

# Transnasal Oesophagoscopy: the Feasibility and Potential Impact on Service Provision of an Office Based Procedure for Upper Gastrointestinal Disorders in Malaysia

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## SUMMARY

A Health Technology Assessment (HTA) was conducted in 2011 to evaluate whether transnasal oesophagoscopy (TNE) should be made available at otorhinolaryngology (ORL) clinics in the Ministry of Health facilities. The safety, efficacy or effectiveness and economic implication of using transnasal oesophagoscopy (TNE) were reviewed. This review provides a summary of the HTA and an updated literature review as well as how this technology might potentially affect services in the Ministry of Health.

## KEY WORDS:

*Transnasal oesophagoscopy, oesophageal disorders, ultrathin endoscopy, health technology assessment*

## INTRODUCTION

### *History of oesophagoscopy*

The American laryngologist, Chevalier Jackson, revolutionized oesophagoscopy more than a century ago when he introduced the first distal lighted rigid hollow endoscopes. In the 1960s, the gastroenterologist Hirchowitz helped develop the first flexible fibreoptic gastroscope<sup>1</sup>. Subsequent modifications have led to the current flexible gastro-oesophagoscopes widely used in clinical practice.

In today's clinical practice, transoral flexible oesophagoscopy and barium radiology represents the primary means by which structural diseases of the oesophagus are investigated. Until 1996, the oesophagoscopy performed by otolaryngologists were primarily with the rigid endoscope via a transoral approach with patients under general anaesthesia. The main indications were foreign body removal, oesophageal dilatation and tumor surveillance.

In the mid 1990s, otolaryngologists began to perform oesophagoscopy utilising an ultra thin, flexible scope passed through the nose in an unsedated patient relying solely on topical anaesthesia. This is called transnasal oesophagoscopy (TNE) in the United States of America (U.S.A.) and transnasal flexible laryngo-oesophagoscopy (TNFLO or TNO) in the United Kingdom (U.K.). The procedure is performed in the clinic and does not require sophisticated patient monitoring or skilled ancillary personnel that is required after

conventional oesophagoscopy performed under sedation or general anaesthesia. It is claimed to have the following advantages over conventional peroral, rigid or flexible oesophagoscopy carried out in a sedated patient; enhanced patient safety, increased practice efficiency and cost-saving<sup>2</sup>.

### *Transnasal oesophagoscope*

The transnasal oesophagoscope has United States of America Food and Drug Regulation (US FDA) approval. The diameter of the scopes range from 4.5 mm to 5.1 mm. There are essentially two types of TNE systems, the difference being the location of the camera. In one system the camera is located at the distal end of the scope while in the other system; the camera is attached at the proximal portion, close to the eyepiece. Provisions are available for air insufflations, water instillation, suction and working channels for biopsy forceps<sup>2,4</sup>.

TNE is a procedure which can be performed in an outpatient setting. No sedation or cardiac monitoring is required. The patient is seated in a standard ENT or examination chair. Topical anaesthesia is applied to both nostrils and the nose is decongested<sup>3,5</sup>.

The health technology assessment for TNE was proposed in 2010 based on accumulating literature on the usefulness of this procedure. The subject was approved for further evaluation by the HTA division of the Ministry of Health Malaysia. An expert committee comprising of otorhinolaryngologists, radiologist, gastroenterologist and experts from the Ministry of Health formed the review committee.

### *Summary of Health Technology Assessment (HTA) on TNE<sup>6</sup>*

There was fair level of evidence to suggest that TNE was effective for detection of oesophageal and extraoesophageal lesions such as for screening examination in patients with dysphagia or globus pharyngeus or reflux symptoms, in head and neck cancer patients and for detection of metachronous esophageal carcinoma in patients with head and neck squamous cell carcinoma. Evidence also suggest that TNE can be used to perform a variety of procedures such as biopsy of suspicious lesions in the upper aerodigestive tract, placement of wireless pH capsule, transnasal balloon dilation of the oesophagus, secondary tracheoesophageal puncture and management of foreign bodies.

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There was fair level of evidence to suggest that TNE was well tolerated and can be safely performed in an office setting with topical anaesthesia. Complications associated with TNE were mild and uncommon. There was evidence to suggest the potential direct cost saving derived by performing TNE in the office setting compared with rigid oesophagoscopy performed under general anaesthesia.

TNE can be performed easily within 20 minutes, while recovery and discharge of patients were possible within two hours. TNE may lead to a change in practice from investigation and treatment in the operating theatre to an office based practice under local anaesthesia.

It is recommended that the use of TNE is to be limited to the Head and Neck Centres for detection of oesophageal and extraoesophageal lesions and for therapeutic procedures to provide more high quality evidence. Organizational issues such as training, manpower and funding need to be addressed.

Full details on the review committee, methodology, evidence and findings can be obtained from the HTA report at [www.moh.gov.my/v/hta](http://www.moh.gov.my/v/hta) or from the authors.

## MATERIALS AND METHODS

A medline search was for articles on transnasal oesophagoscopy from July 2011 (from the last search date of the HTA) using the keyword transnasal oesophagoscopy. Limits placed were articles in the English language and human subjects. Date of last search was 4th November 2012. An additional search was conducted on an institutionally subscribed ScienceDirect database. (Search strategy table is available from corresponding author). Inclusion criteria; all relevant articles comprising randomized controlled trials, cross-sectional studies, reviews and case reports on transnasal oesophagoscopy. Exclusion criteria; animal studies, experimental studies and narrative reviews. All relevant literature was appraised using the Critical Appraisal Skills Programme (CASP) and evidence was graded based on guidelines from U.S./Canadian Preventive Services Task Force and NHS Centre for Reviews and Dissemination (CRD) University of York, Report Number 4(2nd Edition), March 2001 for test accuracy studies<sup>7,8</sup>. The literature was reviewed by the corresponding author.

## RESULTS

A total of 13 titles were identified of which there were 7 relevant abstracts. Five full-text articles and two abstracts were used for this report. Two additional full text articles were obtained from an institutionally subscribed ScienceDirect database. The papers consisted of one review article, one editorial letter, five cross sectional studies (2 abstracts) and two longitudinal case-controls.

The following studies support the findings of the HTA. The paper by Shariff *et al* showed a very good correlation between TNE and standard oesophagoscopy (SE) in the diagnosis of Barrett's Oesophagus<sup>9</sup>. (sensitivity and specificity of 0.98 and 1.00, respectively). Another study of dyspeptic patients who had both TNE and standard oesophagoscopy found that

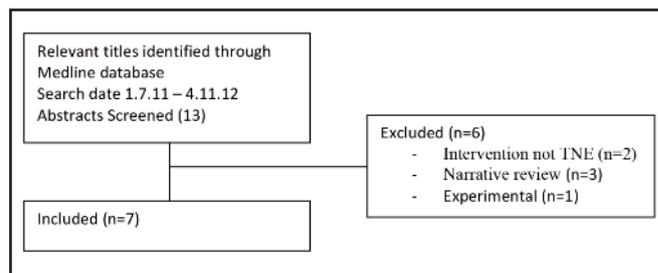


Fig. 1 : Flow chart of study selection.

gastric biopsy for both modalities were suitable for histologic examination. Majority (87%) of the patients preferred TNE to SE<sup>10</sup>. Two cross-sectional studies found TNE to be useful in patients with globus pharyngeus and as a useful screening tool in a primary care setting for oesophageal disorders<sup>11,12</sup>. TNE performed by experienced endoscopists was well tolerated and the mean examination time was 3.7 minutes<sup>12</sup>. TNE was successfully used in an office setting for secondary trachea-oesophageal punctures (TEP) for 13 laryngectomised patients who were unfit for general anaesthesia<sup>13</sup>. In another study of 20 patients with oesophageal stenosis, TNE allowed accurate placement of stents without fluoroscopy in a bedside setting<sup>14</sup>. TNE was used in combination with functional endoscopic evaluation of swallowing (FEES) to evaluate 63 patients with globus pharyngeus. There was no complications with the procedure and the patients rated a low pain score (median =1 of 10) and a high satisfaction score (median =9 of 10)<sup>15</sup>.

## DISCUSSION

There was no systematic review or HTA report retrieved. The findings complement the evidence presented in the HTA. There was evidence that TNE is comparable with flexible oral oesophagoscopy for diagnosis and histologic sampling. Cross sectional studies revealed that TNE is well tolerated and can be safely performed in an office or bedside setting without the need for sedation for a number of indications including TEP, stent placement, evaluation of globus pharyngeus and surveillance of Barrett's Oesophagus<sup>11-15</sup>.

### Who should perform TNE?

Conventional forms of oesophagoscopy are performed by gastroenterologists, surgeons and otorhinolaryngologists; flexible by the former two and rigid, by the latter. TNE can be easily be performed by specialists from any of the above disciplines with adequate training. Physicians and surgeons will need to familiarize themselves with the anatomy of the nasal and pharyngeal passages while otorhinolaryngologists will have to be trained to recognize oesophageal anatomy and pathology. Adler, suggests, that in the future, the ease of which TNE can be performed as an office-based procedure, may see primary care physicians utilizing it in their practices<sup>16</sup>.

### Is TNE suitable for all patients with oesophageal disorders?

There are limitations to TNE. Individuals with narrow nasal passages or hypersensitive gag reflexes should be considered for sedated gastroscopy<sup>1</sup>. The length of transnasal oesophoscopes vary. Shorter scopes only provide

visualization up to the mid-stomach section. Lower gastric or duodenal lesions can be missed<sup>16</sup>. The therapeutic value of TNE is limited by its size and accessories. For example, it may be useful in the diagnosis of a foreign body in the oesophagus but its therapeutic use is limited by the type of foreign body and location<sup>17,18</sup>. Then, there are certain instances in which one may prefer conventional oesophagoscopy. In cases in which it is expected that a significant time may be required to perform the procedure or in paediatric population, the surgeon may prefer the patient to be sedated<sup>19</sup>.

#### *Why has TNE not gained widespread acceptance?*

Early TNE trials found the diagnostic accuracy of TNE to be less than that of conventional oesophagoscopy. However more recent trials have found good visual and histologic correlations between both modalities<sup>11,12</sup>. This improvement in diagnostic outcomes is believed to be due to better scope technologies which utilize high resolution CCD's<sup>1</sup>.

Adler, in his editorial letter in Gastrointestinal Endoscopy believes part of the resistance towards TNE may be due to endoscopists worrying that TNE may disrupt established practices and result in a loss of income<sup>16</sup>. In addition, dissemination of this technology to the clinic may see more family practitioners and primary care physicians expanding the scope of their practices resulting in a loss of procedural opportunities for existing endoscopists.

#### *The potential impact on service provision in Malaysia*

##### Earlier diagnosis of oesophageal cancer

In Peninsular Malaysia in 2006, oesophageal cancer was the 18th most frequent cancers among the males with age-standardized rate (ASR) of 2.7 and the 23rd most frequent cancer among females with the ASR of 1.4<sup>20</sup>. A retrospective cross sectional study of 143 patients in Malaysia diagnosed with oesophageal cancer found that the majority were diagnosed late, (71.3%) were at stage IV, followed by 16.1% at stage III<sup>21</sup>. TNE surveillance may lead to earlier diagnosis or pick-up premalignant lesions.

##### Safety

There are no local studies on the adverse effects of flexible gastroscopy with sedation. However there are reported complications with rigid oesophagoscopy for the diagnosis and removal of foreign bodies by otorhinolaryngologists<sup>22</sup>. The availability of TNE for otorhinolaryngologists will serve as a useful screening tool and therefore avoiding unnecessary exposure to general anaesthesia.

##### Cost

Rigid oesophagoscopy requires pre-procedure investigations prior to general anaesthesia, procedure time, post-procedure recovery and continuous nursing care during and after oesophagoscopy. In contrast, with TNE, recovery and discharge were possible one hour later does not require general anaesthesia, investigations prior to general anaesthesia, operation theatre and patients admission and this will lead to cost saving. The supplies required for performing TNE included intranasal decongestant with oxymetazoline and lidocaine, followed by intranasal packing of the same medications<sup>17</sup>. As the cost of a full rigid oesophagoscopy system and TNE are similar (based on the

author's personal communication with a medical devices supplier) the ancillary savings are expected to be considerable.

##### Wider population coverage, earlier diagnosis and hospital decongestion

Patients with dysphagia are managed in medical, surgical and otorhinolaryngology clinics. The availability of TNE at these clinics will allow immediate assessment of these patients. This will reduce interdisciplinary referrals, provide earlier diagnosis and treatment and reduce the need for multiple visits to the hospital for a single complaint.

The total population for Malaysia in the year 2010 was 28.3 million<sup>26</sup>. The urban population was 71%. However the urban, rural population ratio differs according to states. In states such as Kelantan, Pahang, Perlis, Sarawak and Sabah, about 50 % of the population live in rural areas. Our doctor to population ratio of 1:859 (as at 2010) is set to rise to 1:600 by 2015 and 1:400 by 2020<sup>27</sup>. Specialist services are mainly concentrated in urban areas. The Ministry of Health, Malaysia is rapidly expanding services to district hospitals. Many district hospitals have physicians, surgeons and otorhinolaryngologists. Smaller hospitals have regular visiting specialist services. The availability of an office-based investigative procedure such as TNE will enable rural patients to be adequately investigated for oesophageal disorders. It will also reduce the need for patients with oesophageal complaints to be referred to a bigger hospital.

## **CONCLUSION**

The HTA report and updated literature review provide evidence on the feasibility of TNE, particularly as a screening or diagnostic tool. There is accumulating evidence on its usefulness in an ORL setting. It can be used for foreign body screening, screening of globus pharyngeus, secondary TEP placement, oesophageal dilatation and head and neck cancer surveillance. In addition there is evidence it can be safely used as an office procedure and it is well tolerated for conventional indications of flexible gastroscopy. While it will not replace conventional oesophagoscopy, the evidence suggests that a substantial number of patients will benefit from this technology. More high quality evidence is needed to assess its practicality for general use. The outcome from the designated head and neck centers selected to study the potential usefulness of this procedure may determine whether TNE will change the practice of oesophagoscopy in Malaysia.

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