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

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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 tumour. 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. Since then, it has spread rapidly across the world and is declared as Pandemic by World Health Organisation. It has been reported that secretions of the nasopharynx and oropharynx have high viral load putting otolaryngologists at higher risk. The first reported physician fatality was that of an otolaryngologist at Wuhan. 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. 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 specialty bodies such as ENT UK, American Association of Otolaryngologists and Head and Neck surgeons.
Under the above back drop the diagnosis of HNSSC 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 anaesthesia in an out-patient clinic setting for investigations, diagnosis and therapeutic interventions of common otorhinolaryngology pathologies.1 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, leukoplakia and polypoid degeneration.a

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 and 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
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/CIS 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.
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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
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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. TN O 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 postricoid 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.15,24 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.25 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 EN.T-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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REFERENCES
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