 years.

The inclusion criteria for the purpose of this study were Malaysian citizens aged 16 years and above, with no reported smell impairment and excluded any subjects with perceived smell disturbances of any cause, recent upper respiratory tract infections and any other known nasal or skull base or intracranial diseases. An informed consent was obtained from all participants for a voluntary participation with no monetary incentive or otherwise offered in exchange.

Top International Biotech Smell Identification Test (TIBSIT)

The TIBSIT test kit (International Biotech Co., Ltd., Taipei, Taiwan) consist of a 16 page odour booklet and a questionnaire at the back of the booklet. The first eight odorants in question 1-8 (1st part) are the same as questions 9-16 (2nd part) but in a different order. Each page has one "scratch-and-sniff" blue strip. The fragrant microcapsule is made of melamine, formaldehyde and fragrant oil by condensation polymerization. This process prevents the fragrant oil from evaporating and thereby allowing storage for two years.⁷

After a brief explanation on the test, each test subject is then asked to perform the test without any assistance by the medical personnel by simply scratching onto a blue rectangle area consisting the fragrant microcapsules with a pencil and smelling the fragrance released from the microcapsule. As best as possible, the test is carried out in a well ventilated room. The subject is asked to refrain from ingesting any solid foods or liquid prior and during the test. This includes chewing gum and smoking cigarettes. There is no time limit for the test, only a one minute compulsory break included between 1st part and 2nd part of the questionnaire. During this 1 minute break, the test subject is asked to shade or blacken a small rectangular box (6cm x 3.5cm) found after odour number eight.

After the subject sniffs an odour, they answer the corresponding questions to identify and rate its detectability. Each main question thus contains two sub-questions, namely part A and part B. Part A is a four-choice odour identification question where the subject needs to select one of the given options. Part B is a three-item question, "not detectable" meaning one can smell nothing at all, "detectable, but not sure" meaning one can smell something but unsure of the

smell, and "detectable" meaning one can smell and know exactly what smell it is. All test subjects are reminded prior to starting, to attempt to answer all the questions, even if they fail to detect anything.

Scoring of TIBSIT

When completed, the TIBSIT booklet is collected and a specified scoring system is applied to each response given by the test subject. For part A, the scoring system gives one (1) point for each correctly identified odour and zero (0) if identified wrongly. For part B, the scoring system gives zero (0) points for "not detectable" and one (1) point for "detectable, but not sure". For part B, the scoring system gives two (2) points for "detectable" provided the odour is correctly identified in Part A. If however, the odour is incorrectly identified in Part A, then "detectable" in part B gets zero(0) points. Thus, for each odour tested, the combined score can range from zero (0) to three (3). As such, the maximum point attainable for each completed test kit is 48 points.

Phase 1-Original TIBSIT

A total of 150 test subjects were recruited for this Phase 1. The objective of this exercise was check the feasibility of the using the original TIBSIT test kit for the sample population. The tests were conducted and scored in the same manner as detailed above. The language options available were Mandarin and English, as per the original test kit.

Phase 2-Cultural adaptation of TIBSIT (mTIBSIT)

A total of 50 test subjects were recruited for this Phase 2, again following the inclusion criteria. This limitation of sample size was due to availability of smell kit. The cultural adaptation was carried out to address the odour(s) that gave an identification rate of less than 75% in Phase 1 of the study. Although the odours remained the same within the tests, the distractors were changed to aid in better disparity to the particular odour tested. In addition, visual reinforcement of the odour's substance of origin was shown for each question. Language translation to Bahasa Malaysia (primary language of Malaysia), was given together with the English language.

Statistical analysis

SPSS Version 27 was used for analysis. Descriptive analysis was done for the demographic data. Specific odour detection rate (frequency) was analysed for TIBSIT and mTIBSIT. The two-time odour identification and the combined scores for each odour was analysed using cross tabulation and tested for internal consistency (ICC) for both TIBSIT and mTIBSIT.

RESULTS

The demographic details are available in Table I for both Phase 1 and 2 of the study. Mean age of participants were 38.03 ± 13.598 for the original TIBSIT group and 40.42 ± 11.741 for the mTIBSIT group, with a female preponderance in the original TIBSIT group.

Phase 1-Original TIBSIT

Out of the 150 samples, only 109 were included for the data analysis (22 failed to return the completed smell kit and 19 subjects gave incomplete answers).

Table I: Participant characteristics for both the study of the original TIBSIT and post-cultural adaptation (mTIBSIT)

Participant characteristics	Original TIBSIT	mTIBSIT
Number of participants	109	50
Age (years), (mean ± SD)	16-80 (38.03 ± 13.598)	20-76 (40.42 ± 11.741)
Gender (F, M)	n=70,39; 64.2 %, 35.8 %	n=21,29; 42%, 58%
Smoking status (Y, N)	n=9,109 ;8.3%,91.7%	n=2,48; 4%, 96%

Table II: Percentage detection rate for the odour in the TIBSIT study

Odour ID	Original TIBSIT (n=109)		mTIBSIT (n=50)	
	Percentage detection rate (test, retest)	Average detection rate	Percentage detection rate (test, retest)	Average detection rate
Honey peach	89.0%, 85.3%	87.2%	90.0%, 94.0%	92.0%
Passion fruit	92.7%, 89.9%	91.3%	96.0%, 96.0%	96.0%
Cantaloupe	70.6%, 54.1%	62.4%	98.0%, 98.0%	98.0%
Lemon	72.5%, 80.7%	76.6%	98.0%, 98.0%	98.0%
Plum	56.9%, 65.1%	61.0%	54.0%, 52.0%	53.0%
Coffee	90.8%, 92.7%	91.8%	94.0%, 92.0%	93.5%
Jasmine	94.5%, 94.5%	94.5%	98.0%, 96.0%	97.0%
Garlic	98.2%, 97.2%	97.7%	100.0%, 100.0%	100.0%

Table III: Results of test -retest reliability (ICC) for repeat identification of odours and also the combined score in the original TIBSIT and post-cultural adaptation

	Original TIBSIT				mTIBSIT			
	OID answers (Crosstab)		OID* (Part A)	Combined scores* (Part A + B)	OID answers (Crosstab)		OID* (Part A)	Combined scores* (Part A + B)
	Correct both times	Wrong both times			Correct both times	Wrong both times		
Honey Peach	79.8%	5.5%	.517	.568	88.0%	4.0%	.634	.621
Passion fruit	88.1%	5.5%	.750	.728	92.4%	0.0%	NA	.589
Cantaloupe	48.6%	23.9%	.626	.733	96.0%	0.0%	NA	.339
Lemon	66.1%	12.8%	.596	.622	96.0%	0.0%	NA	.465
Plum	49.5%	27.5%	.692	.812	42.0%	36.0%	.717	.666
Coffee	87.2%	3.7%	.567	.702	88.0%	2.0%	.379	.254
Jasmine	90.8%	0.9%	.244	.297	96.0%	2.0%	.797	.964
Garlic	97.2%	1.8%	.887	.892	100%	0.0%	NA	NA

OID: Odour identification;
 Crosstab: Cross tabulation analysis
 * ICC

NA: Due to low variability between test and retest

Three odours were noted to have less than 75% detection rate at least once within the same test during the study and therefore underwent change of the distractors for the subsequent Phase 2 study. The rest of the odours had a detection rate ranging from an average of 87.2% to 97.7% (Table II).

Phase 2-Cultural adaptation of TIBSIT (mTIBSIT)

Distractors were changed once for Question 3A (honey peach changed to durian) & Question 4A (garlic changed to coconut). Distractors for Question 5A & 15A were changed 3 times as the following description: 1st (jasmine changed to black tea; honey peach to gasoline & mango changed to rose), 2nd (jasmine was changed to coffee), 3rd (jasmine was changed to screw pine leave: honey peach changed to kaffir lime & mango changed to durian). This improved the detection rate for both cantaloupe (98%) and lemon (98%), however the detection rate for plum remained poor at an

average of 53% (Table II). The distractors were mainly changed based on a 70-item odour familiarity survey done on 98 participants for a previous study involving Sniffin' Stick test in authors' institution [unpublished data].

The internal consistency for repeat detection of the same odour and detectability within the same test showed acceptable agreement for all odours except Jasmine in the original TIBSIT study. This occurred despite a consistently correct answers obtained both times in 90.8% of subjects. In the Phase 2 of the study, the agreement was similarly seen for test odours, but coffee showed lowered consistency for this sample even though the consistency in detection was almost like the Phase 1 (Table III).

Overall the total score also showed improvement with improved detectability of the odours after cultural adaptation. Total score ranged from 15-48 (Mean 38.36 ± SD

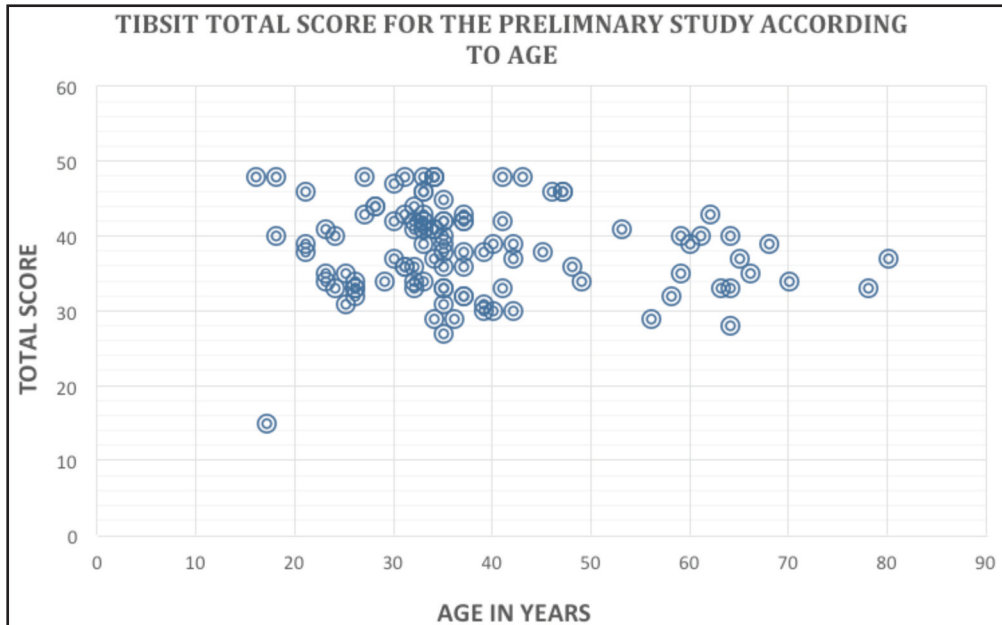


Fig. 1: Total score for the TIBSIT test for each participant in the preliminary study according to the age.

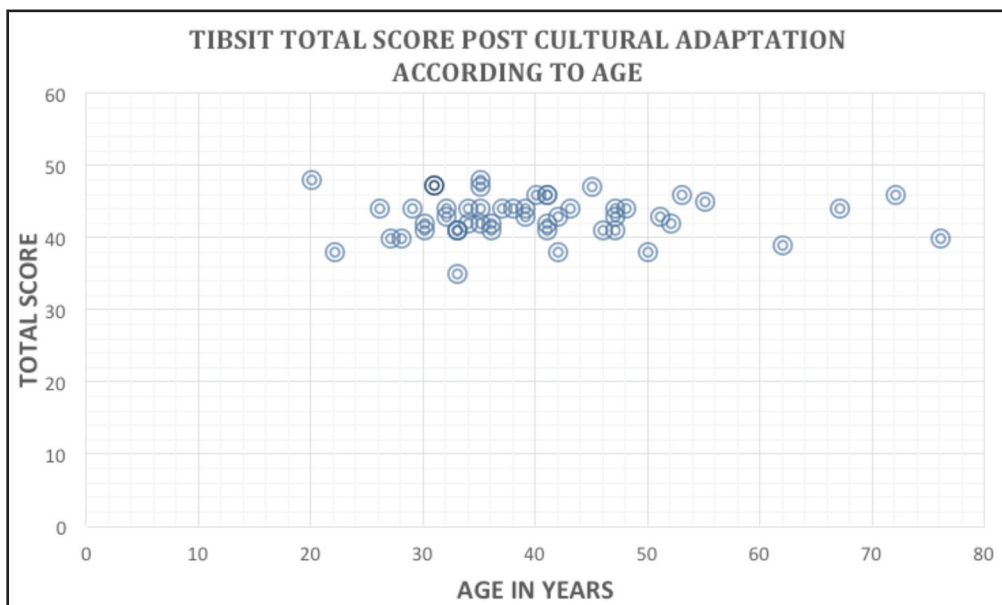


Fig. 2: Total score for the TIBSIT test for each participant post-cultural adaptation according to the age.

5.996) for the original TIBSIT and 35-48(Mean 42.86± SD 2.777) post cultural adaptation (Fig. 1& Fig. 2). Age or gender specific scores were not analysed in this preliminary study.

DISCUSSION

This new smell kit is a self-administered scratch and smell identification test with forced choice answers like the UPSIT but with fewer odorants tested (n=8 versus 40).¹ In contrast, the Sniffin’ Sticks test includes assessment of all 3 components of olfaction; threshold, discrimination and

identification of odors using felt-tipped pens delivering the odour and is administered by a physician.³

There are also several other self-administered smell identification tests developed in the Europe and America that mainly vary in the number of odours tested such as the Smell Diskettes olfaction test (8 odours with visual reinforcement), Cross-Cultural Smell Identification Test (12-item version of UPSIT), 8-items Sensonics Smell Test, 4-items pocket smell test and Q-SIT (3-item smell identification test, not strictly forced choice).^{1,8,9} However, none have a culturally adapted data for Malaysians.

TIBSIT additionally has add-on item (Part B) that also assesses the subjective sensations of the odour irrespective of the familiarity of the odours. Therefore, a patient can indicate if no smell is perceived for the odour tested. The scoring system allows identifying this condition as anosmia and suspect a potential malingerer based on the subjects answer for the smell identification in Part A. Garlic has a pungent trigeminal stimulating odour which may still be detected by a person with olfactory disturbance.⁵ The scoring system is such that the probability of a genuine patient scoring all 0 for identification is low but this could happen if the person is malingering. Therefore, it could serve as a ground for suspecting the condition.

In contrast to other commercially available test, the test odours are also repeated in different sequence within the same booklet to retest the subjects for consistency in their answers.

This new smell kit has shown similar requirement for cultural adaptation despite being produced in another Asian country. The detection rate was good for most odours though the lemon oil was strangely confused with garlic. Removing garlic as a distractor immediately improved the detection rate to 98%. Cantaloupe has a distinct smell, but this too was confused with honey peach requiring the change of the distractor, eventually improving the detection rate to 98%. This is perhaps also contributed by the Malay language translation and visual reinforcement with images of the substance of origin.

However, the plum, though easily available and consumed by many urban Malaysians, showed poor detectability in this study. Despite changing the distractors 3 times, the detection rate was poor. This is perhaps due to the indistinct smell of raw plum. The new distractors used for the plum odour were common local food items with peculiar and distinguishable smell such the screw pine leaf (pandan), kaffir lime and durian. Despite that, about the half the participants struggled to choose the right answer.

The scratch and sniff test are new in the Malaysian setting. The test uses forced choice answers. In the event of non-familiarity of the scent, this sort of test also evaluates the ability to eliminate the impossible choices and thereafter choose a likely answer. Our observation noted that many participants were forcing themselves to choose the most likely familiar smell instead.

The Part B of the test requires a response if a smell was detectable, detectable but the participants are unsure of the smell and lastly if no smell is detected as in the case of anosmia. The second observation that we noted is that several participants (n=19) completely missed answering the Part B if all odours were familiar to them (their data was removed from analysis). In another set of subjects, detectability was equated with getting the answer correct. In this group of subjects, if the smell was not familiar then it was scored as non-detectable instead of detectable but unsure. Therefore, this affected the overall score.

However, this confusion was resolved with better instructions given out in the print form in both the Malay and English language. This is reflected in the improved mean total score of the test in Phase 2.

Test-retest are often done with longer intervals of days to weeks, however, we restricted to the 1-minute interval as instructed by the original investigator. Using this time frame, there was an acceptable agreement between test and retest values for the same odours.

Taking all the above factors into account, familiarity and answering attitudes, most likely the plum odour may need replacement in future booklets to achieve a better total score.

The limitation of this study is the availability of the samples of the smell kit thereby limiting the sample size for a more robust validation study. This includes a process of validation study that includes a formal forward and backward translation process, inclusion of population who have smell disturbances and test-retest reliability of the entire test. A further detailed study of a validated kit would allow data collection for a Malaysian normative value according to the age and gender.

CONCLUSION

TIBSIT provides a quick office-based olfaction testing. In the absence of other available equivalent test, the culturally adapted test kit is a potentially useful screening test for the Malaysian population. It is also safe and excludes the need of the clinician to carry out the test. This becomes especially useful in testing any dysosmia (hyposmia/anosmia) cases suspected of SARS-COV-2 virus infection. Further modification may be necessary to substitute the plum to a more locally familiar scent, to increase detection rate and finally to enable a normative data to be established for the Malaysian population.

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CONFLICTS OF INTEREST

The original TIBSIT copies in Mandarin and English languages were provided by UMMI Surgical Sdn. Bhd. as free samples for the study. This sponsor source had otherwise no role in the design of this study, its execution, analyses, interpretation of the data, or decision to submit results. The authors have no other conflicts of interest to declare.

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Implementing a COVID-19 specialist smell clinic: experience at the Wrightington, Wigan and Leigh Teaching Hospitals (WWL), NHS Foundation Trust, United Kingdom

Michael MH Chu, MRCS (ENT)¹, Darmeena Gopikrishna, MBChB¹, John PJ Rocke, MRCS (ENT)^{1,2}, B Nirmal Kumar, FRCS¹

¹Department of Otolaryngology, Teaching Hospitals, UK, ²ENT Specialist Registrar, Health Education England North West

ABSTRACT

Introduction: It is clear that a proportion of patients continue to suffer long-lasting symptoms following acute infection with coronavirus disease 2019 (COVID-19). Persistent olfactory dysfunction is one of the commonest complaints reported in the condition colloquially known as long COVID (now known as post-acute sequelae of SARS-CoV-2 infection (PASC)). The prevalence, risk factors and clinical course of long COVID olfactory dysfunction are not yet well understood. At present, the main stay of treatment is olfactory training. Quantitative olfactory testing and impacts on patient quality of life have not been widely studied. This study describes our experiences at Wrightington, Wigan and Leigh Teaching Hospitals, UK (WWL) of establishing a COVID-19 smell clinic, along with preliminary data on patient demographics, baseline smell test scores and quality of life questionnaire scores before olfactory training.

Methods: We piloted a COVID-19 smell clinic. We recorded patient demographics and clinical characteristics then performed clinical assessment of each patient. Quantitative measurements of olfactory dysfunction were recorded using the University of Pennsylvania Smell Identification Test (UPSIT). We measured the impact of olfactory dysfunction on patient quality of life using the validated English Olfactory Disorders Questionnaire (eODQ).

Results: 20 patients participated in the clinic. 4 patients were excluded from analysis due to missing data. Median age was 35 years. 81% (n=13) of the participants were female. 50% (n=8) of patients suffered with a combination of anosmia/ageusia and parosmia, whilst 43% (n=7) of patients suffered with anosmia/ageusia without parosmia. Almost all the patients registered UPSIT scores in keeping with impaired olfaction. Patient scores ranged from 22 to 35, with the median score at 30. All patients reported that their olfactory dysfunction had an impact on their quality of life. The median eODQ score reported was 90, with scores ranging from 42 to 169 out of a maximum of 180.

Conclusion: We have demonstrated that it is simple and feasible to set up a COVID-19 smell clinic. The materials are inexpensive, but supervised completion of the UPSIT and eODQ is time-consuming. Patients demonstrate reduced olfaction on quantitative testing and experience significant impacts on their quality of life as a result. More research is needed to demonstrate if olfactory training results in

measurable improvements in smell test scores and quality of life.

KEYWORDS:

Anosmia; parosmia; olfactory dysfunction; COVID-19; long COVID; post-acute COVID-19 syndrome; post-acute sequelae of SARS-CoV-2 infection; olfactory training; smell training; UPSIT

INTRODUCTION

As of March 12th 2021, there have been over 118 million cases of coronavirus disease 2019 (COVID-19), with over 2.6 million confirmed deaths worldwide.¹ At the start of the pandemic ENT United Kingdom (UK) highlighted to the world that loss of smell was a symptom of COVID-19 infection.² Loss of smell and taste is now recognised as one of the main symptoms of acute COVID-19 infection, affecting approximately 65-70% of patients.^{3,5} The majority recover their sense of taste or smell spontaneously. However, in a survey of UK healthcare workers with COVID-19, almost half of the participants had persistent loss of sense of smell/taste 4 weeks after symptom onset.⁶ This dysfunction can manifest quantitatively or qualitatively. Quantitative dysfunction implies a reduction in smell (hyposmia or microsmia), absence of smell (anosmia) or absence in taste (ageusia). Qualitative dysfunction implies abnormal perception of odours (parosmia), a perception of odour that is not present (phantosmia) or abnormal taste perception (dysgeusia).⁴ In addition, patients may also experience chemesthesis, a perception of abnormal sensations in the nose or mouth such as burning or tingling.⁶

It is now clear that many patients continue to exhibit symptoms of COVID-19 long after the acute infection. Multiple terms have been used to describe this syndrome whereby symptoms persist. The terms 'long COVID' and, more recently, 'post-acute COVID-19 syndrome', have been used interchangeably to describe the persistence of symptoms beyond 4 weeks of onset of COVID-19 infection.⁷ This has been further subdivided: patients experiencing symptoms 4-12 weeks after acute infection are categorised as 'ongoing symptomatic COVID-19'. Those with symptoms beyond 12 weeks from acute infection are categorised as 'post-COVID-19' syndrome or 'chronic COVID'.⁷ The National Institutes of Health in the US have recently advocated for the use of the term 'post-acute sequelae of SARS-CoV-2 infection (PASC) to encompass all the aforementioned terms.⁸ The UK Office for

Corresponding Author: Professor B Nirmal Kumar
Email: nirmalkumar@doctors.org.uk

National Statistics reports that 1 in 10 patients continue to exhibit symptoms after 12 weeks following a positive test result.⁹ The true scale of disease burden of COVID associated olfactory dysfunction is beginning to emerge. Hopkins et al have recently completed a 6-month follow-up survey on patients with self-reported smell loss during the pandemic. They estimate that potentially more than 1 million patients worldwide may be suffering with ongoing olfactory dysfunction six months after acute infection.³ Another large study demonstrated that loss of smell is the third most commonly reported symptom in PASC.¹⁰ Olfactory disorders cause noticeable reductions in quality of life and increased rates of depression.¹¹ In addition, patients may no longer be able to detect harmful odours such as spoiled food, gas or smoke. Patients who rely on smell for their occupation may face unemployment. At present, there is a dearth of research regarding the clinical course and potential for recovery from persistent olfactory dysfunction after COVID-19 infection.

Currently, the mainstay of treatment for COVID associated olfactory dysfunction is smell training. The rationale for this has been extrapolated from pre-COVID-19 studies. A systematic review and meta-analysis in 2016 demonstrated how olfactory training was efficacious in treating olfactory dysfunction of multiple aetiologies.¹²

In this paper, we describe our experiences of setting up a COVID anosmia clinic in the UK. We have piloted our service whereby patients undergo clinical assessment and quantitative testing of olfactory dysfunction through psychophysical smell testing. In addition, a validated questionnaire was used to assess the impact of olfactory dysfunction on patient quality of life. Patients were then counselled and initiated on olfactory training. We explain here the logistics of running the clinic and demonstrate its feasibility.

MATERIALS AND METHODS

We piloted an outpatient COVID smell clinic at Wrightington, Wigan and Leigh (WWL) NHS Foundation Trust. Our Trust consists of three district general hospital sites in addition to satellite outpatient clinic facilities. The clinic started in September 2020 after the first wave of the pandemic. It ran once a week, with capacity for four face-to-face appointments. The clinic was led by one ENT consultant and supported by an ENT registrar and an ENT specialist nurse.

Members of staff at our NHS Trust were invited by email to attend a multidisciplinary long COVID clinic if they were suffering with persistent symptoms following COVID-19 infection. The multidisciplinary long COVID clinic was led by one consultant respiratory physician and one rehabilitation medicine consultant. From here, patients with loss of sense of smell or taste were referred to our COVID smell clinic. In addition, we invited referrals directly to the COVID smell clinic from primary care. We accepted 20 patients who had satisfied the criteria detailed in the ENT UK / British Rhinological Society (BRS) COVID anosmia management guideline.¹³ Patients with history of COVID-19 infection confirmed through polymerase chain reaction (PCR) testing

or SARS-CoV-2 spike protein antibody testing were eligible. Given lack of availability of COVID-19 testing early in the first wave, patients with a convincing history of COVID-19 symptoms but without a confirmatory positive test were also eligible. We accepted patients with persistent loss of smell and taste and/or altered smell and taste for greater than three months. Patient occupation, demographics, PCR test history and antibody status were recorded. A clinical history of olfactory dysfunction was taken and the presence of qualitative olfactory dysfunction such as parosmia and phantosmia was recorded. Patients with a history of head trauma, associated neurological symptoms or anosmia secondary to nasal obstruction were excluded.

Baseline olfactory dysfunction was quantified using the validated University of Pennsylvania Smell Identification Test (UPSIT) at the first clinic appointment.¹⁴ The UPSIT is a psychophysical olfactory test, which consists of four 10-page booklets which has been previously validated in the UK population.¹⁵ Each page carries a different odour which is released when the page is scratched. For each page, patients must choose the correct answer from four options. No formal gustatory testing was performed. The impact of loss of smell and/or taste on the patient's quality of life was measured using the validated English Olfactory Disorders Questionnaire (eODQ).¹⁶ The ENT specialist nurse supervised the completion of the UPSIT and the eODQ with the patient. The patients were subsequently reviewed by an ENT clinician. A clinical history was taken to rule out other causes of olfactory dysfunction. An ENT examination including anterior rhinoscopy was performed, and flexible nasendoscopy was performed to rule out other pathology if indicated.

Patients were then counselled on how to perform smell training. They were supplied with perfume testing sticks and a pack of 4 essential oils – rose, lemon, clove and eucalyptus. Patients were advised to gently smell each oil twice a day for 4 months. Strict adherence to smell training was advised. Patients were given information leaflets and directed to online resources by the charities abScent¹⁶ and Fifth Sense¹⁸ for further information. The patients are due to be followed up four months after initial consultation. Repeat UPSIT and eODQ will be recorded to assess for change following smell training and advice.

RESULTS

Sixteen patients were analysed (four patients were excluded due to missing data). Patient age ranged from 20 to 55 years, with the median age being 35 years. 81% (n=13) of the participants were female. All participants were British Caucasian. 56% (n=9) of the patients were healthcare workers, which comprised of two doctors, six nurses and one occupational therapist.

Five patients (31%) received a COVID PCR test at the time of symptom onset. Three patients (19%) received a positive PCR test. 63% (n=10) of patients had SARS-CoV-2 spike protein antibody testing after symptom onset. Of those who received antibody testing, 91% (10 of 11) of patients were seropositive for SARS-CoV-2 spike protein antibodies.

Four patients (25%) reported olfactory dysfunction as their only symptom of acute COVID-19 infection. Eight of the patients (50%) suffered with a combination of anosmia/ageusia and parosmia, whilst 43% (n=7) of patients suffered with anosmia/ageusia without parosmia. One patient reported isolated parosmia with no subjective loss of smell/taste. Coffee was the most common odour which patients had lost the ability to smell (n=3).

Eight (50%) patients reported associated rhinological symptoms: three patients suffered nasal obstruction, two complained of rhinorrhoea, two experienced itchiness and sneezing and one reported unilateral orbital pain.

Almost all the patients registered UPSIT scores in keeping with impaired olfaction. The normative UPSIT data suggests normal olfaction if scores were greater than 34 in males and 35 in females. Our patient scores ranged from 22 to 35, with the median score of 30.

All patients reported that olfactory dysfunction had an impact on their quality of life. The median eODQ score reported was 90, with scores ranging from 42 to 169 out of a maximum of 180 (the higher the score, the greater the negative impact). Patients suffering with parosmia had comparable eODQ scores (median score = 89) compared to those with smell/taste loss alone (median score = 92).

DISCUSSION

Here we describe our experiences setting up a COVID smell clinic. We found that there is significant demand for the service, with many patients still awaiting review. The materials for UPSIT testing and essential oils for smell training can be easily purchased and the eODQ is freely available online.¹⁸

Not surprisingly, we have seen a significant number of healthcare workers in our clinic. At first, referrals to the multidisciplinary long COVID clinic were prioritised for members of staff at our institution as a pilot for the service. It remains to be seen whether healthcare workers represent the majority of patients attending the clinic once we begin to review more patients referred from primary care.

The majority of patients in our cohort were female. This is comparable to other studies which have suggested a female preponderance for olfactory dysfunction associated with COVID-19.^{6,20} Women were 2.5 times more likely to have ongoing loss of smell after 4-6 weeks following acute infection.²¹ It has also been shown that women are more likely to suffer from PASC more generally.¹⁰ Loss of smell was the third most common PASC symptom after fatigue, headache and dyspnoea.¹⁰

Only 19% of our cohort had a confirmed positive COVID PCR test. This may reflect a lack of test availability early during the first wave of the pandemic in the UK. The UK Department of Health only recognised anosmia as an official COVID-19 symptom from May 2020.²² Patients presenting with anosmia alone would not have been eligible for PCR testing prior to

this. 63% of our patients were seropositive for SARS-CoV-2 spike protein antibodies. A recent UK cohort study showed that seropositive patients with acute loss of smell were much less likely to recover their smell after 4-6 weeks compared to seronegative patients.²¹

Parosmia is a symptom that appears to have been overlooked early in the pandemic. A large international survey was conducted early in the first wave in April 2020. They reported only 7% of patients with COVID-19 experienced parosmia.²⁰ A more recent survey of patients with self-reported smell loss after COVID-19 infection demonstrated that 43% of patients experienced parosmia, typically within 2.5 months of onset of anosmia.³ It has been suggested that parosmia is a poor prognostic marker for smell recovery, which could explain why more than half of the patients in our COVID smell clinic reported parosmia or phantosmia.²¹ In contrast, a recent retrospective study suggests parosmia is associated with olfactory recovery following smell training in non-COVID post-infectious olfactory dysfunction.²³ Liu et al postulate that parosmia may represent processing of incomplete afferent sensory information. Smell training helps to improve the cognitive processing of this sensory information, thus leading to improved olfactory outcomes.²³ More research is required to clarify the significance of parosmia in the prognosis of smell recovery following COVID associated olfactory dysfunction.

In this pilot study we used the UPSIT score as a baseline score of olfactory dysfunction, with the aim to monitor for improvements in olfaction following smell training. A study of 50 UK participants with smell loss after COVID-19 recorded a mean UPSIT scores of 29.1, comparable to the median UPSIT score of 30 in our cohort.²¹ There is evidence to suggest that more severe smell loss detected on baseline psychophysical testing was strongly predictive of persistent smell loss.²⁴ This suggests that patients with severe olfactory dysfunction as demonstrated by low UPSIT scores should be carefully counselled about the potential for long term smell loss. Adherence to smell training may be even more important for these patients if they hope to regain their sense of smell, but more research is required to investigate this.

Psychophysical smell testing alone does not measure the entire impact of olfactory disorders on the individual. Our results show a broad range of eODQ scores, reflecting varying impacts on the quality of life in our patients. Olfactory dysfunction can be devastating for those who depend on smell for their livelihoods. It may threaten employment for chefs, sommeliers, fire fighters and many other occupations. It has been reported that up to one third of patients with smell disorders suffer from symptoms of depression, with patients experiencing parosmia particularly at risk.¹¹

This study was limited by its small sample size, and thus interpretation of these preliminary data should be done cautiously. Given this was an initial pilot and feasibility study, we have not yet assessed the impact of our smell training intervention. Separate assessment of gustatory function may have added more depth to the assessment of dysfunction and how that might affect quality of life.

There is good evidence for smell training in treating non-COVID smell loss.¹² However, there is a paucity of research on the outcomes of COVID associated anosmia following smell training. We plan to follow up our patients after four months of smell training and obtain observational data, assessing for changes in their repeat UPSIT and eODQ scores.

CONCLUSION

In conclusion, we have demonstrated that it is simple and feasible to set up a COVID smell clinic. The materials are inexpensive, but supervised completion of the UPSIT and eODQ can be time-consuming. More research is required into the outcomes of smell training in COVID olfactory dysfunction and we hope to add observational data to the literature soon. We are predicting a huge burden of COVID associated olfactory dysfunction on otolaryngology services in the months and years to come. These patients will require sensitive and holistic treatment, which may indirectly help to reduce the impending mental health crisis caused by the COVID-19 pandemic.²⁵

ETHICAL CONSIDERATIONS

No formal ethical approval was required as this was an implementation and evaluation of a new clinical service based on the national guideline as described by the ENT UK / BRS consensus paper on the management of new onset loss of smell during the COVID-19 pandemic.¹³

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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Nil.

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Use of office based transnasal oesophagoscopy in management of Head & Neck conditions during the COVID-19 pandemic at the Royal Albert Edward Infirmary, Wigan, United Kingdom

Goyal Megha, MS¹, McNally George, MRCS¹, Batra Ankur, MRCS², Izzat Steve, FRCS¹, Pothula Vijaya, FRCS¹

¹Department of ENT, The Royal Albert Edward Infirmary, Wrightington Wigan and Leigh, NHS Foundation Trust, ²Department of ENT, Royal Hampshire County Hospital, Hampshire Hospital NHS Foundation Trust

ABSTRACT

Objectives: To assess the clinical and cost effectiveness of transnasal oesophagoscopy (TNO) in cases of suspected upper aerodigestive tract malignancy and define its role as a safe alternative to panendoscopy. We have also analysed if the implementation of TNO during the COVID-19 pandemic was beneficial in order to provide uninterrupted care to the patients with the limited resources available in these challenging times.

Methods: All patients who underwent TNO guided biopsies or dilatation attempted over a 7 month period during COVID-19 pandemic were included by searching the hospital and department database at The Royal Albert Edward Infirmary. A comparative group of patients who underwent panendoscopy over 9 months were included for comparison. Demographic data, histological diagnosis, second procedure and cost involved were recorded.

Results: During this period, 20 TNO procedures (16 biopsies and 4 dilatations) were attempted which were compared with 20 panendoscopy procedures. The diagnostic accuracy of TNO biopsy for identifying benign and malignant pathology was 81.1%. The sensitivity and specificity for identifying malignancy was 76.9% and 100% respectively. The most common lesion location was laryngeal (43.8%) followed by oropharyngeal (37.5%), more specifically located at the tongue base. The median waiting period between the procedure being listed and TNO being performed was 5.5 days compared to 12 days for panendoscopy. There were 12/16 patients who did not require further interventions for histological diagnosis of the tumor. The TNO procedure was well tolerated with no complications and all were done under local anaesthesia as outpatient procedure without need for admission. TNO resulted in cost saving of £356 per case on a standard NHS tariff.

Conclusion: TNO is a valuable diagnostic tool for patients with suspected UADT malignancy and dysphagia and has proven to be an asset during the COVID-19 pandemic when we have to make the best use of the limited theatre time and resources. Also, the cost analysis showed that outpatient based TNO can provide significant cost savings for the current standard of care. Furthermore, it has shown better

patient tolerability, lesser complications and shortened the time for diagnosis and hence starting timely treatment for these patients.

KEYWORDS:

Transnasal oesophagoscopy, dysphagia, Upper aerodigestive tract malignancy, panendoscopy

INTRODUCTION

COVID-19 was first diagnosed in Wuhan in Hubei province, China in November 2019.¹ Since then, it has spread rapidly across the world and is declared as Pandemic by World Health Organisation.² It has been reported that secretions of the nasopharynx and oropharynx have high viral load putting otolaryngologists at higher risk.^{3,4} The first reported physician fatality was that of an otolaryngologist at Wuhan.⁵

Head and Neck Squamous cell Carcinoma (HNSCC) is a deadly disease with mortality in the range of 40-50% if untreated. HNSCC can arise from the mucous membranes and the diagnosis and treatment often results in potential viral exposure to patients, staff and health care workers. Many clinicians in Otolaryngology have closed their clinics during this pandemic limiting access and care for HNSCC patients. While virtual consultations were available, they provide limited examination and diagnosis for suspected cancer patients needing evaluation.⁶ Operating theatres and procedural units have closed or working with reduced capacity in some hospitals due to staff sickness, deployment of staff to Covid care in intensive care units (ICU) and Wards. Staff were advised to wear personal protective equipment (PPE) at outpatients, in patients and operating theatres. All patients requiring admission for surgeries into the hospital were tested for COVID-19 by RT-PCR test and if positive their procedures were deferred due to risk of serious consequences due to COVID-19 infection and surgery. Primary care physicians also stopped face to face consultations and offered only virtual consultations. Various protocols have been devised by speciality bodies such as ENT UK, American Association of Otolaryngologists and Head and Neck surgeons.

Corresponding Author: Goyal Megha
Email: dr.meghagoyal@gmail.com

Under the above back drop the diagnosis of HNSCC was delayed and patients started presenting with advanced stage of cancers. We at Royal Albert Edward Infirmary (RAEI), Wigan started using TNO which offered quick diagnosis and biopsy due to limited access to the operating theatre. TNO can be performed safely and swiftly under local anaesthetic in an out-patient clinic setting for investigations, diagnosis and therapeutic interventions of common otolaryngology pathologies.⁷ Whilst TNO is mostly used for symptoms of dysphagia and globus, gastro oesophageal reflux disease and foreign bodies, the applications have been widened and used for biopsies of upper aero digestive tract (UADT) tumours involving nasopharynx, oropharynx, hypopharynx, and larynx, balloon dilatations of hypopharyngeal and upper oesophageal strictures, secondary trachea-oesophageal puncture and insertion of speech valve, vocal cord medialisation for paralysed vocal cords and use of lasers for benign laryngeal lesions such as papillomatosis, granulomas, leucoplakia and polypoid degeneration.⁸

TNO is an appealing alternative to traditional panendoscopy and rigid oesophagoscopy for patients with suspected UADT malignancy. Patients with head and neck cancers are elderly with multiple co morbidities increasing their risk of general anaesthetic or being deemed unfit for surgery. An office-based procedure for biopsy under local anaesthetic reduces aerosol generation, risk of covid infection to staff, length of hospital stay and time to diagnosis, helping to achieve the national cancer targets for the management of Head and Neck cancers.^{9,10} The primary aim of this study was to determine the efficacy, cost effectiveness and safety of TNO during COVID-19 pandemic.

MATERIALS AND METHODS

This is a retrospective study including all patients who underwent TNO in ENT department at RAEI between May 2020 to November 2020. The database was searched for this procedure and the data was collected anonymously. The data collection and analysis required no ethical consideration.

Indications, patient's assessment and screening

The patients primarily had two clinical indications. First group were those who needed tissue biopsies for diagnosis from the Upper Aero Digestive Tract (UADT) when found to have abnormal lesions on out-patient consultation including fibre optic examination. The second group of patients who had severe dysphagia due to post radiotherapy for pharyngeal or laryngeal malignancies or post cricoid web and need oesophageal balloon dilatation. The above patients would conventionally have the procedures under general anaesthesia (GA) in the operation theatres but had biopsies and dilatations under local anaesthetic (LA) with TNO.

Detailed information on the TNO procedure under topical anaesthetic spray was provided to all patients beforehand and informed consent was obtained. Exclusion criteria included patients presenting with stridor due to large laryngeal tumours and potentially could have complete respiratory obstruction during the procedure or if prior investigation revealed a totally fibrosed cricopharyngeal passage. TNO procedure was carried out at the main hospital

where the room containing adequate air exchanges, proximity of facility to decontaminate the scopes quickly and availability of help from other medical services in case of any emergency requirement. All the procedures requiring biopsy were done after the imaging by MRI and CT to avoid exaggeration of size of tumour due to inflammation resulting from the biopsy. Surgeons and nurses donned the PPE involving surgical gown, FFP3 mask, visor and gloves as per the hospital guidelines. The patient also wore a surgical mask covering only the mouth during the procedure.

Procedure

The patients were seated on a comfortable examination chair during the procedure and co-phenylcaine local anaesthetic low pressure spray (lidocaine hydrochloride 5%, phenylephrine 0.5%) was administered to both nostrils and oropharynx. After spraying, the patient was asked to hold the anaesthetic solution (4% lidocaine solution) in the back of their throat and gargle before swallowing. We also instilled 4% lidocaine solution by epidural catheter into the larynx if the biopsy is required from supra glottis or glottis. Examination and biopsies were carried out using shorter length TNO (645 mm and 4.9 mm diameter, Olympus, Japan) and all procedures were recorded. The procedure was labelled successful if we were able to obtain a diagnosis from the biopsy sample or perform the therapeutic procedure (oesophageal dilatation) satisfactorily.

After the procedure patients were requested to wait for 30 minutes in an isolated waiting room before being discharged. PPE was doffed as per local hospital protocols. The endoscope was sent for disinfection to the endoscopy decontamination unit and room was disinfected and closed for 20 minutes.

Cost Analysis

Cost analysis was performed from a clinical diagnostic perspective, thus secondary costs such as travel expenses, capital expenditure and time off work for patients and family members were not accounted for. For each of the 20 patients that underwent TNO, costs in British pounds for all materials and procedures were obtained.

We compared this data with a group of 20 consecutive patients who underwent a diagnostic procedure by panendoscopy which is a standard practice, under GA by searching in our hospital database and the costs were calculated. All the GA procedures were listed as day case admissions with 3 patients requiring overnight stay which was accounted for in the cost analysis.

Data collection

Data was collected for demographics, indication, site of lesion, histopathology, success of performing procedure, need for second procedure, patient tolerability and complications. The financial implications of this procedure during the pandemic were analysed after consulting the finance department.

To calculate the diagnostic accuracy of TNO biopsies (true positive+ true negative/- total population) in identifying malignant and benign laryngeal and pharyngeal lesions, histology reports were divided into two groups: a malignant

Table I: Patient characteristics

Characteristic	TNO	%	Panendoscopy	%
Procedures	20		20	
Biopsies	16	80.0	16	80.0
Dilatations	4	20.0	4	20.0
Sex (females)	7	35.0	7	35.0
Age (median, range)	72, 39-88		68.5, 43-88	
Location of lesion				
Nasopharynx	1	6.3	0	0.0
Oropharynx	6	37.5	9	56.3
Larynx	7	43.8	5	31.3
Hypopharynx	2	12.5	2	12.5
Histopathology				
Invasive carcinoma ¹	6	37.5	12	75.0
Lymphoma ²	1	6.3	0	0.0
Severe dysplasia/CIS	3	18.8	0	0.0
Reactive ³	3	18.8	0	0.0
Benign ⁴	3	18.8	3	18.8
Normal	0	0	1	6.3

Abbreviations: CIS, carcinoma in situ.

1: Squamous cell carcinoma; 2: Diffuse large B-cell lymphoma; 3: Ulcer, vasculitis, inflammatory; 4: Squamous epithelium.

Table II: Further diagnostic procedures

Initial TNO Biopsy Report	2nd Diagnostic Procedure	2nd Biopsy Report	3rd Diagnostic Procedure	3rd Biopsy Report	Treatment
Reactive*	Repeat TNO	Moderate dysplasia	Micro-laryngoscopy & biopsy	SCC	Palliative radiotherapy
Benign*	US-guided core biopsy of lymph node	SCC	Not required	-	Chemotherapy & radiotherapy
Vasculitis	EUA nose & biopsy	Vasculitis	Not required	-	Rheumatology referral
Benign*	Panendoscopy & biopsy	Benign	US-guided core biopsy of lymph node	SCC	Neck dissection

Abbreviations: TNO, transnasal oesophagoscopy; US, ultrasound; SCC, squamous cell carcinoma; EUA, examination under anaesthetic.

* Inconsistent with clinical suspicion.

group including reports of invasive carcinoma and severe dysplasia/ carcinoma in situ (CIS); a benign group including reactive (ulcerative, inflammatory, vasculitic) or benign histology reports. The sensitivity and specificity of TNO biopsies for identifying malignancy was also determined. The results were defined as true positive or true negative when the biopsy report was consistent with clinical suspicion based on clinical history, endoscopic appearance of the lesion and if additional biopsies or imaging identified equivalent pathology. If reports were inconsistent with clinical context, further investigations or procedures under general anaesthesia were performed. The data was collated and analysed on Microsoft Excel.

RESULTS

A total of 20 patients underwent TNO from May to November 2020 including 13 males and 7 females with a median age of 72 years (range 39-88 years). Table I provides detailed data on patient characteristics. This included taking biopsies for 16 patients and performing balloon dilatations on 4 patients. The median waiting period between the procedure being listed and TNO was 5.5 days compared to 12 days for panendoscopy (Figure 1). All cases were performed under local anaesthetic in the outpatient setting with none of the patients requiring hospital admission after the procedure. No complications were recorded.

TNO findings and biopsy reports

The most common site of lesion was laryngeal (43.8%) followed by oropharyngeal (37.5%), more specifically located at the tongue base (Figure 2). The histopathology showed malignant lesions in 10 patients (62.5%), including six squamous cell carcinomas (SCC), three severe dysplasia/ carcinoma in situ and one report of diffuse large B-cell lymphoma. Three patients had reactive histopathology defined as ulcerative, vasculitic or inflammatory and three patients had benign pathology (no malignancy) identified.

We managed to biopsy all 16 cases successfully (100%) compared to the overall procedural accuracy of 86% reported by Mohammed et al (22).

The diagnostic accuracy of TNO biopsy for identifying benign and malignant pathology was 81.1%. The sensitivity and specificity for identifying malignancy was 76.9% and 100% respectively.

Balloon dilation

Four patients had cricopharyngeal narrowing after completing treatment for post-cricoid cancer and they all underwent balloon dilatation using TNO (Figure 3). Three patients tolerated the procedure well with successful resolution of dysphagia, whereas one patient complained of pain, hence abandoned and the procedure under GA was arranged.

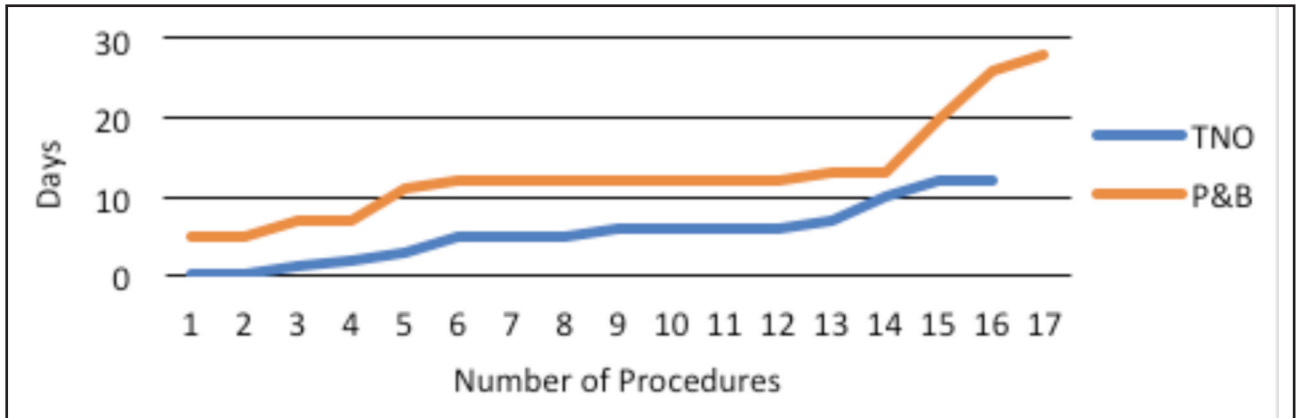


Fig. 1: Time between listing and operation date for transnasal oesophagoscopy (TNO) and panendoscopy & biopsy (P&B).

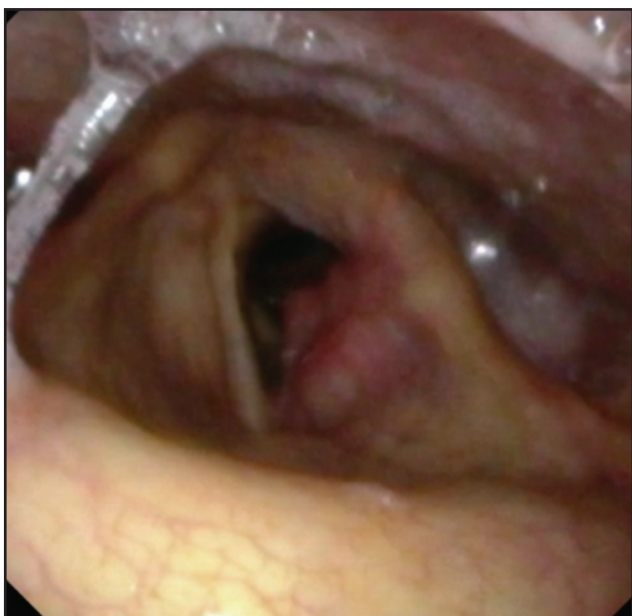


Fig. 2: Suspicious laryngeal lesion seen with TNO which was biopsied.

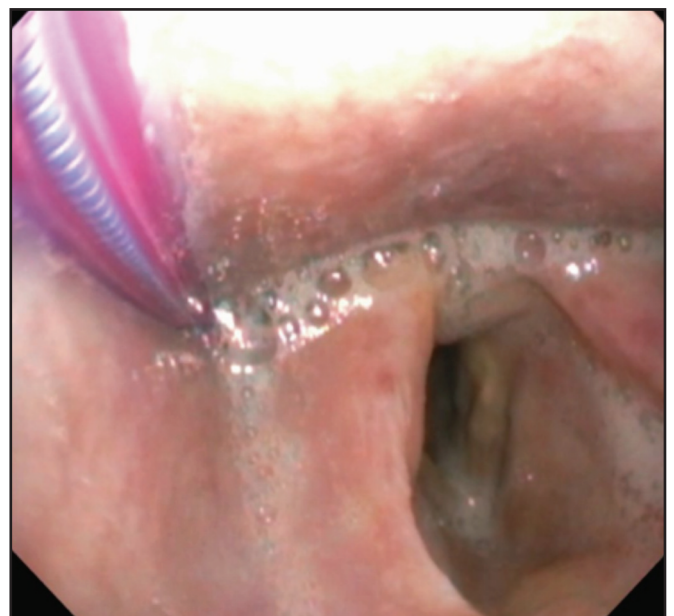


Fig. 3: Balloon catheter introduced for dilatation.

Further Diagnostic Procedures

Four patients underwent further diagnostic procedures after initial TNO biopsy (Table II). One patient had EUA (examination under anaesthesia) nose & biopsy which again confirmed previous biopsy results taken by TNO and was referred to Rheumatology department. Three patients required further procedures due to a reactive or benign initial TNO biopsy report despite a high clinical suspicion of malignancy: the first patient underwent microlaryngoscopy & biopsy under GA reported as SCC; two patients had unknown primary and the biopsy with TNO as well as panendoscopy did not confirm any primary source. Both were diagnosed as SCC on performing US-guided core biopsy of the lymph node and were later diagnosed as metastatic node of unknown primary.

Cost analysis

Cost analysis for the first group (i.e., patients with suspected UADT malignancy) revealed significant cost difference in favour of TNO. TNO resulted in cost saving of £356 per case on a standard NHS tariff.

DISCUSSION

Office based transnasal oesophagoscopy was first reported by Jonathan Aviv in 1990's who demonstrated that it could be performed in an out-patient setting, without sedation in consecutive patients.¹¹

This procedure has gained wide acceptance and is currently used for various other applications. The current practice of panendoscopy involving examination of pharynx, larynx and oesophagus to assess the extent of the lesion, taking

biopsies and rule out synchronous primary has anaesthetic and surgical risks. Although according to the American Association of Anaesthesiologists, ASA 1 patients have a GA related mortality of 0.4/100,000, this raises to 27/100,000 in ASA 3 patients. Patients aged 40-75 years have a GA related mortality of 5.2/100,000 rising to 21/100,000 in those over 75 years, the group of patients generally need head neck cancer related procedures.¹² Risks or complications of rigid endoscopy include dental injuries of 25% during anaesthesia and 6.5% during suspension laryngoscopy and minor mucosal injuries in 75% of patients.^{13,14} In addition, oesophageal perforation rate of 0.2-0.6% and the yield of second primary tumour on rigid oesophagoscopy is very small in the reported literature and ranges from 0% to 1.8%.¹⁵ Moreover, there is significant rate of abandoned rigid endoscopy procedures amounting to 10%.¹⁶ The UADT endoscopy is considered to be an aerosol generating procedure especially if supplemented by general anaesthesia, as airway interventions like intubation and extubation increase the risk of COVID-19 by 6.6 times among the team members performing them.¹⁷

TNO which avoids all the above risks and can be done under a local anaesthetic as office-based procedure and offer similar or better results will gain wide acceptance. TNO also avoids the need for overnight hospital admission, thereby decreasing the risk of hospital acquired COVID-19 infection and reducing stress on an already stretched healthcare services during the pandemic.¹⁸ From the patient perspective, out-patient based procedures have decreased recovery time.¹⁹ From the health system perspective, there is more flexibility as out-patient procedure and planned operating lists are not disrupted. Hence theatre time and resources can be utilised for other emergency cases. Therefore, the long waiting period for GA procedure with limited theatre capacity was avoided by performing TNO in the outpatient setting. This resulted in timely diagnosis and management of these patients, the majority of whom had UADT malignancy. Furthermore, the need for 14 days of self-isolation and COVID-19 testing protocols before a GA procedure were avoided by performing TNO under LA, which could have otherwise further delayed the diagnosis.

An accurate diagnosis was made after performing TNO in 13 patients (81.1%), which is comparable to the study done by Belafsky et al and Aviv et al although the site of biopsies was different.^{11,20} We had a success rate of postcricoid or upper esophageal dilatations in 3/4 (75%) patients. We do admit these numbers are very small to make a meaningful conclusion of percentage of success. Howell R et al reported similar success in 22 patients.²¹

One of the largest retrospective case series involving 134 TNE-guided procedures done by Mohammed et al 22 reported 89% success rate for histological diagnosis whilst our experience shows accuracy rate (diagnosis consistent with clinical suspicion) of 93.7%. The overall advantage of TNO is the favourable patient acceptance and fewer complications as compared to the traditional panendoscopy and rigid oesophagoscopy. Howell et al mentioned minor complication rates of 10.7% including superficial lacerations and epistaxis during TNO, whereas oesophageal perforation and even death have been reported as major complications

of rigid endoscopy.¹⁵⁻¹⁶ There were no major complications noted in our study population and the procedure was tolerated well by all patients. One of the minor complication reported by Mohammed et al, is superficial laceration to the esophagus, in which case a close and careful examination of the lacerated area needs to be undertaken to ensure the integrity of the muscular wall of the esophagus.²² Epistaxis is another commonly encountered minor complication of this procedure, which is usually self-limiting or occasionally may require some conservative measures. In the literature also, no major complications have been reported during this procedure as described by Polat et al in their prospective study of 314 patients.²³

Our analysis revealed that outpatient based TNO is more cost effective with significant cost savings compared to traditional panendoscopy especially in patients with suspected malignancy. This is consistent with the data published by Wallenstein D et al.²⁴

As per recommendations to limit the number of team members to avoid exposure to AGPs during the COVID-19 pandemic, TNO procedure was deemed safer as it involved 3 team members in comparison to a full theatre team (of around 8-10 members) involved in GA procedure. Full PPE was worn by all members as recommended by ENT-UK guidelines and none of our team members reported any COVID-19 symptoms or tested positive during the study period.²⁵ Therefore, we found TNO to be an extremely safe diagnostic modality for patients as well as healthcare staff during the current pandemic.

Finally, we acknowledge the limitations of our study including small cohort of patients at a single institution which might have introduced a selection bias. Our reported sensitivity and specificity need to be validated in a larger sample. The inter hospital variability of infrastructure and lack of uniform protocols might not give the same safety results in other settings.

CONCLUSION

TNO is a valuable diagnostic tool for patients with suspected UADT malignancy and dysphagia and has proven to be an asset during the COVID-19 pandemic when we had to make the best use of the limited theatre time and resources. Also, the cost analysis showed that outpatient based TNO can provide significant cost savings for the current standard of care. Furthermore, it has shown better patient tolerability, lesser complications and shortened the time to diagnosis and treatment of these patients.

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Preliminary findings of performing aerosol generating procedures using a novel innovative mask in times of COVID-19 pandemic

Eugene Hung Chih Wong, Ms ORL-HNS¹, Maher Sefein, Dip², Jidon Janaun, PhD³

¹Department of Surgery, Faculty of Medicine and Health Sciences, Universiti Malaysia Sabah, Kota Kinabalu, Sabah, ²Department of Medical Education, Faculty of Medicine and Health Sciences, Universiti Malaysia Sabah, Kota Kinabalu, Sabah, Malaysia, ³Faculty of Engineering, Universiti Malaysia Sabah, Kota Kinabalu, Sabah, Malaysia

ABSTRACT

This article describes an innovative mask consisting of a newly fabricated 3-ply surgical face mask with a custom made attachment consisting of a plastic dome and a one-way valve port that allows endoscopes to be inserted through it. The mask was tested in-vitro with simulated sneezing using fluorescent dyes and also received positive feedbacks from field tests of 30 masks on real users in different hospitals. This innovative mask is useful in providing extra barrier for endoscopic procedures in ENT and can be used beyond this pandemic in patients with other infectious diseases.

INTRODUCTION

COVID-19 infection rates among ENT surgeons are higher compared to other clinicians due to exposure to respiratory aerosols and droplets containing high viral load reservoir during head and neck examinations and endoscopic procedures in the nasal cavity and nasopharynx.¹ This is partly because majority of ENT outpatient procedures involve deep instrumentation that triggers cough reflex where jets of droplets and aerosols generated can reach the healthcare workers, especially those in close proximity, at high volume and velocity.²

This article describes an innovative mask, called "One Way Mask™" (1WM), which has been developed since March 2020 by a team of ENT surgeons and engineers, that allows endoscopic examinations to be performed through it.

MATERIALS AND METHODS

The 1WM is a newly fabricated 3-ply surgical face mask by a local mask production company with a custom made attachment consisting of a plastic dome and a one-way valve port (Figure 1). The transparent feature of the dome allows easy visualisation of the patient's nostrils and oral cavity and the flexibility of the dome allows room to manoeuvre different scopes to reach the target area of examination easily. The plastic dome is waterproof and is made of biodegradable material as this is a single-use (disposable) product.

The port is centrally placed to allow easy manoeuvring of the scopes to each nostrils and to the oral cavity. If usage of 70

degree rigid endoscope is required, a gauze can also be pre-placed in the inner surface of the plastic dome before patient wears them, which allows sufficient friction for anterior pulling of patient's tongue from the outside surface of the dome. The port also contains a soft silicone one-way valve that allows endoscopes to be inserted while forming a tight seal around them and closes completely on withdrawal of the endoscopes, therefore prevent leakage of droplets and aerosols throughout the procedure.

The 1WM has been tested in-vitro and with real end-users. To mimic a sneeze producing aerosolisation during endoscopy, 10mls of fluorescent dye was atomized at maximal pressure from behind a plastic model's nasal cavity. The amount of dye deposited on a piece of white PPE (percentage surface area) with and without the 1WM was compared using an ultraviolet light.

The phase 1 of field test on real end users (Figure 2) took place in October 2020 where thirty masks was distributed among four different hospitals to be tried by ENT surgeons for diagnostic endoscopies in ENT departments. A survey in the form of questionnaire (Figure 3) (based on a similar study by Curran et al.),³ comprised of 9 questions with Likert scores, was also conducted for both ENT surgeons and patients. Based on the feedbacks received, modifications were made to the masks and a phase 2 of field test on real end-users was carried out in January 2021 and is currently still ongoing. The One Way Mask™ has also been filed for patent and industrial design.

RESULTS

There were significant spray of fluorescent dye observed over a significant portion (>80% surface area) of the PPE as well as on the floor and surfaces 200 meters behind the PPE without a mask. On the other hand, in the plastic model wearing the 1WM, all the fluorescent dyes were contained inside the mask with no droplets or aerosols observed on the PPE or in the surrounding.

The Likert scores from the questionnaire from phase 1 of field test revealed a mean score of 4.2 and 4.5 among doctors and patients respectively. Majority of doctors find it easy to insert, withdraw and manoeuvre the endoscopes using this mask and patients have no issues breathing or experience any

Corresponding Author: Eugene Hung Chih Wong
Email: eugene.wong.hc@gmail.com

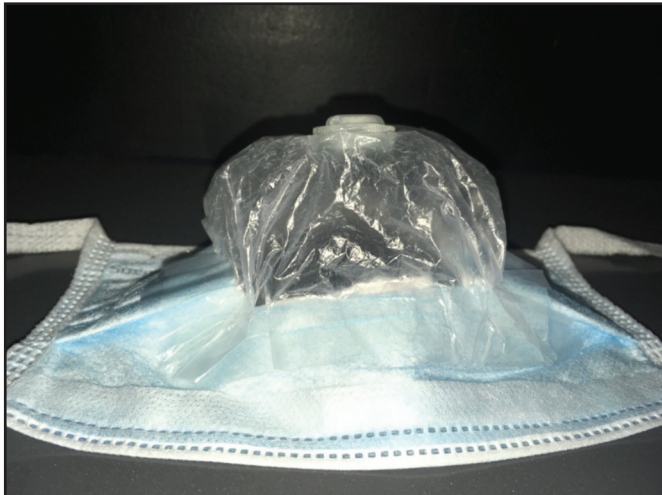


Fig. 1: The One Way Mask™ prototype showing the transparent and flexible plastic dome attachment with a one-way silicone valve port.

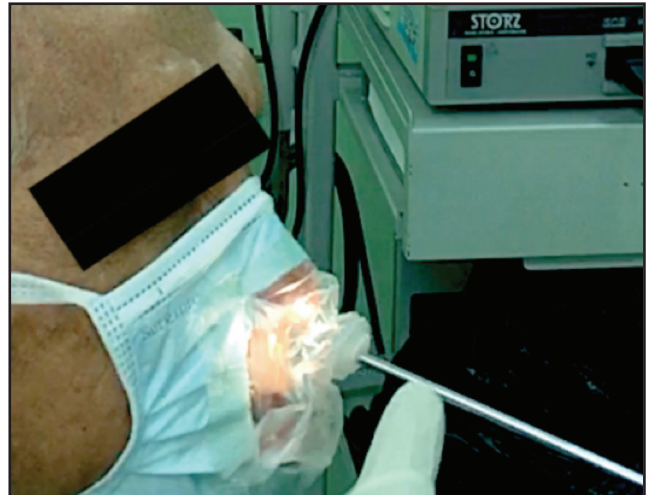


Fig. 2: The One Way Mask™ in use in a clinic.

User Details:							
Name:							
E-mail:							
Job Title: Consultant Specialist MO							
Usage Details:							
Location of usage: Ward Clinic A&E Others							
Scope used: Rigid endoscope (0°) Rigid endoscope (70°) Flexible nasendoscope							
Purpose of scope (examination of): Nose Throat Both							
Feedbacks:							
1-Strongly disagree 2-Disagree 3-Neutral 4-Agree 5-Strongly agree							
a) Patients							
1.	Easy to put on (tie) the mask	1	2	3	4	5	N/A
2.	Easy to breathe while wearing the mask	1	2	3	4	5	N/A
Other comments:							
b) Doctors							
1)	Easy to insert scope through the valve?	1	2	3	4	5	N/A
2)	Easy to see where to move the scope to (nostrils or mouth)?	1	2	3	4	5	N/A
3)	Easy to move the scope to desired area (nostrils or mouth)?	1	2	3	4	5	N/A
4)	Easy to slide the scope to examine different areas (nostrils or mouth)?	1	2	3	4	5	N/A
5)	Easy to perform 70° rigid scope with this?	1	2	3	4	5	N/A
6)	Easy to withdraw the scope after usage?	1	2	3	4	5	N/A
7)	Mask prevented aerosols and droplets from escaping (if patient sneezed or coughed)?	1	2	3	4	5	N/A
Other comments:							

Fig. 3: Questionnaire used during field test with end users.

discomfort when being examined while wearing it. Minor modifications suggested include increasing the size of the dome and usage of softer materials for easier manipulations of endoscopes between nostrils and oral cavity. These changes were made on the prototypes used in phase 2 of field test on real end users.

DISCUSSION

Patients are currently required to either partially or completely remove their masks to allow insertion of endoscopes, where the procedure can inadvertently induce sneezing and coughing. Even if the healthcare workers in close proximity wear adequate PPEs during the procedures, the aerosolised COVID-19 viral particles can remain viable and infectious in the air for at least 3 hours and can also stay on surfaces for up to 72 hours⁴ and spread as fomites, where healthcare workers may touch the contaminated surfaces and get infected.⁵

Therefore, it is important for ENT surgeons, innovators and inventors to collaborate and develop strategies to reduce the risks of spread of infection from endoscopic procedures during this pandemic. For example, Workman et al.⁶ described using a customised standard surgical mask with a central part replaced with a piece of non-latex glove to allow passage of endoscopes. Other masks innovations include the SNAP (Safe Nasendoscopic Airway Procedure) valved endoscopic port,⁵ modified adult endoscopy mask with a 3mm slit,⁷ the negative airway respirator made from standard Ambu mask,⁸ 3-D printed endoscopy masks⁹ and usage of an anaesthetic “closed” facemask and DAR connector (L-shaped device with closable hole).³

We described another innovative mask in this article that protects clinical staffs as well as the clinical environment to prevent fomite transmission of COVID-19. The mask can also be used not only during the pandemic but also in any infective patients such as patients with Tuberculosis (TB) or during common flu seasons in the future.

Further objective study using laser particle analysis will be carried out during final manufacturing process to assess the bioaerosol cloud pattern generated while using the mask.

CONCLUSION

This article introduced a novel innovative mask with a custom made attachment consisting of a plastic dome and a one-way valve port. Preliminary testing have shown containment of fluorescent droplets and aerosols within the mask with positive feedbacks from end users during first phase of field test. More objective in-vitro testing and second phase of field test is underway to further improve this innovation to provide extra barrier for ENT surgeons during endoscopic procedures.

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Tracheostomy during the COVID-19 pandemic in Malaysia; a revised guideline

Rohaizam Japar Jaafar, MMed ORL-HNS¹, Tham Yik Seng, FRCS ORL-HNS¹, Zakinah Yahaya, MS ORL-HNS¹, Mohd Razif Mohamad Yunus, MS ORL-HNS², Marina Mat Baki, MS ORL-HNS, PhD²

¹Department of Otorhinolaryngology, Hospital Kuala Lumpur, Kuala Lumpur, Malaysia, ²Department of Otorhinolaryngology-Head and Neck Surgery, Universiti Kebangsaan Malaysia Medical Centre, Hospital Canselor Tuanku Muhriz, UKM, Malaysia

ABSTRACT

Performing tracheostomy on COVID-19 patients poses a significant risk to the procedural team. Such procedures should be evaluated individually via close communication between the otorhinolaryngology-head and neck surgeon and the intensivist. Comprehensive examination and preparation should be well-planned before tracheostomy, optimal technique during tracheostomy and special care following the surgery. We would like to highlight our revised guidelines at Hospital Kuala Lumpur, Malaysia on the timing of tracheostomy, management of anticoagulant and the surgical planning in COVID-19 patients during these challenging times.

INTRODUCTION

As of July 1, 2021, Malaysia is battling with 758967 total COVID-19 cases, 6988 new cases, and 5254 deaths.¹ As such a revision of the previous tracheostomy guidelines anticipating open tracheostomy in COVID-19 patients is clearly needed.

Tracheostomy is an aerosol-generating procedure (AGP) and one of the most high-risk surgeries in COVID-19 patients.^{2,3} Many clinicians believe that it should be avoided if possible as the secretion that spatter during the procedure poses a significant risk to surgeons, anaesthetists, and the staff in the operation theatre.⁴ However, tracheostomy is necessary in some cases; after prolonged intubation or difficult weaning, as it eases the work of breathing, reduces dead space, and facilitates tracheobronchial toileting.⁵

Decisions regarding the need for open tracheostomy in COVID-19 patients must balance the risks and benefits to the patient as well as the medical staff involved. In some circumstances, open tracheostomy is inevitable.^{2,6} Various recommendations are available, focusing not only on the indications of the tracheostomy, but also on the safety of the health care workers.

Thus it is timely for us to revise the tracheostomy guidelines that was published in 2020.⁷ These revisions will highlight the timing of the tracheostomy, its surgical planning as well as the management of anticoagulants.

RECOMMENDATIONS FOR TRACHEOSTOMY MANAGEMENT IN VENTILATED COVID-19 PATIENTS

A. Candidacy and timing of the tracheostomy

Candidacy is based on confirmed COVID-19 status via the reverse transcription-polymerase chain reaction (rt-PCR), the viral load as shown with the availability of cycle threshold (CT) value, and the general medical condition optimised for the procedure of the patients.^{5,6} The benefits of tracheostomy have been proven but its timing remains controversial.⁸ In critically ill non- COVID-19 patients, Andriolo et al, defined early tracheostomy as ≤ 10 days post tracheal intubation and late tracheostomy as >10 days post-intubation. Although the result of time spent on mechanical ventilator was variable, he found that patients with early tracheostomy had lower mortality rates.⁸

There are three timings for tracheostomy in ventilated COVID-19 patients based on recently published articles in the English literature, which are;

- *Less than 10 days:* Although this is not specifically for COVID-19 patients, this timing remains controversial, with many surgeons not agreeing to it. The TracMan trial showed no difference in 30 days mortality rate (30.8% early vs. 31.5% late) and two years mortality (51.0% early vs. 53.7% late). Median intensive care unit (ICU) stay (13 days early vs. 13.1 days late) were similar as were total hospital stay or the duration of the mechanical ventilation.⁹ However, early tracheostomy showed a significant decrease in sedation.⁹ Ahn et al. proposed on performing tracheostomy in COVID-19 patients whenever they were indicated, regardless of timing.¹⁰
- *Ten to 20 days:* COVID-19 viral load becomes undetectable around two weeks, reducing the exposure risk during tracheostomy.¹¹ Ferri et al. performed tracheostomies after 14 days of intubation in COVID-19 patients and found a mortality rate of 25%, which was similar with the previously reported overall mortality rate in ICU COVID-19 patients of 26%. They concluded that tracheostomy did not impact the natural course of the disease in these patients.¹² Martin-Villares et al. looked at 1,890 patients with a median time to tracheostomy of 12 days. These patients were followed up for one month with a mortality rate being 24%.¹³ Prior studies have focused on tracheostomies performed between 10-20 days post-intubation and have demonstrated variable mortality rates of 7%-24%.¹³

Corresponding Author: Rohaizam bin Japar @ Jaafar
Email: konno_81@yahoo.com

- *More than 21 days:* There were no previous studies that have evaluated outcomes of COVID-19 patients who underwent tracheostomy after 21 days of intubation. A few reports suggest that tracheostomy to be done after at least 21 days of ventilation for COVID-19 patients. This led to the recommendation to perform tracheostomies from 21 days onward.^{11,13,14} Martin-Villares et al. suggested that waiting longer (at least 21 days) does not change the weaning process but may reduce the mortality risk.¹³ Another study showed that waiting longer, on average 20 days, had a much lower mortality rate (11%). The report suggests that careful patient selection, with the patient having feasible respiratory dynamics, the outcomes after tracheostomy seemed promising.¹⁵

Our view is similar with Ahn et al., who demonstrated that the wait of 21 days is practically not feasible as negative conversion could take up to 43 days, thus delaying appropriate management and weaning. Ahn advocated that tracheostomy can be performed whenever indicated, regardless of time from intubation or COVID-19 test results.¹⁰

Hence, a multidisciplinary discussion should be held between the primary team, procedural team, and family to establish the overall prognosis, and expected benefits of tracheostomy.

B. Antithrombotic Management

COVID-19 may lead to a hypercoagulable state due to a combination of complement-mediated endothelial injury, stasis, and changes in circulating prothrombotic factors.¹⁶ Hospital Kuala Lumpur (HKL), Malaysia is in line with international centres instituting aggressive protocols of anticoagulation in patients with COVID-19. Subcutaneous fondaparinux 2.5mg daily or subcutaneous enoxaparin 20mg daily is started in high-risk patients. Studies have found that tracheostomies might be safely performed while on therapeutic anticoagulation, with full-dose anticoagulation needing to be discontinued or withheld for a short peri-operative period.¹⁷

Antiplatelet therapy in HKL, aspirin and/or clopidogrel therapy, are not withheld before surgery. Since February 2021, with a total of 60 patients, and to date we have not had any bleeding complications. Nevertheless, we recommend platelet count of more than 60,000/ μ L, international normalized ratio (INR) of less than 1.5 and urea of less than 25mg/dL.

Nevertheless, these recommendations should not substitute appropriate clinical judgment and critical discussion between the intensivist and otorhinolaryngology-head and neck team regarding the patient's antithrombotic regimen.

C. Procedure prerequisites

The protection of the surgeon, anaesthetist, and staff during the procedure should be given utmost consideration.

- The procedure should be done in a dedicated operating room to minimise contamination, with a clean runner antechamber (as the only conduit to the outside). We suggest a negative pressure operating room if available.
- Any unnecessary endoscopic examinations should be avoided, as endoscopies are aerosol-generating procedure (AGP) as well.

- Adequate personal protective equipment (PPE) with proper training and familiarisation of the donning and doffing of the PPE upon entering and exiting the operation room.
- The minimum PPE requirements are: (a) double-layered disposable gloves; (b) double gowning, fluid barrier protection or coverall; (c) N95 masks; (d) full-face visor or goggles for eye protection; (e) disposable surgical cap; and (f) shoe and boot covers.
- We advocate a powered air-purifying respirator (PAPR) device for all positive Covid-19 patients diagnosed within 28 days. With compliance to these rules, we have yet to see any of our procedural team contracting COVID-19 after the procedure.
- The number of staff during the procedure should be minimum. Our practice is that only one or two experienced surgeons are involved during the procedure.

D. Preoperative planning

When there are limited ICU beds and shortage of ventilators, early tracheostomy is more appropriate as the best form of continuation of care. Under such circumstances, tracheostomy may liberate patients from the ventilator and facilitate transfer out of the ICU. Frequent positional changes of patients, copious bronchial secretions, and pronounced laryngeal oedema associated with COVID-19, make tracheostomy safer than endotracheal intubation.

1. Tracheostomy in COVID-19 patients should be a planned semi-elective procedure and not done as an emergency procedure.
2. A designated tracheostomy team should comprise of a senior otorhinolaryngology-head and neck surgeon, a senior otorhinolaryngology-head and neck trainee, a senior anaesthetist and senior operation theatre nurse.
3. The operation should occur in a dedicated operation room or preferably a negative pressure isolation room in ICU (if available) with an isolated donning/doffing room. Ideally, the tracheostomy should be performed in the ICU to avoid unnecessary movement of the patient.
4. We recommend the use of long-term cuffed non-fenestrated tracheostomy tubes to minimise tracheostomy tube change.
5. The patient must be relatively stable and able to tolerate supine position and brief apnoea. A complete paralysis with muscle relaxant throughout the procedure is used to reduce the risk of coughing and aerosolisation.

E. Intraoperative procedure

The operative procedure is similar to that stated in the previous Ministry of Health Malaysia, 2020 guidelines on tracheostomy.⁷ We feel that adherence to the guidelines is feasible and safe.

1. The trays are opened, and instruments are laid out for easy access.
2. A 10ml syringe and catheter mount are attached to the preselected tracheostomy tube, to allow for readily inflation of the tracheostomy balloon.
3. A closed in-line suction must be used for the endotracheal tube (ETT) and tracheostomy tube.
4. The patient is then prepared for surgery.

5. A standard open tracheostomy is done through a horizontal neck incision.
6. Sutures or LigaClips are preferred instead of diathermy to prevent vaporization of viral particles.
7. The surgeon must inform the anaesthetist before incising the trachea.
8. The anaesthetist must ensure that the patient is totally paralyzed.
9. The anaesthetist is required to pre-oxygenate the patient, followed by turning off the flow, and allowing for passive expiration on an open APL valve.
10. The ETT is then clamped and advanced inferiorly, so that the cuff is beyond the planned tracheostomy site.
11. A tracheal window is created (rather than slit) taking care not to pierce the ETT cuff.
12. The ETT cuff is then deflated and withdrawn proximally until beyond the tracheal window under direct vision.
13. The surgeon must ensure the window is sufficient to allow easy insertion of the tracheostomy tube.
14. A cuffed, non-fenestrated tracheostomy tube (long term cuffed double-lumen silicone tube, if available) is inserted.
15. The tracheostomy tube cuff is immediately inflated, attaching it back to the circuit. Ventilation is resumed, and the tube position is confirmed with end-tidal CO₂ (to avoid contamination of the stethoscope).
16. The clamped ETT is withdrawn carefully.
17. The tracheostomy tube is secured with sutures and tracheostomy tapes.
18. An appropriate tracheostomy dressing is applied.

F. Post-operative care

We recommend that the following items be at the patient's bedside: A tracheostomy grab bag, consisting of a basic tracheostomy set with the tracheal dilator, suction equipment, spare inner cannula, and extra double-lumen silicone cuffed non-fenestrated tracheostomy tube which is one size smaller. This must be checked and restocked regularly.

When the patient is ready for weaning, a T-piece system with a viral filter on the expiratory end and an in-line suction catheter may be used. Placing a surgical mask over the tracheostomy site may also limit droplet spread. Patients who are weaned to a tracheostomy mask can undergo speaking valve trials as placement of the speaking valve and capping helps decrease the aerosolization.

Nursing care

Extreme care must be taken in transferring or positioning the patient. We prefer to use a heat moisture exchanger (HME), and if possible to avoid the use of a humidified oxygen. The suction circuits should be closed-line at all times and the cuff pressure is checked periodically. The nursing staff must be protected with the appropriate PPE as well.

Tracheostomy change

The first tracheostomy tube change should be delayed to days 8-10. The same sequence of pause in ventilation with flows off is advised before deflating the cuff. This is followed by insertion of a new tracheostomy tube with immediate inflation of the cuff and reconnection of the closed-circuit. Subsequent tracheostomy tube change is planned at 30-day intervals.

Decannulation

The decannulation should be decided on a case-to-case basis. Ideally, the decannulation is deferred until the patient is confirmed COVID-19 negative. It should be done as per standard decannulation protocols.

CONCLUSION

According to our revised guidelines at HKL, tracheostomy in COVID-19 patient needs to be pre-planned, taking into consideration the needs and well-being of the patients and the healthcare workers. All cases should be evaluated on a case per case basis with close communication between the otorhinolaryngology-head and neck surgeon and the intensivist.

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Teaching and training in Otorhinolaryngology (ORL) during the pandemic and beyond, in the United Kingdom

John Roche, MRCS(ENT), Catrin Evans, MRCS, B Nirmal Kumar, FRCS

Health Education England & Wrightington, Wigan and Leigh Teaching NHS Foundation Trust, UK

INTRODUCTION

The novel SARS-CoV-2 coronavirus (COVID-19) has forced major changes to the delivery of clinical care worldwide. The speciality of Ear, Nose and Throat (ENT) was particularly impacted largely because of the virus' transmission pathway. It is understood that COVID-19 transmission is predominantly airborne from the upper aero-digestive tract.¹⁻³ COVID-19 can be transmitted by particles smaller than 10µm which have been shown to be the most likely to penetrate the lung tissue and cause infection.⁴ This has therefore precipitated a need for personal protective equipment to also protect against air borne transmission particularly when completing aerosol generating procedures. High viral titres have been found in the nasal, oral, pharyngeal and laryngeal areas (collectively known as upper airway) which are commonly examined and instrumented as part of the practice of an ENT clinician or an allied healthcare team.⁵

As a result, the protection and safety of staff, working in close proximity to the upper airway, was a priority.

This led to wide-ranging action to halt the spread of COVID-19, protect the workforce, and allow increased capacity of intensive care areas. Whilst these measures were effective in their aims there were inevitable impacts on ENT services including teaching and training. Here we discuss the issues that arose specifically in medical education and training, with a focus on our experience in the United Kingdom (UK), and how they are being addressed to ensure that these impacts on training are diminished.

Personal Protective Equipment

There was initially a disparity between the provision of appropriate Personal Protective Equipment (PPE) and the need. The British Association of Otorhinolaryngology – Head and Neck Surgery (ENT UK) conducted a survey of 258 ENT surgeons in March 2020 relating to the availability of PPE.¹ In 5 respondents said that PPE was unavailable, even for Aerosol Generating Procedures (AGPs), and FFP2/N95 masks were available to only 27%.⁶

As a result of this survey and feedback from the Association of Otolaryngologists in Training (AOT) clear guidance was released for PPE within the speciality.^{6,7} ENT UK also engaged with Public Health England (PHE) to reiterate concerns regarding AGPs and instrumentation of the upper aerodigestive tract. As our understanding developed surrounding the COVID-19 transmission, what constituted an AGP and specific risks related to differing air-flow environments the guidance was adapted and updated.⁸

Clarity regarding what was deemed an AGP was a necessary part of creating guidance for PPE use. Within ENT procedures the consensus is that the primary procedures proven to be aerosol generating are - tracheobronchial suctioning, nasopharyngeal aspirate, nasopharyngeal and oropharyngeal swabbing, emergency front of neck access and any procedure deemed to trigger a cough.⁹ Coughing itself has also been defined as an AGP in several studies.⁹ Sneezing has also been proven to be an AGP, with a dramatic increase in the distance of droplet transmission with some studies showing transmission of droplets by up to 7 to 8 metres.¹⁰

Personal Protective Equipment is a broad umbrella term, within the pandemic this has encompassed gloves, apron, eye protection and a facemask. The decision about which facemask is most appropriate has been a subject of discussion and review throughout the pandemic. Respirators are a broad range of masks including Filtering face piece masks e.g. FFP3 and Non-oil masks e.g. N95. The numbers associated with the FFP masks i.e. 1, 2 and 3 reflect the reduction in concentration of the hazardous substance - 4, 10 and 20 fold respectively.¹¹ In a similar manner, the N95 mask has been shown in test conditions to block transmission of 95% of solid and liquid aerosol particles.¹²

The use of PPE in the form of a fluid resistant surgical facemask for both the patient and staff plus other precautions in the form of the 2m distance rule has been shown to reduce transmission risk by 80% in non-aerosol generating procedures.⁴ Studies have shown that an N95 mask is sufficient protection from droplet transmission with a close range cough, however a surgical facemask would be insufficient.¹³⁻¹⁶

Therefore, most recent guidance has shown that the use of an FFP mask with an overlying surgical mask while reviewing patients who may require an AGP is the safest option to minimise time to change equipment and to reduce wastage of PPE.¹⁷

Stephenson et al created a registry of ENT Surgeons testing positive for COVID-19; where 14.5% of respondents were trainees. 60.3% of 66 entrants, between 3rd April and 2nd July 2020, felt that they had contracted the virus whilst at work. Two respondents required hospital admission and one sadly died, this was widely reported in the media at the time and highlighted the importance of PPE for all ENT clinicians including trainees.¹⁸

Corresponding Author: B Nirmal Kumar
Email: nirmalkumar@doctors.org.uk

The COVIDSurg collaborative analysed 1137 consecutive patients undergoing primary surgery for head and neck cancer with a curative intent. 3% of these patients tested positive within 30 days post-operatively. In 3.5% of the procedures members of the surgical team tested positive for COVID-19 and there was an association between cases where patients tested positive too. Infections in staff members were also associated with high community incidence of COVID-19, oral tumour site, use of tracheostomy and with surgical complications. The authors highlighted the importance of PPE and appropriate cross-infection measures to prevent morbidity and virus transmission.¹⁹

Theatre Utilisation

The emergence of COVID-19 and the associated burden of disease on secondary and tertiary healthcare led to swift action and a multitude of changes in the provision of services. The most severe phenotype of COVID-19 increased the need for Intensive Care and High Dependency beds. Intubated COVID-19 patients were cared for in theatre environments that are usually reserved for elective activity. As elective activity continues, stringent cleaning and fallow times, in addition to increases in pre- and post-procedural checks has led to a decrease in theatre utilisation.

The Federation of Surgical Speciality Associations (FSSA) developed a pan-speciality guide that categorises surgical procedures based on priority. This categorisation is reviewed monthly and helps to guide local prioritisation of operations amongst different specialities. The scale goes from Emergency Procedures to be performed within 24 hours (Priority 1a), such as acute airway obstruction and neck trauma, to procedures to be performed in >3 months (Priority 4) such as Grommets and Septoplasty.^{7,20} Whilst this prioritisation has allowed appropriate stratification of surgical cases across specialities it has meant that surgical training is weighted towards emergency procedures and oncological cases that are usually within the Head and Neck. This has meant that trainees have been less exposed to routine rhinology and otology cases especially. The Speciality Advisory Committee for ENT understands that just 30% of index procedures were completed by trainees during the COVID-19 outbreak particularly affecting those operations in the Priority 4 category where a significant number of ENT procedures were categorised.

Delays were not confined to elective work; however, cancer care was also affected despite the higher priority that it was understandably assigned. Maringe et al, using a population-based modelling study examining colorectal, breast, oesophageal and lung cancer, that substantial increases in the number of avoidable cancer deaths were to be expected in the next 6 years because of delays to treatment secondary to COVID-19.²¹

As a result of a reduction in elective and semi-elective operating time procedural and operative based training opportunities have been diminished. Trainees in the UK are required to be involved in 2000 procedural cases during training and there is concern that this may be difficult to attain, and training extensions may be required. Utilisation of virtual reality and digital simulation has been mooted as

a potential solution to reduce the impact on trainees who are missing valuable operative experience.²²

New Training Methods

Reduced exposure to theatre cases has required trainers and trainees to adapt to a new way of educating and learning.

Each case in theatre has increased importance due to this comparative lack in exposure. Sharing these opportunities amongst trainees is important to ensure a broader educational gain from a single case. Good communication between those involved is paramount to ensure specific learning needs are met across the current surgical landscape. ENT is implementing a new curriculum this year which moves away from Workplace Based Assessments (WBAs) to Multi-Consultant Reports (MCRs). As the curriculum develops it will be important to understand, and comment upon, what impact COVID-19 continues to have on a trainee’s development.

There have been significant recent developments within cognitive simulation and augmented reality (AR) in the last decade. A recent systematic review demonstrated that AR was favoured, over cadaveric models, in simulation of surgical procedures. There was also no difference or improved surgical performance with AR when compared to traditional teaching methods. The utilisation of such adjuncts is paramount in the modern world where theatre time is reduced.^{22,23}

Redeployment

Numerous ENT trainees were asked to work in unfamiliar environments to help with increased workload for medical and intensive care colleagues, increased staff sickness and staff shielding. Whilst this did allow for some trainees to gain exposure to procedural care in the intensive care environment and involvement in management of ventilated patients, including difficult airway, intubations, and tracheostomies, it was not necessarily specific to their individual curriculum aims for their period of training. The areas of redeployment were often areas where COVID-19 was prevalent and as such it was and remains paramount to consider stress and fatigue in trainees that were or are working in such wards.²⁴

Remote Consultations

There has been a significant change in the provision of inpatient, but particularly outpatient, consultations during the COVID-19 outbreak. There has been a shift towards remote, either telephone or online consultations, to reduce clinician to patient contact. Recent audits, published by the ENT National Trainee Collaborative in the UK (INTEGRATE), demonstrated that 8.5% of patients presenting to secondary care with epistaxis and 38.5% of those presenting with tonsillitis/quinsy, had telephone follow-up appointments arranged.^{25,26}

It was recommended that remote consultations were suitable to triage new referrals, initiate new treatments and discuss results or treatment responses in follow up discussions.²⁴ Triage tools were developed to aid this process in the field of Head and Neck Surgery to stratify cancer referrals in high and low risk groups for malignancy. Whilst it was clear that

remote consultations had benefits, one of the issues raised was the difficulty of supervision and reduced exposure to examination skills for trainees.²² Providing appropriate support to trainees who are learning to develop consultation skills in this remote manner is important to ensure their clinical skills and acumen are developing.

International Trainees

The UK benefits from many international graduates who travel to work in the country to gain a new experience and further training within the National Health Service (NHS). Many also enrol in post-graduate courses in surgery which are usually delivered in a face-to-face format. The pandemic has meant that their experiences have been limited in both the hospital environment and in the classroom. Surgical opportunities for this group of doctors have been limited and courses have been moved online. Their opportunity to integrate into the society has also been reduced due to coronavirus restrictions preventing social activities and thereby reducing the valuable experience of working and training in a different country and healthcare environment.

Online Teaching

The use of online platforms has allowed the adaptation of regular trainee teaching with curriculum-based aims to continue. Whilst there are limitations in this virtual environment, feedback has been largely positive, and trainees are now settled into this new way of teaching. Conferences and courses have also been moved online allowing sessions to be recorded and providing a wide resource for the ENT community both nationally and internationally. As such online platforms have allowed a wider range of international speakers, without the previous travel costs, and are likely to continue as the pandemic comes under control. There are now a range of talks for trainees that are freely accessible online in preparation for exams and to develop their breadth of knowledge.

Examinations

COVID-19 has also caused disruption to ENT examinations. There have been delays and cancellations to both MRCS and FRCS sittings which has, as a result, unsettled the usual structured nature to exam preparations and applications to subsequent stages of a clinician's career. Adaptations have been made, including the possibility for some exams to be sat remotely, and for trainees to progress without the required examinations as long as these requirements are completed at a pre-specified later date.

Research

As the COVID-19 pandemic evolved and the risks to ENT clinicians was understood there were numerous research opportunities that were developed, with trainee involvement, in a multitude of areas related to patient and staff safety. As previously mentioned, guidance relating to the management of both epistaxis and tonsillitis/quinsy was audited by INTEGRATE, the national trainee research collaborative in ENT. This demonstrated a shift to out-patient management of these conditions to prevent inpatient contact and increase bed-capacity for COVID-19 patients.^{25,26} The association between olfactory dysfunction and COVID-19 has also

resulted in numerous opportunities for trainees to develop their research portfolios under the tutelage of their consultant supervisors.

CONCLUSION

COVID-19 has impacted a wide variety of areas related to the attainment of competencies in ENT training. It has required, in some cases, redeployment of these trainees to unfamiliar environments and initially there were concerns regarding provision of PPE. Trainees and their supervisors have had to be flexible and adaptable to a rapidly evolving and ever-changing situation. Some of the enforced changes such as remote consultations and virtual teaching platforms are likely to be integrated in to our clinical and education processes in targeted cases due to successes and positive feedback in these areas. As the COVID-19 situation evolves it may be that these training impacts result in the requirement for supplementary experience prior to progressing to the next stage in a career, and it is important that new and innovative methods for training including digital solutions are embraced to ensure that the next generation is ready for independent practice.

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COVID-19, circuit breaker and safe reopening - perspective from an ENT practice at a tertiary hospital in Singapore

Valerie Khoo Yu Hui, MBBS, Lim Ming Yann, FAMS ORL, Yeo Seng Beng, FAMS ORL

Department of Otorhinolaryngology, Tan Tock Seng Hospital, Singapore

ABSTRACT

COVID-19 has affected every walk of life, including the healthcare sector. In this article, we discuss how an Otolaryngology department in a tertiary hospital in Singapore had to adapt to the pandemic in areas of outpatient care, elective surgeries, personal protection, residency training, education and research.

Documenting our experience has helped us to understand the areas of work which can be affected in a pandemic and the factors that have helped to mitigate disruption. This will prove useful in our approach to subsequent pandemics.

KEYWORDS:

Coronavirus, COVID-19, circuit breaker, pandemic, Otolaryngology, Personal protection equipment

INTRODUCTION

Coronavirus disease 2019 (COVID-19), caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), started in Wuhan, China in December 2019 and was subsequently declared as a global pandemic on 11th March 2020.^{1,2} Globally, as of 21st December 2020, 75,479,471 cases have been confirmed over 220 countries and has resulted in the deaths of 1,686,267 people.³ Hopes have been raised as the first few COVID-19 vaccines have been granted emergency approval to be used while maintaining the safety of these vaccines.^{4,5} As every country continues to battle this deadly virus, the unprecedented magnitude of the fallout on every aspect of society is painfully felt, in areas such as trade, tourism, leisure and recreation, and workplace challenges. Singapore has been no exception. Singapore confirmed its first local case on 23rd January 2020.⁶ On the 7th April, the country went into a two month "Circuit Breaker" lockdown period to stem its ever-increasing number of COVID-19 infections, and has since observed a very gradual and safe reopening of the country starting from 1 June 2020.^{7,8}

The healthcare sector was affected in different ways by the pandemic, and as Singapore moves into its second and third phases of reopening on 18th June 2020 and 28th December 2020 respectively, the healthcare sector has adapted to this "new normal" of balancing healthcare needs with safety aspects, for both healthcare workers and patients. In this article, we look at how COVID-19 has affected the healthcare sector, and in particular the Ear-Nose-Throat (ENT) practice at our hospital.

Outpatient Care and Elective Surgeries:

In compliance with Singapore's social distancing rules, which stipulate that individuals must keep at least 1 metre apart, the number of seats available in the department's outpatient waiting area was reduced.⁹

In addition, the Ministry of Health directed that nonessential appointments be postponed during the 2 month "circuit-breaker" period. During this time, clinic cases were screened beforehand, and patients whose condition was stable or had normal investigation results were updated of their results over the phone and had their appointments postponed to a later date. This helped reduce the number of patients waiting in clinic, and led to our lowest clinic number of 781 patients in May 2020 during the peak of the COVID outbreak in Singapore (Figure 1).

Similarly, non-urgent surgeries were also postponed or cancelled. Operating theatres were segregated into COVID and non COVID areas, and manpower redistributed. This resulted in our ENT department's low number of 122 surgical cases in May (Figure 2). While this led to a longer waiting time for nonessential surgeries, the essential surgeries such as malignancy-related surgery continued as per usual, ensuring that patient safety was not compromised during this unprecedented global pandemic.

As the COVID-19 situation improved in Singapore and the country gradually reopened over the 2nd half of 2020, routine healthcare services were slowly resumed. Despite continuing to adhere to social distancing measures, the ENT department was able to restore clinic outpatient attendances to normal by the end of the year (Figure 1). Similarly, reopening of operating theatres resulted in a total of 977 operations in November, or around 90% of our usual surgical case load. By Jan 2021, the department will have resumed our normal 2 operating theatres per day. Despite the increase in number of clinic patients and surgeries, safe distancing regulations, stringent national level contact tracing procedures and appropriate personal protective equipment have ensured continued safe operation of healthcare services.

Personal Protection Equipment during patient contact

ENT surgeons are at a higher risk of contracting COVID-19 due to our exposure to higher viral loads during aerosol generating procedures, i.e. clinical examination and invasive procedures related to the respiratory tract and airway-connected cavities.¹⁰ A published article by our department recommended different levels of Personal Protective Equipment (PPE) based on surgical risk factors.¹¹

Corresponding Author: Lim Ming Yann
Email: ming_yann_lim@ttsh.com.sg

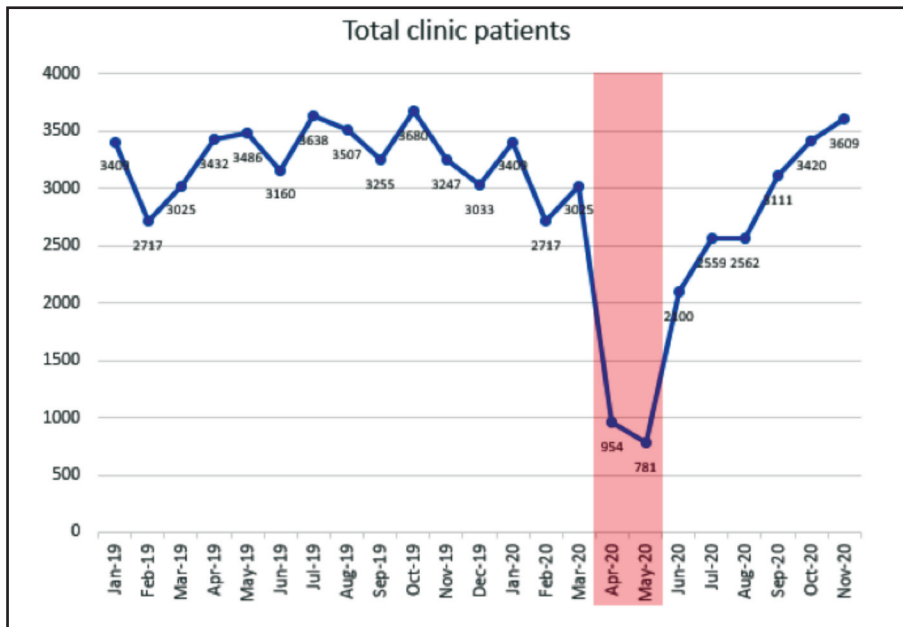


Fig. 1: Monthly number of outpatient visit in the ENT clinic. Shaded area indicates circuit breaker period of April and May 2020.

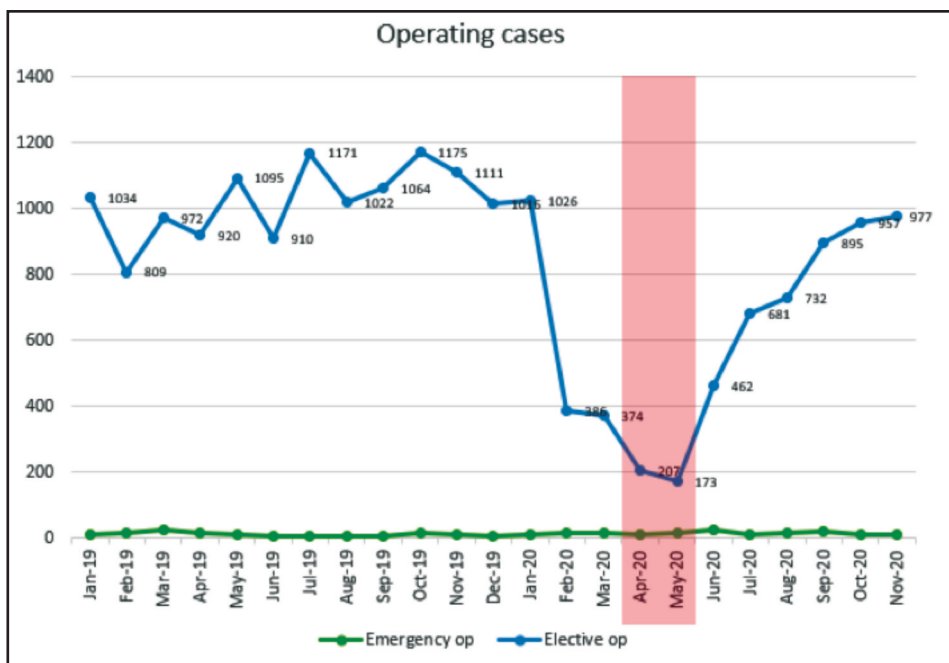


Fig. 2: Monthly number of surgical cases. Shaded area indicates circuit breaker period of April and May 2020.

PPE can be divided into 3 levels.¹¹

Level 1: Surgical mask, eye protection, disposable gloves, gown, surgical cap

Level 2: Fitted N95 mask, eye protection, disposable gloves, gown, surgical cap

Level 3: Powered Air-Purifying Respirator (PAPR), eye protection, disposable gloves, gown, surgical cap, shoe covers

Level 1 is recommended for general patients who need procedures without any drilling or access to the upper aerodigestive tract.

Level 2 is recommended for general patients requiring airway or oropharyngeal or sinonasal procedures, or otological procedures that require drilling, or head and neck surgeries that require access of the upper aerodigestive tract.

Level 3 is recommended for all patients suspected or diagnosed with COVID-19 especially when they require procedures involving drilling or access of the upper aerodigestive tract

Currently, despite the low number of COVID-19 cases in Singapore, continued vigilance is still maintained to protect

both patients and healthcare staff. Thus, our department is still continuing with the PPE recommendations for all clinic patients and operations, and carefully titrating downwards, cognisant of the known psychological and thermal impacts of PPE on healthcare workers.

Manpower requirements for COVID frontline work

During the peak of the local outbreak, manpower from the ENT department was necessarily redeployed to serve in higher manpower requirement areas, such as the Emergency Department or the National Centre for Infectious Diseases (NCID) where COVID-19 patients were managed. This redeployment of manpower was only possible because of the concomitant reduction in nonessential ENT workload.

Following the reduction in the number of active covid-19 patients in Singapore towards the 2nd half of 2020, manpower has also been returned to the department, with only a standby roster for redeploying doctors if there is a future wave of COVID outbreak in Singapore.

Resident training

COVID-19 has had a significant impact on ENT resident training. Ultimately, reduced outpatient numbers accompanied by a resultant lesser number of surgeries, meant that clinical exposure was proportionately reduced for residents. An additional impediment was the national directive to limit interhospital movement of healthcare individuals, to limit cross infection, but also resulting in residents being unable to benefit from subspecialty rotations to other hospitals (e.g. paediatrics).

Limiting interhospital movement also meant that it was necessary to move the National Residency teaching programme onto an internet platform (eg. Zoom). Interestingly, this resulted in improved attendances at the didactic sessions, possibly because of increased convenience of the zoom platform, although interpersonal interaction between senior and resident was reduced.

Annual academic examinations were also delayed for a few months to reduce interhospital contact among both examiners and candidates, until the outbreak situation improved.

Towards the end of 2020, with Singapore gradually reopening in phases 2 and 3, residents have been able to re-establish their previous training norms prior to the onset of COVID-19.

Education and research

Department meetings and CME (continuing medical education) meetings were held with strict social distancing and mandatory mask wearing. Subspecialty board meetings which involved participation of other institutions were necessarily held over teleconferencing platforms to eliminate interhospital interaction amongst individuals.

Unexpectedly, this COVID crisis did create many opportunities to research and publish, with many journals fast-tracking relevant publications important to the developing pandemic. This resulted in a surge of research

projects within the department, including papers on safety considerations in performing tracheostomy in COVID patients, levels of PPE for ENT procedures and operations, the prevalence of anosmia in COVID patients, and other unique experiences of our ENT department in this pandemic.¹¹⁻¹³

CONCLUSION

COVID has affected the ENT department in every aspect of our practice for the major part of 2020. But thanks to a Singapore whole-nation effort to contain the outbreak, rather than just efforts restricted to the healthcare industry, the incidence of COVID infection in the community has reduced to the point where we are now practicing ENT only slightly differently from previously. The main differences revolve around safety aspects such as social distancing, tracking of the movement of individuals with contact tracing, the mandatory use of face masks by both staff and patients, and heightened awareness that aerosol generating procedures (AGPs) remain a high risk procedure in ENT. Benefits that have accrued from the outbreak include increased COVID research and publications in the realm of Otolaryngology, and more widespread CME because of internet conferencing platforms.

Documenting our experience has helped us to understand the areas of work which can be affected in a pandemic and the factors that have helped to mitigate disruption. This will prove useful in our approach to subsequent pandemics.

Continued vigilance remains crucial in this time of uncertainty, and to prevent the possibility of a dreaded next wave of infection in Singapore. In our fight against COVID-19, our department will continue to adapt as necessary to ensure that our ENT services remain available and accessible to the public.

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Strategies in confronting the COVID-19 pandemic at a tertiary public hospital for Otorhinolaryngology services in Perak, Malaysia

Purushotman Ramasamy, MS ORL-HNS (UM)¹, Vigneswaran Kumarasamy, MMS ORL-HNS (UM)¹, Philip Rajan, MMed. ORL-HNS (USM)^{1,2}

¹Department of Otorhinolaryngology – Head & Neck Surgery, Hospital Raja Permaisuri Bainun, Ipoh, Perak, Ministry of Health, Malaysia, ²Clinical Research Centre, Hospital Raja Permaisuri Bainun, Ipoh, Perak, Ministry of Health, Malaysia

ABSTRACT

The COVID-19 pandemic has led to a significant shift in the practice of almost all medical fields. Surgical specialities were particularly hard hit as these services had to give way to the more urgent management of COVID-19 patients both in-ward and in intensive care units. In otorhinolaryngology (ORL) practice, an additional issue to be dealt with was a relatively higher risk of being exposed to viral droplets from aerosol-generating procedures and examination of oral and nasal cavities of patients. This article describes our experience in managing ORL services at a government tertiary referral hospital, Hospital Raja Permaisuri Bainun, Ipoh, during the current COVID-19 outbreak since the year 2020. Two novel strategies were introduced namely the outsourcing of radiotherapy services for cancer patients and an innovative design in endoscopic examination of patients.

KEYWORDS:

Otorhinolaryngology, COVID-19, radiotherapy, endoscopy, innovation

INTRODUCTION

Otolaryngologists are at a higher risk of COVID-19 droplets exposure from infected patients. The first casualty reported from among physicians worldwide was an Otolaryngologist.¹ The COVID-19 symptoms consisting of sore throat, runny nose and anosmia and the routine examination of the oronasal cavities with or without endoscopes have greatly increased the infection risks amongst otolaryngologist significantly.²⁻⁴

The term aerosol-generating procedure (AGP) was coined to appreciate the dangers and the necessity to modify airway related practices, not only among the otolaryngologists but also among the other practitioners such as anaesthetists and oral-maxillofacial-dental surgeons. Health Protection of Scotland clarified AGP as medical and patient care procedures that result in the airborne particles that can transmit infection that otherwise can only be transmitted by the droplet route.⁵ Coughing and sneezing were excluded from the AGP list as the droplets emitted are larger and spread to a shorter distance. The Ministry of Health Malaysia, ORL services issued guidelines in March 2020 on outpatient and inpatient services and AGP.⁶

In Perak, Malaysia, surgical ORL services are available in the following places: at Ipoh; Hospital Raja Permaisuri Bainun (HRPB), Taiping; Hospital Taiping and Teluk Intan; Hospital Teluk Intan. The Movement Control Order (MCO) was first declared in Malaysia on 1st March 2020 to halt the spread of the COVID-19 pandemic. Travel restrictions, curfews, closure of public areas, social distancing and other preventive measures were introduced. HRPB was declared a Hybrid Covid Hospital that mandates the hospital to manage COVID-19 patients and other emergencies/semi-emergencies.⁷

One of the strategies proposed to maintain the continuity of ORL surgical services was to decant surgical services to Hospital Teluk Intan (HTI) and Hospital Taiping. HTI however, was one of the first hospitals in Malaysia to be affected by the COVID-19 pandemic. On the 8th March 2020, two hospital personnel were confirmed to be positive for COVID-19, subsequently spreading to another 47 of hospital staff. The first case in Hospital Teluk Intan was traced to have originated from a medical officer who attended the 'tabligh'-religious meeting that was one of the initial source of cases in Malaysia.⁸ The rising number of COVID-19 cases thence eventually led to Hospital Taiping and Hospital Teluk Intan managing Covid patients. Therefore, decanting of our surgical services was not a feasible option.

Overview of ORL Services at HRPB, Ipoh

ORL services at HRPB, Ipoh consists of the core ORL services besides audiology and speech therapy services. The core ORL services include outpatient clinics, in-ward patient management and surgical services, including daycare surgical services. A comparison of workload between 2019 and 2020 is provided below (Table I).

The total number of outpatients seen in 2019 was 33,093. The number dropped to 16.1% to 24,892 in 2020. Similarly, the audiological and speech outpatients' visits were cut down tremendously, which recorded a marked drop to 43.4% and 43.1%, respectively. The routine outpatient procedures such as incision and drainage of superficial abscess under local anaesthesia, nasal and nasopharyngeal biopsies, aspiration of lump and bumps, fine needle aspirations for cytology were reduced to 7% compared to the previous year.

Corresponding Author: Philip Rajan
Email: prajan333@yahoo.com

Table I: Decrease in the number of patients in outpatient services

Year	Outpatient ENT	Outpatient Audiology	Outpatient Speech	Outpatient Procedures
2019	22528	7538	3027	17695
2020	18907	4263	1722	16458
Percentage of decrease (%)	16.1	43.4	43.1	7.0

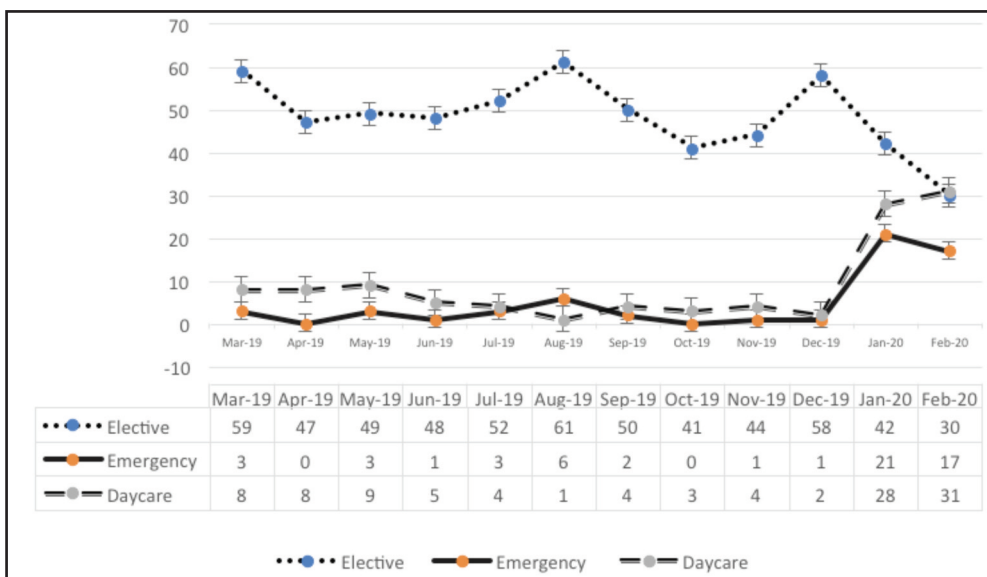


Fig. 1: Number of operations done within 12 months before the pandemic.

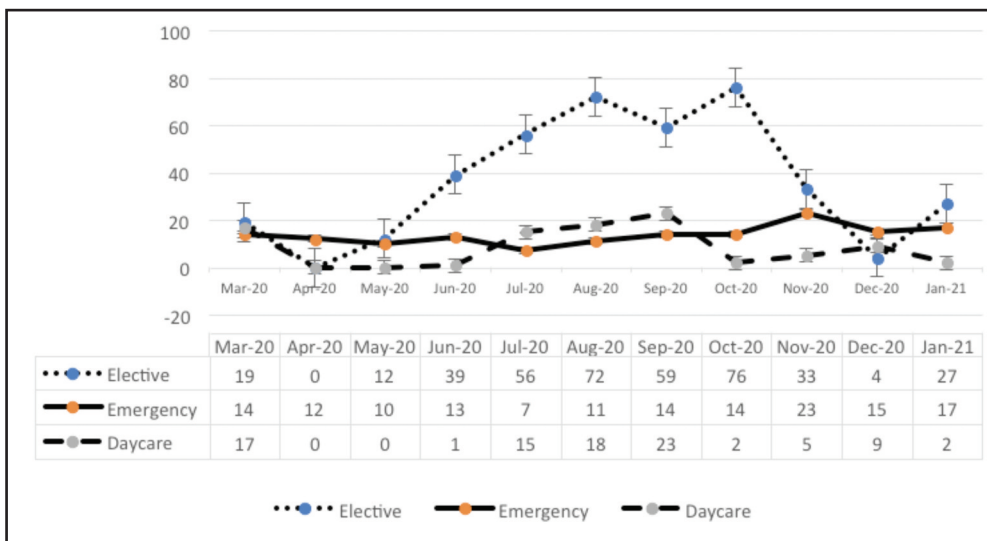


Fig. 2: Number of operations done within 12 months during the pandemic.

Other than the clinics, there was a marked shift in the trend of surgical procedures performed. Figure 1 and 2 which compares the number of procedures performed in the 12 months duration, before and after the pandemic. The total number of cases performed in our department in HRPB was reduced to 8.58% compared to the year before. This reduction by 28.4% were mainly in the elective procedures. Meanwhile, a 64.4% rise in the number of emergency cases was observed.

Since most cases were posted as semi-emergency rather than under elective operating list. Day-care procedures were wholly stopped in April and May 2020 and only one case was done in June 2020. However, 54.4% of the day-care cases performed during the pandemic were done between July until September 2019 to clear the pending cases and when the outbreak was better controlled.

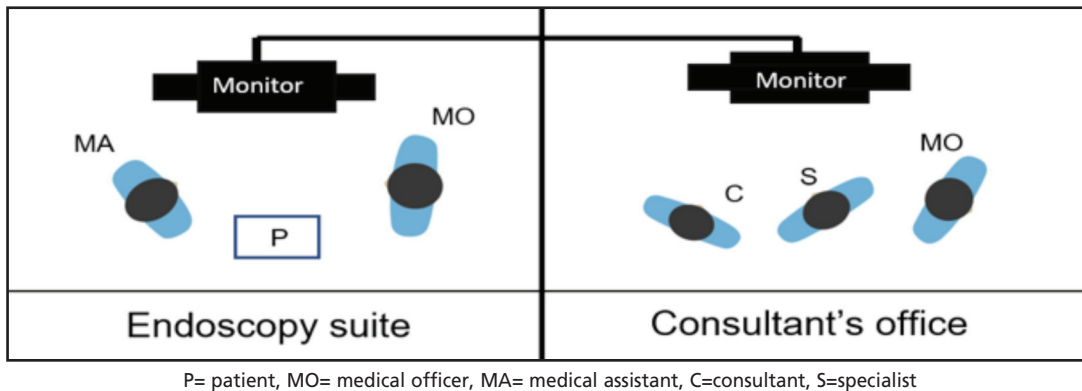


Fig. 3: Schematic depiction of the wire connected monitors in the endoscopy suite and consultant's room.

Strategies adopted in the Outpatient and Endoscopic Services

Part of the new norms in preventing the spread of COVID-19 was social distancing and the need to reduce over-crowding. Thus, the number of patients who could be seen in the clinic at any given time had to be reduced. The clinic appointments were rescheduled based on the priority of the cases, and some patients were interviewed via telephone calls. There was a 16.1% drop for ORL patients while the figure was higher for audiology and speech therapy clinics being 43.4 and 43.1%, respectively.

Triaging and screening counters were set within the first week of the outbreak to minimise the number of patients in the clinic. Standard screening questionnaires by the Ministry of Health, Malaysia were used. A medical officer was permanently scheduled to be at the screening counter. In the waiting area, social distancing was implemented in the seating arrangement. Hand sanitising were emphasised and monitored among the staff and patients. All healthcare personnel in the clinic were required to at least wear a 3-ply surgical mask, apron, and face shield according to the Ministry of Health guidelines. Training for donning and doffing of personal protective equipment (PPE) was given.

Endoscopies were only performed for the essential cases. The number of the personnel within the endoscopy suite were limited to only two at a time, one medical officer and a medical assistant donning a complete set of disposable PPE with N95 mask. Epistaxis, sinusitis patient's refractory to treatment or possible complications, malignancies were the absolute indications for nasal endoscopy. Endoscopes and instruments were sterilised with MedistelTM, which has virucidal activity by 10 minutes. Patients were scoped while their mouth was covered with a mask. Cotton pledgets were used to decongest and anaesthetise the nasal cavity instead of the regular nozzle sprays. When nasal toileting were required, we used a non-fenestrated suctioning tip to reduce aerosolisation.

An innovation in the clinic was that the monitor in the endoscopy suite (Karl Storz system) was wire connected to another monitor in the room of consultants to project the images in real-time (Figure 3). This was the most significant step forward to contain the spread of infection. Thus,

consultants were able see the endoscopy findings without the need to break the barrier created in the endoscopy suite. This also helped to optimise the use of PPE, which was in shortage during the beginning of the pandemic.

Routine otoscopies in patients with otorrhea were suspended to avoid proximity with face of patients. Instead, we shifted to endoscopic examination of the ears of patients as the standard examination. In fact, the middle ear mucosa is in continuum with the upper airway mucosa and theoretically has the risk of harbouring viral particles. However, evidence on the positive COVID-19 swabs from middle ear samples are relatively weak.^{9,10}

The staff in the ORL clinic were organised into teams with a designated schedule for providing services. This was to ensure continuity of service should any team member or team contract or come in contact with a COVID-19 patient; the members of the remaining team can be functional. Pharmacy services were also changed to reduce congestion in the hospital. Drive-through services and home delivery services were among the services introduced or strengthened.¹¹ Whilst speech therapy sessions were carried out as virtual sessions.

A new norm of the operating room

As soon as the outbreak of COVID-19 was announced, we postponed all elective cases. The available resources were conserved for operating only on the emergency cases. All patients were required to undergo a COVID-19 PCR test 48 hours before the surgery unless in the emergency cases where a rapid antigen test was acceptable.¹² The most senior surgeon was listed to perform the surgery to ensure rapid turnover time in the theatre. The personnel within the OT were kept limited. During the operation, powered instruments and electric scalpels were avoided to reduce generating aerosol. We realised that prior briefing and planning made ensured the procedure went smoothly as communication was at times difficult when personnel donned the complete PPE.

At the beginning of the pandemic, we did not have any positive airway pressure respirator (PAPR) at our disposal in HRPB. Thus, performing tracheostomy became a daunting

task. We again had to resort to our creativity to minimise aerosolization during tracheostomy. The protocol we followed was that the surgeon announces to the anaesthetist before making the tracheal incision. The anaesthetist will then switch off the circuit to create an apnoea for a brief moment to ensure to aerosols or secretions are not expelled while the incision is being made. After the tracheostomy tube is inserted and the cuff is inflated, the circuit is reconnected.

Semi-emergencies; The Challenges in Managing Head and Neck Malignancies

Managing of head and neck malignancies posed a unique challenge at this time. Many of these patients required chemoradiation in addition to surgery. Hence, the challenge was two-fold, to prioritise the surgeries. Secondly, to ensure early access to oncologic care, as HRPB was not equipped with radiotherapy facilities. Patients who required radiotherapy had to be referred to Hospital Kuala Lumpur (HKL). The travel restrictions and disruption of visiting oncology services from HKL could delay management and subsequently the outcomes.

Many cases of malignancy were initially transferred to Hospital Taiping for surgical management as Hospital Taiping was a designated Head and Neck surgical oncologic centre. As surgical services gradually resumed in HRPB after the initial disruption following the announcement of the MCO, priority was given to the patients with malignancy or suspected with malignancy. Figure 2 shows a sudden increase in elective cases from June, of which priority was for malignancies or suspected malignancies.

The Ministry of Health set up a special COVID-19 fund, Malaysia to outsource services to Private Hospitals (as all COVID-19 patients were admitted to government hospitals only at that time). On the 3rd of November, 2020, the Department of ORL became the first speciality in Perak, Malaysia to utilise this fund to outsource radiotherapy services to a private hospital in Ipoh. Out of 36 patients who required radiotherapy, 25 patients (69.4%) received it in nearby private centres after consultation with oncologists from HKL.

CONCLUSION

The COVID-19 pandemic resulted in many new problems. New and innovative solutions had to be sought in order to deliver our services to patients not just in clinical practice but also in service delivery. The changes instituted by the Department of ORL HRPB Ipoh managed continuity of care, specialist level care in a timely manner, especially for the priority groups of patients. Some of these changes have improved our service provision and will now continue to be part of routine ORL practice in the future.

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Otorhinolaryngology services at a district hospital in Sabah, Malaysia during the COVID-19 Pandemic

Gagandeep Singh Mann, MS(ORLHNS)¹, Philip Rajan, MMed(ORLHNS)², Halimuddin Sawali, MS(ORLHNS)³

¹Department of ORL, Hospital Tawau, 91007, Tawau, Malaysia, ²Department of ORL and Clinical Research Centre, Hospital Raja Permaisuri Bainun, Ipoh, Malaysia, ³Department of ORL, Hospital Queen Elizabeth, Kota Kinabalu, Malaysia

INTRODUCTION

The SARS-CoV-2 Virus, commonly referred to as the COVID 19 virus has transformed the way we live our lives. Ever since it was first detected in the city of Wuhan, China at the end of 2019, this virus has spread across the globe, with 107 million confirmed cases and 2.36 million deaths at the time of writing.¹ This number continues to increase on a daily basis. It is on course to become one of the worst respiratory virus related pandemics to hit the human populate. Every aspect of our life, from the way we eat at a restaurant, the way we do our groceries, the way we travel and also the way we work has been affected. This article will describe how the pandemic has affected the way the Otorhinolaryngology (ORL) service is managed in a district hospital in East Malaysia.

Tawau district saw a huge number of cases during this outbreak. From March 2020 to August 2020, Hospital Tawau registered 100 COVID admissions, and the next wave from September 2020 to January 2021 saw 5990 admissions.

COVID 19 was first officially declared a pandemic in Malaysia on the 1st of March 2020 with a three month implementation of a complete lockdown termed a movement control order (MCO). The first case of COVID 19 in Sabah was reported in Tawau Hospital on the 12th of March 2020, in a 58 year old gentleman who had previously attended a religious ceremony in Sri Petaling, Kuala Lumpur.² This gentleman also became the first fatality in the state of Sabah. He died on the 20th of March, 8 days after his admission to Hospital Tawau.³ There was a total of 4314 cases nationwide during the first MCO.⁴

Hospital Tawau is classified as a district hospital offering specialist services. The specialities include General Surgery, General Medicine, Obstetrics & Gynaecology, Orthopaedics, Paediatrics, Anaesthesia, Psychiatry, Ophthalmology, Imaging and Diagnostics, Emergency Medicine as well as Otorhinolaryngology. The hospital has 401 beds and is the main referral centre for the South-eastern part of Sabah. As such, it is the point of referral for the cluster hospitals in the region, mainly Hospital Kunak, Hospital Lahad Datu and Hospital Semporna. The Otorhinolaryngology department in Hospital Tawau consisted 2 specialists and 5 medical officers at the time.

COVID in ORL Practice

The common manifestations of COVID are generally ORL related, and they include sore throat, rhinorrhoea, nasal

congestion, hyposmia, anosmia, dyspnoea, and also headaches or dizziness.^{5,6} These presentations tend to render the ORL Department the first point of contact for a potential COVID-19 patient. Also, considering the full clinical examination of a patient with an ORL symptom will involve nasal endoscopy and laryngeal endoscopy, both of which are aerosol generating procedures, it is imperative the ORL surgeon takes proper precautions prior to attending these patients.

Changes in Clinical Practice

The ORL Department in Hospital Tawau at the beginning of the COVID-19 pandemic consisted of two ORL surgeons and five medical officers. Early in 2020, with the increasing number of cases especially in the South-eastern part of Sabah, our hospital personnel quickly became overwhelmed with the requirements for hospital beds and ICU ventilators. A hospital level COVID taskforce was set up on the 12th of March 2020, under the stewardship of the Hospital Director, Physicians as well as the Emergency Physicians. Most departments were requested to release a number of their medical officers to help out with the COVID team as quarantine centres were set up in a community hall and sports centre near the hospital in stages beginning March 2020, during the second wave. The Forensic Department was converted into a fever centre to screen patients for COVID and screening services started on the 12th of March 2020. Eventually we also converted a small portion of the nursing college next door to accommodate the increasing number of patients. Our department loaned out two of our medical officers to the COVID team in March 2020, leaving us with three medical officers and two specialists.

Considering the ORL services would be a potential first port of call for patients with mild COVID Symptoms, we enforced a strict cut down of our total clinic numbers. We only focused on patients with acute and emergency problems as well as cases where malignancy was suspected.

Our clinic protocol included having patients take a mandatory Covid Antigen Rapid Test Kit (RTK) test prior to coming in to the clinic from the month of March 2020. RTK tests were taken at the COVID Screening area at the Emergency Department and patients would usually wait between 90 to 120 minutes for their results prior to coming into the clinic. This RTK test included any persons who were going to accompany the patients in the clinic. We also limited the number of persons who could accompany a

Corresponding Author: Gagandeep Singh Mann
Email: dr.gaganmann@gmail.com

Clinic and Operating Theatre Statistics

Time Period	Outpatient Clinic Patients	Inpatient Admissions	Elective OT cases	Emergency OT Cases
Jan – Dec 2019 (12 months) Pre-COVID Pandemic	10306	393	231	179
Mar 2020 – Feb 2021 (12 months) COVID Pandemic	3107	344	60	44

patient to one. All consultations were limited to a maximum of 15 minutes per patient and patients were not allowed to remove their masks in the consultation room.

Clinical examinations were performed in the Endoscopy room, which is separate from the consultation room. The Endoscopy room was manned by dedicated Medical Assistants who wore Personal Protective Equipment, including a 3 ply surgical mask, face shield, gowns, as well as gloves for every procedure. Any of the doctors performing scopes also applied to the same personal protection. Endoscopy procedures were reserved for patients with acute or emergent problems and in situations where we needed to assess for presence of malignancy.

Patients with acute ORL symptoms seen in the Emergency Department were attended to with full Personal Protective Equipment and all instruments were disinfected immediately post procedure. Patients who required admission with a RTK or PCR result that was pending was sent to the Severe Acute Respiratory Illness (SARI) ward. The SARI ward was specially created for patients awaiting the results of the COVID test, and once they were clear of COVID, they were admitted to our ward.

Due to the increasing number of beds required to accommodate the COVID patients, all surgical specialities shared one ward and the rest of the wards were allocated to COVID patients. Patients who required Chemotherapy were sent to the Field Hospital which was set up by the Armed Forces of Malaysia, and the field hospital received the first of the non Covid patients on the 22nd October 2020. The field hospital was also used for patients who were stable post-surgery, for example patients with neck abscesses which had been drained, requiring IV antibiotics. Our medical officers would go and review the patients in the field hospital each morning before heading to the main hospital to start the day. The ORL surgeons took turns to be present at the clinic during the pandemic to reduce the risk of COVID transmission. In the event of any contamination it would allow the other specialist to be available to provide on call cover. The number of staff allowed in the clinic pantry was limited to one at a time, and eating meals together was strictly prohibited.

Patients admitted to the ward for emergency procedures all underwent mandatory urgent Polymerase Chain Reaction (PCR) tests. And once they were cleared of COVID, the cases would be booked for Emergency Theatre. None of the patients had a dire enough emergency that could not wait for a PCR test to be completed. Our plan for any such case which required immediate surgery was to proceed with full PPE cover in the operating theatre.

Prior to the pandemic, the ORL Department of Tawau also provided monthly Visiting specialist clinics to Hospital Lahad Datu as well as 2 monthly visits to Hospital Kunak and Hospital Semporna. All visiting clinics were indefinitely postponed from the month of March 2020. Emergent cases were advised to be sent directly to Tawau Hospital.

COVID Positive Patients

Our experience showed that even with the RTK test being negative, there were two instances where the patients seen were found to be subsequently COVID positive. We immediately shut the clinic down and carbolysed the areas where those patients had been present, namely the consultation room and the endoscopy room. ORL Staff exposed to the patients all underwent mandatory PCR tests and were quarantined until their results were known. Thankfully none of the staff were infected with COVID. Our strict movement protocols in the department was probably the reason we managed to avoid cross contamination to our staff.

We performed two tracheostomy procedures for COVID patients requiring prolonged ventilation. We reserved the surgery until day 21 post diagnosis of COVID to reduce the risk of transmission. Even then, we performed the procedures with the full protective equipment, including using Powered Air Purifying Respirators (PAPR)

CONCLUSION

At the time of writing, the State of Sabah continues to deal with the third wave of the COVID in Malaysia. The absolute numbers are not as bad as the first or second wave, however the proportion of ill patients in Stage 4 & 5 are just as bad as the previous waves. It remains to be seen if these numbers will go down over the coming months considering a Movement Control Order is in place. The one thing we have learnt from the multiple waves is, it's always better to be safe than sorry so it is imperative we keep our guard up for the time being.

CONFLICT OF INTEREST

The authors declare no conflict of interest in writing this paper.

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Endoscopic ear surgery during COVID-19 pandemic

Tengku Mohamed Izam Tengku Kamalden, FRCS, Khairunnisak Misron, MMed

Department of Otorhinolaryngology – Head and Neck Surgery, Hospital Sultan Ismail, Jalan Mutiara Emas Utama, Taman Mount Austin Johor Bahru, Johor, Malaysia

SUMMARY

Similar to other surgical fraternities, endoscopic ear surgery (EES) faced great challenges during the COVID-19 pandemic. Many elective operations involving EES needed to be postponed, resulting in accumulated cases. Throughout one year during COVID-19, Hospital Sultan Ismail, Johor, Malaysia continued to perform various EES procedures. Although EES is an aerosol-generating procedure, it has become evidence that this minimally-invasive surgical approach offers lesser bony drilling and shorter operative time as compared to open mastoidectomy. Thus, this reduced the risk of viral transmission to the surgeons and operating staffs.

INTRODUCTION

No one ever imagined that the entire world would engage in a dramatic transformation because of the coronavirus disease 2019 (COVID-19) pandemic. This pandemic has spread rapidly all over the world, ever since it was first reported in Wuhan City, Hubei Province of China in November 2019. Most countries had to be put into lockdown, resulting in the restriction of most social activities, with the hope of containing the rate of transmission. In Malaysia, the movement control order (MCO) was first enforced from 18th March 2020 to 3rd May 2020. As the number of COVID-19 cases increased, a second MCO was reinforced on January 2021, followed by a third MCO on May 2021.

The medical faced and is facing the greatest challenge due to such a tremendous outbreak. Hospital facilities including beds and medical equipment had to be used for the purpose of screening and managing COVID-19 cases. Some wards were converted into dedicated COVID-19 units. Besides, the Intensive Care Unit received an increased number of COVID-19 patients who required mechanical ventilation. Medical staff from the level of paramedics, medical officers and specialists were deployed to assist the COVID-19 screening centres and the designated wards for positive cases.¹ As a result, there was a shortage of medical staff, which affected the flow of work at clinics, wards and operation theatres. Anaesthesiology teams also need to reschedule the duties of their staff, because of the demanding critical care services. Therefore, the number of operations, especially elective surgeries, were interrupted in response to the COVID-19 outbreak.

Impact of COVID-19 towards EES

Endoscopic ear surgery (EES) is an evolving otologic procedure that has gained popularity in recent years. Many

otologic procedures including external ear, middle ear and lateral skull base pathologies are now feasible with the use of endoscope via the transcanal route. Similar to other surgical fraternities, EES was largely affected during the current COVID-19 period. During this unprecedented situation, many elective operations had to be postponed. Specific precautions were re-enforced to ensure the safety of all medical staff involved during operations.

In comparison to rhinology and head and neck procedures, otologic cases are perhaps the least to requiring prompt surgical intervention.² Nevertheless, concerns have arisen about whether EES is an aerosol-generating procedure, as the operation involves the middle ear cavity, since this area is lined by the respiratory epithelium, which is interconnected to the nasopharynx through the Eustachian tube. Thus, any ear surgery has potential of viral transmission. A recent study revealed the presence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the middle ear and in the mastoid in 2 out of 3 autopsies of positive COVID-19 patients. The absence of this virus in one of the autopsies was likely due to duration heterogeneity when the sample was taken.³

Restructuring EES during COVID-19

Hospital Sultan Ismail (HSI), Johor, Malaysia serves as an Otologic Centre that receives referrals from several district hospitals. EES started in HSI since 2014, and it has become one of the leading otologic centres that performs EES in Malaysia. During this pandemic, several adjustments were implemented. Due to inadequate staffing following deployment to COVID-19 centres, anaesthetists had cut down the number of elective operations in response to preparation for the surge in critically-ill COVID-19 cases. With regard to emergency operations requiring EES, procedures continue to be carried out with stringent precautions.

The Department of Otorhinolaryngology of HSI created a guideline to restructure EES during this period. The cases that necessitate EES were reclassified into emergency operations, elective operations which cannot be deferred, and elective operations which can be deferred by prioritising on a case-by-case basis, depending on the availability of elective surgery allocations. Any postponement needed to be informed to the patients via phone calls with justifications, and to be documented in the medical records of patients.

Similar to other surgical fraternities, all cases subjected for EES underwent COVID-19 swab testing. As for the elective cases, patients were contacted a few days prior to their hospital admission, to ensure that they are free of any

Corresponding Author: Khairunnisak Misron
Email: nis875@gmail.com

Table I: Lists of EES performed at our institution throughout one-year COVID-19 pandemic (March 2020 till February 2021)

Types of EES	Pathology	Number of procedures, n (%)
External ear: • Endoscopic canaloplasty and mastoidectomy	Canal cholesteatoma	1 (4.8)
Middle ear: • Transcanal endoscopic atticoantrostomy/ mastoidectomy	Middle ear cholesteatoma	8 (38.1)
• Endoscopic myringoplasty/ tympanoplasty	Perforated tympanic membrane	3 (14.3)
• Myringotomy and ventilation tube insertion	Middle ear effusion	4 (19.0)
• Ossiculoplasty	Ossicular discontinuity	1 (4.8)
• Endoscopic biopsy	Middle ear tumour	2 (9.5)
• Transcanal endoscopic facial nerve decompression	Traumatic facial nerve paresis	1 (4.8)
Lateral skull base: • Infrapromontorial approach excision of tumour	Intracanalicular vestibular schwannoma	1 (4.8)

**Fig. 1:** Setting up of endoscopic ear surgery during COVID-19 pandemic.

symptoms such as fever, sore throat, difficulty in breathing or anosmia. Our department established a temporary quarantine area for nasopharyngeal swab RTK-Ag COVID-19 testing for all new admissions. In negative COVID-19 swab testing, appropriate PPE during the operation is highly recommended, as EES is considered to be an aerosol-generating procedure. The surgeons, scrub nurses and anaesthetists were well-equipped with surgical masks and face shields (Figure 1). In fact, the usage of face shield was easier during EES procedure than while using the microscope. One year into the pandemic, despite the delay and deferment of the elective surgeries, we managed to perform 21 EES procedures that included external ear, middle ear and lateral skull base pathologies, with the stringent safety protocols shown in Table I. Most of the procedures involved middle ear diseases (90.5%) that required bone drilling or curetting.

It is pertinent that otologic procedures involve drilling of the bone. The implementation of protective measures while using a high-speed drill can protect surgeons from bone debris containment.⁴ A chisel is an option to reduce the bone debris load produced by a high-speed drill.⁵ In contrast to open mastoidectomy, EES offers a minimally-invasive

technique that requires less bone drilling with usage of a low-speed drill. Besides, it has been reported that the bony droplet formation following an endoscopic procedure is significantly reduced compared to open mastoidectomy.⁶ Although there is no study comparing the safety of EES with open mastoidectomy with regards to COVID-19 transmission, EES should be a prioritised choice for any otologic surgeries during this pandemic based on aforementioned evidence.⁷

The literature available on EES reports that endoscopic tympanoplasty shortens the operating time as compared to the microscopic approach.⁸ In contrast to the conventional postauricular approach, EES also offers a shorter hospital stay postoperatively, and no external scars.⁹ These factors are in favour with practices of any otologic surgeries during this pandemic, as it reduces the duration of exposure in the operation theatre, thus minimising the risk of spreading the infection.¹⁰ Restriction in a number of attendees in the operating theatre is highly encouraged to control the spreading of the disease. Trainee doctors are not recommended to join the surgery physically, to minimise the crowd in the operating theatre. A video recording of the EES allows continuous learning opportunities for the trainees.

Practice of EES aftermath

Although the timing for any surgery is still controversial, a new strategy is mandated to overcome such a situation. It must be remembered that cholesteatoma can progressively worsen and patients might present with acute life-threatening complications. Further, delaying the operation might impose anxiety to both the patients and the surgeons.¹¹ Otolologists are advised to continuously implement safety and protective measures during EES, even in negatively-tested patients for COVID-19, since there remains to be a risk of false-negative results. The discovery of a vaccine towards COVID-19 gives the world more hope in combating this pandemic. Similarly, it brings to light for EES in the near future in the otology field.

CONCLUSION

To date, the world is still struggling in battling COVID-19 infections. COVID-19 invariably left a significant mark in the practice of EES, especially among otologists, during this outbreak. Despite all these challenges, the practice in EES needs to move on, as this procedure has evolved rapidly just before the COVID-19 era. Based on our experience, the practice of EES during COVID-19 pandemic is preferable as compared to open postauricular mastoidectomy in view of lesser bony drilling, reduce operating time and shorter hospital stay. It is of utmost importance for the surgeons to choose the appropriate surgical technique with least viral exposure during this pandemic.

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Challenges in conducting post graduate otorhinolaryngology-head and neck surgery specialty examination in the time of pandemic

Irfan Mohamad, MMED ORL-HNS^{1,2}, Aneeza Hamizan, PhD³, Baharudin Abdullah, MMED ORL-HNS^{1,4}

¹Department of Otorhinolaryngology-Head & Neck Surgery, School of Medical Sciences, Universiti Sains Malaysia, Kubang Kerian, Kelantan, Malaysia, ²Post Graduate Office, School of Medical Sciences, Universiti Sains Malaysia, Kubang Kerian, Kelantan, Malaysia, ³Department of Otorhinolaryngology-Head and Neck Surgery, Faculty of Medicine, Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur, Malaysia, ⁴Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan, Malaysia.

INTRODUCTION

Ever since it was first established, the Malaysian Otorhinolaryngology-Head and Neck Surgery (ORL-HNS) specialty conjoint clinical exam (exit examination) for Master of Surgery/Master of Medicine program has been conducted every 6 months. The examination is conducted twice a year to accommodate the dual intake of June and December academic semesters. Customarily, the venue of exam is determined immediately after the completion of a professional examination which is rotated between the three public teaching hospitals offering the program ie Universiti Malaya (UM), Universiti Kebangsaan Malaysia (UKM) and Universiti Sains Malaysia (USM). Other universities taking part in the conjoint board examination are Universiti Islam Antarabangsa Malaysia (IIUM) and Kumpulan Perubatan Johor (KPJ) Healthcare University College.

Problems in conducting examination during the pandemic With the COVID-19 pandemic outbreak and the subsequent restriction of travel under the Movement Control Order (MCO) imposed by the National Security Council (MKN), not only does it severely affect teaching and learning in higher education centers, but this restriction also disrupt the conduct of professional examination, particularly clinical examination that involves face-to-face setting amongst patients, candidates and examiners.¹ The usual mid-year examination in May 2020 was deferred with the hope that it can be rescheduled to a later date, once the situation settles down. With the emergence of the third wave of COVID-19 infection, the examination scheduled in the month of November 2020, especially those involving physical interaction such as clinical and viva sessions, was at risk of being annulled. In reality, the examination could not be put off further as it has already affected the May cohort of final-year candidates from graduating and thus, forestalling them from returning to serve the Ministry of Health (MOH). Annulling the November examination would compound the problem, making it worse and more complicated, as two cohorts (May and November) of final year candidates would be affected.

In some way, new challenge requires new thinking and approach. Candidates nationwide especially the undergraduates were not allowed to enter their university's

campus and thus, need to continue with online learning from their hometowns.² Similarly, the final year postgraduate Master candidates who were supposed to join in-campus learning in preparation for their examination were advised to remain at their current hospitals until the condition was under control. Thus, the idea of decentralizing the examination was proposed with the intention to resolve this problem.

Examination in the new normal

The idea of decentralizing examination was brought about by several specialty conjoint committees, and later was brilliantly coordinated and executed by the Medical Dean Council. The objective of decentralization was to allow the examination to proceed, while limiting movement of all the three parties involved specifically the examiners, candidates and patients. As most organizing centers are located in the Klang Valley (an urban area in Malaysia centered in Kuala Lumpur and includes its adjoining cities and towns in the state of Selangor), a cross state border travel would be difficult, and not encouraged even with police approval. The consideration of movements of candidates and examiners must take into account the zoning of area based on the Ministry of Health (MOH) of Malaysia. According to MOH a red zone is when there are 41 cases or more, yellow zone is an area with one to 40 cases and green zone is an area with zero cases in the span of two weeks. The goal is to reduce the possibility of disease transmission especially from the red zones in the West Coast states (under conditional MCO) to the green zones (in the East Coast). Decentralized examination simply means the examination is conducted in different hospitals concurrently, limiting movement within the same zones only. If the number of eligible examiners is insufficient, examiners from other states were required to come in, with all the standard operating procedures (SOPs) strictly followed. In the worst-case scenario, the presence of examiners and even the observers could be accomplished via online platforms such as Zoom and Webex (Figure 1).

Standard operating procedure and troubleshooting

Clinical examinations co-organized by universities from different zones are challenging as those from red zones are not encouraged to cross into green zones for fear of spreading the COVID-19 virus. Instead of hosting the examination in

Corresponding Author: Baharudin Abdullah
Email: baharudin@usm.my

one centre as customarily done, the conjoint board clinical examination was decentralized and conducted in the candidate's own centre. Therefore, this avoided movement across zones and the risk of contracting or spreading COVID-19 infection. Furthermore, there would be less candidates taking examination in each university and this avoided crowding and allowed for physical distancing. Planning the decentralized examination needs to be a balance between health safety and maintaining the fairness and integrity of the examination. To avoid movements, candidates would take their theory (written) examination in their own centre or nearby centre, with marking standardized in all centres. The questions for the theory examination need to be distributed safely to other examination venues but it must be well protected and guarded from 'question leak'. The candidates' skills to perform otorhinolaryngology examination, potentially with high viral load, need to be assessed, but they must be protected from contracting COVID-19.³ Extra precautions need to be integrated into every part of the examination while maintaining as much of the original format as possible.

Standard operating procedure (SOP) for examination conducted during COVID-19 was available from the Medical Deans Council of Malaysia, which was circulated to all Malaysian universities. However, the COVID-19 pandemic was incredibly fluid and the SOPs were amended day by day. The organizers of the examination needed to stay alert about the ever changing situation and make adjustments accordingly. Universities were also allowed to use their own SOPs which were in line with this general guideline. Based on this understanding, all candidates, examiners and patients must fill up a health declaration form, one day before each examination day. This was done using an online survey form which was checked by a designated person. This health declaration form served as a reminder to always self-check for COVID-19 symptoms and risk of exposure, act responsibly and remain vigilant during the examination. Candidates from other red zones were allowed to come for examination provided they did not have any COVID-19 symptoms or were recently exposed to anyone infected with COVID-19. If a candidate becomes a COVID-19 suspect, having close contact or developed symptoms, the affected candidate would have to defer the examination. All involved must scan their attendances using the 'MySejahtera' application with temperature scans at the entrance of the examination venue. The 'MySejahtera' application is developed by the Government of Malaysia to monitor COVID-19 outbreak by empowering users to assess their health risk against COVID-19 and assists MOH with the necessary information to plan for early and effective countermeasures.

To ensure health safety during clinical examination, all involved must wear at least a three-ply face mask, face shield and apron at all times (Figure 2). Candidates were not allowed to bring any equipment (pen torch or personal headlight) into the examination hall to prevent candidates from using poorly sanitized apparatus. It is a well-known fact that COVID-19 virus is able to survive on plastic or metal surface for up to 72 hours as fomites.⁴ Examinations were held in open spaces and doors left open to ensure adequate ventilation. Closed small rooms were not used to avoid

crowding. The number of examiners were limited per room to allow physical distancing. The risk of infection is reduced in a room with good ventilation and half occupancy.⁵ The commonly recommended safe distance is 1 to 2 metres apart, however this may not be adequate during clinical examinations as patients would need to pull down their mask to expose their nose. A mathematical study calculated that a distance of 1.6 to 3 metres is recommended to prevent aerosol transmission from mouth while speaking.⁵ However, patients may sneeze or cough during endoscopic examination without their masks on and this can cause aerosol particles to travel up to 30 metres.⁶ Therefore, full personal protective equipment; PPE (which includes the three-ply mask, face shield, gown and gloves) was worn by both students and examiners during clinical examinations involving patients. Observers were permitted but only through online platform. As the clinical examinations were held three days in a row, at the end of each day, the organizers would review any issues, anticipate problems for the next examination day and take proactive remedies.

The clinical examinations were held in the outpatient clinic and the clinic SOPs were adapted during the examinations. Extra donning and doffing areas were created and instruction for its proper method were pasted on the wall for reference. Proper donning and doffing of PPE was important as viral transmission may occur through contaminated PPEs.⁷ The patients' nasal cavity and throat were well anesthetized to reduce cough or gag during endoscopic examination, which could disseminate the virus.⁸ The procedure of local anaesthesia application involved the use of 10 % lignocaine throat spray and Moffat's nasal packing, which was done beforehand with all persons involved wearing PPE. As each patient was allocated for 2-3 candidates, if topping was required, patients would undergo the same procedure.

A slim 2.5 mm 0-degree endoscope was used to examine the nasal cavity to reduce its contact with nasal mucosa that may initiate sneezing or reactionary watery eyes.⁹ Flexible nasopharyngolaryngoscope was used to examine the larynx instead of using the 70-degree endoscope. This is safer as students would not need to hold the patients tongue, reduces gagging and only the nasal cavity need to be exposed for endoscopy.

Transitioning from green to red zone during examination

The ever changing circumstances during the pandemic is best exemplified by one venue (USM) which has a green zone status initially prior to the clinical examination but changed suddenly to red zone in the middle of the examination. In USM, all potential patients were recruited from the nearby hospitals in the same locality. By this mean, the movement of patients was controlled and restricted to within the same area in the green zone. The patients were sourced from Hospital Raja Perempuan Zainab 2 (HRPZ 2), Hospital Tanah Merah and Hospital Kuala Krai. These are the MOH hospitals providing ORL-HNS specialty service. The sourcing of patients from the other three hospitals was necessary due to less number of patients available or willing to come due to fear of infection. To ensure safety of everyone involved in the examination, one of the criteria for the selection of patients was negative COVID-19 screening test. As the clinical



Fig. 1: During the clinical examination, a candidate is being evaluated by 3 examiners and 1 virtual examiner (enabled by the availability of webcam and lap top computer on the left side of the candidate).



Fig. 2: All candidates (in blue gown) must wear protective gear before they encounter patients during the clinical examination.

examination was decentralized, low number of patients was involved and this was one of the strategies to minimize crowding and exposure. Nevertheless, the same standard was used in terms of clinical findings expected to be seen in patients and the distribution of cases according to the subspecialties such as rhinology, otology, laryngology and head and neck.

The patients were transported using MOH ambulance after they have completed the COVID-19 declaration form and clinically screened negative from COVID-19 symptomatically. Similarly, the candidates sitting for the examination were required to be in-campus and not allowed to travel outside the state within the two-week period close to the examination date. The reason being the SOP of anyone returning from red zone requires quarantine for 14 days besides the negative RT-PCR test for COVID-19. Before the examination started, USM was in the green zone and the examiners were mainly from USM and HRPZ 2, thus the movements were only from the same locality or zone. However, USM did have several examiners from other green zones outside Kelantan (one from Terengganu and two from Pahang), in which travel was permissible and allowed. On the second day of examination, the district of Kota Bharu where USM is located was declared as a red zone after a new cluster was identified in a location just adjacent to venue. Thus, extra precautionary measures were taken. Examination candidates, as well as the examiners were required to gear up in a PPE and hand sanitizers were provided at every station.

Feedbacks from candidates/examiners and recommendation Remarkably, there were no grave complaints from the candidates involved in the clinical examination. Issues related to the use of PPEs for example fogging of the face shield or goggle didn't arise. As the use of PPEs might hinder normal conversation and affect candidates during history taking for the long clinical examination, prearrangement was made for an additional time of 10 minutes to be added.

Similarly, for the short cases clinical examination, additional 3 minutes was added, in anticipation of difficulty interpreting findings using PPEs.

In addition, we received encouraging feedbacks from the examiners involved in the clinical examination. Despite the challenging condition, equal standard was maintained at all centres with similar type of cases. This was possible as there was an agreement before hand, to select patients with good visible findings and parallel 'difficulty' index.

It was suggested to have more frequent examination trial using online method such as Zoom or Webex in order for candidates and examiners to familiarize with the format and identify any shortcomings. Additional recommendation includes increasing 'internet bandwidth' of all centres to minimize disruption of the online assessments especially in anticipation of more candidates and examiners taking part in future.

CONCLUSION

Throughout the conduct of the professional examination, there were no new cases detected or new examination clusters identified. Thus, the examination by decentralization was considered as successfully held in this new normal.

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A proposed model for postgraduate entrance evaluation amidst the COVID-19 pandemic

Mawaddah Azman, Ms, Aneza Khairiyah Wan Hamizan, PhD, Salina Husain, MD

Department of Otorhinolaryngology – Head and Neck Surgery, Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur, Malaysia

SUMMARY

The COVID-19 pandemic has affected the entrance evaluation for postgraduate studies (PGS) in various medical specialties. The PGS in otorhinolaryngology (ORL) continue to be relevant amidst the pandemic, with more than 150 applicants this year. We share here our recent experiences in managing ORL entrance examinations during the height of the COVID-19 pandemic. It is possible to conduct virtually the multi-institutional, multi-faceted evaluation for PGS entrance during pandemic situations whilst conforming to the already established format and standards.

INTRODUCTION

In the first months of 2021, the rapid community spread of the COVID-19 infection has forced many cities into the third wave and lock down with implementation of safe distancing. Following the cancellation of student enrolment and professional examination of high-stakes in the first half of 2020, the national health system in Malaysia is currently feeling the pinch to provide manpower to cope with the health of Malaysians during the pandemic. The situation in Malaysia is better compared to other badly hit countries such as Italy and the United Kingdom where medical students are fast-tracked into their workforce without sitting for the mandatory practical examinations.^{1,2}

DISCUSSION

As teachers become familiar with managing the virtual environment and evaluation methods, adapting to the strengths, weaknesses, opportunities and threat analysis ease decision making in whether or not to conduct the post graduate entrance examination in a virtual environment. An example of such an analysis, as in our case is illustrated in Figure 1.

The onus in ensuring fidelity

Among the many challenges for conducting postgraduate entrance evaluations in a virtual environment is maintaining the usual format and standards. Even in detailed formats such as the clinical examination, this task has been shown to be achievable, though difficult and laborious.³ In prior exercises outside of the pandemic, postgraduate candidates are expected to pass a multifaceted entrance evaluation conducted physically, which consist of: 1) thirty multiple-choice questions (MCQ) answered in an

examination hall in the presence of a panel of invigilators; and a 2) viva-voce evaluating candidates clinical experience and breadth of service in the national health system, conducted by a panel of expert examiners comprised of consultants and lecturers from both the health system and universities. Cumulative marks from these two components determines whether a candidate is eligible to enrol into a postgraduate study (PGS) in otorhinolaryngology (ORL).

Translating the multifaceted evaluation into a virtual environment comparable to the previous physical environment became the priority for the organizing committee from the Department of ORL, UKM Medical Centre. The team members consisted of a consultant and three specialists experienced in conducting entrance interviews. They deliberated on the feasibility of each virtual platform to conduct the PGS entrance evaluation. The team listed important determinants on the feasibility of such platforms. These determinants include confidentiality, content sharing across different institutions, assessment reliability, ease of use and technical support required. The team then gave a score between 0 to 5 (0: least favourable, 5: most favourable) based on their experience using each platform. The virtual platform with scores of less than five in any of the determinant was eliminated (Figure 2).

Risk assessment and management

Electronic evaluation has inherent problems and risks associated with integrity and equipment reliability.⁴ Other risks identified included candidate and interviewer benightments with platforms used and internet connectivity issues.⁴ Risk associated with integrity was addressed by utilising a virtual proctoring application, Quilgo® (Native Platform Ltd, London) which was embedded into Google Forms (Google LLC, USA). Virtual proctoring has been shown to avoid adjustments, keeping to the same format of prior evaluation and reduces dissatisfaction among candidates.⁵ Equipment reliability, user benightments with platforms used and internet connectivity issues are mitigated by series of trial runs targeted to specific user profiles involved in the evaluation process.

Our experiences in conducting a high-stakes otorhinolaryngology postgraduate entrance evaluation during the COVID-19 pandemic.

We have described the SWOT analysis framework and we decided to proceed with the ORL postgraduate entrance

Corresponding Author: Assoc Prof Dr Mawaddah Azman
Email: mawaddah1504@yahoo.com

	Helpful	Harmful
Internal factors	Strengths (S) <ul style="list-style-type: none"> Breadth of knowledge on various virtual applications Sufficient experience and confidence using various virtual applications Understands advantages and limitations of various virtual applications Able to appraise the risks involved and mitigate them Able to collaboratively work in the virtual environment Adhering to safe distancing: candidates and examiners stay at their places 	Weaknesses (W) <ul style="list-style-type: none"> Inadequate equipment to resource a large number of users Inadequate financial resources Lack of trained personnel to handle technical issues (may be mitigated by prior training and exposure)
External factors	Opportunities (O) <ul style="list-style-type: none"> Segregating virtual platforms according to ease of handling Easy to handle platforms for majority of users (examiners and candidates), can potentially be familiarised via trial runs Difficult to handle platforms for select minority of users, familiar with the platform. Utilize virtual proctoring to ensure integrity of evaluation 	Threats (T) <ul style="list-style-type: none"> Poor internet connectivity (may be mitigated or identified during trial runs) Insufficient equipment or device Virtual cheating

Fig. 1: SWOT analysis on conducting a postgraduate entrance examination in a virtual environment.

Multiple Choice Questions		Viva-voce			
		Asynchronous experience evaluation		Synchronous clinical evaluation	
Google Forms		Microsoft Teams		Zoom with breakout rooms (locked)	
Confidentiality	0	Confidentiality	5	Confidentiality	5
Content sharing across institution	5	Content sharing across institution	0	Content sharing across institution	5
Assessment reliability	0	Assessment reliability	5	Assessment reliability	5
Ease of use	5	Ease of use	2	Ease of use	5
Technical support required	0	Technical support required	0	Technical support required	5
Google Forms with Quilgo		E-mail		Microsoft Teams	
Confidentiality	5	Confidentiality	3	Confidentiality	5
Content sharing across institution	5	Content sharing across institution	5	Content sharing across institution	0
Assessment reliability	5	Assessment reliability	5	Assessment reliability	5
Ease of use	5	Ease of use	0	Ease of use	0
Technical support required	5	Technical support required	5	Technical support required	2
Microsoft Forms		Drive sharing		Google Meet	
Confidentiality	5	Confidentiality	5	Confidentiality	3
Content sharing across institution	2	Content sharing across institution	5	Content sharing across institution	5
Assessment reliability	3	Assessment reliability	5	Assessment reliability	5
Ease of use	5	Ease of use	5	Ease of use	3
Technical support required	2	Technical support required	5	Technical support required	5
Moodle					
Confidentiality	5				
Content sharing across institution	2				
Assessment reliability	2				
Ease of use	4				
Technical support required	3				

Legends: 5: Most favourable; 4: More favourable; 3: Favourable; 2: Neutral; 1: Not favourable; 0: Least favourable
 Fig. 2: The elimination method based on specific determinants used to decide on the best virtual platform.

evaluation during the COVID-19 pandemic. The evaluation comprised MCQ and viva voce examination. The MCQs were done using Google Forms (Google LLC, USA) incorporated with Quilgo® (Native Platform Ltd, London). Personalised test links were emailed to the devices of a total of 158 candidates five minutes prior to the time of the examination. Quilgo® (Native Platform Ltd, London) injects a timer and behaviour tracking tools into the created Google Forms (Google LLC, USA). The personalised test link, strict individual timing and camera tracking enabled us to ensure high levels of fidelity and integrity in this component of the virtual evaluation. In this virtual proctoring, the Quilgo® (Native Platform Ltd, London) algorithm detects multiple faces and multiple windows opened on candidate's device and a report is generated after the Google Forms (Google LLC, USA) expires. It is made known to all candidates that marks will be discredited if this report shows such deviations. This prevents cheating during the evaluation and creates fear. Technical difficulties were encountered among candidates who sat for the MCQs in certain hospitals where personal devices were not used. This problem was easily countered by asking the candidate to use mobile phones to attempt the MCQs.

The viva-voce component was further compartmentalised into two sections: 1) asynchronous evaluation of breadth of experience in national health system; and 2) synchronous evaluation of clinical experience by panel of examiners. Candidates were instructed to provide the necessary supporting documents, filed unanimously into a dedicated Google Drive (Google LLC, USA) account. A select panel of examiners, would then appraise the supporting documents and give marks according to a standardised evaluation sheet. This evaluation sheet is then signed, dated and uploaded into the candidate's file on Google Drive (Google LLC, USA). The asynchronous evaluation of the candidates experience profile was completed one week prior to the synchronous evaluation. The synchronous evaluation of clinical experience by panel of examiners took place within half an hour after the MCQ examination ends. A total of 158 candidates and 42 examiners were gathered on Zoom platform, when the viva voce took place. Three examiners examined each candidate

and gave individual marks using a standardised marking sheet on Google forms. Average mark was then used to ensure a high level of fidelity and integrity. The MCQ and the viva voce evaluation for a total of 158 candidates from various states from all over Malaysia was successfully completed in six hours. All 42 examiners agreed that this evaluation was reliable to select the ORL PGS candidates.

CONCLUSION

The virtual postgraduate entrance evaluation integrates desirable advantages including cost⁶ and effectiveness of time,⁷ whilst maintaining fidelity to established formats and standards,^{3,8} as well as respecting safe distancing.^{6,9}

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We're making it work! UKM'S Speech Sciences Programs' teleclinic experience in the time of COVID-19

Yazmin Ahmad Rusli, PhD Sp-Lg Sc, Ohio, USA^{1,2}, Fatimah Hani Hassan, PhD Sp-Lg Sc, Ohio, USA^{1,2}, Siti Munirah Haris, BSc. Sp Sc, UKM¹, Hafizah Mohd Azraai, BSc. Sp Sc, UKM¹, Siti Nabihah Md Almi, BSc. Sp Sc, UKM¹

¹Speech Sciences Program, Faculty of Health Sciences, Universiti Kebangsaan Malaysia, ²Centre for Rehabilitation & Special Needs (ICaRehab), Faculty of Health Sciences, Universiti Kebangsaan Malaysia

ABSTRACT

This paper highlights issues, challenges, and lessons learnt from implementing a speech-language therapy teleclinic service delivery model by the Speech Sciences Program, Universiti Kebangsaan Malaysia (UKM) during the wake of the recent COVID-19 pandemic. The teleclinic service provision was initially started to help our student cohorts attain and complete the required direct contact speech-language therapy clinical hours for graduation during the pandemic. It has since evolved to be an integral part of the clinical practicum curriculum and a service delivery model that is here to stay. Although far from perfect, the program hopes to systematically continue our endeavours in telerehabilitation as one of our niche areas, realising the wealth of benefits that this service delivery model has to offer.

INTRODUCTION

Universiti Kebangsaan Malaysia's Speech Sciences program is a 4-year entry-level degree program for speech-language pathology (SLP); the first designed in the Southeast Asia region catering to the needs of individuals with speech, language, communication, and swallowing disorders across their lifespan. To date, the program has produced 21 graduating cohorts (with an estimate of over 300 entry-level speech-language therapists, SLTs) since the first graduating class in 1999.¹

At the Audiology and Speech Sciences Clinic (KASP), UKM Kuala Lumpur, SLT services are provided primarily via service clinics by the program members or supervised student clinical practicums. All practicums are typically conducted via traditional face to face (FTF) sessions through individual and group/classroom therapy settings.

The abrupt transition to student's clinical practicums began when the pandemic hit mid-March 2020. We officially started our teleclinic experience by trialling three online therapy sessions with our final year students and interested clients and parents/caregivers for this purpose. All other clinics were put on hold during this time to give room for the program to embark on this new learning curve. The commentary follows on through three points of time from the start of the first movement control order (MCO) in March 2020- which are (i) the initial set up, (ii) issues mid-way in, and (iii) plans for the way forward.

In the Beginning (Mid-March 2020; End of Semester 2, Academic Session 2019-2020)

Fitting teleclinic into the student clinical practicum curriculum

Telerehabilitation has been used by SLPs since before the pandemic, primarily for clients who have logistic difficulties in accessing services. Telecommunication technologies are used to deliver SLT services at a distance to connect the clinician to clients or their parents/caregivers, provided that the standard of care is assured to be on par with the gold standard FTF consultation.² The potential outcomes of telerehabilitation have been examined in assessing and managing selected developmental and acquired language and communication disorders, fluency, motor speech and voice disorders.³ Despite the rapid expansion in research across these areas of SLP practices, telerehabilitation appears to be theoretically posited and not readily implemented in the local scene and the region.⁴

With the drastic shift from FTF to online learning in educational institutions nationwide, the Faculty of Health Sciences (FSK) encouraged all its programs to explore different means of alternative learning and evaluation modalities. Teleclinic intuitively followed suit as the service delivery model used to run student clinical practicums.

Setting up and orientation

Immediate challenges posited were the setting up of infrastructures for teleclinic, specifically the hardware and software for both program members, who were by this time working from home, and students who were in their hometowns following the MCO. Compared to the prescribed decision making guidelines in implementing telerehabilitation, which are (i) determining the nature and type of telerehabilitation system required to provide the specific service, (ii) ascertaining staffing needs and training, (iii) evaluating the safety to and acceptability of patients, and (iv) determining to what extent the telerehabilitation service is valid and reliable when compared to the FTF modality, at this point of time, the program opted for a much more simplified view of telerehabilitation due to the pressing circumstances.⁵

Both program members and students teamed up to explore various online meeting platforms. The university's Undergraduate and Alumni Affairs Division took the lead in

Corresponding Author: Yazmin Ahmad Rusli
Email: yazmin@ukm.edu.my

supporting students at this stage to help kick start their online learning needs (i.e., liaising B40 students with Zakat UKM for purchasing laptops, supplying start-up prepaid cards to all students for Wi-Fi services etc.).

In order to familiarise themselves with the clinical process in telerehabilitation, the program welcomed resource persons in the field- a few private practitioners who have had some experience conducting teleclinic (even though not as their primary service delivery model) for a sharing session. Four months into the pandemic, on 28 July 2020, the program hosted our first webinar on *The impact of COVID-19 on SLT practices in Malaysia*. Representatives from the program, private practices, public hospitals, and a final year student clinician who had completed the teleclinic trial run exchanged views on using teleclinic, describing the feasibility, benefits and troubleshooting roadblocks together. Peer learning ensued with the pairing of student clinicians within and across cohorts in subsequent clinical practicums.

The supervisory and administrative experience

Typically, supervision in SLP progresses on a continuum that warrants change over time in the amount and type of involvement of both supervisor and student clinician. As the student progresses from novice to independent in managing cases, the supervisor shifts roles from directive (*evaluation-feedback stage*) to consultative (*self-supervision stage*).⁶

Throughout the initial teleclinic sessions, we had the opportunity to experience learning collaboratively, from structuring to implementing an SLT session. Most times, students took the lead and showcased outstanding autonomy. They exercised independence, especially in researching, experimenting and building therapy resources. Since all practicums were conducted in-house and supervision was taken on only by the program members, the supervisory workload was at its highest with each academician and in-house clinician taking on double or triple their typical student supervision load.

On the administrative side, since the Speech Sciences Program was the first to opt for teleclinic, the program's clinicians were instrumental in preparing the standard operating procedures (SOP) (adding on the necessary COVID-19 precautionary measures) not only for the program but for all clinical programs in the faculty. For KASP, these included: (i) guidelines on overall client management, (ii) procedures in client management, (iii) client registration procedures, and (iv) revised clinic policies; whereas the SOPs for the faculty's online sessions comprised of: (i) guidelines on payment, (ii) client registration procedures, and (iii) procedures on managing clients. The program also initiated an online teleclinic resource library via collating essential readings, learning resources, assessment and therapy materials from program members and students. This database utilised free bio link tools such as the Linktree™, Google Drive, and the university's Microsoft Teams. This basic essential setup made the process more predictable and helped supervisors, student clinicians and their client's parents/caregivers navigate the initial flow of the teleclinic sessions.

The teleclinic experience with clients and parents/caregivers
The experience of moving clinical practicum online produced

unexpected benefits as well as drawbacks. The working paradigm then for both parents/caregivers was similar to that of the supervisors- we were all juggling between work and family, which meant that there were varying readiness levels in the session, yet more empathy emerged from this. Students had the opportunity to relate first-hand to these observations, circumstances, and feelings, which allowed them to become more understanding than how they typically would in FTF sessions. For some, it bolstered their conversational skills when playing the consultant role in therapy with parents/caregivers. However, others persisted primarily with prescriptions and directives to maintain control or keep the session going.

Building rapport with young children via online platforms was also a challenging feat.⁷ In FTF sessions, together with the clever selection of toys and engaging activities, proximity becomes an ally in bonding. In teleclinics, student clinicians capitalised on parallel play (with both student and their client and parents/caregivers playing alongside each other using similar sets of toys/materials), and screen activities (e.g., Microsoft PowerPoint presentations, YouTube, green-screen effects, free or paid online speech and language websites/applications etc.). Students were able to exercise creativity as they would in preparing for FTF sessions. However, the successful outcomes of a teleclinic session with young children really depended on how well parents/caregivers were able to take on the therapist's role-playing, interacting, and facilitating their child's learning in the session.

Overall, teleclinic provided (i) ease in access to therapy sessions (i.e., parents/caregivers who were at work could attend their child's therapy session separately through the designated online meeting platforms), (ii) flexibility in scheduling appointments and minimal hold-ups (e.g., traffic, bad weather), (iii) the convenience of being at home (i.e., clinicians are able to observe the child in their most natural setting instead of the artificial set up at the university clinic), and (iv) more understanding of- and hands-on practice on key teaching strategies relayed in therapy. Students were required to really know what, how and why they do what they do by guiding parents/caregivers in teleclinic sessions.

Mid-Way In (October 2020; Semester 1, Academic Session 2020-2021)

By this time, the university was able to open its doors to clinical students who were required to complete their practicum in-house or at external clinical placements around Selangor and Kuala Lumpur vicinity. FTF sessions resumed. When the MCO was reinstated in January 2021, the program fell back to teleclinics (even for service clinics) and expanded the clientele to include adults.

Getting parents/caregivers onboard

For one and a half semesters, students were primarily getting their clinical training through the university clinic. Subsequently, a few external clinical practicum sites started to join the teleclinic bandwagon. For adults clients, the reception of teleclinics was good. Clients reported that they valued how much they saved on travelling (i.e., time, expenditures, effort) for FTF appointments when they can benefit equally in teleclinic sessions. In turn, there were high

rates of client turnovers following the initial teleclinic trials for cases of childhood speech-language disorders. It was either due to the family's commitments at the time, relocation due to MCO, or dropouts (seeing that not all parents/caregivers continued to be in favour of teleclinic sessions). Many still sought FTF sessions, claiming that their child would attend and respond better to the 'clinician', hence benefit more from therapy. This response resonated with findings from studies abroad, whereby doubts on the effectiveness of telerehabilitation is usually the chief reason for the client's refusal of teleclinics.⁸

Realistically, telerehabilitation is not a one size fits all solution. The understanding of key components of teleclinics, i.e., characteristics of the environment and client selection (ruling out severe physical, cognitive, sensory and communication limitations which may affect the client's ability to participate in teleclinics) indefinitely contributes to the outcomes of telerehabilitation.⁸ However, with the second MCO in place and the university closed, the program was only able to either offer teleclinic appointments or refer the clients to other available/preferred SLT services.

As an effort to relay information to the public and professionals and promote and continue signing in interested clients and parent/caregivers into the student clinical practicum, the program organised two more webinars on (i) *'What is Speech-Language teletherapy? A guide for Parents'* (9 October 2020), (ii) *'Teletherapy and e-Learning: Creating Your Own Materials'* (17 March 2021).

Major ongoing challenges

Key challenges continues to be helping students meet the minimum required training hours and managing a variety of cases due to limited external clinical placement. Another is ensuring confidentiality, as it would require investing in a dedicated server to store reports and other client data. The changes would require modifications to existing SOP and considerations in future planning and budget allocations at the program and participating external clinical practicum sites.

Inadequate infrastructure and the stability of internet connectivity is another issue.⁷ This breakdown could either be at the therapist/student clinician or client's end. Although all data collated are used for educational purposes, the students use their personal internet lines and devices, compromising client confidentiality. On the client's end, there are families or individuals with disabilities who do not have the resources (be it device or connectivity) to partake in teleclinic sessions.

Most resort to rudimentary online communication applications such as WhatsApp and Telegram, which are not able to fully support the functions of mainstream online meeting platforms.

Future Directions- What's Next for Us? (October 2021 onwards; Semester 1, Session 2021-2022)

With the substantial preliminary data conducting teleclinic acquired this past 1 ½ years, the program now has sufficient data to begin evaluating and deciding future trajectories of teleclinic services in our teaching and learning and research activities. The program is also ready to initiate and resume existing collaborations that have been put on hold following the pandemic. Telerehabilitation has not only helped us solve our initial pressing issue regarding the student clinical practicum. It has ultimately opened doors for us to go one step further on a route that has been there in the field yet not always considered.

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Sudden sensorineural hearing loss in COVID-19: A case series from the Wrightington, Wigan and Leigh Teaching Hospitals, United Kingdom

Saumil Mehul Shah, MBBS^{1,3}, John Rocke, MBChB^{2,3}, Kathryn France, FRCS³, Moustafa Izzat, FRCS^{3,4}

¹Hull York Medical School, United Kingdom, ²University of Sheffield, United Kingdom, ³Wrightington, Wigan and Leigh NHS Trust, ⁴Royal College of Surgeons, Edinburgh, Scotland

ABSTRACT

Sudden sensory neural hearing loss (SSNHL) needs to be identified and managed correctly in a secondary or tertiary centre. Whilst 45% of presentations are said to be idiopathic in nature, several viruses have been linked to its aetiology. It was noted, anecdotally, that more patients were presenting with SSNHL during the COVID-19 pandemic to our ENT service at Wrightington Wigan and Leigh teaching hospitals, UK (WWL). We identified 4 COVID-19 positive patients who presented to our ENT service with SSNHL. Despite normal findings on external ear examination, three of the patients showed bilateral hearing loss, whilst one had a predominantly unilateral loss. Given our findings we would like to present these four cases, as well as providing hypotheses on possible aetiology of this association. This may aid in research, diagnosis and treatment of future COVID positive patients with SSNHL.

INTRODUCTION

Sudden sensory neural hearing loss (SSNHL) has traditionally been defined as a 30 dB or greater hearing loss over less than 72 hours.^{1,2} However, lack of access to pure tone audiometry (PTA) means General Practitioners (GPs) can only rule out conductive causes and refer to specialist clinics for investigation.

The most prevalent identifiable causes are: infectious (13%) otologic (5%), traumatic (4%), vascular or haematologic (3%) and neoplastic (2%).³ It has long been thought that viral infection may be one of the causes of SSNHL.³ It is hypothesised that viral reactivation and inflammation causes damage to critical inner ear structures such as the organ of Corti, tectorial membrane and stria vascularis.⁴

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a large, enveloped single stranded RNA virus that first appeared in Wuhan, China in December 2019, primarily with respiratory manifestations. It primarily binds through spike proteins to ACE2 receptors in the respiratory tract.⁵ A small study has isolated SARS-CoV-2 in the mastoid air cells and middle ear of cadavers of known positive patients.⁶ SARS-CoV-2 was also found in the brains of 21 (53%) of 40 deceased patients and viral proteins were detected in cranial nerves originating from the lower brainstem.⁷ The proven presence of this virus in various parts of the brain and

peripheral nervous system suggests there may be neurological manifestations of SARS-CoV-2 which could affect auditory pathways.

Olex-Zarychta et al. report a case of a 52-year-old patient who developed left sided SSNHL between 3kHz and 8kHz with a normal right ear. The case subsequently improved with intratympanic corticosteroids.⁸ Munro et al. observed 138 adults with SARS-CoV-2, 16 (13.2%) and reported a change in hearing and/or tinnitus following diagnosis.⁹ Koumpa et al. report a case of a 45-year-old asthmatic male requiring ITU care for SARS-CoV-2 who reported left sided sensory neural hearing loss with a PTA that confirmed 2, 3, 4 and 6kHz frequencies being the most affected. His symptoms improved with intratympanic steroid injection, with partial improvement of his PTA thresholds.¹⁰ Mustafa et al. showed that in 20 cases with proven SARS-CoV-2 there was significant deterioration of hearing to high frequency pure tone thresholds and worsened TEOAE amplitudes.¹¹

Anecdotally our ENT department noticed that the number of patients presenting with SSNHL has increased since the beginning of the COVID-19 pandemic. Given the propensity for viruses to cause sensory neural hearing loss, we have described a retrospective observational case series of four patients with proven COVID positive PCR testing, that presented to our ENT clinics with SSNHL.

METHODS

We retrospectively analysed our clinic logs to identify patients who had been referred to ENT Clinic after 11 March 2020 with SSNHL. This was 2 weeks before the first national lockdown in the UK. Patients could be referred through GP, A+E or the ENT casualty clinic for suspected SSNHL.

Patients with a detectable cause for SSNHL were excluded from the study as were patients who have no official positive result for SARS-2-Cov.

Retrospective data was collected using the electronic patient record system (EPR), the electronic notes and reporting system (HIS) and PTAs. All data was collected on pre-designed proforma, and any additional information for each patient was recorded separately.

Corresponding Author: Dr Saumil Mehul Shah
Email: saumil.shah@doctors.net

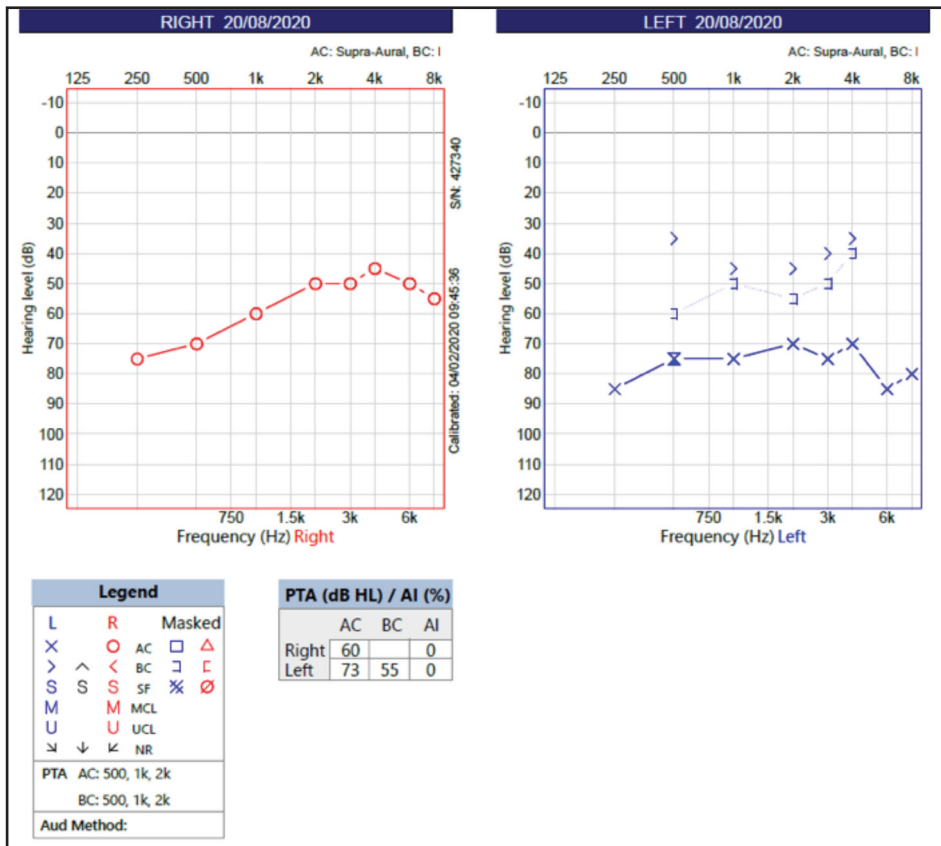


Fig. 1: Pure Tone Audiometry for Patient 1.

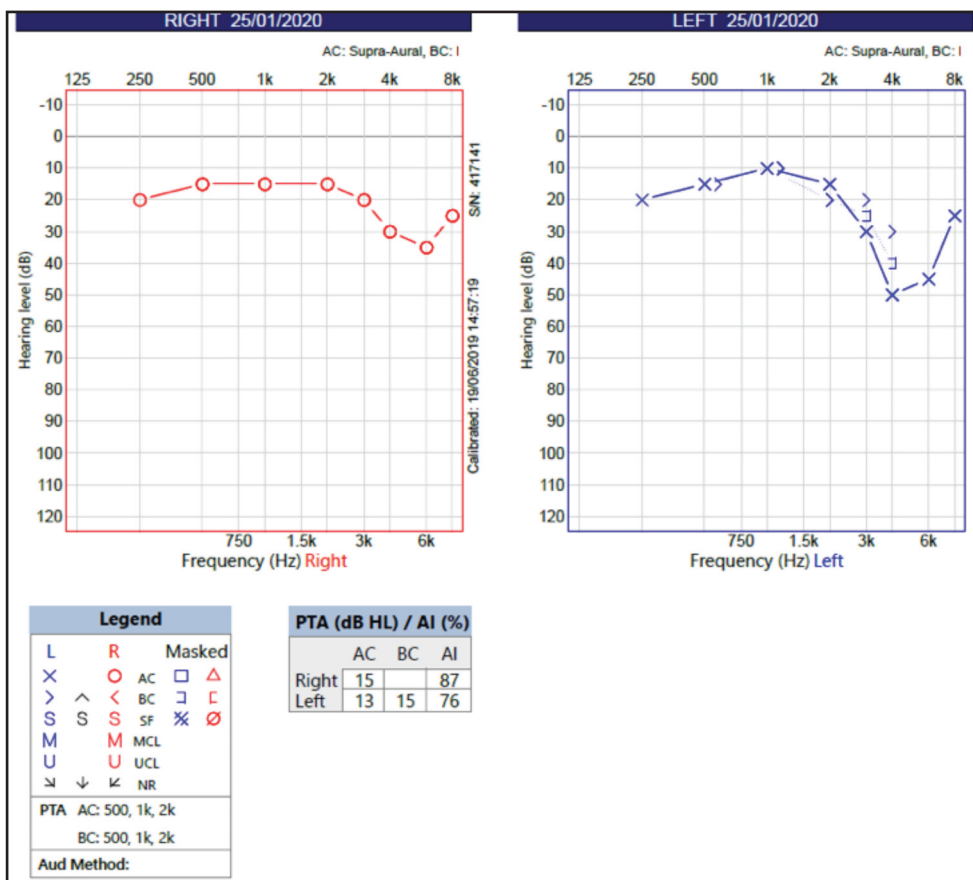


Fig. 2: Pure tone audiometry for patient 2.

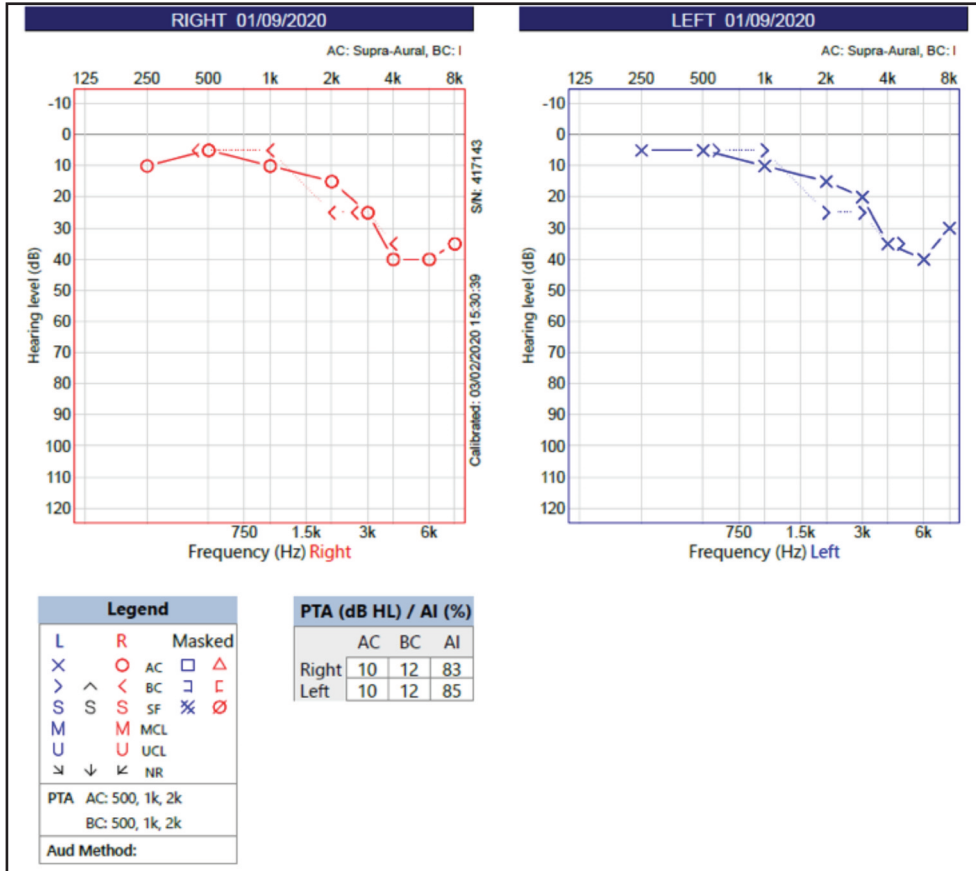


Fig. 3: Pure Tone Audiometry for Patient 3.

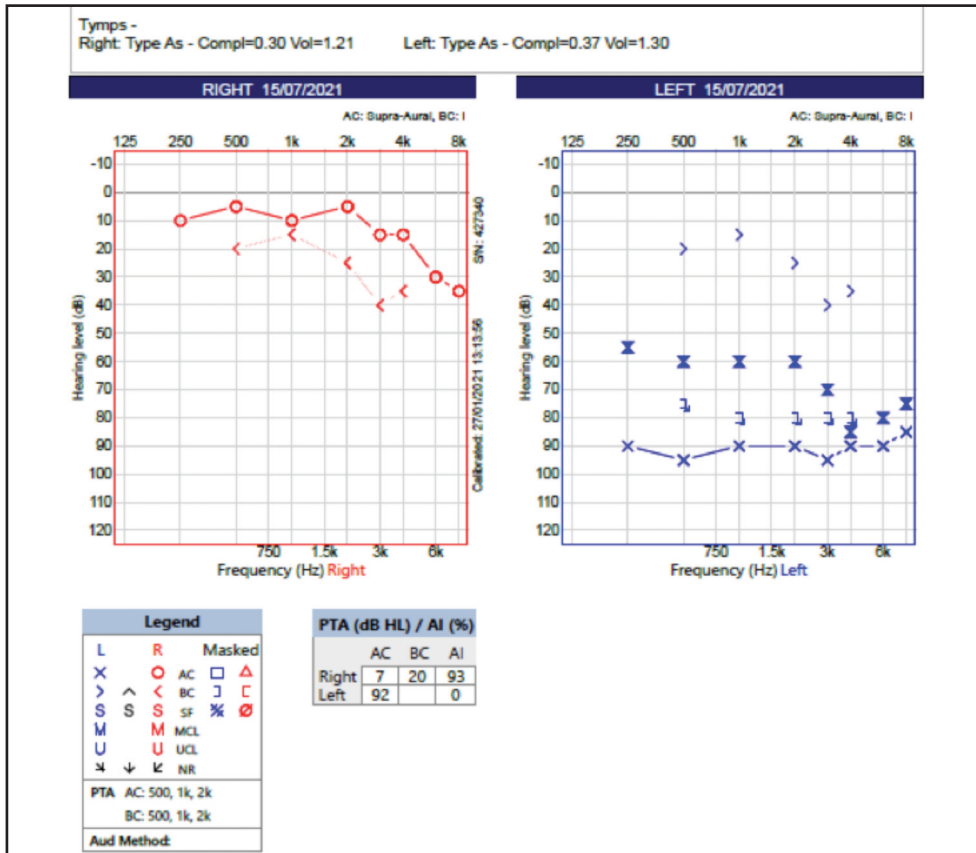


Fig. 4: Pure Tone Audiometry for Patient 4.

Results:

A total of three patients met the criteria for selection.

Patient 1

This 46-year-old female presented after contracting SARS-COV-2 in April 2020. During which she developed anosmia, loss of taste and 'flu-like' symptoms. She subsequently recovered.

Approximately 3 weeks after initial onset, she developed bilateral muffled hearing, pulsatile tinnitus and dizziness. Her imbalance was exacerbated when moving from a lying to sitting position.

Due to the persistent symptoms, she was referred by her GP to the ENT clinic, where she was assessed 7 weeks after onset of symptoms. Her initial assessment was with a telephone consultation. At this point the working diagnosis was otitis media with effusion and Otovent was prescribed. Patient was not prescribed oral steroids.

At the subsequent face-to-face appointment, she denied otalgia or discharge from either ear. On examination both tympanic membranes were normal. A pure tone audiogram demonstrated right sided moderate to severe sensorineural hearing loss, and on the left the PTA showed a mixed picture. She had type B tympanometry bilaterally (Figure 1). The patient was not given oral steroids as it was more than 8 weeks from onset of her hearing loss.

A grommet was inserted to help improve the conductive aspect in the left ear. She was also referred for hearing aids as the sensorineural component had not improved.

Patient 2

This patient was a 43-year-old female. She presented to her GP with a short history of vertigo. She was seen by the ENT department face to face two weeks later. She has previously tested COVID positive, her predominant symptom was loss of smell and flavour.

At the face-to-face clinic she was assessed for other possible causes of vertigo, however, she showed no signs of benign positional paroxysmal vertigo (BPPV), or Meniere's disease. Her neurological exam was normal. A full ENT exam was performed which was normal. She was prescribed balance exercises, advised to avoid vestibular sedatives and referred for tinnitus therapy. No steroids were prescribed.

Pure tone audiometry revealed a sensorineural loss bilaterally in the range of 4000 to 8000 Hz (fig. 2). An MRI IAM was normal.

Patient 3

A 54-year-old lady presented with right unilateral pulsatile tinnitus and hearing loss for 2 months. The onset was a few weeks after she was diagnosed with SARS-CoV-2 and she had recovered from mild associated symptoms. Due to COVID 19 a telephone consultation was conducted. She did not report of any other ENT symptoms at the time.

As she presented 2 months after onset of symptoms, it was decided not to start the patient on oral corticosteroids. MRI IAM was normal. Pure tone audiometry once again showed a decreased hearing threshold in the range of 4000 to 8000 Hz (Fig. 3). Due to the prolonged hearing loss this patient was referred for fitting of hearing aids.

Patient 4

A 51 year-old male presented with increased dyspnoea cough who had recently tested positive via a COIVD PCR test. His chest x-ray confirmed the diagnosis of SARS CoV-2 with bilateral patchy infiltrates. He was started on oxygen to maintain saturations, dexamethasone, remdesivir, thiamine, dalteparin and ascorbic acid. He had no significant past medical history. Over the course of the next two months the patient was managed in our intensive care unit for respiratory support.

After being stepped down from ICU the patient complained of sudden unilateral right sided hearing loss and tinnitus. The patient did not complain of any vertigo, ear fullness, otorrhoea or otalgia. On examination the tympanic membranes were intact and healthy bilaterally. The patient was commenced on oral prednisolone 40mg for 1 week. After 4 days there was no improvement with the steroid treatment and an MRI of the internal auditory meatus was performed which was normal. The patient's pure tone audiogram demonstrated a profound sensory neural hearing loss on the left side. Unfortunately, the patient's hearing did not improve when subsequently reviewed in ENT clinic. As a result, he has been referred to audiology for CROS – aids and appropriate symptom management.

DISCUSSION:

Interestingly, three of the patients showed hearing loss bilaterally. Patients two and three only showed this loss at higher frequencies while patient 1 had decreased hearing in both ears, worse at higher frequencies. This result is similar to patients observed in the study by Mustafa et. al.¹¹ Patient four developed a unilateral dead ear, and had the most severe reaction to COVID-19. Unilateral hearing loss is generally more typical of viral illnesses, but various viruses have shown bilateral hearing loss too.⁴ It should be noted the fourth patient developed hearing loss despite various courses of IV and Oral steroids through the course of his treatment.

ACE-2 is not shown to be well expressed in the endothelium of the neural structures and vessels.¹² Instead, the receptors basigin (BSG) and neuropilin-1 (NRP-1) have been shown as potential docking receptors for SARS-CoV-2.^{13,14,15} Knockout of NRP-1 has been shown to lead to progressive hearing loss in mice, due to disorganized outer spiral bundles and enlarged micro vessels of the stria vascularis in the cochlea.^{15,16} Destruction of the outer spiral bundles would lead to hearing loss at higher frequencies. Hearing loss at higher thresholds was seen in 3 of our patients, correlating to these areas identified in animal studies. While in the fourth patient all frequencies were equally effected. In cases 2 and 3 the hearing loss is specifically in the higher frequencies; it could be due to other pathologies such as noise induced hearing loss. However, given the onset of complaint of hearing loss

(within weeks of the COVID-19 infection) and descriptions from other papers such as Musafa et. al, Koumpa et. al, and Olex-Zarychta et. al, who have reported hearing loss as similar ranges. This SSNHL may be secondary to the viral infection within the outer spiral bundles.^{8,10,11}

In more advanced stages the virus is shown to compromise the endothelial barrier (NRP-1 and NSG are both expressed here) leading to infiltration of monocytes and neutrophils causing oedema in addition to triggering an intravascular coagulation response leading to thrombotic complications such as myocardial ischaemia, pulmonary embolisms and limb ischaemia.¹⁷ Additionally, Lowenstein et. al. postulate that it may simultaneously be causing a microvascular inflammatory response as well as a microvascular thrombotic response.^{18,19} Interestingly, SSNHL has been shown to have a significant association with the prospective development of cardiovascular disease (HR, 2.18; 95% CI, 1.20-3.96).²⁰ This suggests that SSNHL could present as an early sign for a patients in hypercoagulable states.

It has also been suggested that SARS-CoV-2 may also shed proteins of damaged cells into the blood stream that can act as PAMPs and damage associated molecular patterns inducing an innate immune response from cells expressing toll-like receptors.¹⁵

SARS-CoV-2 has also shown delayed manifestations due to immune responses that typically take a few weeks to manifest.¹⁵ Various studies have noted an increase in patients presenting with Guillain-Barré Syndrome (GBS)/ Miller-Fisher syndrome and one study in particular presented a case of a patient who presented with miller-fisher like symptoms twenty days after contracting SARS-CoV-2. In the CSF, presence of anti-ganglioside antibodies may have been implicated in causing an immune response in the peripheral nervous system.²¹ Hence SARS-CoV-2 may be affecting the peripheral nervous system without infecting the CNS, as part of the post COVID syndrome.

We have presented here four patients in this retrospective case series who developed SSNHL around the time they had SARS-CoV-2. As there is a lack of pre-infection audiograms it is difficult to ascertain for sure if SARS-CoV-2 was the direct cause of their otological pathology. All patients are between the ages of 40-50 with few other comorbidities, no previous otological complaints and no history of previous significant noise exposure. The timing of their onset of SSNHL with relation to the infection, would lead us to propose that there may be an association between SSNHL and SARS CoV-2 infection. We have also discussed various pathophysiological mechanisms that may explain this association but further work is required to confirm or refute this.

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Our experience in tracheostomy for COVID positive patients in Hospital Tawau: A case series

Luqman Afiq Mohamad Ishak, (MBBCh), Gagandeep Singh Mann, MS (ORLHNS)

Department of Otorhinolaryngology, Hospital Tawau, Sabah, Malaysia

ABSTRACT

The Coronavirus Disease (COVID-19) pandemic has led to an increase in the number of critically ill patients requiring intensive care unit admissions and mechanical ventilation. The sequential effect is that these patients may then require a tracheostomy. Tracheostomy guidelines were established to help minimise the risk of viral transmission to the personnel performing the procedure. Safety measures regarding preoperative planning, surgical technique and nursing care are important to minimise the risk of transmission to medical personnel. We describe our experience in conducting tracheostomies for two COVID-19 patients at a referral centre in Sabah, Malaysia.

KEYWORDS:

COVID-19, tracheostomy, protocol, technique, duration

INTRODUCTION

The pandemic Coronavirus disease 2019 (COVID-19) has emerged as global health emergency crisis. The virus is transmitted via respiratory droplets or aerosols from the infected persons. In the healthcare setting, there is a high likelihood of virus transmission during any clinical procedure. The risk is significantly higher during aerosol generating procedures such as clinical nasal, pharyngeal and laryngeal examinations, tracheostomy procedures, intubation, dental procedures, bronchoscopies and oral suctioning.¹ Thus, strict compliance to protective measures is imperative to reduce the risk of infection.

Infected persons display varying features, ranging from being completely asymptomatic to acute respiratory distress syndrome requiring mechanical ventilation. Critically ill patients may require prolonged ventilation and subsequently tracheostomy. Guidelines for tracheostomy pre-planning, procedure and outcomes help in assuring the safety of the health workers and is optimal during such high-risk procedures during the COVID-19 situation.² Following appropriate guidelines during tracheostomy can minimise contact time with aerosol particles intraoperatively and subsequently decrease risk to the operators of such procedures. We describe our experience in conducting tracheostomies for two COVID-19 patients. These surgeries were performed in Hospital Tawau (HT), Sabah which is the referral hospital for the East Coast of Sabah, serving Tawau as well as the districts of Semporna, Kunak and Lahad Datu.

CASE REPORTS

Case 1

A 40-year-old lady with underlying obesity, diabetes mellitus and hypertension presented to the Emergency Department of HT with a 4-day history of nonproductive cough, fever and difficulty breathing since 26th October 2020. She had history of recent contact with her relative who was COVID-19 positive. A COVID-19 rapid antigen test was positive on 29th October 2020. She was tachypnoeic on arrival and chest radiography showed bilateral lung consolidation. She subsequently required intubation for respiratory distress. A diagnosis of category 5 COVID infection with multiorgan involvement was established and she was treated with antiviral, immune-modulator and anticoagulant. She required ventilatory support for a total duration of 45 days and also developed atrial fibrillation with 3 failed attempts at extubation. At that point she was referred to the otorhinolaryngology (ORL) team for a tracheostomy.

Once the patient was medically optimized, a tracheostomy was performed at day 46 of COVID-19 illness for prolonged ventilation. No repeated polymerase chain reaction (PCR) COVID-19 test was performed prior tracheostomy as the patient was beyond day 21 of illness. The protocol at HT at the time was such that once a patient was beyond day 21 of illness, they were considered to be non-infective and thus did not require further testing. Medical personnel involved used personal protective equipment (PPE), face shields and Powered Air Purifying Respirators (PAPR). Mobilization of the patient from the COVID intensive care unit (ICU) to the operating theatre (OT) was via a dedicated isolated interconnected walkway.

Intraoperatively, the routine surgical technique of layered fascial dissection was carried out until the trachea was encountered and identified. The cuff on the endotracheal tube was hyperinflated by the anesthesiology team prior to incision on the trachea. Transtracheal local anaesthesia injection of 0.5cc Lignocaine 1% was given to suppress the cough reflex. Patient was rendered apnoeic by the anaesthesiologist prior to the tracheal incision. Ventilation was resumed after cuff inflation. The tracheostomy procedure was uneventful.

Postoperatively, there was a tracheostoma wound breakdown on day 22 post tracheostomy whereby she required wound debridement and secondary wound suturing under general anesthesia at day 79 of illness. The first tracheostomy tube change was done under the same setting in OT. She remained

Corresponding Author: Luqman Afiq Bin Mohamad Ishak
Email: luqman_afiq90@yahoo.com

in ICU due to recurrent nosocomial infection and poor lung function with ventilator dependence. She was transferred out from the COVID ICU after the ventilator requirements decreased on day 43 post tracheostomy. Her wound subsequently healed well. Two weekly tracheostomy tube change was attended using basic PPE. She was discharged well, with no oxygen requirements on a long-term double lumen tube. She is still under follow-up as an outpatient.

Case 2

A 53-year-old gentleman with no known medical illness presented to the Emergency Department of HT on the 7th of December 2020 with dizziness and sudden loss of consciousness at home. Glasgow Coma Scale (GCS) at the Emergency Department was E2V1M5 with pin-point pupils. Cardiovascular and respiratory examinations were unremarkable. He had no respiratory symptoms prior to the event. He required intubation due to his low GCS and computed tomography (CT) scan of the brain showed a brainstem bleed with intraventricular hemorrhage. His COVID-19 rapid antigen screening prior to hospital admission was found to be positive. He was tested positive again using PCR on the next day and was treated as COVID stage 3. He had no history of COVID-19 contact. He underwent external ventricular drainage of the intracranial bleed and was extubated 3 days later conscious and stable.

Three days later, the patient experienced a sudden reduction in his consciousness and required reintubation. An urgent CT scan showed residual hemorrhage and a second surgical intervention was performed. Revision of the ventriculo-subgaleal shunt and tracheostomy was performed at day 22 of illness due to prolonged ventilation and poor GCS recovery. This patient too, did not have a second COVID PCR test in line with the HT protocols at the time.

The surgical steps were conducted as stated in our first case. This gave us the advantage of minimising aerosol contact during the tracheostomy procedure. No intraoperative issues arose during the surgical procedure. On day 28 of illness, the patient was transferred out to the general ward. Post-operative tracheostoma wound had healed well. The patient was put on a double lumen tracheostomy tube. This tube was changed while using basic PPE as the patient was beyond day 21 of illness. He was discharged home and is still under our follow-up.

DISCUSSION

A tracheostomy is a surgical procedure whereby an incision is made over the anterior neck as an artificial airway to facilitate breathing. It is one of the aerosol generating procedures that is commonly performed in the healthcare setting. Indications for tracheostomy may include respiratory failure or neurological insult which require prolonged mechanical ventilation, upper airway obstruction due to various causes, as an elective procedure done alongside major head and neck surgeries as well as to facilitate clearance of tracheobronchial secretions. In the era of the COVID-19 pandemic, tracheostomy should be only performed in cases with clear and defined indications due to high risk of viral transmission towards the operator.

COVID-19 patients with severe acute respiratory syndrome may require prolonged mechanical ventilation support. However, with this, potential complications can arise such as ventilator associated pneumonia and laryngeal complications such as mucosal ulceration, intubation granuloma, cricoarytenoid joint displacement, posterior glottis or tracheal stenosis and tracheoesophageal fistula. Indications for tracheostomy need to outweigh the risks of prolonged ventilation at the expense of viral exposure to the health care worker.³ In acute upper airway obstruction, tracheostomy is considered a lifesaving procedure and thus warrants urgent intervention.⁴

Tracheostomy protocols during COVID-19 was created with the aim to protect medical personnel during the surgery. Once the decision for a tracheostomy procedure is made, the preoperative assessment should be thoroughly performed by a multidisciplinary team such as physician, anaesthetist and surgeon. Indications and planned timing for the surgery is reviewed once again by all parties and they should be in agreement to proceed. The patient should be medically and anaesthetically optimised to reduce potential complications that may arise from underlying comorbidities or COVID-19 itself. It is recommended that tracheostomy is performed after day 10 of COVID-19 illness as the viral load is reduced at that juncture.⁵⁻⁶

Surgery is recommended to be performed in a negative pressure room.⁷ Assisting staff must be familiar with PPE including using PAPR. The tracheostomy team should be limited to a senior ORL surgeon with a registrar, anaesthesiologist and a senior OT nurse. In our cases, tracheostomy was performed in a normal OT due to a logistic limitation at our centre wherein the hospital did not have a negative pressure room. On the day of surgery, tracheostomy equipment should be prepared and checked by the medical assistants in the OT. The timing of the surgery is decided in advance by the medical, anaesthetic and ORL teams. The OT staff are briefed and prepared to receive the patient accordingly.

Aseptic precautions are important during preparation of the patient for the procedure. Appointed staff will transfer the COVID-19 patient from the ICU or ward to OT following the pre-planned hospital route. All designated staff should be equipped with complete PPE and know their roles throughout the procedure to avoid miscommunication. The patient is positioned and adequately paralyzed. A few protocols recommend minimising the use of cautery due to increased aerosol generating potential.^{2,8} Upon identification of the trachea, it is suggested to push the endotracheal tube (ETT) further downwards to avoid puncture of endotracheal cuff.⁹ Transtracheal local anaesthesia injection may be considered. The patient is rendered apnoeic prior to the tracheal incision. The trachea wall is sutured to the skin (maturation suture) using non absorbable suture to ensure stoma patency.¹⁰ Ventilation is only resumed after insertion of the tracheostomy tube and inflation of the cuff. In both our cases, an appropriately sized single lumen cuffed tracheostomy tube was used. Placement of tracheostomy tube is confirmed with chest rise, vapour in ventilation tubing and capnography waveforms. Auscultation is not encouraged due to risk of contamination.⁹

The crucial factor during tracheostomy of a COVID-19 patient is to minimise the duration of contact with the patient itself. In our cases, duration of exposure remained less than 5 minutes from the tracheal incision until tracheostomy tube inflation as we elected not to perform the maturation sutures.

Post operatively, it is essential to ensure that the tracheostomy tube is secured and anchored well to prevent dislodgement. A closed suction system is encouraged compared to the open system due to lower risk of aerosol spread. Dressing change is advised only if there is sign of infection. Wound inspection is to be done daily by the primary team. It is advisable to put a heat and moisture exchanger (HME) once the patient is disconnected from the ventilator. Tracheostomy tube change may be delayed up to 4 weeks or once the COVID status is negative.⁸ However, any hint of a partially obstructed tracheostomy would indicate a scope and change of the tracheostomy tube if deemed necessary. Hence, regular suctioning is required for the patient with a single lumen tube. Double lumen tube usage may be considered once the patient is weaned from the ventilator. Decannulation is delayed until the patients have recovered from the infection and do not have any other contraindications for decannulation.

CONCLUSION

Tracheostomy protocols are to guide health care workers with the main purpose of minimising the rate of COVID-19 transmission. Meticulous preparation of the patient, use of full PPE and good communication skills across various disciplines are crucial. It is also best for an experienced surgeon to perform the operation with their own familiar surgical technique to reduce the duration of procedure and contact.

Post-operative tracheostomy care plays an important role due to prolonged patient exposure with nursing staff. Well trained personnel should attend to the patient in any emergency related to the tracheostomy. Ideally, health care workers should minimise their exposure time with the COVID-19 patient during surgery and nursing care. By following proper safety precautions, risks of COVID-19 transmission among medical personnel can be effectively reduced.

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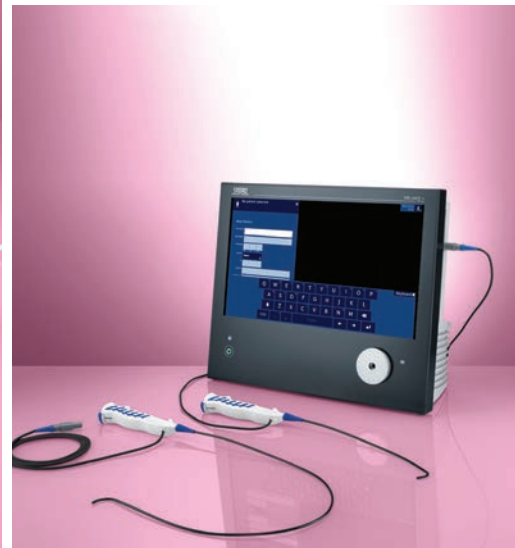
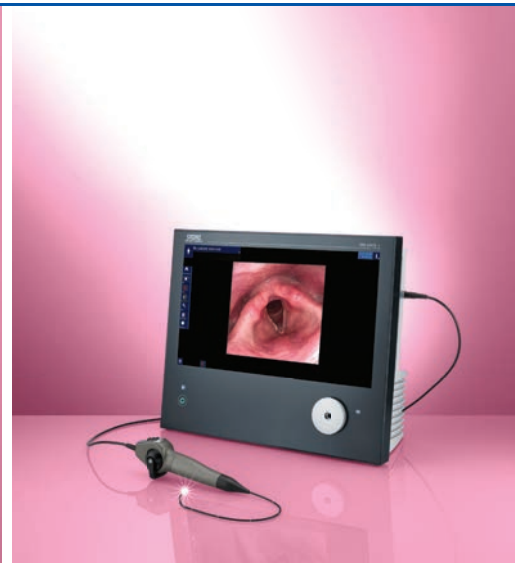
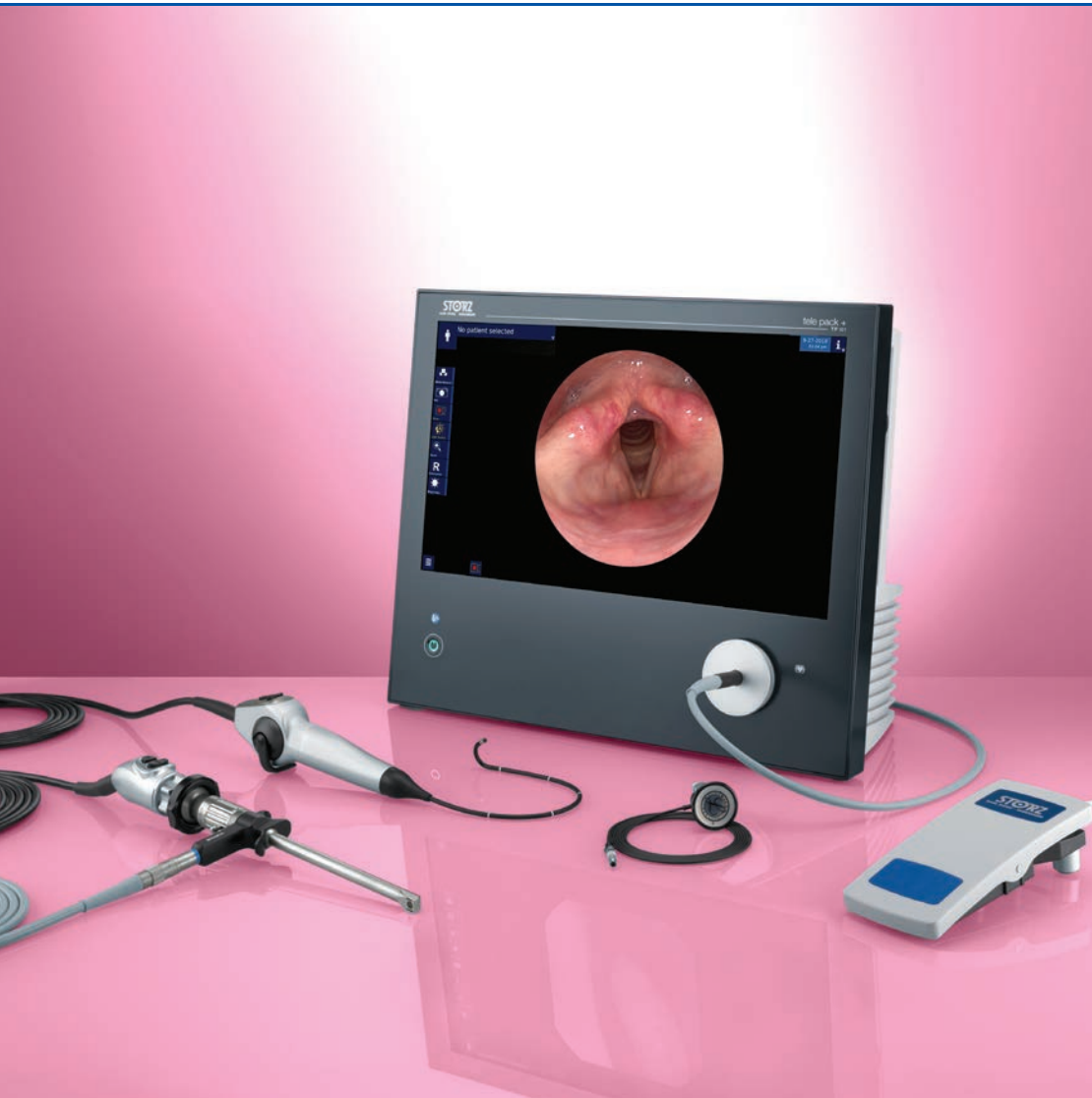


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