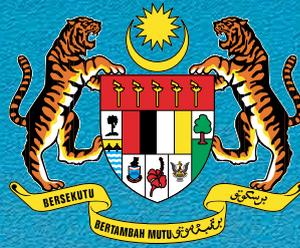


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MINISTRY OF HEALTH MALAYSIA



TRANSNASAL OESOPHAGOSCOPY

MaHTAS

Malaysian Health Technology Assessment Section

MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

HEALTH TECHNOLOGY ASSESSMENT REPORT

Published by**Malaysian Health Technology Assessment Section, (MaHTAS)**

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MINISTRY OF HEALTH MALAYSIA

Health Technology Assessment Report

TRANSNASAL OESOPHAGOSCOPY (TNE)

DISCLAIMER

This Health Technology Assessment has been developed from analysis, interpretation and synthesis of scientific research and/or technology assessment conducted by other organisations. It also incorporates, where available, Malaysian data, and information provided by experts to the Ministry of Health Malaysia. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of the review.

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DISCLOSURE

The authors of this report have no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia.

EXECUTIVE SUMMARY

Background

Oesophagoscopy and barium radiological studies represent the primary means by which structural diseases of the oesophagus may be investigated. Until 1996, the oesophagoscopy performed by otolaryngologists has primarily been transoral approach using rigid oesophagoscope with patients under general anaesthesia. Beginning mid 1990s, otolaryngologists began to perform oesophagoscopy utilising an ultra thin, flexible scope passed transnasally, with the patients not sedated, solely relying on topical anaesthesia. This approach is called transnasal oesophagoscopy (TNE). Indications for TNE can be divided into three major categories: oesophageal, extraoesophageal and procedure related. Currently, TNE is not yet available in the Ear, Nose and Throat (ENT) department in Ministry of Health facilities in Malaysia.

Technical features

There are two different types of TNE systems available. One is a video chip flexible endoscope system where the camera is located at the distal tip of the endoscope and the scope is attached to a video processor. The other is an add-on camera flexible endoscope system in which a camera is attached to the proximal portion of the fiberscope, usually at the eyepiece. The fiberoptic add-on camera system can incorporate a single-use, disposable TNE EndoSheath. Transnasal oesophagoscopy is an office-based procedure. The patient is seated in a standard ENT examining chair. No cardiac monitoring is necessary unlike the conscious sedation. The key to successful examination is adequate topical nasal anaesthesia and decongestion.

Policy question

Should TNE be made available in ENT specialist clinics in Ministry of Health hospitals in Malaysia?

Objective

To assess the safety, efficacy or effectiveness and economic implication of using TNE compared with conventional oesophagoscopy for oesophageal and extraoesophageal diagnostic and therapeutic procedures by otolaryngologists.

Methods

Electronic databases such as MEDLINE, EBM Reviews-Cochrane Database of Systematic Reviews, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Reviews-HTA databases, EBM Reviews-Database of Abstracts of Review of Effects, EBM Reviews-NHS Economic Evaluation Database were searched through Ovid interface. PubMed, INAHTA database, Horizon scanning database, ASERNIP-S and FDA database were searched. No limits were also applied to the search. Additional articles were identified from bibliographies of retrieved articles and contacting the authors. Studies were selected based on inclusion and exclusion criteria. 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.

Results and conclusion

A total of 67 relevant titles were identified and 39 abstracts were screened using the inclusion and exclusion criteria. Seventeen full text articles were included in this report. The articles comprised of one cross sectional diagnostic study, 13 cross sectional studies, two cross sectional studies with economic evaluation and one case report.

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, evaluation of patients with head and neck cancer and for detection of metachronous esophageal squamous carcinoma in patients with head and neck squamous cell carcinoma. Evidence also suggested 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 to measure the pH levels in the oesophagus, transnasal balloon dilation of the oesophagus, secondary tracheoesophageal puncture and management of foreign bodies.

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 such as self limited epistaxis, vasovagal reactions that required no treatment and self limited laryngospasm. There was no reported oesophageal perforation or major complication. There was evidence to suggest there was potential direct cost saving derived by performing TNE in the office setting compared with rigid oesophagoscopy performed under general anaesthesia.

Studies have shown that 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 office based practice under local anaesthesia.

Recommendation

Based on the above review, there seemed to be a potential cost saving derived by performing TNE in the office setting compared with rigid oesophagoscopy performed under general anaesthesia. However, the evidence for effectiveness was only of fair level of evidence. 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. More quality clinical research is warranted to provide more high quality scientific evidence. Organizational issues such as training, manpower and funding need to be considered.

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ABBREVIATIONS

| | |
|------------------|--|
| HTA | Health Technology Assessment |
| TNE | Transnasal oesophagoscopy |
| TNFLO | Transnasal flexible laryngo-oesophagoscopy |
| GERD/GORD | Gastroesophageal reflux disease |
| GER | Gastroesophageal reflux |
| ASR | Age standardized rate |
| U.S.A. | United States of America |
| U.K. | United Kingdom |
| LPR | Laryngopharyngeal reflux |
| ENT | Ear, Nose and Throat |
| SCJ | Squamocolumnar junction |
| UES | Upper oesophageal sphincter |
| LES | Lower oesophageal sphincter |
| EGD/OGDS | Oesophagogastroduodenoscopy |
| HNSCC | Head and neck squamous cell carcinoma |
| TEP | Tracheoesophageal puncture |
| CI | Confidence interval |
| SD | Standard deviation |

1 BACKGROUND

The oesophagus is a muscular tube, which runs from the cricopharyngeus to the oesophagogastric junction. Anatomically, in the normal adult, the oesophagogastric junction is approximately 38 cm from the incisor teeth. Histologically, the mucosal lining comprises squamous epithelium with surrounding layers of circular and longitudinal muscle. There are many oesophageal conditions affecting human such as gastroesophageal reflux disease (GERD), oesophageal web, Plummer-Vinson syndrome, oesophagitis, Barrett's oesophagus, oesophageal ulcer, oesophageal stricture, achalasia, oesophageal cancer, benign oesophageal tumours, Mallory-Weiss tear, oesophageal varices, and oesophageal ring (Schatzki's ring).¹ In a cross sectional study, Rosaida MS, Goh KL found that from 1,000 consecutive patients undergoing endoscopy for upper abdominal discomfort in University of Malaya Medical Centre, Kuala Lumpur, 13.4% had endoscopic evidence of reflux oesophagitis. Hiatus hernia was found in 6.7% and Barrett's oesophagus in 2% of the patients. Of the patients with reflux oesophagitis, 20.1% had grade C and D oesophagitis.²

In Peninsular Malaysia in 2006, oesophageal cancer was the 18th most frequent cancers among the males with age-standardized incidence rate (ASR) of 2.7 per 100,000 population and the 23rd most frequent cancer among females with the ASR of 1.4 per 100,000 population. It primarily affects those aged over 60 years and was more common among Indians followed by Chinese and Malays.³ Rajendra S, Kutty K, Karim N conducted a study looking at the prevalence of erosive oesophagitis and Barrett's oesophagitis in 1,985 patients undergoing elective gastroscopy for predominantly upper abdominal or reflux complaints at Hospital Ipoh, Malaysia. They found that the prevalence of endoscopically documented oesophagitis among the 1,985 patients was 6.1%. The majority of which were mild, Grade 1 or 2 (88%). There was a preponderance of Indians with oesophagitis, as well as males ($P < 0.05$) and those with hiatus hernia ($P < 0.01$). Long segment Barrett's oesophagus was found in 1.6% of patients, and short-segment Barrett's in 4.6%. Indians had the highest prevalence of Barrett's oesophagus compared with Chinese ($P < 0.05$) or Malays ($P < 0.01$). Hiatus hernia and erosive oesophagitis were both positively associated with Barrett's metaplasia ($P < 0.01$).⁴

A retrospective cross sectional study by Abdullah M, Karim AA, Goh KL at University of Malaya Medical Centre, Kuala Lumpur among 143 patients diagnosed with oesophageal cancer found that the mean age of patients was 63.1 ± 12.1 years with male to female ratio of 1.8 was to 1. Of these, 50.3% were Indians, 32.9% Chinese and 16.8% Malays. The histological types of the oesophageal cancer were squamous cell carcinoma (79.0%) and adenocarcinoma (21.0%). At diagnosis, majority of the cases (71.3%) were at stage IV, followed by 16.1% at stage III and 12.6% at stage II. They concluded that majority of the oesophageal cancer presented late and only a minority of patients underwent curative surgery.⁵

Oesophagoscopy and barium radiological studies represent the primary means by which structural diseases of the oesophagus may be investigated. Until 1996, the oesophagoscopy performed by otolaryngologists has primarily been transoral approach using rigid oesophagoscope with patients under general anaesthesia. Beginning mid 1990s, otolaryngologists began to perform oesophagoscopy utilising an ultra thin, flexible scope passed transnasally, with the patients not sedated, solely relying on topical anaesthesia. This approach is called transnasal oesophagoscopy (TNE) in the United States of America (U.S.A.) but it is known as transnasal flexible laryngo-oesophagoscopy (TNFLO) in the United Kingdom (U.K.). Transnasal oesophagoscopy is performed in the clinic without the sophisticated patient monitoring. Skilled ancillary personnel are required during and after oesophagoscopy performed on patients with conscious sedation in the endoscopy suite or room. Transnasal oesophagoscopy is claimed to have the following advantages over conventional peroral, rigid or flexible oesophagoscopy carried out in a sedated patient. This TNE procedures is said to enhance patient safety, improve survival of oesophageal adenocarcinoma, increase practice efficiency and cost-saving.⁶

Indications for TNE can be divided into three major categories: oesophageal, extraoesophageal and procedure related. Oesophageal indications include dysphagia, oesophageal symptoms that persist despite an appropriate trial of therapy, odynophagia, screening and possibly surveillance for Barrett's oesophagus, caustic ingestion evaluation, foreign body evaluation and possible removal, and longstanding GERD. Extraoesophageal indications for TNE include patients with globus pharyngeus, chronic cough, cervical dysphagia, head and neck cancer, poorly controlled asthma, and moderate to severe laryngopharyngeal reflux (LPR).^{7,8} Transnasal oesophagoscopy may be used to perform a wide variety of procedures. These include biopsies, use of lasers, oesophageal dilation, secondary tracheoesophageal puncture, treatment of achalasia, feeding tube insertion, and the insertion of wireless pH capsule.⁷⁻¹²

Currently, TNE is not yet available in the Ear, Nose and Throat (ENT) department in Ministry of Health facilities in Malaysia. Oesophageal and extraoesophageal diagnostic and therapeutic procedures are currently conducted by otolaryngologists using rigid oesophagoscope, transorally under general anaesthesia. With the latest advancement in oesophagoscopy technology, a Health Technology Assessment (HTA) is required to look into the safety, efficacy or effectiveness and economic implications of TNE and to compare it with the conventional peroral, rigid or flexible oesophagoscopy. This HTA was requested by an otolaryngologist from Raja Permaisuri Bainun Hospital, Ipoh, Perak.

2 TECHNICAL FEATURES

2.1. Transnasal oesophagoscopy (TNE)

2.1.1. Transnasal oesophagoscope

The transnasal oesophagoscope ranges in diameter from 4.5 mm to 5.1 mm. There are two different types of TNE systems available:-¹³

- One is a video chip flexible endoscope system where the camera is located at the distal tip of the endoscope and the scope is attached to a video processor.
- The other is an add-on camera flexible endoscope system in which a camera is attached to the proximal portion of the fiberscope, usually at the eyepiece. The fiberoptic add-on camera system can incorporate a single-use, disposable TNE EndoSheath.

The distal chip endoscopes and endosheaths have a channel for air insufflation or water instillation and for suction. A working channel allowing passage of 1.8 mm cup forceps, biopsy brushes, or flexible lasers is also available.^{6,13} Transnasal oesophagoscope has United States of America Food and Drug Administration (U.S. FDA) pre-market notification 510(k).¹⁴

Examples of transnasal oesophagoscope include;-

- EE-1580K Colour Video Oesophagoscope, belong to the KayPENTAX family¹⁵
 - The scope features an ultra-slim 5.1 mm insertion tube perfect for transnasal insertion, and houses a 2.0 mm instrument channel
 - Contains a built-in colour CCD that generates full-screen, high resolution images, and utilise the new EPK-1000 Digital Colour Video Processor with Digital Signal processing (DSP) technology
 - It has air/water delivery capabilities, and is designed with a 600 mm insertion tube working length so it can be used for pharyngo-laryngeal applications as well as for oesophageal observation and procedures
- EndoEYE Flexible Video Transnasal Oesophagoscope (PEF-V) from Olympus¹⁶
 - Digital imaging utilizing a CCD at the scope tip produces clear and vivid images
 - Miniaturised Colour CCD provides consistent colour reproduction without separation for improved observation

- 5.3 mm outer diameter allows for smooth insertion without sedation
- Air/water insufflations and suction capability is easily activated on the control section to maximise visualisation
- 2 mm biopsy channel makes PEF-V compatible with a number of Olympus endotherapy accessories for a variety of diagnostic and therapeutic procedures
- VISERA™ video system allows digital recording of still and moving images for documentation and management purposes
- Long 650 mm working length lets the user reach the stomach and observe the cardia more easily

2.1.2. TNE technique

Transnasal oesophagoscopy is an office-based procedure. The patient is seated in a standard ENT examining chair. No cardiac monitoring is necessary unlike the conscious sedation. Although not absolutely necessary, it is preferable that the patient does not eat or drink for at least three hours before TNE. This ensures the stomach is empty during the examination. No conscious or intravenous sedation is used. The key to successful examination is adequate topical nasal anaesthesia and decongestion.^{8,13}

Figure 1. Transnasal oesophagoscopy (TNE) procedure



The patient's nasal cavity is anaesthetised and vasoconstricted with a topical agent, typically lidocaine 1% to 2% with epinephrine 1:100,000 or oxymetazoline 0.05%. The hypopharynx may be lightly anaesthetised with benzocaine 20% spray administered via the oral cavity. The lubricated endoscope is then inserted through the nose and depending on the patient, the TNE is inserted into the oesophagus using two different techniques. In one technique, the patient is asked to eructate. During the burp, the cricopharyngeus opens and the endoscope can be passed posterior to the cricoids into the cervical oesophagus. The other technique, which is more frequently used, is to have the patient tuck their chin toward their chest and swallow.¹³

Once the oesophagus is entered, the endoscope is passed to the region of the squamocolumnar junction (SCJ) and lower oesophageal sphincter (LES). The middle and proximal oesophagus is examined in greater detail during withdrawal of the endoscope. The SCJ is visualised, and the presence of pathology in this region is evaluated. Having the patient swallow during this portion of examination will open the LES and help to visualise the terminal linear blood vessels and the SCJ. The endoscope is then passed deeper into the stomach, and a retroflexed view of LES is obtained. After examining the oesophagogastric junction and gastric cardia from below, the stomach is suction free of air, and the oesophagoscope is straightened and gently withdrawn. Every millimetre of oesophagus mucosa is visualised during removal of the endoscope. The postcricoid area is visualised by generous air insufflations as the endoscope is removed from the oesophagus and the videotape can be reviewed, since often only a few frames of this region are obtained.¹³

2.2. Competing technologies

2.2.1. Flexible rhinolaryngoscopy and Direct laryngoscopy

Flexible rhinolaryngoscopy is used for visualising the nasal cavity, the sinuses, the pharynx and the larynx. The technique utilises small-caliber flexible endoscope and can be performed in an office setting. Direct laryngoscopy has the advantage of permitting both diagnostic and therapeutic intervention. It is performed with the patients under general anaesthesia and intubated.¹⁷

2.2.2. Flexible oesophagoscope and Rigid oesophagoscope (conventional oesophagoscope)

Oesophagoscopy plays an important role in the evaluation of patients with dysphagia, odynophagia, caustic ingestion, trauma, ingested foreign body, suspected foreign bodies, suspected anomalies, and upper aerodigestive tract malignancies. The procedure can be performed perorally with either a flexible or a rigid scope. The flexible oesophagoscope is used with local anaesthesia and sedation in a monitored setting. The primary application for flexible oesophagoscopy is diagnosis particularly useful in elderly patient with limited spinal mobility. Rigid oesophagoscope can be used to treat a variety of problems, including foreign bodies, haemorrhage and endobronchial tumours. Rigid oesophoscopes are used with the patient under general anaesthesia.¹⁷

2.2.3. Barium swallow

The classical radiological investigation of the oesophagus has been barium swallow. Structural lesions such as ulcers and strictures are readily identified. It is claimed to be safer than endoscopy for the examination of oesophageal pouches, webs, and rings, since it is performed without sedation or instrumentation.¹

2.2.4. Oesophagogastroduodenoscopy (EGD) or OGDS

Conventional sedated EGD or transnasal unsedated EGD has been performed by gastroenterologists for diagnostic and therapeutic reasons such as heartburn and chronic acid reflux, dysphagia, odynophagia, surveillance of Barret's oesophagus, removal of foreign bodies that have been ingested, application of dynamic therapy for treatment of oesophageal malignancies and dilating or stenting of stenosis or achalasia.¹⁸

3 POLICY QUESTION

Should TNE be made available in ENT specialist clinics in Ministry of Health hospitals in Malaysia?

4 OBJECTIVE

- 4.1. To assess the safety and efficacy or effectiveness of TNE compared with conventional oesophagoscopy for detection and management of oesophageal and extraoesophageal lesions.
- 4.2. To assess the cost implication of using TNE compared with conventional oesophagoscopy.
- 4.3. To determine the social and organizational issues related with the use of TNE.

The following research questions were addressed:-

- How safe is TNE compared with conventional oesophagoscopy when use for detection and management of oesophageal and extraoesophageal lesions.
- How effective is TNE compared with conventional oesophagoscopy for detection and management of oesophageal and extraoesophageal lesions.
- What is the diagnostic accuracy of TNE when used for diagnosis of oesophageal and extraoesophageal lesions.
- What is the economic implication of using TNE to the health system.

5 METHODS

5.1. Literature search strategy

Studies were identified by searching electronic databases. The following databases were searched through the Ovid interface: MEDLINE(R) In-process and other Non-Indexed Citations and Ovid MEDLINE(R) 1948 to present, EBM Reviews-Cochrane Database of Systematic Reviews (2005 to June 2011), EBM Reviews-Cochrane Central Register of Controlled Trials (3rd Quarter 2011), EBM Reviews – Database of Abstracts of Review of Effects (3rd Quarter 2011), EBM Reviews-Health Technology Assessment (3rd Quarter 2011), EBM Reviews-NHS Economic Evaluation Database (3rd Quarter 2011). Parallel searches were run in PubMed. No limits were applied to the search. No filters were applied. Appendix 4 showed the detailed search strategies. Other databases searched include INAHTA database, Horizon Scanning databases (Australia and New Zealand Horizon Scanning, Defra-UK Horizon scanning, National Horizon Scanning Centre), ASERNIP-S and FDA database. The last search was run on 15 July 2011. Additional articles were identified from reviewing the bibliographies of retrieved articles and contacting the authors. General search engine was used to get additional web-based information.

5.2. Study Selection

Based on the policy question the following inclusion and exclusion criteria were used:-

5.2.1. Inclusion criteria

- Study design: HTA report, Systematic Review, Randomised Controlled Trials (RCT), non randomised controlled trial, cross sectional diagnostic studies, cross sectional studies, case series, case reports and studies which include economic evaluation.
- Population: Patients with oesophageal lesions and / or extraoesophageal lesions.
- Intervention: Transnasal oesophagoscopy (TNE), transnasal flexible laryngo-oesophagoscopy (TNFLO).
- Comparators:
 - No comparators.
 - Conventional oesophagoscopy - rigid or flexible.
 - Barium swallow.
 - Laryngoscopy.
 - Oesophagogastroduodenoscopy or oesophagogastroscopy (EGD) or OGDS.

- Outcome:
 - Detection of oesophageal lesions such as Gastroesophageal reflux disease (GERD), oesophagitis, Barrett's oesophagus, oesophageal ulcer, oesophageal cancer, benign oesophageal tumours, oesophageal web, Plummer-Vinson syndrome, oesophageal varices, oesophageal ring, achalasia, Mallory-Weiss tear.
 - Detection of extraoesophageal lesions such as globus pharyngeus, head and neck cancer, laryngopharyngeal reflux (LPR).
 - Effectiveness for therapeutic procedures such as oesophageal balloon dilation, secondary tracheoesophageal puncture, delivery of flexible lasers, insertion of wireless pH capsule and foreign body removal.
 - Adverse events or complications related to the use of TNE.
 - Cost, cost-utility, cost-effectiveness, cost implication of using TNE compared with conventional oesophagoscopy.
 - Sensitivity, specificity, positive predictive value and negative predictive value of TNE.
- Type of publication: Full text articles published in English

5.2.1. Exclusion criteria:-

- Study design : Animal study, experimental study and narrative review.
- Type of publication: Non English full text article.

Based on the above inclusion and exclusion criteria, study selection were carried out independently by two reviewers. The titles and abstracts of all studies were assessed for the above eligibility criteria. If it was absolutely clear from the title and / or the abstract that the study was not relevant, it was excluded. If it was unclear from the abstract and / or the title the full text article was retrieved. Two reviewers assessed the content of the full text articles. Disagreement was resolved by discussion.

5.3. Quality assessment strategy

The methodological quality of all the relevant full text articles retrieved was assessed using the Critical Appraisal Skills Programme (CASP) tool depending on the type of study design.¹⁹ Quality assessment was conducted by two reviewers. All full text articles were graded based on guidelines from the U.S./ Canadian Preventive Services Task Force (Appendix 1)²⁰ or NHS Centre for Reviews and Dissemination (CRD) University of York, Report Number 4(2nd Edition), March 2001 for test accuracy studies (Appendix 2).²¹

5.4. Data extraction strategy

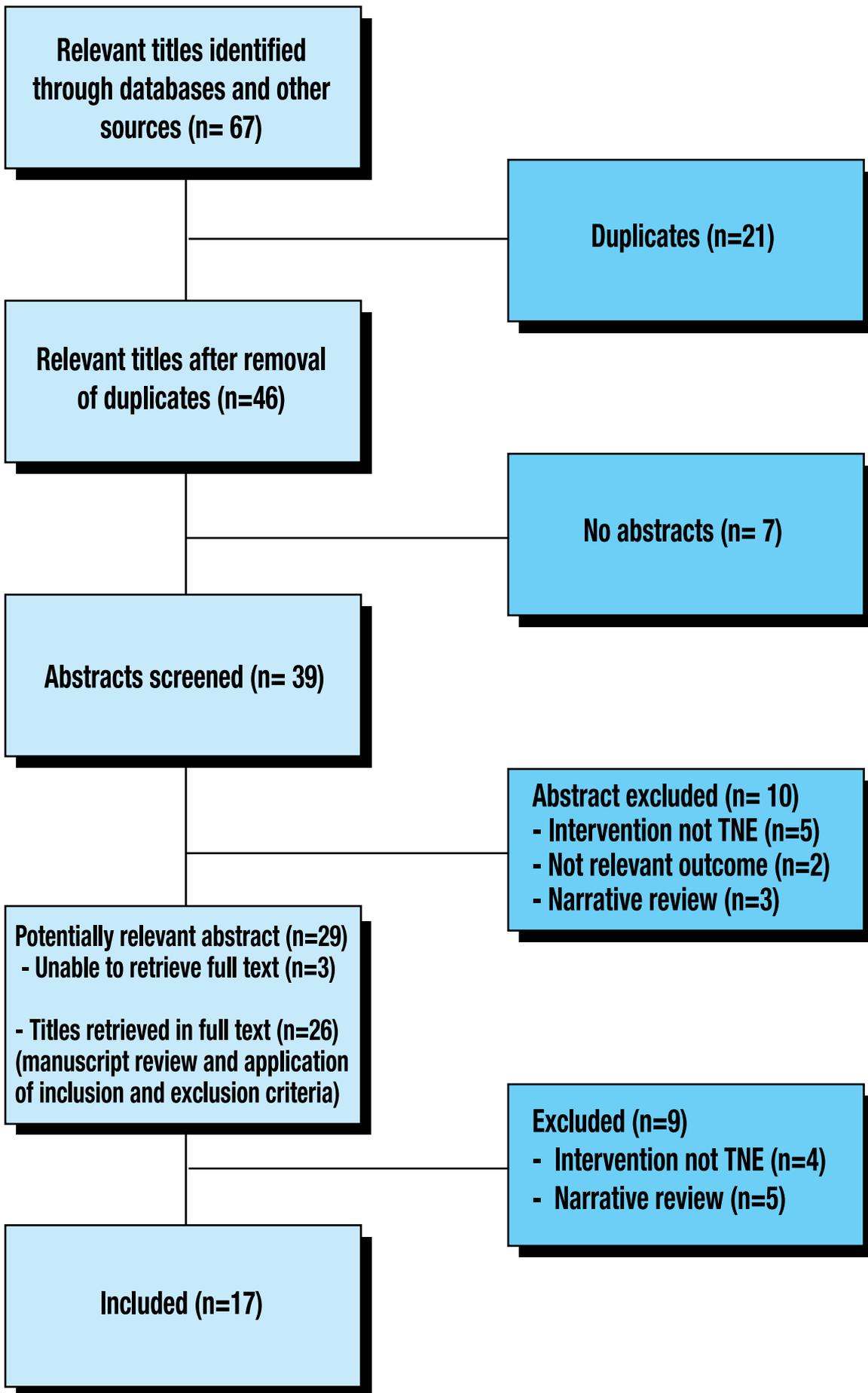
Data were extracted from included studies by a reviewer using a pre-designed data extraction form (evidence table as shown in Appendix 5) and checked by another reviewer. Disagreements were resolved by discussion. Details on: (1) methods including study design; (2) study population characteristics including gender, age, indications for TNE; (3) type of intervention (TNE or TNFLO), (4) type of comparators such as conventional oesophagoscopy, barium swallow, laryngoscopy, EGD or OGDS or no comparator (5) type of outcome measures: a) detection of oesophageal and / or extraoesophageal lesions such as GERD, oesophagitis, Barrett's oesophagus, oesophageal ulcer, oesophageal cancer, benign oesophageal tumours, oesophageal web, Plummer-Vinson syndrome, oesophageal varices, oesophageal ring, achalasia, Mallory-Weiss tear, globus pharyngeus, head and neck cancer, LPR, b) effectiveness of therapeutic procedures such as neopharyngeal stricture balloon dilation, secondary tracheoesophageal puncture, delivery of flexible lasers, insertion of wireless pH capsule and foreign body removal, c) adverse events or complications related to the use of TNE, d) cost, cost-utility, cost-effectiveness or cost implication of using TNE, e) sensitivity, specificity, positive predictive value, negative predictive value of TNE and (6) any information on social or organizational aspect related to the use of TNE were extracted. The extracted data were presented and discussed with the expert committee.

6 RESULTS

A total of 67 relevant titles were identified and 39 abstracts were screened using the inclusion and exclusion criteria. Of these, ten abstracts were found to be irrelevant. Twenty nine potentially relevant abstracts were attempted for retrieval. Of these, 26 potentially relevant articles were retrieved in full text, and full text for three abstracts cannot be retrieved. After reading and appraising full text articles, 17 full text articles were included as shown in Figure 2. Nine full text articles were excluded based on inclusion and exclusion criteria and are listed in Appendix 6.

The 17 articles finally selected for this review comprised of one cross sectional diagnostic study, 13 cross sectional studies, two cross sectional studies with economic evaluation and one case report. The search did not yield any health technology assessment report, systematic review or randomised controlled trial. There were no controlled trials which compared TNE with its comparators such as conventional oesophagoscopy (rigid or flexible), barium swallow, laryngoscopy, EGD or OGDS.

Figure 2. Flow chart of study selection



6.1.1. Detection of oesophageal and extraoesophageal lesions

a. Screening examination in patients with dysphagia or globus pharyngeus or reflux symptoms

Since the introduction of TNE, there have been several studies conducted by otolaryngologists in the U.S.A., U.K., Japan and Taiwan. The first article by an otolaryngologist on TNE was published in 2001 by Aviv *et al.* who conducted a cross sectional study in Columbia University, U.S.A. using TNE in an office setting among 14 patients with dysphagia. There was no significant difference between the larynx and oesophagus in terms of quality of optical image; larynx (mean, 1.1; range, 1 to 2, standard deviation (SD), 0.1) and oesophagus (mean, 2.1; range, 1 to 6, SD, 0.3) whereby one represented excellent image quality and ten represented very poor image quality. They found that all patients completed the TNE with the oesophagus readily intubated and oesophageal mucosa clearly visualised. Pathological oesophageal findings included a proximal oesophageal stricture, a patulous upper oesophageal sphincter and a Zenker's diverticulum. Incidental finding of left nasopharyngeal mass was noted in one patient.^{22 level II-3}

The largest consecutive report of TNE examinations has been published by Postma *et al.* in the U.S.A. in which they reported on 700 consecutive patients. A total of 611 consecutive patients who underwent TNE using VE-1530, Pentax Precision Instrument Corporation, Orangeburg, New York between January 28, 2001 and January 1, 2004 were compared with 100 consecutive patients previously reported. The patients presented primarily with reflux or globus pharyngeus and / or dysphagia. Only 2.8% (17) procedures were aborted secondary to an inability to pass the endoscope through a tight nasal vault and 0.3% (two) were aborted secondary to self-limited vasovagal responses. Significant findings were noted in 49.7% (294/592) of patients. The most common findings in the oesophagus were oesophagitis (17.0%), hiatal hernia (8.0%), Barrett's metaplasia (5.0%), candidiasis (5.0%), stricture (4.0%), and carcinoma (4.0%).^{23 level II-3} The results were similar to their initial report of 100 consecutive patients whereby significant findings were found in 43.7% (42/96) of patients and four procedures (4.0%) were aborted secondary to a tight nasal vault.^{24 level II-3} The authors concluded that TNE may replace radiographic imaging of the oesophagus in otolaryngology patients with reflux, globus pharyngeus and dysphagia.^{23-24 level II-3}

Andrus *et al.* who evaluated the findings of TNE conducted among 30 patients presenting with dysphagia, GER or LPR and oesophageal surveillance for head and neck cancer found that 43.3% of them had positive findings and patient management was affected after TNE. Findings include: Barrett's oesophagus, candidal oesophagitis, posterior glottis oedema, postcricoid mass, oesophageal diverticulum, oesophageal dysmotility, oesophageal stricture, patulous oesophagus and gastritis. Patients with Barrett's oesophagus were referred to a gastroenterologist for further evaluation and management. Patient with oesophageal stricture was dilated successfully with a number 36 bougie dilator at the time of TNE and being followed symptomatically. Patients with negative examinations were followed by the otolaryngologist. Seven patients who would normally have been evaluated with a barium swallow for globus pharyngeus or dysphagia did not undergo the test as a result of negative TNE.^{25 level II-3}

Similarly, Price *et al.* demonstrated the diagnostic capabilities of TNFLO using Pentax 80K series digital video endoscope (EE 1580K, Pentax, Slough, U.K.) in the U.K. A total of 116 TNFLO procedures were performed. Indications for TNFLO included screening examination for symptoms of globus pharyngeus, dysphagia, dysphonia and head and neck cancer. All patients were investigated and treated under local anaesthesia and no patients required sedation or any other medication. Only 1.8% (1/56) of patients with globus pharyngeus did not tolerate the procedure. Of the 56 patients with globus pharyngeus, 10.7% (6/56) of patients were found to have pathology and 87.5% (49/56) of patients with no identifiable pathology were discharged. Among patients with dysphagia, lesions such as foreign bodies, complete oesophageal stenosis, benign oesophageal stricture, post-cricoid tumour, post-cricoid webs and benign pharyngeal pouches were identified. As for 14 patients who presented with dysphonia the findings were: one had normal larynx, one had Reinke's oedema, one had vocal cord palsy (had vocal cord medialization procedure using TNFLO), ten had suspicious lesions of the larynx and biopsies were taken and one had recurrent respiratory papillomatosis which was successfully treated with Nd-YAG laser.^{26 level II-3}

Another cross sectional study conducted by McPartlin *et al.* among 16 patients with symptoms of globus pharyngeus or mild dysphagia at Cross Hospital, London, U.K., found that 43.7% of patients had mild Gastroesophageal reflux (GORD) or GORD. Quality of views obtained was rated as excellent in 62.5% (10/16), good in 31.3% (5/16) and fair in 6.2% (1/16). None were rated as poor.^{27 level II-3}

The utility of office-based TNE in the evaluation of patients with chronic dysphagia, globus sensation and a sensation of “food sticking” with swallowing was also demonstrated by Kumar VV and Amir MR in their two case reports at the University College of Medicine, Philadelphia, Pennsylvania, U.S.A. In the first case, TNE revealed a solitary mid-oesophageal diverticulum with otherwise normal mucosa. Patient underwent endoscopic diverticulectomy. On follow-up office visits, the patient reported resolution of his dysphagia symptoms and resumption of a regular diet. In the second case, TNE revealed multiple diverticuli and a tortuous oesophagus. The patient underwent endoscopic staple-assisted diverticulectomy of the Zenker’s diverticulum and also underwent oesophagoscopy and dilation. The patient’s swallowing impairments improved and he was subsequently able to tolerate solid foods.^{28 level II-3}

In contrast, Koufman *et al.* from Wake Forest University, U.S.A. in their cross sectional study involving 58 patients with pH documented LPR, who underwent TNE with biopsies found that the prevalence of oesophagitis and Barrett’s metaplasia was 19.0%. They concluded that these data confirm the clinical impression that the patterns, mechanisms, and manifestations of LPR differ from those of classic oesophageal reflux disease. Unlike GERD, patients with LPR uncommonly have oesophagitis. Thus, although oesophagoscopy may be an excellent method for screening of the oesophagus, it is not the method of choice for diagnosing LPR.^{29 level II-3}

b. Patients with head and neck cancer

Panendoscopy is part of the standard evaluation of individual with head and neck squamous cell carcinoma. Often, these patients possess comorbidities that increase the risk of general anaesthesia. In-office TNE allows an examination of the aerodigestive tract without the morbidity of anaesthesia. TNE has been demonstrated to be safe and well tolerated in the vast majority of patients including those with head and neck cancer.^{23,24,26 level II-3} The role of TNE in head and neck oncology was further emphasised by Postma *et al.*³⁰ Transnasal oesophagoscopy was performed in a prospective fashion in 17 patients with known lesions of the upper aerodigestive tract in Wake Forest University, U.S.A. All masses were suspected to be malignant. Each of these individuals underwent TNE with biopsies and soon thereafter went to the operating room for standard panendoscopy with biopsies. Their findings were entirely congruent between the two modalities. TNE provided 100% sensitivity and 100% specificity in biopsy results and staging of the tumour when compared with standard panendoscopy.

The authors concluded that TNE gives the surgeon the ability to perform a remarkable variety of procedures in the outpatient setting without sedation. It may obviate the need for routine panendoscopy in head and neck cancer patients.³⁰ level 3

The ability of TNE for detecting metachronous oesophageal squamous carcinoma in patients with head and neck squamous cell carcinoma (HNSCC) was evaluated by Su *et al.* at a tertiary medical centre in Taiwan.³¹ In total, TNE was performed 398 times in 293 previously treated patients with HNSCC between December 2007 and January 2009. The site distributions of HNSCC were 63% in the oral cavity, 14% in the oropharynx, 15% in hypopharynx and 8% in the larynx. Metachronous oesophageal squamous carcinoma was detected in 5.1% (15/293) of patients. The median time to the diagnosis of oesophageal carcinoma was 15 months (range, 7-76 months). Eleven (73.0%) of them were found within three years after HNSCC was diagnosed. The prevalence rate was 15.9% (7/44) in patients with hypopharyngeal cancer which is significantly higher than the 8.3% (2/24) in laryngeal, 7.1% (3/42) in oropharyngeal, and 1.6% (3/183) in oral cancer (P=0.001). The stage distributions of oesophageal squamous carcinoma were I-II in 80% (12/15) and III-IV in 20% (3/15) of patients. Subsequently, curative strategies were performed in 87% (13/15) of patients.³¹ level II-3

6.1.2. TNE assisted procedures

a. Biopsy of suspicious lesions in the upper aero-digestive tract

Studies have reported the use of TNE for biopsies of suspicious lesions in the upper aerodigestive tract. Postma *et al.* and Belafsky *et al.* described the use of TNE for biopsy of suspicious lesions in the laryngopharynx, while Price *et al.* described the use of TNE for biopsy of suspicious lesions in the larynx, post nasal space and the uvula.^{23,24,26} In a study by Belafsky *et al.*, five of the eight biopsies (63%) resulted in a diagnosis of squamous cell carcinoma, one biopsy found a laryngeal fungal infection and two were non diagnostics.²⁴ level II-3 Price *et al.* found that eight of the twelve biopsies in the larynx (66.7%), one of the five biopsies in the post-nasal space (20.0%) and one biopsy in the uvula (100.0%) resulted in a diagnosis of invasive squamous cell carcinoma.²⁶

level II-3

b. Placement of wireless pH capsule

Belafsky *et al.* prospectively evaluated 46 patients undergoing unsedated TNE and wireless pH capsule placement at the Scripps Centre for Voice and Swallowing La Jolla, California, U.S.A. between January 1, 2003 and July 31, 2003. The indications of the procedure were: chronic cough in 39.1% (18/46) of patients, GERD in 39.1% (18/46) of patients and LPR in 21.8% (10/46) of patients. Of the procedures performed, 85% (39/46) were successful. Of the seven procedures that failed, two capsules could not be passed because of a tight nasal vault, three capsules failed because of technical reasons (early detachment in two and delivery system failure in one), one patient went into laryngospasm and could not complete the capsule placement, and one patient lost a wireless data recorder after a successful capsule placement. They concluded that transnasal placement of a wireless pH capsule is a safe and effective diagnostic adjunct to unsedated transnasal oesophagoscopy.^{32 level II-3}

Belafsky *et al.* conducted another study with the aim of evaluating the effect of sedation on the 48-hour wireless pH testing by comparing unsedated pH capsule placement (via transnasal during unsedated TNE, transnasal during unsedated oesophageal manometry, transoral unsedated based on the location of SCJ at a previous EGD) with sedated pH capsule placement (peroral during sedated EGD). They found that the overall reproducibility of the daily pH recordings (day one versus day two) was 77%. All the reflux parameters such as mean reflux episodes, mean time (%) pH < 4 and mean composite score were slightly lower for the sedated group but the difference was not significant ($P>0.05$). The authors concluded that intravenous sedation does not appear to have a significant effect on the results of 48-hour wireless pH testing.^{33 level II-3}

c. Transnasal balloon dilation of the oesophagus

The use of TNE in conjunction with balloon dilation of the oesophagus allows the physician an opportunity to dilate all areas of the oesophagus through the nasal cavity. The safety and efficacy of transnasal balloon dilation of the oesophagus was evaluated by Rees CJ, Fordham T and Belafsky PC at University of California-Davis School of Medicine (UCD) and Wake Forest University School of Medicine (WFU), U.S.A. The cross sectional study involved a retrospective chart review of all persons undergoing transnasal balloon dilation of the oesophagus at the two universities from January 1, 2007 to December 31, 2008. The study was conducted using Pentax VE-1530 transnasal oesophagoscope (Pentax Precision Medical Co, KayPentax, Lincoln Park, New Jersey) and multidiameter hydrostatic wire-guided controlled radial expansion oesophageal dilators (Boston Scientific, Natick, Massachusetts).^{34 level II-3}

Transnasal balloon dilation of the oesophagus was performed with topical anaesthesia or with the patient under conscious sedation, at the preference of the patients. The study involved 38 patients who presented with cricopharyngeal dysfunction, benign stricture, oesophageal web and Schatzki ring. Fifty four transnasal oesophageal balloon dilations were performed in 38 patients. Twenty procedures (37.0%) were performed using topical anaesthesia in the office setting and 34 procedures (63.0%) were performed with conscious sedation in an outpatient surgical suite. The most common site of dilation (63.0%) was the upper oesophageal sphincter (UES). Mid oesophageal locations were the next most common (26.0%) followed by the LES (7%) and both the EUS and LES (4.0%). Ninety six point three percent of the procedure was well tolerated. Two procedures (3.7%) were aborted secondary to self-limited laryngospasm or gagging. The authors concluded that transnasal oesophagoscopy balloon dilation can be performed in unsedated or sedated patients with low complications rate. This technique, formerly available only through larger calibre oral gastroscopes and under sedation, allows for office-based oesophageal balloon dilation in an otolaryngology practice.^{34 level II-3}

d. **Secondary Tracheoesophageal Puncture (TEP)**

Tracheoesophageal puncture (TEP) is a means of restoring voice in patients after laryngectomy. LeBert *et al.* evaluated the outcomes of voice restoration using office-based TNE to guide placement of the secondary TEP in three tertiary care medical centres in the U.S.A. They conducted a retrospective chart review of patients who underwent TNE-assisted TEP between January 2004 and December 2008. A total of 39 patients were included in the study. Total laryngectomy was the most common surgical procedure underwent by the patients (64.1%, n=25) followed by total laryngectomy with partial pharyngectomy (20.5%, n=8), total laryngopharyngectomy (12.8%, n=5) and one unknown. Eighteen of the 39 patients (46.1%) underwent radiation therapy before surgical treatment.^{35 level II-3}

They reported an overall success rate of TNE-assisted TEP as 97.4% (38/39) with one unsuccessful attempt (2.6%). There was no statistically significant correlation between patients having undergone radiation therapy or cricopharyngeal myotomy and a successful TEP placement, difficulty in placing the TEP, complications associated with TEP, using the TEP prosthesis, and speech intelligibility at the last follow-up visit ($P>0.05$). Thirty one of the thirty nine patients (79.5%) were still using their TEP prosthesis for speech at the last follow-up visit and 64.5% (20/31) were rated as understandable all the time (PSS-HN Understandability of Speech Subscale Score =100). They concluded that in-office TNE-assisted TEP placement can safely be performed, with excellent speech outcomes.^{35 level II-3}

e. Management of foreign bodies

The utility of TNE for evaluation of possible foreign bodies were reported by Postma *et al.* and Belafsky *et al.*^{23-24 level II-3} Postma *et al.* reported that 12 patients underwent TNE for the evaluation of a suspected foreign body. In six patients a foreign body was found and in five patients the foreign body was pushed during oesophagoscopy into the stomach without difficulty.^{23 level II-3} Belafsky *et al.* reported that two patients underwent TNE for evaluation of a suspected foreign body whereby both examinations were found to be negative. These patients eventually underwent rigid oesophagoscopy in the operating room under general anaesthesia and were found to be negative.^{24 level II-3}

Bennet *et al.* reported the use of TNE under local anaesthesia for the diagnosis and removal of foreign bodies from the pharynx and oesophagus in adults at the Norfolk and Norwich University Hospitals, U.K. Five patients aged between 22 to 72 years were examined and found to have foreign bodies involving cod bones (n=2), haddock bone (n=1), plum stone (n=1) and lamb bone (n=1). Two of the foreign bodies were located at the upper oesophagus, one at the pyriform fossa, one at the post cricoids and one at the base of the tongue. Two of the foreign bodies were extracted via the nose, one extracted via the mouth, one pushed into the stomach and one removed by direct pharyngoscopy under general anaesthesia. The authors concluded that TNE represents an improvement in the diagnosis and subsequent treatment of a selected group of foreign bodies as compared with established methodologies.^{36 level II-3}

Similarly, the ability of using TNE for management of pharyngeal and laryngeal foreign bodies was described by Sato *et al.* at the School of Medicine, Kurume Japan. Seventeen patients, aged between eight to 89 years with complained of pharyngeal and laryngeal foreign bodies were included. They found that five foreign bodies located at the medial to the posterior portions of the lateral wall of the oropharynx, seven foreign bodies located at the anterior wall of the oropharynx and one foreign body located at the supraglottis can be extracted with videoendoscope without a hood at its tip through the nasal passage (pernasal endoscopy).^{37 level II-3}

6.2. SAFETY

6.2.1. Complications of TNE

Studies have shown that TNE can be safely performed with topical anaesthesia in an office setting for diagnostic and therapeutic procedures.^{22-24,26-28,31-32, 34-35 level II-3} Aviv *et al.*, McPartlin *et al.*, Kumar VV, Amir MR and LeBert *et al.* reported no complications associated with the use of TNE in their studies.^{22,27-28,31,35 level II-3} Epistaxis represents the most frequent minor complications of TNE (0.9% to 4.3%), but it was self limited whereby bleeding was controlled with direct pressure.^{24,26,32 level II-3} Other minor complication encountered include vasovagal reaction that required no treatment (0.2% to 2.2%).^{23-24,32 level II-3} Rees *et al.* in their study on transnasal balloon dilation of the oesophagus reported self limited laryngospasm in one patient (1.8%) and intractable gagging in another patient (1.8%).^{34 level II-3} In a study on placement of wireless pH capsule, Belafsky *et al.* reported laryngospasm in two patients (4.3%).^{32 level II-3} One of the most feared complications of oesophagoscopy is oesophageal perforation. There was no reported oesophageal perforation or major complication associated with the use of TNE.^{22-24,26-28,32, 34-35 level II-3}

6.3. PATIENT TOLERANCE

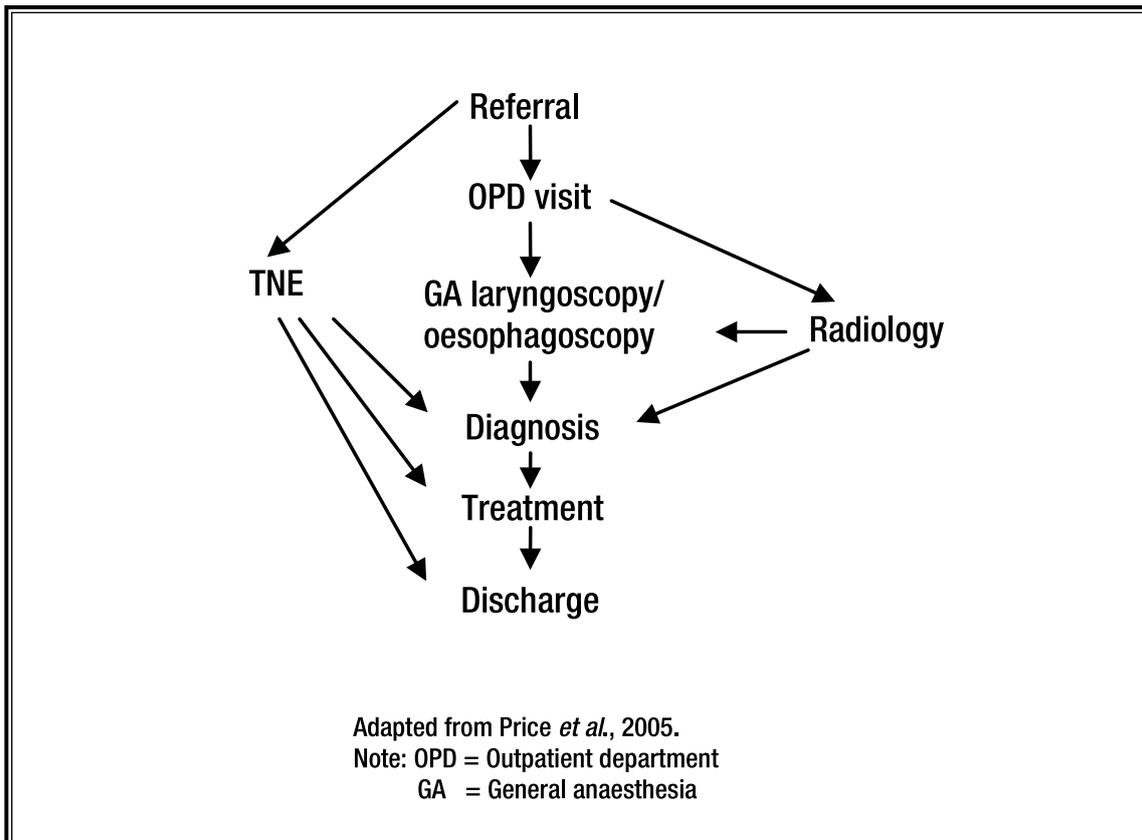
Aviv *et al.* evaluated patients' tolerance by using a validated 10-point analog scale. Patients were asked to rate their level of tolerance to the nasal and oesophageal aspects of the procedure by assessing their anxiety, pain and choking sensation or gagging. In all cases, the rating system was such that one represented no discomfort, well tolerated and ten represented severe discomfort, very poorly tolerated. The overall patient tolerance to TNE was rated as 2.0 (range, 1 to 4; standard deviation, 1.2). All patients indicate that they would repeat the TNE if requested by their physician.^{22 level II-3} Similarly, Price *et al.* in their study involving 116 patients also reported an average score of less than one for all types of discomfort on a visual analogue scale of zero to ten.^{26 level II-3} Other studies have concluded that TNE was well tolerated by patients with local anaesthesia alone.^{23-24,27-28,31 level II-3}

6.4. COST/ COST-EFFECTIVENESS / ECONOMIC EVALUATION

No robust cost-effectiveness analysis (CEA) or cost-utility analysis (CUA) regarding the economic value of TNE is available. However, two full text articles on economic evaluation related to the use of TNE were included in this report. As already been emphasised, sedation is not required for TNE.

Price *et al.* from U.K. evaluated the economic impact of using TNE or TNFLO as the result of the shift from investigation and treatment in the operating theatre, to a procedure room based practice under local anaesthesia. They demonstrated improved efficiency in management of certain patients such as patients investigated with swallowing problem (dysphagia or globus) with fewer steps involved in the pathway. By using TNE, referral for radiology investigations and laryngoscopy or oesophagoscopy under general anaesthesia can be reduced as shown in figure 3.

Figure 3. Patient pathway with and without TNE when investigated for a swallowing problem (dysphagia or globus).



This translates to monetary saving in terms of reduction in the reliance of radiological investigations (barium swallow \pm £150), reduced follow-up clinic appointments (\pm £80) and a reduction in the cost of inpatient investigations with reduced admissions and use of inpatient theatres (general anaesthetic oesophagoscopy \pm £450). Resource saving applied not only to the hospital but also to the patient.²⁶

The cost implications of employing TNE as standard care for patients with globus pharyngeus and mild dysphagia was also analysed by McPartlin *et al.* from Charing Cross Hospital, London U.K. In their department, an average of 84 barium swallow investigations were requested annually for globus pharyngeus and mild dysphagia at the cost of £240 for investigation and £40 for a follow-up appointment (source: Trust's Finance Department). This brings the cost of the 'post-initial-consultation' investigations to £23,520 per annum. On the other hand, the capital cost of purchasing naso-oesophagoscope was around £20,000, with disposable sheaths costing £50 each. Using these assumptions, the capital cost of purchasing a naso-oesophagoscope will be fully met after 86 investigations, which in their institution translates to just over one year of use. After that the technology leads to savings of £230 (82%) per patient investigated for symptoms of upper aero-digestive tract pathology.²⁷

As this technology may have great economic impact, we calculated the potential direct cost savings derived by performing TNE in the office setting compared with rigid oesophagoscopy performed under general anaesthesia in the operating theatre. As shown in Figure 4, the pathway starts with referral which leads to the outpatient visit in the otorhinolaryngology (ORL) clinic where TNE is done enabling diagnosis, treatment and discharge to be made in a single visit. In contrast, booking for general anaesthesia (GA)/ anaesthetic clinic visit/ admission are additional steps needed before the result is achieved. Cost calculations were based on Fee schedule; i) Fees Act 1951, Fees (Medical) (Amendment) (No. 2) Order 1994, ii) Fees Act 1951, Fees (Medical) (Full Paying Patient) Order 2007 and iii) Private Healthcare Facilities and services (Private Hospitals and other private healthcare facilities) Regulations 2006 as shown in Table 1.³⁸⁻⁴⁰

Figure 4. Patient pathway with and without TNE when investigated for a swallowing problem (dysphagia or globus).

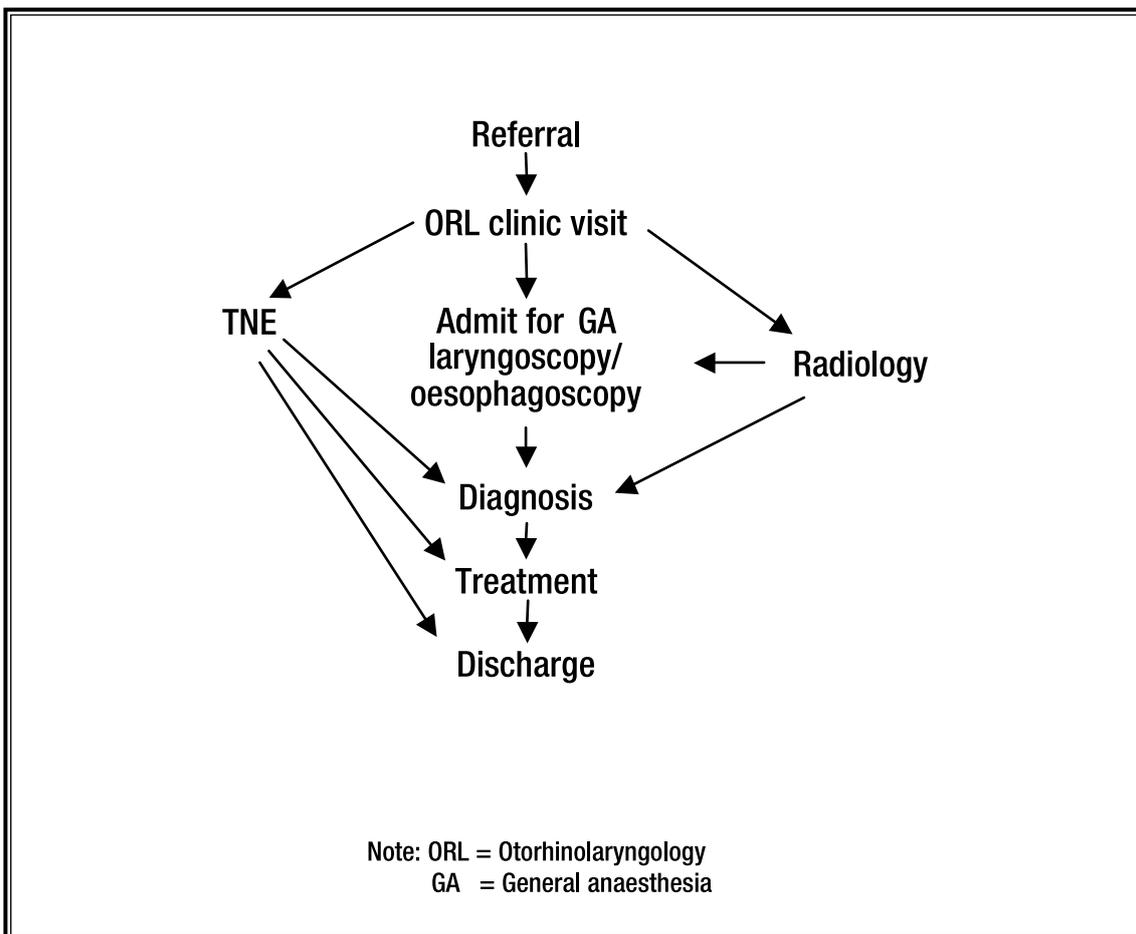


Table 1. Fees related with the use of rigid oesophagoscopy according to Fees Act 1951 and Private Healthcare Facilities and Services (private hospitals and other private healthcare facilities) Regulation 2006

| Types of fees | Fees Act 1951 Fees (Medical) (Amendment) (No.2) Order 1994 | | | Fees Act 1951 Fees (Medical) (Full Paying Patient) Order 2007 | Private Healthcare Facilities and Services (private hospitals and other private healthcare facilities) Regulation 2006 |
|--|--|----------------------------|---------------------------|--|--|
| | 1 st | 2 nd | 3 rd class | | |
| Procedure fee Rigid oesophagoscopy (plus/minus biopsy / removal/dilatation) | Operation charges inclusive of anaesthesia RM 300 RM150 RM20 | | | RM121 - 200 | (Professional Fee) Surgeon RM755 |
| Anaesthetic fee General anaesthesia | | | | RM120 | Professional Fee Anaesthetist = RM380 Not available |
| Investigations fee Barium swallow | RM100 | RM40 | RM17 | RM100 | RM100 |
| Treatment (inpatient) fee | RM10 | RM5 | Free | Not applicable | Not available |
| Investigations prior to general anaesthesia - Chest X-ray (two views) - Electrocardiography (ECG) - Full blood count - BUSE | RM50 RM30 RM10 RM10 | RM20 RM10 RM5 RM5 | RM10 RM5 RM2 RM2 | RM60 RM25 RM10 RM10 | RM60 RM70 Not available Not available |
| Consultation fee | Not applicable | | | RM60 | RM160-180 |
| Others Operation theatre per hour or any part thereof | Not applicable | | | RM250 | Not available |
| In patient bed fee per person/per day | RM30-80 | RM20 | RM3 | Executive (RM300) 1 st class (RM80-RM160) | Not available |

Rigid oesophagoscopy requires pre-procedure investigations prior to general anaesthesia, procedure time, post-procedure recovery and continuous nursing care during and after oesophagoscopy. Revadi G, Philip R and Gurdeep S in their study involving 36 patients with suspected foreign body of the oesophagus who underwent rigid oesophagoscopy under general anaesthesia in Hospital Ipoh reported the majority of patients were admitted for two days (58.0%) and three days (27.7%) of which 52.7% had no foreign bodies.^{41 level II-3} In contrast, with TNE, recovery and discharge were possible one hour later.

36 level II-3

The fees associated with performing rigid oesophagoscopy with an average of two days hospital admission varies from RM45 to RM570 for those admitted to government hospitals (depending on ward class). The fee for barium swallow investigation varies from RM17 to RM100. For full paying patients service, the fee varies from RM816 to RM1,335 and the fee for barium swallow investigation is RM100. Under the Private Healthcare Facilities and Services (private hospitals and other private healthcare facilities) Regulation 2006, a maximum of RM380 anaesthetist fees is charge for rigid oesophagoscopy performed in the operating theatre. In contrast, TNE performed in the office 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.

The capital cost of purchasing TNE system is around [REDACTED], while the cost of adult rigid oesophagoscope system is around [REDACTED] and the cost of OGDS system is around [REDACTED]. If the TNE system is to be made available at the five Head and Neck Centres (Hospital Pulau Pinang, Hospital Taiping, Hospital Raja Permaisuri Bainun Ipoh, Hospital Selayang and Hospital Melaka), the total capital cost of purchasing the system is around [REDACTED].

6.5 OTHER CONSIDERATIONS

6.5.1. Organizational

TNE is a new technology that allows the otolaryngologist to examine the upper aero-digestive tract from the nasal vestibule to the gastric cardia in the out patients department with topical local anaesthesia and without the need of sedation. An assessment of ease of use of equipment demonstrated that 43.7% (7/16) were rated as very easy to use and 56.3% (9/16) were rated as easy to use by the examiner. None were rated as difficult or very difficult to use.^{27 level II-3} Aviv *et al.* evaluated the ease of nasal insertion and oesophageal insertion using a validated 10-point analog scale. In all cases, the rating system was such that one represented extremely easy and ten represented extremely difficult. For the ease of nasal insertion the mean rating was 1.3; range, 1 to 2, SD, 0.5 and for the ease of oesophageal insertion the mean rating was 2.9; range, 1 to 5; SD, 1.1, P<0.001.^{22 level II-3} In a study using office-based TNE to guide placement of the secondary TEP in 39 patients, technical difficulty in performance of the puncture was encountered in seven patients (17.9%) due to scar formation, nasopharyngeal stenosis, cervical oesophageal stenosis and an aberrant course of the cervical oesophagus that was difficult to cannulate.^{35 level II-3}

Price *et al.* found that TNE or TNFLO takes an average of ten minutes to perform. The duration was slightly longer when therapeutic procedures were included (vocal cord medialization with collagen takes around 20 minutes). All patients treated in the outpatients were discharged within 2 hours. Using TNE or TNFLO, the authors have been able to discharge the majority of patients with globus (89.1%) and 47.8% of those with dysphagia after the initial visit to the department.^{26 level II-3} In a study for detection of metachronous oesophageal carcinoma in patients with HNSCC, Su *et al.* reported that the entire transnasal oesophagoscopy procedure time, including evaluation of upper aerodigestive tract and multiple biopsies of suspicious lesions, ranged from 10 to 40 minutes (median, 15 minutes).^{31 level II-3} Bennet *et al.* reported an overall procedure time of less than 20 minutes, while recovery and discharge were possible one hour later in their study on management of patients with foreign bodies in the pharynx and oesophagus.^{36 level II-3}

Two studies reported a change of practice with the introduction of TNE. Belafsky *et al.* reported that in their department, TNE has replaced barium swallow as a screening examination of the oesophagus in patients with reflux, globus and dysphagia.^{24 level II-3} Similarly, Price *et al.* highlighted that there has been a very substantial shift from investigation and treatment in the operating theatre, to a procedure room-based practice under local anaesthesia.^{26 level II-3}

Postma *et al.* and McPartlin *et al.* reported that TNE technique is an easy to learn procedure and the technique is quickly learned by operators familiar with the use of fibreoptic nasoendoscopes.^{23,27 level II-3} Falcone *et al.* conducted a study to determine the interobserver variability of findings reviewed by an otolaryngologist and a gastroenterologist. Fifty patients with throat symptoms presenting to the voice centre were asked prospectively to undergo TNE. The findings were videotaped and reviewed by an otolaryngologist and a gastroenterologist blinded to the patients presenting complaint. They found that 50% of patients were identified as having normal oesophageal findings by the gastroenterologist which was similar to the otolaryngologist findings (42%). The agreement was moderate, kappa score (κ) = 0.44 (CI, 0.19-0.68) with a percent agreement of 72%. The percent agreement (kappa scores) for various pathological findings was as follows: Barrett oesophagus 86% (κ =0.45); oesophagitis, 88% (κ =0.43); hiatal hernia, 76% (κ =0.39); oesophageal stricture, 96% (κ =0.73); patulous gastroesophageal junction, 98% (κ =0.73); and oesophageal diverticulum, 100% (κ =1.0).^{42 level II-3}

7 DISCUSSION

There was no systematic review or HTA report retrieved. This review did not find any study comparing TNE with other competing technologies such as conventional oesophagoscopy (rigid or flexible), barium swallow, laryngoscopy, EGD or OGDS. This limits our ability to compare the ability of TNE with the other competing technologies. However, cross sectional studies revealed that TNE was well tolerated and can be safely performed in an office setting without the need for sedation. Among the thousands of TNE cases performed there were no reported oesophageal perforation or major complications. Minor complications were also uncommon. Because of its very nature, unsedated TNE eliminates all sedation related events such as cardiopulmonary unplanned events secondary to conscious sedation.⁴³

The role of TNE continues to evolve in both diagnostic and therapeutic, particularly because of a high yield of pathology found on unsedated TNE examinations performed in an otolaryngology practice, with rates of pathological findings approaching 50 percent.²³⁻²⁵ The main utility of office based TNE is in the evaluation of patients with dysphagia or globus pharyngeus or reflux symptoms.²²⁻²⁸ The review found that TNE may be used to perform a wide variety of procedures such as biopsies, placement of wireless pH capsule, transnasal balloon dilation of the oesophagus, secondary tracheoesophageal puncture and management of foreign bodies with high success rate.^{23,24,26,32-37} The success rate of transnasal placement of wireless pH capsule was 85% compared with 89% via transoral.⁴⁴ The diagnostic accuracy of biopsies taken using TNE matches those taken at standard panendoscopy.³⁰ Similarly, studies that compared unsedated transnasal EGD with sedated transoral EGD have shown no difference between the two techniques with respect to patient safety, feasibility and tolerance.⁴⁵⁻⁴⁷

Evidence showed that TNE can be performed within less than 20 minutes, while recovery and discharge was possible within one to two hours.^{26,36 level II-3} In contrast, for rigid oesophagoscopy patients need to be admitted for a few days.⁴¹ The introduction of TNE has led to a change in practice such as TNE replacing barium swallow as screening examination in patients with reflux, globus pharyngeus or dysphagia and also a substantial shift from investigation and treatment in operating room to procedure room-based practice under local anaesthesia.^{24,26 level II-3} With this change, theatre resources can be more suitably utilised for procedures requiring a theatre environment. This may lead to potential direct cost saving compared with conventional oesophagoscopy.²⁶⁻²⁷ The increased direct costs of conventional oesophagoscopy include longer procedure time, operation theatre, recovery room and recovery time, costs associated with investigations prior to general anaesthesia, medications, nursing and monitoring. The resource savings applied not only to the hospital but also to the patient in terms of days lost from work.

TNE technique has been described as easy to learn procedure. However, the interpretation of the findings was found to be challenging. Interpretations of TNE may vary within a speciality or between specialities.⁴² Proper training is required before the proper use of TNE can be achieved and its full benefit can be obtained.

Although TNE may be used to detect oesophageal and extraoesophageal lesions or to perform a variety of procedures, it is not a substitute for conventional oesophagoscopy. 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.⁴⁸

Limitations

Our study has several limitations. There were no controlled trials comparing TNE and other competing technologies retrieved. Most of the included studies were cross sectional studies and retrospective in nature. There was only one study which provides evidence on diagnostic accuracy of TNE for patients with head and neck cancer. Although there was no restriction in language during the search but only English full text articles were included in the report. Although every effort has been made to retrieve full text articles, there were three abstracts which the authors failed to retrieve full text.

8 CONCLUSION

8.1. Efficacy or Effectiveness of TNE

- i. There was fair level of evidence to suggest that TNE was effective for detection of oesophageal and extraoesophageal lesions such as:
 - a. For screening examination in patients with dysphagia or globus pharyngeus or reflux symptoms and evaluation of patients with head and neck cancer
 - b. For detection of metachronous esophageal squamous carcinoma in patients with head and neck squamous cell carcinoma
- ii. There was fair level of evidence to suggest that TNE can be used to perform a variety of procedures such as:
 - a. Biopsy of suspicious lesions in the upper aerodigestive tract
 - b. Placement of wireless pH capsule
 - c. Transnasal balloon dilation of the oesophagus
 - d. Secondary Tracheoesophageal Puncture
 - e. Management of foreign bodies

8.2. Safety

There was fair level of evidence to suggest that TNE can be safely performed in an office setting with topical anaesthesia. Complications associated with TNE were mild and uncommon. There was no reported oesophageal perforation or major complication.

8.3. Patient tolerance

There was fair level of evidence to show that TNE was well tolerated by patients with local anaesthesia alone.

8.4. Cost / Cost-effectiveness / Economic evaluation

There was evidence to suggest there was potential direct cost saving derived by performing TNE in the office setting compared with rigid oesophagoscopy performed under general anaesthesia.

8.5. Other considerations

- i. There was fair level of evidence to suggest that TNE can be performed easily but the interpretations of the findings may pose a challenge.
- ii. TNE can be performed within 20 minutes, while recovery and discharge of patients were possible within two hours.
- iii. TNE may lead to a change in practice from investigation and treatment in the operating theatre to office-based practice under local anaesthesia.

9 RECOMMENDATION

Based on the above review, there seemed to be a potential cost saving derived by performing TNE in the office setting compared with rigid oesophagoscopy performed under general anaesthesia. However, the evidence for effectiveness was only of fair level of evidence. 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. More quality clinical research is warranted to provide more high quality scientific evidence. Organizational issues such as training, manpower and funding need to be considered.

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HIERARCHY OF EVIDENCE FOR EFFECTIVENESS STUDIES

DESIGNATION OF LEVELS OF EVIDENCE

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

HIERARCHY OF EVIDENCE FOR TEST ACCURACY STUDIES

| Level | Description | |
|-------|--|--|
| 1. | A blind comparison with reference standard among an appropriate sample of consecutive patients | |
| 2. | Any one of the following |  <ul style="list-style-type: none"> Narrow population spectrum Differential use of reference standard Reference standard not blind Case control study |
| 3. | Any two of the following | |
| 4. | Any three or more of the following | |
| 5. | Expert opinion with no explicit critical appraisal, based on physiology, bench research or first principles. | |

SOURCE: NHS Centre for Reviews and Dissemination (CRD) University of York, Report Number 4 (2nd Edition)

HEALTH TECHNOLOGY ASSESSEEMENT (HTA) PROTOCOL PROSTATE CANCER SCREENING

1. BACKGROUND INFORMATION

The oesophagus is a muscular tube, which runs from the cricopharyngus to the oesophagogastric junction. Anatomically, in the normal adult, the oesophagogastric junction is approximately 38 cm from the incisor teeth. Histologically, the mucosal lining comprises squamous epithelium with surrounding layers of circular and longitudinal muscle. There are many oesophageal conditions affecting human such as gastro-oesophageal reflux disease (GERD), oesophageal web, Plummer-Vinson syndrome, oesophagitis, Barrett's oesophagus, oesophageal ulcer, oesophageal stricture, achalasia, oesophageal cancer, benign oesophageal tumours, Mallory-Weiss tear, oesophageal varices, and oesophageal ring (Schatzki's ring). In a cross sectional study, Rosaida MS, Goh KL found that from 1,000 consecutive patients undergoing endoscopy for upper abdominal discomfort in University of Malaya Medical Centre, Kuala Lumpur, 13.4% had endoscopic evidence of reflux oesophagitis. Hiatus hernia was found in 6.7% and Barrett's oesophagus in 2% of the patients. Of the patients with reflux oesophagitis, 20.1% had grade C and D oesophagitis.

In Peninsular Malaysia in 2006, oesophageal cancer was the 18th most frequent cancers among the males with age-standardized incidence (ASR) of 2.7 and the 23rd most frequent cancer among females with the ASR of 1.4. It primarily affects those aged over 60 years and was more common among Indians followed by Chinese and Malays. Rajendra S, Kutty K, Karim N conducted a study looking at the prevalence of erosive oesophagitis and Barrett's oesophagitis in 1,985 patients undergoing elective gastroscopy for predominantly upper abdominal or reflux complaints at Hospital Ipoh, Malaysia. They found that the prevalence of endoscopically documented oesophagitis among the 1,985 patients was 6.1%, the majority of which were mild, Grade 1 or 2 (88%). There was a preponderance of Indians with oesophagitis, as well as males ($P < 0.05$) and those with hiatus hernia ($P < 0.01$). Long segment Barrett's oesophagus was found in 1.6% of patients, and short-segment Barrett's in 4.6%. Indians had the highest prevalence of Barrett's oesophagus compared with Chinese ($P < 0.05$) or Malays ($P < 0.01$). Hiatus hernia and erosive oesophagitis were both positively associated with Barrett's metaplasia ($P < 0.01$). A retrospective cross sectional study by Abdullah M, Karim AA, Goh KL at University of Malaya Medical Centre, Kuala Lumpur among 143 patients diagnosed with oesophageal cancer found that the mean age of patients was 63.1 ± 12.1 years with male to female ratio of 1.8 was to 1. Of these, 50.3% were Indians, 32.9% Chinese and 16.8% Malays.

The histological types of the oesophageal cancer were squamous cell carcinoma (79.0%) and adenocarcinoma (21.0%). At diagnosis, majority of the cases (71.3%) were at stage IV, followed by 16.1% at stage III and 12.6% at stage II. They concluded that majority of the oesophageal cancer presented late and only a minority of patients underwent curative surgery.

Oesophagoscopy and barium radiology represents the primary means by which structural diseases of the oesophagus may be investigated. Until 1996, the oesophagoscopy performed by otolaryngologists has primarily been transoral approach using rigid oesophagoscope with patients under general anaesthesia. Beginning mid 1990s, otolaryngologists began to perform oesophagoscopy utilising an ultra thin, flexible scope passed transnasally, with the patients not sedated, solely relying on topical anaesthesia. This approach is called transnasal oesophagoscopy (TNE) in the United States of America (U.S.A) but it is known as transnasal flexible laryngo-oesophagoscopy (TNFLO) in the United Kingdom (U.K). TNE is performed in the clinic without the sophisticated patient monitoring. Skilled ancillary personnel are required during and after oesophagoscopy performed on patients with conscious sedation in the endoscopy suite or room. It is claimed to have the following advantages over conventional peroral, rigid or flexible oesophagoscopy carried out in a sedated patient: 1) enhanced patient safety, 2) improved survival of oesophageal adenocarcinoma, 3) increased practice efficiency. Currently, there are two basic types of flexible endoscopes in general use to perform a TNE. One system is a distal video chip endoscope in which the camera is built into the tip of the endoscope. The distal chip endoscopes are generally available with internal channels so that suction, biopsy, and air and insufflations can take place. The other system is an add-on camera system where the camera is placed on the proximal portion of the flexible fiberoptic endoscope. Various single use, disposable endosheaths may be used with the add-on camera TNE scope system so that suction and biopsy capabilities are possible as well.

Indications for TNE can be divided into three major categories: oesophageal, extraoesophageal and procedure related. Oesophageal indications include dysphagia, oesophageal symptoms that persist despite an appropriate trial of therapy, odynophagia, screening and possibly surveillance for Barrett's oesophagus, caustic ingestion evaluation, and longstanding GERD. Extraoesophageal indications for TNE include patients with globus pharyngeus, chronic cough, cervical dysphagia, head and neck cancer, poorly controlled asthma, and moderate to severe laryngopharyngeal reflux (LPR).^{7,8} A variety of procedures can be performed using the TNE. These include biopsies, use of lasers, oesophageal dilation, secondary trachea-oesophageal puncture, treatment of achalasia, feeding tube insertion and the insertion of wireless pH capsule. Currently, TNE is not available in Ministry of Health facilities in Malaysia. With the latest advancement in oesophagoscopy technology, a Health Technology Assessment (HTA) is required to look into the safety, effectiveness and cost-effectiveness of TNE and to compare it with conventional peroral, rigid or flexible oesophagoscopy. This HTA was requested by an otolaryngologist from Raja Permaisuri Bainun Hospital, Ipoh, Perak.

2. POLICY QUESTION

Should TNE be made available in ENT specialist clinics in Ministry of Health hospitals in Malaysia?.

Research questions

- i. How safe is TNE compared with conventional oesophagoscopy when use for detection and management of oesophageal and extraoesophageal lesions.
- ii. How effective is TNE compared with conventional oesophagoscopy for detection and management of oesophageal and extraoesophageal lesions.
- iii. What is the diagnostic accuracy of TNE when used for diagnosis of oesophageal and extraoesophageal lesions.
- iv. What is the economic implication of using TNE to the health system.

3. OBJECTIVE

- 3.1. To assess the safety and efficacy or effectiveness of TNE compared with conventional oesophagoscopy for detection and management of oesophageal and extraoesophageal lesions.
- 3.2. To assess the cost impact of using TNE compared with conventional oesophagoscopy.
- 3.3. To determine the social and organizational issues related to the use of TNE.

4. METHODS

4.1. Search Strategy

Electronic database will be searched for published literatures pertaining to the use of TNE for detection and management of oesophageal and extraoesophageal lesions.

4.1.1 Databases as follows; MEDLINE, EBM Reviews-Cochrane Database of Systematic Review, EBM-Reviews-Cochrane Central Register of Controlled Trials, EBM Reviews-Health Technology Assessment, EBM Reviews-DARE and EBM Reviews-NHS Economic Evaluation Database through the Ovid interface. Searches will also be conducted in PubMed, Horizon Scanning database, INAHTA database, and FDA database.

4.1.2 Additional literatures will be identified from the bibliographies of the retrieved articles.

4.1.3 General search engine will also be used to get additional web-based materials and information.

4.1.4 There will be no limitation applied in the search.

4.1.5 The detail of the search strategy will be presented as appendix

4.2. Inclusion and exclusion criteria

4.2.1. Inclusion criteria

- a. Study design: HTA report, Systematic Review, Randomised Controlled Trials (RCT), non randomised controlled trial, cross sectional diagnostic studies, cross sectional studies, case series, case reports and studies which include economic evaluation.
- a) Population: Patients with oesophageal lesions and / or extraoesophageal lesions.
- b) Intervention: Transnasal oesophagoscopy (TNE), transnasal flexible laryngo-oesophagoscopy (TNFLO).
- c) Comparators:
- i. No comparators.
 - ii. Conventional oesophagoscopy - rigid or flexible.
 - iii. Barium swallow.
 - iv. Laryngoscopy
 - v. Oesophagogastroduodenoscopy or oesophagogastroscopy (EGD) or OGDS.
- d) Outcome:
- i. Detection of esophageal lesions such as Gastro-oesophageal reflux disease (GERD), oesophagitis, Barrett's oesophagus, oesophageal ulcer, oesophageal cancer, benign oesophageal tumours, oesophageal web, Plummer-Vinson syndrome, oesophageal varices, oesophageal ring, achalasia, Mallory-Weiss tear.
 - ii. Detection of extraoesophageal lesions such as globus pharyngeus, head and neck cancer, laryngopharyngeal reflux (LPR).
 - iii. Effectiveness for therapeutic procedures such as oesophageal balloon dilation, secondary tracheoesophageal puncture, delivery of flexible lasers, insertion of wireless pH capsule and foreign body removal.
 - iv. Adverse events or complications related to the use of TNE.
 - vi. Cost, cost-utility, and cost-effectiveness and cost implication of using TNE compared with conventional oesophagoscopy.
 - vii. Sensitivity, specificity, positive predictive value and negative predictive value of TNE.
- e) Type of publication: Full text articles published in English

1.1.2 Exclusion criteria

b. Study design: Animal study, experimental study and narrative review.

c. Type of publication: Non English full text article.

Based on the above inclusion and exclusion criteria, study selection will be carried out independently by two reviewers. Disagreement will be resolved by discussion.

4.3 Data extraction strategy

The following data will be extracted:

4.3.1 Details of methods and study population characteristics

4.3.2 Details of intervention and comparators

4.3.3 Details of individual outcomes for safety, efficacy or effectiveness and cost evaluation associated with the use of TNE

4.4.4 Details on diagnostic accuracy of TNE

Data will be extracted from selected studies by two reviewers using a pre-designed data extraction form.

4.4 Quality assessment strategy

The methodology quality of all retrieved literatures will be assessed using the relevant checklist of Critical Appraisal Skill Programme (CASP) by two reviewers depending on the type of the study design.

4.5 Methods of analysis/synthesis

Data on the safety, efficacy or effectiveness and cost implication of using TNE for the detection and management of oesophageal and extraoesophageal lesions will be presented in tabulated format with narrative summaries. No meta-analysis will be conducted for this Health Technology Assessment.

5 REPORT WRITING

Appendix 4

SEARCH STRATEGY

Ovid MEDLINE® In-process & other Non-Indexed citations and OvidMEDLINE® 1948 to present

1. exp Esophageal Diseases/ or exp Esophagus/ or exp Esophagitis/
2. exp Esophageal Achalasia/
3. ?esophag\$.tw.
4. (?esophagogastric adj1 junction\$).tw.
5. (gastro?esophageal adj1 junction\$).tw.
6. (?esophageal adj1 disease\$).tw.
7. (barrett\$ adj1 (?esophagus or syndrome or epithelium)).tw.
8. Dysphagia.tw.
9. ((swallowing or deglutition) adj1 disorder\$).tw.
10. ((oropharyngeal or ?esophageal) adj1 dysphagia).tw.
11. ?esophageal.mp. and gastric vari\$.tw. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
12. (?esophageal adj1 (diverticulosis or vari\$ or atresia\$ or cyst\$ or fistula\$)).tw.
13. (?esophag\$ adj3 (cancer\$ or neoplasm\$ or perforation\$ or stricture or stenosis\$)).tw.
14. (eosinophilic adj2 ?esophagit\$).tw.
15. achalasia\$.tw.
16. (?esophageal adj1 achalasia\$).tw.
17. cardiospasm\$.tw.
18. mega?esophagus.tw.
19. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 10 or 11 or 13 or 14 or 15 or 16 or 17 or 18
20. Hernia, Hiatal/
21. ((para?esophageal or ?esophageal or hiatal) adj2 hernia\$).tw.
22. 20 or 21
23. Gastroesophageal Reflux/
24. ((gastro-?esophageal or gastro ?esophageal or gastro?esophageal or ?esophageal) adj1 reflux).tw.
25. gastro?esophageal reflux disease.tw.
26. gerd.tw.
27. 23 or 24 or 25 or 26
28. Pharyngeal Diseases/
29. Esophageal Motility Disorders/
30. (pharynx\$ adj2 disease\$).tw.
31. globus pharyngeus.tw.
32. (?esophageal adj1 dysmotilit\$).tw.
33. (?esophageal motility adj1 disorder\$).tw.
34. (nutcracker adj1 ?esophagus).tw.
35. 28 or 29 or 30 or 31 or 32 or 33 or 34
36. Regurgitation, Gastric/
37. (laryngopharyngeal adj1 reflux\$).tw.
38. 36 or 37

39. (Head and neck neoplasm).mp. [mp=protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier]
40. ((head or neck or uadt or upper aerodigestive tract) adj3 (neoplasm\$ or cancer\$)).tw.
41. 39 or 40
42. Pharyngeal Neoplasms/
43. Tracheoesophageal Fistula/
44. (pharyn\$ adj3 (cancer\$ or neoplasm\$)).tw.
45. ((?esophagotracheal or trachea?esophageal) adj1 fistula\$).tw.
46. tracheo?esophageal puncture.tw.
47. 42 or 43 or 44 or 45 or 46
48. Foreign Bodies/
49. (foreign adj1 bod\$).tw.
50. 48 or 49
51. Hypopharyngeal Neoplasms/
52. (hypopharyngeal adj1 (cancer\$ or neoplasms)).tw.
53. 51 or 52
54. 19 or 22 or 27 or 35 or 38 or 41 or 47 or 50 or 53
55. transnasal ?esophagoscopy.tw.
56. transnasal flexible laryngo-oesophagoscopy.tw.
57. 55 or 56
58. ?esophagoscope\$.tw.
59. ((rigid or flexible) adj ?esophagoscope).tw.
60. 58 or 59
61. (barium adj (swallow or x-ray)).tw.
62. Laryngoscopy/
63. laryngoscope\$.tw.
64. (laryngoscopic adj2 procedure\$).tw.
65. 62 or 63 or 64
66. Endoscopy, Digestive System/
67. ?esophagogastroduodenoscopy.tw.
68. EGD.tw.
69. OGDS.tw.
70. OGDs.tw.
71. 66 or 67 or 68 or 69 or 70
72. 54 and 57
73. 54 and 61
74. 54 and 65
75. 54 and 71
76. 54 and 60
77. 60 or 61 or 65
78. 60 or 61 or 65 or 71
79. 54 and 57 and 77
80. 54 and 57 and 78

1. exp Esophageal Diseases/ or exp Esophagus/ or exp Esophagitis/
2. exp Esophageal Achalasia/
3. ?esophag\$.tw.
4. (?esophagogastric adj1 junction\$).tw.
5. (gastro?esophageal adj1 junction\$).tw.
6. (?esophageal adj1 disease\$).tw.
7. (barrett\$ adj1 (?esophagus or syndrome or epithelium)).tw.
8. Dysphagia.tw.
9. ((swallowing or deglutition) adj1 disorder\$).tw.
10. ((oropharyngeal or ?esophageal) adj1 dysphagia).tw.
11. ?esophageal.mp. and gastric vari\$.tw. [mp=title, text, subject heading word]
12. (?esophageal adj1 (diverticulosis or vari\$ or atresia\$ or cyst\$ or fistula\$)).tw.
13. (?esophag\$ adj3 (cancer\$ or neoplasm\$ or perforation\$ or stricture or stenosis\$)).tw.
14. (eosinophilic adj2 ?esophagitis\$).tw.
15. achalasia\$.tw.
16. (?esophageal adj1 achalasia\$).tw.
17. cardiospasm\$.tw.
18. mega?esophagus.tw.
19. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 10 or 11 or 13 or 14 or 15 or 16 or 17 or 18
20. Hernia, Hiatal/
21. ((para?esophageal or ?esophageal or hiatal) adj2 hernia\$).tw.
22. 20 or 21
23. Gastroesophageal Reflux/
24. ((gastro-?esophageal or gastro ?esophageal or gastro?esophageal or ?esophageal) adj1 reflux).tw.
25. gastro?esophageal reflux disease.tw.
26. gerd.tw.
27. 23 or 24 or 25 or 26
28. Pharyngeal Diseases/
29. Esophageal Motility Disorders/
30. (pharynx\$ adj2 disease\$).tw.
31. globus pharyngeus.tw.
32. (?esophageal adj1 dysmotility\$).tw.
33. (?esophageal motility adj1 disorder\$).tw.
34. (nutcracker adj1 ?esophagus).tw.
35. 28 or 29 or 30 or 31 or 32 or 33 or 34
36. Regurgitation, Gastric/
37. (laryngopharyngeal adj1 reflux\$).tw.
38. 36 or 37
39. (Head and neck neoplasm).mp. [mp=title, text, subject heading word]
40. ((head or neck or uadt or upper aerodigestive tract) adj3 (neoplasm\$ or cancer\$)).tw.
41. 39 or 40
42. Pharyngeal Neoplasms/
43. Tracheoesophageal Fistula/

44. (pharyn\$ adj3 (cancer\$ or neoplasm\$)).tw.
45. ((?esophagotracheal or trachea?esophageal) adj1 fistula\$).tw.
46. tracheo?esophageal puncture.tw.
47. 42 or 43 or 44 or 45 or 46
48. Foreign Bodies/
49. (foreign adj1 bod\$).tw.
50. 48 or 49
51. Hypopharyngeal Neoplasms/
52. (hypopharyngeal adj1 (cancer\$ or neoplms)).tw.
53. 51 or 52
54. 19 or 22 or 27 or 35 or 38 or 41 or 47 or 50 or 53
55. transnasal ?esophagoscopy.tw.
56. transanasal flexible laryngo-esophagoscopy.tw.
57. 55 or 56
58. 54 and 57

Evidence Table Question : **Efficacy/Effectiveness**
 : **Is transnasal oesophagoscopy (TNE) effective in detection & therapeutic procedures for oesophageal and extraoesophageal lesions?**

| | |
|---|---|
| Bibliographic citation | 1. Aviv JE, Takoudes TG, MA G <i>et al.</i> Office-based esophagoscopy: A preliminary report. <i>Otolaryngology-Head and Neck Surgery</i> .2001;125(3):170-175 |
| Study type | <p>Cross sectional study conducted in Columbia University, U.S.A. The aim was to describe the unседated, transnasal esophagoscopy (TNE) in an office setting.</p> <p>Prospective study on 14 consecutive out-patients with dysphagia whose initial oropharyngeal dysphagia evaluation was insufficient to reveal the cause of their swallowing problem. TNE was carried out without conscious sedation while the patients were sitting in an examination chair. The endoscope used was a flexible video-chip camera oesophagoscope VE-1530 (Pentax Precision Instrument Corporation, Orangeburg, New York). Ease of endoscope insertion, optical quality of images, and examination findings were assessed. Heart rate before and after the procedure and incidence of epistaxis and airway compromise was also determined. Patient were asked to rate the level of discomfort of TNE on a validated 10-point scale (1 representing none/well tolerated and 10 severe/poorly tolerated).</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>14 patients with dysphagia:-</p> <ul style="list-style-type: none"> - 8 females (57.0%) - 6 males (43.0%) - Mean age -61.9 years (range, 42 to 90) <p>Had a variety of underlying diagnosis:-</p> <ul style="list-style-type: none"> - 6 head and neck cancer - 4 laryngo -pharyngeal reflux (LPR) - 1 amyotrophic lateral sclerosis - 1 Zenker's diverticulum - 1 history of foreign body - 1 vocal fold paralysis |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | - |
| Length of follow up | - |
| Outcome measures/ Effect size | <p>Detection</p> <ul style="list-style-type: none"> • All patients completed TNE with the oesophagus readily intubated and oesophageal mucosa clearly visualised. • Pathological oesophageal findings included a proximal oesophageal stricture, a patulous upper oesophageal sphincter and a Zenker's diverticulum. • Incidental finding of left nasopharyngeal mass was noted in one patient. <p>Quality of optical image</p> <ul style="list-style-type: none"> • Optical quality, larynx (mean, 1.1; range, 1 to 2, SD, 0.1) • Optical quality, oesophagus (mean, 2.1; range, 1 to 6, SD, 0.3) <p>Ease of use (subjective physician assessment)</p> <ul style="list-style-type: none"> • Ease of nasal insertion (mean rating, 1.3; range, 1 to 2, SD, 0.5) • Ease of oesophageal insertion (mean rating, 2.9; range, 1 to 5; SD, 1.1), P<0.001 <p>Authors conclusion</p> <p>TNE is well tolerated and can be safely performed in patients with dysphagia in an office setting. TNE may have a role in the comprehensive evaluation of dysphagic patient patient in the office.</p> |
| General comments | |

Evidence Table : **Efficacy/Effectiveness**
Question : **Is transnasal oesophagoscopy (TNE) effective in detection & therapeutic procedures for oesophageal and extraoesophageal lesions?**

| | |
|---|--|
| Bibliographic citation | 1. Postma GN, Cohen JT, Belafsky PC <i>et al.</i> Transnasal Esophagoscopy: Revisited (over 700 consecutive cases). <i>Laryngoscope</i> . 2005;115:321-323 |
| Study type | <p>Cross sectional study conducted at the Centre for Voice Disorders of Wake Forest University, U.S.A.</p> <p>The aim was to report the author's present experience and to compare it with previously reported experience in using TNE.</p> <p>Retrospective review of 611 consecutive patients who underwent TNE (VE-1530, Pentax Precision Instrument Corporation, Orangeburg, New York) between January 28, 2001 and January 1, 2004) were compared with 100 consecutive patients previously reported.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>611 consecutive patients who underwent TNE between February 28, 2001 to January 1, 2004 for various indications;-</p> <ul style="list-style-type: none"> - 490 as a screening examination in patients with reflux/ globus/ dysphagia - 45 as screening examination in head and neck cancers patients - 42 for biopsy of known lesions in laryngopharynx - 12 for evaluation of possible foreign body - 10 for tracheoscopy - 6 for dilatation of oesophageal stricture <p>6 for replacement of trachea-oesophageal puncture under direct vision</p> |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Detection and therapeutic procedures</p> <p>Seventeen procedures (2.8%) were aborted secondary to an inability to pass the endoscope through a tight nasal vault and two (0.3%) were aborted secondary to self-limited vasovagal responses.</p> <p>Of the 592 completed examinations, significant findings were noted in 294/592 (49.7%).</p> <p>The most common findings in the oesophagus were oesophagitis (n=98; 17.0%), hiatal hernia (n=47; 8.0%), Barrett's metaplasia (n=27; 5.0%), candidiasis (n=27; 5.0%), stricture (n=24; 4.0%) and carcinoma (n=22; 4.0%).</p> <p>Evaluation of suspected foreign body:-</p> <ul style="list-style-type: none"> • In 6 cases a foreign body was found and in 5 cases, the foreign body was pushed during oesophagoscopy into the stomach without difficulty <p>Six laryngectomy patients underwent successful tracheoesophageal puncture under direct vision.</p> <p>Authors conclusion</p> <p>TNE is safe and well tolerated by patients and easy to learn with a short learning curve. TNE may replace radiographic imaging of the oesophagus in otolaryngology patients with reflux, globus and dysphagia</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection & therapeutic procedures for oesophageal and extraoesophageal lesions?

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|---|--|
| Bibliographic citation | 3. Belafsky PC, Postma GN, Daniel E <i>et al.</i> Transnasal esophagoscopy. <i>Otolaryngology-Head and Neck Surgery</i> .2001; 125:588-589 |
| Study type | <p>Cross sectional study conducted at the Centre for Voice Disorders of Wake Forest University, U.S.A.</p> <p>The aim was to report the author's experience in using TNE.</p> <p>Retrospective review of 100 consecutive patients undergoing TNE between October 1, 2000 and February 28, 2001. TNE was conducted with patient sitting in an examination chair cross from the endoscopist. The patient's more patent nasal cavity is first sprayed with 1.1 oxymetazoline 0.05% and lidocaine 4%. Two Tessalon Perles (benzonatate) are given to the patient. Two sprays of 20% benzocaine are then administered to the oropharynx. The endoscope (VE-1530, Pentax Precision Instrument Corporation, Orangeburg, NY) is lubricated with 2% viscous lidocaine. The endoscope is then passed into the nasal cavity either along the floor of the nose or between the middle of inferior turbinates.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>100 consecutive patients who underwent TNE between October 2000 to February 2001 for various indications;-</p> <ul style="list-style-type: none"> - 79 as a screening examination for evaluation of reflux, globus, and/or dysphagia - 8 for biopsy of known lesions in laryngopharynx - 5 as screening examination in head and neck cancers patients - 4 for tracheoscopy - 2 for evaluation of possible foreign body - 1 for dilatation of oesophageal stricture - 1 for replacement of trachea-oesophageal puncture under direct vision |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Detection and therapeutic procedures</p> <p>Four procedures (4%) were aborted secondary to a tight nasal vault.</p> <p>Significant findings were found in 42/96 (43.7%). The most frequent findings in the oesophagus were esophagitis (n=19; 20.0%), Barrett's metaplasia (n=6; 6.0%), carcinoma (n=5; 5.0%) and hiatal hernia (n=4; 4.0%), stricture (n=4; 4.0%).</p> <p>Biopsies of known lesions in laryngopharynx:-</p> <ul style="list-style-type: none"> • 5/8 (62.5%) squamous cell carcinoma • 1/8 (12.5%) laryngeal fungal infection • 2/8 (25.0%) non diagnostic <p>Evaluation of suspected foreign body:-</p> <ul style="list-style-type: none"> • Both examinations were negative confirmed with rigid oesophagoscopy <p>One patient underwent successful dilation of the of oesophageal stricture.</p> <p>One patient underwent successful replacement of tracheoesophageal puncture under direct vision.</p> <p>Authors conclusion</p> <p>TNE is safe and well tolerated by patients with topical anaesthesia alone. TNE may replace radiographic imaging of the oesophagus in otolaryngology patients with reflux, globus and dysphagia</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

| | |
|---|--|
| Bibliographic citation | 4. Andrus JG, Dolan RW, Anderson TD <i>et al.</i> Transnasal Esophagoscopy: A High-Yield Diagnostic Tool. <i>Laryngoscope</i> . 2005;115:993-996 |
| Study type | <p>Cross sectional study conducted at Boston Medical Centre, U.S.A.</p> <p>The aim was to describe the TNE techniques, indications, outcomes, advantages, limitations, and impact on patient care.</p> <p>Retrospective charts review of 30 patients undergoing TNE during the time period of March 31, 2004 to August 9, 2004. Patient were examined fully awake and sitting upright with a Pentax flexible endoscope.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>30 patients:-</p> <ul style="list-style-type: none"> - 16/30 (53.0%) women - 14/30 (47.0%) men - age, 32 to 84 years <p>Indications for TNE:-</p> <ul style="list-style-type: none"> - Dysphagia, - Screening eosophagoscopy (GER/LPR) - Surveillance for Head and Neck squamous cell carcinoma - Globus - Epigastric pain - Cough - Extrinsic oesophageal compression - Oral/laryngeal candidiasis |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Detection and patient management</p> <p>13/30 (43.3%) of patients had positive findings on TNE and 17/30 (56.7%) negative findings.</p> <ul style="list-style-type: none"> • No one finding was predominant • Findings include:- Barrett's oesophagus, candidal oesophagitis, posterior glottis oedema, postcricoid mass, oesophageal diverticulum, oesophageal dysmotility, oesophageal stricture, patulous oesophagus, gastritis. <p>Patient management was promptly affected after TNE.</p> <p>Patients with Barrett's oesophagus were referred to a gastroenterologist for further evaluation and management.</p> <p>Patient with oesophageal stricture was dilated successfully with a number 36 bougie dilator at the time of TNE and being followed symptomatically.</p> <p>Patients with negative examinations were followed by the otolaryngologist. Seven patients who would normally have been evaluated with a barium swallow for globus or dysphagia did not undergo the test as a result of negative TNE</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is TNE /transnasal flexible laryngo-oesophagoscopy (TNFLO) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

| | |
|---|---|
| Bibliographic citation | 5. Price T, Sharma A, Snelling J <i>et al.</i> How we do it: The role of trans-nasal flexible laryngo-oesophagoscopy (TNFLO) in ENT: one year's experience in a head and neck orientated practice in the UK. <i>Clinical Otolaryngology</i> . 2005.30;551-556 |
| Study type | Cross sectional study conducted at the Norfolk and Norwich University Hospital, UK. The aim was to report the experience of using transnasal flexible laryngo-oesophagoscopy (TNFLO) in the UK and Europe. A prospective review of patients undergoing transnasal flexible laryngo-oesophagoscopy (TNFLO) at the Norfolk and Norwich University Hospitals from January 1, 2004 to January 1, 2005. Information was gathered on patient demographics, symptoms, indications and therapeutic procedures performed. A Pentax 80K series Digital Video Endoscope (EE 1580K; Pentax, Slough, UK) was used. |
| LE | II-3 |
| Number of patients & Patient characteristics | 116 TNFLO procedures Indications for TNFLO:- <ul style="list-style-type: none"> - 56 patients for screening examination for symptoms of globus pharyngeus - 5 patients for acute dysphagia - 18 patients with chronic dysphagia - 14 patients with dysphonia - 16 patients as part of surveillance of their head and neck cancer |
| Intervention | Transnasal flexible laryngo-oesophagoscopy (TNFLO) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Detection and therapeutic procedures</p> <p>Patients with Globus pharyngeus (56 patients):-</p> <ul style="list-style-type: none"> • 6/56 patients (10.7%) found to have pathology • 1/56 patients (1.8%) did not tolerate the procedure • 49/56 patients (87.5%) with no identifiable pathology were discharged <p>Patients with dysphagia (acute and chronic) - 23 patients:-</p> <ul style="list-style-type: none"> • One had impacted plum stone • One had a fish bone • One complete oesophageal stenosis • One benign oesophageal stricture • One post-cricoid tumour • Two post-cricoid webs • Six benign pharyngeal pouches <p>Patients with dysphonia (14 patients):</p> <ul style="list-style-type: none"> • One normal larynx • One Reinke's oedema • One vocal cord palsy (had vocal cord medialization procedure using TNFLO) • 10 had suspicious lesions of the larynx and biopsies were taken <p>One had recurrent respiratory papillomatosis and was successfully treated with Nd-YAG laser</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is TNE /transnasal flexible laryngo-oesophagoscopy (TNFLO) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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|---|--|
| Bibliographic citation | 5. Price T, Sharma A, Snelling J <i>et al.</i> How we do it: The role of trans-nasal flexible laryngo-oesophagoscopy (TNFLO) in ENT: one year's experience in a head and neck orientated practice in the UK. <i>Clinical Otolaryngology.</i> 2005.30;551-556 |
| Study type | <p>Cross sectional study conducted at the Norfolk and Norwich University Hospital, UK.</p> <p>The aim was to report the experience of using transnasal flexible laryngo-oesophagoscopy (TNFLO) in the UK and Europe.</p> <p>A prospective review of patients undergoing transnasal flexible laryngo-oesophagoscopy (TNFLO) at the Norfolk and Norwich University Hospitals from January 1, 2004 to January 1, 2005. Information was gathered on patient demographics, symptoms, indications and therapeutic procedures performed. A Pentax 80K series Digital Video Endoscope (EE 1580K; Pentax, Slough, UK) was used.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>116 TNFLO procedures</p> <p>Indications for TNFLO:-</p> <ul style="list-style-type: none"> - 56 patients for screening examination for symptoms of globus pharyngeus - 5 patients for acute dysphagia - 18 patients with chronic dysphagia - 14 patients with dysphonia - 16 patients as part of surveillance of their head nad neck cancer |
| Intervention | Transnasal flexible laryngo-oesophagoscopy (TNFLO) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Detection and therapeutic procedures</p> <p>Patients with head and neck cancer surveillance (16 patients):-</p> <ul style="list-style-type: none"> • Two radio-recurrent tumours were identified and a number of voice prosthesis problems were resolved including secondary tracheoesophageal puncture and valve insertion. <p>Other indications:-</p> <ul style="list-style-type: none"> • TNFLO was used to biopsy other regions of the upper aero-digestive tract (UADT) laryngeal, post-nasal space, uvula). <p>Duration and procedure:-</p> <ul style="list-style-type: none"> • Average under 10 minutes to perform • Slightly longer when therapeutic procedures were included (vocal cord medialization with collagen takes around 20 minutes) • All patients treated in the outpatients were discharged within 2 hours • Using TNFLO, authors have been able to discharge the majority of patients with globus (89.1%) and 47.8% of those with dysphagia after the initial visit to the department. |
| General comments | |

Evidence Table : **Efficacy/Effectiveness**
Question : **Is TNE /transnasal fiberoptic oesophagoscopy (TFO) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?**

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|---|---|
| Bibliographic citation | 6. McPartlin DW, Nouraei SA, Tatla T <i>et al.</i> How do we do it: Transnasal fibreoptic oesophagoscopy. <i>Clinical Otolaryngology.</i> 2005;30:547-550 |
| Study type | <p>Cross sectional study conducted at the Charing Cross Hospital, London, UK.</p> <p>Patients presenting to the outpatients department with symptoms of globus pharyngeus or mild dysphagia were investigated with TFO, excluding from the experience those patients with symptoms suggestive of malignancy. The endoscope (Vision Sciences® TNE-2000D with Slide-On™ TNE sheath), comprised of a flexible fibreoptic endoscope of 4 mm diameter with a working length of 665 mm. At the end of the procedure patients completed a questionnaire incorporating two separate visual analogue score (VAS), one for procedural pain and one for unpleasantness /discomfort. In addition, the examiner filled out an assessment form including the indication for the examination, the clinical findings, and assessment of ease of use of the equipment and the quality of views obtained.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>16 patients with symptoms of globus pharyngeus or mild dysphagia.</p> <p>Age range, 35 to 68 years</p> <p>7/16 (44.0%) males and 9/16 (56.0%) females</p> |
| Intervention | Transnasal fiberoptic oesophagoscopy |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Oesophageal findings:-</p> <ul style="list-style-type: none"> 9 out of 16 patients (56.3%) had normal findings 7 out of 16 patients (43.7%) had mild Gastro-oesophageal reflux disease (GORD) / GORD <p>Quality of views obtained:-</p> <ul style="list-style-type: none"> 10 out of 16 (62.5%) were rated excellent 5 out of 16 (31.3%) were rated good 1 out of 16 (6.2%) were rated fair <p>Ease of use:-</p> <ul style="list-style-type: none"> 7 out of 16 (43.7%) were rated very easy 9 out of 16 (56.3%) were rated easy <p>Authors conclusion</p> <p>Our findings suggest that TFO is well tolerated under local anaesthesia, without the need for sedation. As such it is a useful diagnostic tool for use in the outpatients setting. It is quick and easy to perform and yields good views of the mucosal surfaces, from nasal vestibule to the gastric cardia. It is a highly viable economic option and be valuable addition to the diagnostic of the ENT clinic.</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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|---|---|
| Bibliographic citation | 7. Kumar VV, Amir MR. Evaluation of Middle and Distal Esophageal Diverticuli with Transnasal Oesophagoscopy. <i>Ann Otol Rhinol Laryngol.</i> 2005; 114:276-278 |
| Study type | Two case reports, University College of Medicine, Philadelphia, Pennsylvania, U.S.A. The aim was to emphasise the utility of office-based transnasal oesophagoscopy (TNE) in the evaluation of patients with swallowing complaints. Two patients presented with complaints of chronic dysphagia, globus sensation, and a sensation of “food sticking” with swallowing. Fiberoptic laryngoscopy revealed normal laryngeal anatomy. The patients were counselled to undergo in-office TNE. |
| LE | III |
| Number of patients & Patient characteristics | Case 1. A 70 year old man who had 6 month history of dysphagia and a sensation of food sticking in his chest. Case 2. A 79 year old man had complaints of several years of dysphagia and regurgitation of ingested food. |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | Oesophageal findings and management. Case 1 <ul style="list-style-type: none"> TNE revealed a solitary midoesophageal diverticulum with otherwise normal mucosa. Patient underwent endoscopic diverticulectomy. On follow-up office visits, the patients reported resolution of his dysphagia symptoms and resumption of a regular diet. Case 2 <ul style="list-style-type: none"> TNE revealed multiple diverticuli and a tortuous oesophagus. The patient underwent endoscopic staple-assisted diverticulectomy of the Zenker’s diverticulum and also underwent esophagoscopy and dilation. The patient’s swallowing impairments improved, and he was subsequently able to tolerate solid foods. |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

| | |
|---|--|
| Bibliographic citation | 8. Koufman JA, Belafsky PC, Bach KK <i>et al.</i> Prevalence of Esophagitis in Patients with pH-Documented Laryngo-pharyngeal Reflux. <i>Laryngoscope</i> . 2002;112:1606-1609 |
| Study type | <p>Cross sectional study conducted at the Centre for Voice Disorders, Wake Forest University, U.S.A.</p> <p>The aim was to report the prevalence of oesophagitis in patients with pH-documented laryngopharyngeal reflux (LPR).</p> <p>All patients presenting with otolaryngologic symptoms and a diagnosis of LPR established by ambulatory 24-hour double probe (simultaneous oesophageal and pharyngeal) pH monitoring between November 1, 2000 and March 21, 2001 were included. All patients completed a self-administered reflux symptom index (RSI). Transnasal oesophagoscopy with directed biopsies was performed on all study subjects. The prevalence of oesophagitis and Barrett's metaplasia was calculated from the TNE data.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>58 patients with pH-documented laryngopharyngeal reflux (LPR):-</p> <ul style="list-style-type: none"> • Mean age was 49 ± 13 years • 31/58(53.0%) males and 27/58 (47.0%) females |
| Intervention | Transnasal oesophagoscopy (TNE) and biopsy |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Prevalence of oesophagitis</p> <ul style="list-style-type: none"> • Overall prevalence of oesophagitis was 7/58 (12.1%). • The overall prevalence of Barrett's metaplasia was 4/58 (6.9%). • Only 39.7% (23/58) of the cohort had heartburn and 48.3% (28/58) had abnormal oesophageal reflux by pH monitoring criteria. <p>Authors conclusion</p> <p>In the present series of patients with documented laryngopharyngeal reflux the prevalence of oesophagitis and Barrett's metaplasia was 19.0%. These data confirm the clinical impression that the patterns, mechanisms, and manifestations of laryngopharyngeal reflux differ from those of classic oesophageal reflux disease. Unlike gastroesophageal reflux disease, patients with laryngopharyngeal reflux uncommonly have oesophagitis. Thus, although oesophagoscopy may be an excellent method for screening of the oesophagus, it is not the method of choice for diagnosing laryngopharyngeal reflux.</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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|---|---|
| Bibliographic citation | 9. Postma GN, Bach KK, Belafsky PC <i>et al.</i> The role of Transnasal Esophagoscopy in Head and Neck Oncology. <i>Laryngoscope</i> . 2002;112:2242-2243 |
| Study type | <p>Cross sectional diagnostic study conducted at the Centre for Voice Disorders of Wake Forest University, U.S.A.</p> <p>The aim was to review the current role of TNE in all aspects of head and neck cancer patient treatment.</p> <p>A retrospective database and chart review of head and neck cancer patients. TNE was performed in a prospective fashion in 17 patients with known lesions of the upper aerodigestive tract. Each of the individuals underwent TNE (VE-1530; Pentax Precision) with biopsy and soon thereafter went to the operating room for standard panendoscopy with biopsies.</p> |
| LE | 3 |
| Number of patients & Patient characteristics | <p>17 patients with known lesions of the upper aerodigestive tract. All masses suspected to be malignant.</p> <p>3 patients with head and neck cancer presenting with dysphagia following laryngectomy (time from surgery ranged from 5 to 18 months)</p> <p>Patients with head and neck cancer presenting with dysphagia after undergoing concurrent radiation therapy with chemotherapy.</p> |
| Intervention | <p>Transnasal oesophagoscopy (TNE) with biopsy</p> <p>TNE with biopsy</p> |
| Comparison | Standard panendoscopy with biopsy |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Diagnosis</p> <p>100% accuracy in biopsy results and staging of the tumour when compared with standard panendoscopy:-</p> <ul style="list-style-type: none"> • 12/12 has cancer (positive) • 5/5 negative for malignancy • (sensitivity =100%, specificity=100%) <p>Demonstrated a neopharyngeal stricture in two patients and the third has recurrent squamous cell carcinoma.</p> <p>Diagnosed oesophageal stricture and oesophageal fungal infections using TNE in the patients.</p> <p>Authors conclusion</p> <p>They concluded that TNE gives the surgeon the ability to perform a remarkable variety of procedures in the outpatient setting without sedation. It may obviate the need for routine panendoscopy in head and neck cancer patients.</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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| Bibliographic citation | 10. Su YY, Fang FM, Chuang HC <i>et al.</i> Detection of metachronous esophageal squamous carcinoma in patients with head and neck cancer with use of transnasal esophagoscopy. <i>Head & Neck</i> . DOI 10.1002/hed June 2010:780-785 |
| Study type | <p>Cross sectional study conducted at Koohsiung Chang Gung Memorial Hospital, which is a tertiary medical centre in Taiwan.</p> <p>The aim was to assess the ability of TNE for detecting metachronous oesophageal squamous cell carcinoma in patients with head and neck carcinoma.</p> <p>A total of 398 transnasal oesophagoscopies were performed in 293 previously treated patients with head and neck squamous cell carcinoma (HNSCC) between December 2007 and January 2009.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>293 previously treated head and neck squamous cell carcinoma (HNSCC) patients.</p> <ul style="list-style-type: none"> - Male to female ratio: 289:4 - Median age of 55 years (range, 33-83 years) <p>The site distributions of HNSCC were 63% in the oral cavity, 14% in the oropharynx, 15% in hypopharynx and 8% in the larynx.</p> |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Detection of metachronous esophageal carcinoma</p> <ul style="list-style-type: none"> • Detected in 5.1% (15/293) of patients. • Median time to the diagnosis of oesophageal carcinoma was 15 months (range, 7-76 months). Eleven (73.0%) of them were found within three years after HNSCC was diagnosed. The prevalence rate was 15.9% (7/44) in patients with hypopharyngeal cancer which is significantly higher than the 8.3% (2/24) in laryngeal, 7.1% (3/42) in oropharyngeal, and 1.6% (3/183) in oral cancer (P=0.001). • Stage distributions of oesophageal squamous carcinoma were I-II in 80% (12/15) and III-IV in 20% (3/15) of patients. Subsequently, curative strategies were performed in 87% (13/15) of patients. <p>Procedure time</p> <ul style="list-style-type: none"> • The entire transnasal oesophagoscopy procedure time, including evaluation of UADT and multiple biopsies of suspicious lesions, ranged from 10 to 40 minutes (median, 15 minutes). <p>Authors conclusion</p> <p>Transnasal oesophagoscopy can be used as a routine survey technique in patients with HNSCC to detect metachronous esophageal squamous cell carcinoma, especially in those with hypopharyngeal cancer.</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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| Bibliographic citation | 11. Belafsky PC, Allen K, Rosario LC, Roseman D <i>et al.</i> Wireless pH testing as an adjunct to unsedated transnasal esophagoscopy: The safety and efficacy of transnasal telemetry capsule placement. <i>Otolaryngology-Head and Neck Surgery</i> .2004; 131(1):26-28 |
| Study type | <p>Cross sectional study conducted at the Scripps Centre for Voice and Swallowing, La Jolla, California, U.S.A.</p> <p>The aim was to describe the authors experience with transnasal wireless pH capsule placement.</p> <p>All patients undergoing unsedated TNE and wireless pH capsule placement between January 1, 2003 and July 31, 2003 were prospectively evaluated. The Medtronic wireless Bravo pH telemetry capsule was placed transnasally in all cases through the same nare as the TNE immediately after completion of the endoscopy. Data concerning patient tolerance, success of capsule placement and function, complications, and pH recordings were collected. Any study with less than 36-hours of data recording was considered a failure.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>46 patients:-</p> <ul style="list-style-type: none"> • Equal number of males and females • Mean age = 52 years <p>Indications for oesophagoscopy and pH testing was:-</p> <ul style="list-style-type: none"> • Oesophageal reflux disease (18/46) • Chronic cough (18/46) <p>Laryngopharyngeal reflux (10/46)</p> |
| Intervention | Unsedated transnasal oesophagoscopy and wireless pH capsule placement |
| Comparison | |
| Length of follow up | 48 hours |
| Outcome measures/ Effect size | <p>Transnasal capsule placement</p> <p>Successful placement::-</p> <ul style="list-style-type: none"> • 39/46 (85.0%). <p>Failed capsule placement::-</p> <ul style="list-style-type: none"> • 7/46 (15.0%). <p>Reasons for failed capsule placement:-</p> <ul style="list-style-type: none"> • 2 failed secondary due to a tight nasal vault • 3 due to technical reasons (early detachment and delivery system failure) • 1 due to laryngospasm resulting in aborted procedure • 1 patient lost a wireless data recorder after a successful capsule placement. <p>Mean time data recording was 44.9 (± 7.0 hours).</p> <p>Mean number of reflux episodes per 2-day study period was 121 (± 89).</p> <p>Mean percentage of time the pH was less than 4 was 7.5 (± 7.8%).</p> <p>Authors conclusion</p> <p>The transnasal placement of a wireless pH capsule is a safe and effective diagnostic adjunct to unsedated transnasal oesophagoscopy.</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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| Bibliographic citation | 12. Belafsky PC, Godin DA, Garcia JC <i>et al.</i> Comparison of Data Obtained from Sedated versus Unsedated wireless Telemetry Capsule Placement: Does Sedation Affect the Results of Ambulatory 48-Hour pH Testing? <i>Laryngoscope</i> .2005;115:1109-1113 |
| Study type | <p>Cross sectional study conducted at the Centre for Voice and Swallowing, University of California, U.S.A.</p> <p>The aim was to evaluate the day to day variability and the effect of sedation on the 48-hour wireless pH testing.</p> <p>Charts of all patients undergoing 48-hour wireless pH testing between June 1, 2003 and December 31, 2004 were retrospectively evaluated. Data concerning study indications, route of pH capsule placement, duration of pH recording and test results were collected. Day to day variability was evaluated and the results obtained from persons with sedated and unsedated pH capsule placement were compared.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>206 patients (studies).</p> <ul style="list-style-type: none"> - 67.0% females - 23.0% males <p>Indications for examinations:-</p> <ul style="list-style-type: none"> - Gastroesophageal reflux disease (146/206) - Chronic cough (36/206) - Laryngo-pharyngeal reflux (LPR - 24/206) |
| Intervention | <p>Unsedated pH capsule placement:-</p> <ol style="list-style-type: none"> a. pH capsule placement <ul style="list-style-type: none"> - transnasal during unsedated TNE b. pH capsule placement <ul style="list-style-type: none"> - transnasal during unsedated oesophageal manometry c. pH capsule placement <ul style="list-style-type: none"> - transoral unsedated based on the location of SCJ at a previous EGD <p>(total 128)</p> |
| Comparison | <p>Sedated pH-capsule placement:-</p> <p>pH capsule placement</p> <ul style="list-style-type: none"> - peroral during sedated esophago-gastroduodeno- scopy (EGD) <p>(total =78)</p> |
| Length of follow up | 48 hours |
| Outcome measures/ Effect size | <p>Results of 48-hour wireless pH testing</p> <ul style="list-style-type: none"> • 62.1% of studies performed without sedation. • Overall reproducibility of the daily recordings in 48-hour wireless pH testing (day 1 versus day 2) was 77% for those who underwent sedated capsule placement and also 77% for those who had unsedated capsule placement. • All the reflux parameters such as mean reflux episodes, mean time (%) pH < 4 and mean composite score were slightly lower for the sedated group but the difference was not significant (P>0.05). <p>Authors conclusion</p> <p>Intravenous sedation does not appear to have a significant effect on the results of 48-hour wireless pH testing.</p> |
| General comments | |

Evidence Table : **Efficacy/Effectiveness**
Question : **Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?**

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| Bibliographic citation | 13. Rees CJ, Fordham T, Belafsky PC. Transnasal Balloon dilation of the Esophagus. <i>Arch Otolaryngol Head Neck Surg.</i> 2009;135 (8):781-783 |
| Study type | <p>Cross sectional study conducted at University of California Davis School of Medicine (UCD) and Wake Forest University School of Medicine (WFU), U.S.A.</p> <p>The aim was to evaluate the safety and efficacy of transnasal balloon dilation of the oesophagus.</p> <p>A retrospective chart review of all persons undergoing transnasal balloon dilation of the oesophagus at the UCD and WFU from January 1 2007 to December 31, 2008. The Pentax VE-1530 transnasal oesophagoscope (Pentax Precision Medical Co, KayPentax, Lincoln Park, New Jersey) and multidiameter hydrostatic wire-guided controlled radial expansion oesophageal dilators (Boston Scientific, Natick, Massachusetts) were used in all procedures. Transnasal balloon dilation of the oesophagus can be performed with topical anaesthesia or with the patient under conscious sedation, at the preference of the patient.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>38 patients:-</p> <ul style="list-style-type: none"> - mean age was 65.3 years (range, 13-88 years) - 29/38 (76.0%) males and 9/38 (24.0%) females <p>Indications for dilation:-</p> <ul style="list-style-type: none"> - Cricopharyngeal dysfunction - Benign stricture - web - Schatzki ring. |
| Intervention | Transnasal oesophageal balloon dilations |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Transnasal balloon dilations.</p> <p>54 transnasal oesophageal balloon dilations were performed in 38 patients.</p> <ul style="list-style-type: none"> • Procedure well tolerated (96.3%) • 20 procedures (37.0%) were performed using topical anaesthesia in the office setting • 34 procedures (63.0%) were performed with conscious sedation in an outpatient surgical suite <p>Common sites of dilations:</p> <ul style="list-style-type: none"> • Upper oesophageal sphincter (UES) = 63.0% • Mid oesophageal locations = 26.0% • Lower oesophageal sphincter (LES) = 7.0% • Both UES and LES = 4.0% <p>Authors conclusion</p> <p>Transnasal oesophagoscopy balloon dilation can be performed in unsedated or sedated patients with low complications rate. This technique, formerly available only through larger calibre oral gastroscopes and under sedation, allows for office-based oesophageal balloon dilation in an otolaryngology practice.</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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| Bibliographic citation | 14. LeBert B, McWhorter AJ, Kunduk M <i>et al.</i> Secondary Tracheoesophageal Puncture With In-Office Transnasal Esophagoscopy. <i>Arch Otolaryngol Head Neck Surg.</i> 2009;135 (12):1190-1194 |
| Study type | <p>Cross sectional study conducted at three tertiary care medical centres in the U.S.A.</p> <p>The aim was to evaluate the outcomes of voice restoration using office-based transnasal oesophagoscopy (TNE) to guide placement of the secondary tracheoesophageal puncture (TEP).</p> <p>A retrospective chart review of patients who underwent TNE-assisted TEP at three tertiary care medical centres in the U.S.A between January 2004 and December 2008 was conducted. The patients' charts were reviewed to document answers to clinical questions regarding the ease, efficiency, and complications of the procedure as well as to evaluate communication-related outcomes.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>39 patients:-</p> <ul style="list-style-type: none"> • Average age was 65 years (age range; 47 to 83 years) • 82.0% males and 18.0% females <p>Histological diagnosis:-</p> <ul style="list-style-type: none"> - 35/39 (89.7%) had squamous cell carcinoma - 3/39 (7.7%) had papillary thyroid carcinoma - 1/39 (2.6%) had spindle cell carcinoma <p>Surgery:-</p> <ul style="list-style-type: none"> - 25 /39 (64.1%) had total laryngectomy - 8/39 (20.5%) had total laryngectomy with partial pharyngectomy - 5/39(12.8%) had total laryngo-pharyngectomy - 1/39 (2.6%) unknown |
| Intervention | Secondary tracheo-esophageal puncture (TEP) with transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Secondary tracheoesophageal puncture outcome:-</p> <ul style="list-style-type: none"> • Overall success rate of TNE-assisted TEP was 38/39 (97.4%) with one unsuccessful attempt (2.6%). • 7/39 (17.9%) was graded difficult by surgeon. • No statistically significant correlation between patients having undergone radiation therapy or cricopharyngeal myotomy and a successful TEP placement, difficulty in placing the TEP, complications associated with TEP, using the TEP prosthesis, and speech intelligibility at the last follow-up visit ($P>0.05$). • 31/39 patients (79.5%) were still using their TEP prosthesis for speech at the last follow-up visit and 20/31 (64.5%) were rated as understandable all the time (PSS-HN Understandability of Speech Subscale score =100). <p>Authors conclusion In-office TNE-assisted TEP placement can safely be performed, with excellent speech outcomes.</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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| Bibliographic citation | 15. Bennet AMD, Sharma A, Price T <i>et al.</i> The management of foreign bodies in the pharynx and esophagus using transnasal flexible laryngo-oesophagoscopy (TNFLO). <i>Ann R Coll Surg Engl.</i> 2008.90;13-16 |
| Study type | <p>Cross sectional study conducted at the Norfolk and Norwich University Hospital, UK.</p> <p>The aim was to describe the authors' experience of the diagnosis and removal of foreign bodies from the pharynx and oesophagus using transnasal flexible laryngo-oesophagoscopy (TNFLO) under local analgesic.</p> <p>A Pentax 80K series Digital Video Endoscope (EE 1580K; Pentax, Slough, UK) was used. The TNFLO was passed transnasally examining the oro and hypopharynx and then passed into the oesophagus. The presence, type and site of a foreign body could then be established. If a foreign body was detected, it was extracted using flexible grabbing forceps passed down the instrument channel and delivered through the nasal or oral cavity. Object was then inspected to ensure removal of its' entirely.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>5 cases</p> <p>Age range, 22 to 72 years</p> <p>4/5 (80.0%) females and 1/5 (20.0%) male</p> |
| Intervention | Transnasal flexible laryngo-oesophagoscopy (TNFLO) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Detection and removal of foreign bodies from the pharynx and oesophagus</p> <p>Type of foreign body:-</p> <ul style="list-style-type: none"> • Two cod bones • One haddock bone • One plum stone • One lamb bone <p>Location of foreign body:-</p> <ul style="list-style-type: none"> • Two upper oesophagus • One pyriform fossa • One post cricoid • One base of tongue <p>Management:-</p> <ul style="list-style-type: none"> • Two extraction via nose • One extraction via mouth • One pushed into stomach • One removed by direct pharyngoscopy under general anaesthesia <p>Speed and efficiency:-</p> <ul style="list-style-type: none"> • Overall procedure taking less than 20 minutes • Recovery and discharge are possible one hour later <p>Authors conclusion</p> <p>TNFLO represents an improvement in the diagnosis and subsequent treatment of a selected group of foreign bodies as compared with established methodologies.</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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| Bibliographic citation | 16. Sato K, Nakashima T. Office-Based Foreign-Body Management Using Videoendoscope. <i>American Journal of Otolaryngology</i> . 2004;25(3):167-172 |
| Study type | <p>Cross sectional study conducted at the Kurume University, School of Medicine, Kurume, Japan.</p> <p>The aim was to describe the office-based pharyngeal and laryngeal foreign-body management using videoendoscope.</p> <p>Three types of videoendoscopes were used in the study (EH-1530T, EB-1530T3, rigid video-endoscope, Asahi Optical Co). Patients were examined and treated in a sitting position on a procedure chair at the otolaryngology outpatient clinic. The insertion tube of the videoendoscope without a hood at its tip was performed through the nasal passage (pernasal endoscopy) and that of the videoendoscope equipped with hood at its tip and a rigid videoendoscope was inserted through the oral passage (peroral endoscopy) Foreign-body forceps for a 2-mm instrument channel, and tweezers were used for the extraction of foreign bodies.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>17 patients who complained of pharyngeal and laryngeal foreign bodies</p> <ul style="list-style-type: none"> - Aged 8 to 99 years • 8 males (47.0%) • 9 females (53.0%) |
| Intervention | <p>3 types of videoendoscopes:-</p> <ul style="list-style-type: none"> - videoendoscope without a hood at its tip (EB-1530T3 Asahi Optical Co)- pernasal endoscopy - videoendoscope with a transparent hood at its tip (EH-1530T, Asahi Optical Co)- peroral endoscopy - rigid videoendoscope (Asahi Optical Co).- peroral endoscopy |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Detection and removal of foreign bodies from the pharynx and larynx.</p> <p>Extraction of foreign bodies with videoendoscope without a hood at its tip through the nasal passage (pernasal endoscopy):-</p> <ul style="list-style-type: none"> • Five foreign bodies located at the medial to the posterior portions of the lateral wall of the oropharynx • Seven foreign bodies located at the anterior wall of the oropharynx • One foreign body located at the supraglottis <p>Extraction of foreign bodies with rigid videoendoscope through the oral passage (peroral endoscopy):-</p> <ul style="list-style-type: none"> • Three foreign bodies located at the lateral wall of the oropharynx <p>Extraction of foreign bodies with videoendoscope with a hood at its tip through the oral passage (peroral endoscopy):-</p> <ul style="list-style-type: none"> • One foreign body located at the right piriform sinus of the hypopharynx <p>Authors conclusion Foreign-body extraction using a videoendoscope is one of the reliable procedures that has widened the indications for office-based endoscopy.</p> |
| General comments | |

Evidence Table : Efficacy/Effectiveness
Question : Is transnasal oesophagoscopy (TNE) effective in detection and therapeutic procedures for oesophageal and extraoesophageal lesions?

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| Bibliographic citation | 17. Falcone MT, Garrett CG, Slaughter JC <i>et al.</i> Transnasal eosphagoscopy findings: Interspecialty comparison. <i>Otolaryngology-Head and Neck Surgery</i> .2009; 140: 812-815 |
| Study type | <p>Cross sectional study conducted at the Vanderbilt University Medical Centre, Nashville, U.S.A.</p> <p>The aim was to assess the prevalence of oesophageal pathology in patients presenting with throat symptoms and to determine the interobserver variability of the findings reviewed by an otolaryngologist and a gastroenterologist.</p> <p>Consecutive patients presenting to the voice centre were invited to undergo TNE between September 2006 and November 2007. Eligibility for participation was based on the presence of throat symptoms. Exclusion criteria were prior oesophagogastroduodenoscopy and pregnancy. Unsedated TNE (using the Olympus EndoEYE flexible video transnasal oesophagoscope partial expiratory flow-volume) was performed and videotaped by an otolaryngologist unfamiliar with the patient's history. The findings were videotaped and reviewed by an otolaryngologist and a gastroenterologist blinded to the patients' presenting complaint.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>50 patients presenting with throat symptoms such as:-</p> <ul style="list-style-type: none"> • Hoarseness, sore throat, cough, throat clearing, dysphagia, globus sensation. • Median age was 49 years. <p>54.0% females and 46.0% males.</p> |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Oesophageal findings, percent agreement and kappa value (κ).</p> <p>Normal findings:- Otolaryngologist (Oto) =42.0%, Oesophagologist (Eso) = 50.0% % agreement = 72% κ = 0.44 (CI, 0.19-0.68)</p> <p>Barrett oesophagus :- Oto =18.0%, Oeso = 12.0% % agreement = 86% κ = 0.45 (CI, 0.07-0.78)</p> <p>Oesophagitis :- Oto =14.0%, oeso = 10.0% % agreement = 88% κ = 0.43 (CI, 0.01-0.84)</p> <p>Hiatal hernia :- Oto =20.0%, oeso = 32.0% % agreement = 76% κ = 0.39 (CI, 0.13-0.7)</p> <p>Oesophageal stricture :- Oto =6.0%, oesophagologist = 10.0% % agreement = 96% κ = 0.73 (CI, NA)</p> <p>Patulous GE junction:- Oto =0.0%, oesophagologist = 2.0% % agreement = 98% κ = 0.0 (CI, NA)</p> <p>Oesophageal diverticulum and poor study:% agreement = 100%, κ = 1</p> |
| General comments | |

Evidence Table : Safety
Question : Is transnasal oesophagoscopy (TNE) safe?

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| Bibliographic citation | 1. Aviv JE, Takouides TG, MA G <i>et al.</i> Office-based esophagoscopy: A preliminary report. <i>Otolaryngology-Head and Neck Surgery</i> .2001;125(3):170-175 |
| Study type | <p>Cross sectional study conducted in Columbia University, U.S.A.</p> <p>The aim was to describe the unsedated, transnasal esophagoscopy (TNE) in an office setting.</p> <p>Prospective study on 14 consecutive out-patients with dysphagia whose initial oropharyngeal dysphagia evaluation was insufficient to reveal the cause of their swallowing problem. TNE was carried out without conscious sedation while the patients were sitting in an examination chair. The endoscope used was a flexible video-chip camera oesophagoscope VE-1530 (Pentax Precision Instrument Corporation, Orangeburg, New York). Ease of endoscope insertion, optical quality of images, and examination findings were assessed. Heart rate before and after the procedure and incidence of epistaxis and airway compromise was also determined. Patient were asked to rate the level of discomfort of TNE on a validated 10-point scale (1 representing none/ well tolerated and 10 severe/poorly tolerated).</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>14 patients with dysphagia:-</p> <ul style="list-style-type: none"> - 8 females (57.0%) - 6 males (43.0%) - Mean age -61.9 years (range, 42 to 90) <p>Had a variety of underlying diagnosis:-</p> <ul style="list-style-type: none"> - 6 head and neck cancer - 4 laryngo-pharyngeal reflux (LPR) - 1 amyotrophic lateral sclerosis - 1 Zenker's diverticulum - 1 history of foreign body - 1 vocal fold paralysis |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Safety</p> <p>Pre-TNE and post-TNE heart rate:-</p> <ul style="list-style-type: none"> • Pre-TNE HR = 68-88, Mean-80.3 • Post-TNE HR= 68-88, Mean- 81.1 (P=0.3356) <p>Pre-TNE and post-TNE respiratory rate:-</p> <ul style="list-style-type: none"> • Pre-TNE RR = 12-20, Mean-14.5 • Post-TNE RR= 12-20, Mean- 15.1 (P=0.1648) <ul style="list-style-type: none"> • No instances of epistaxis or airway compromise. <p>Patient tolerance</p> <ul style="list-style-type: none"> • Overall patient tolerance to TNE was rated as 2.0 (range, 1 to 4; Standard Deviation, 1.2) with all patients indicating they would repeat the TNE if requested by their physician. <p>Authors conclusion</p> <p>TNE is well tolerated and can be safely performed in patients with dysphagia in an office setting. TNE may have a role in the comprehensive evaluation of dysphagic patient in the office.</p> |
| General comments | |

Evidence Table : Safety
Question : Is transnasal oesophagoscopy (TNE) safe?

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| Bibliographic citation | 2. McPartlin DW, Nouraei SA, Tatla T <i>et al.</i> How do we do it: Transnasal fiberoptic oesophagoscopy. <i>Clinical Otolaryngology</i> . 2005;30:547-550 |
| Study type | Cross sectional study conducted at the Charing Cross Hospital, London, UK. Patients presenting to the outpatients department with symptoms of globus pharyngeus or mild dysphagia were investigated with TFO, excluding from the experience those patients with symptoms suggestive of malignancy. The endoscope (Vision Sciences® TNE-2000D with Slide-On™ TNE sheath), comprised of a flexible fiberoptic endoscope of 4 mm diameter with a working length of 665 mm. At the end of the procedure patients completed a questionnaire incorporating two separate visual analogue score (VAS), one for procedural pain and one for unpleasantness /discomfort. In addition, the examiner filled out an assessment form including the indication for the examination, the clinical findings, and assessment of ease of use of the equipment and the quality of views obtained. |
| LE | II-3 |
| Number of patients & Patient characteristics | 16 patients with symptoms of globus pharyngeus or mild dysphagia. Age range, 35 to 68 years 7/16 (44.0%) males and 9/16 (56.0%) females |
| Intervention | Transnasal fiberoptic oesophagoscopy |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | Safety Procedure was well tolerated in most patients with any discomfort usually confined to the nose. |
| General comments | |

Evidence Table : Safety
Question : Is transnasal oesophagoscopy (TNE) safe?

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| Bibliographic citation | 3. Kumar VV, Amir MR. Evaluation of Middle and Distal Esophageal Diverticuli with Transnasal Oesophagoscopy. <i>Ann Otol Rhinol Laryngol</i> .2005;114:276-278 |
| Study type | Two case reports, University College of Medicine, Philadelphia, Pennsylvania, U.S.A. The aim was to emphasise the utility of office-based transnasal oesophagoscopy (TNE) in the evaluation of patients with swallowing complaints. Two patients presented with complaints of schronic dysphagia, globus sensation, and a sensation of “food sticking” with swallowing. Fiberoptic laryngoscopy revealed normal laryngeal anatomy. The patients were counselled to undergo in-office TNE. |
| LE | III |
| Number of patients & Patient characteristics | Case 1. A 70 year old man who had 6 month history of dysphagia and a sensation of food sticking in his chest. Case 2. A 79 year old man had complaints of several years of dysphagia and regurgitation of ingested food. |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | Safety Procedures were well tolerated and without complications in both patients. |
| General comments | |

Evidence Table : Safety
Question : Is transnasal oesophagoscopy (TNE) safe?

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| Bibliographic citation | 4. Su YY, Fang FM, Chuang HC <i>et al.</i> Detection of metachronous esophageal squamous carcinoma in patients with head and neck cancer with use of transnasal esophagoscopy. <i>Head & Neck</i> . DOI 10.1002/hed June 2010:780-785 |
| Study type | Cross sectional study conducted at Koohsiung Chang Gung Memorial Hospital, which is a tertiary medical centre in Taiwan. The aim was to assess the ability of TNE for detecting metachronous oesophageal squamous cell carcinoma in patients with head and neck carcinoma. A total of 398 transnasal oesophagoscopies were performed in 293 previously treated patients with head and neck squamous cell carcinoma between December 2007 and January 2009. |
| LE | II-3 |
| Number of patients & Patient characteristics | 293 previously treated head and neck squamous cell carcinoma (HNSCC) patients. - Male to female ratio: 289:4 - Median age of 55 years (range, 33-83 years) The site distributions of HNSCC were 63% in the oral cavity, 14% in the oropharynx, 15% in hypopharynx and 8% in the larynx. |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | Safety <ul style="list-style-type: none"> No airway obstruction, neurological shock, life-threatening bleeding from biopsy or other obvious discomfort occurred during or after the procedure. Patient tolerance All patients including the 12 with dysphagia tolerated the procedure well and no one was converted to general anaesthesia. |
| General comments | |

Evidence Table : Safety
Question : Is transnasal oesophagoscopy (TNE) safe?

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|---|--|
| Bibliographic citation | 5. LeBert B, McWhorter AJ, Kunduk M <i>et al.</i> Secondary Tracheoesophageal Puncture With In-Office Transnasal Esophagoscopy. <i>Arch Otolaryngol Head Neck Surg</i> . 2009;135 (12):1190-1194 |
| Study type | Cross sectional study conducted at two tertiary care medical centres in the U.S.A. The aim was to evaluate the outcomes of voice restoration using office-based transnasal oesophagoscopy (TNE) to guide placement of the secondary tracheoesophageal puncture (TEP). A retrospective chart review of patients who underwent TNE-assisted TEP at two tertiary care medical centres in the U.S.A between January 2004 and December 2008. The patients' charts were reviewed to document answers to clinical questions regarding the ease, efficiency, and complications of the procedure as well as to evaluate communication-related outcomes. |
| LE | II-3 |
| Number of patients & Patient characteristics | 39 patients:- <ul style="list-style-type: none"> Average age was 65 years (age range; 47 to 83 years) 82.0% males and 18.0% females Histological diagnosis:- <ul style="list-style-type: none"> 35/39 (89.7%) had squamous cell carcinoma 3/39 (7.7%) had papillary thyroid carcinoma 1/39 (2.6%) had spindle cell carcinoma Surgery:- <ul style="list-style-type: none"> 25 /39 (64.1%) had total laryngectomy 8/39 (20.5%) had total laryngectomy with partial pharyngectomy 5/39(12.8%) had total laryngopharyngectomy 1/39 (2.6%) unknown |
| Intervention | Secondary tracheo-oesophageal puncture (TEP) with transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | Safety: There were no complications associated with TNE-assisted TEP placement. Authors conclusion In-office TNE-assisted TEP placement can safely be performed, with excellent speech outcomes. |
| General comments | |

Evidence Table : **Safety**
Question : **Is transnasal oesophagoscopy (TNE) safe?**

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|---|---|
| Bibliographic citation | 6.Belafsky PC, Postma GN, Daniel E <i>et al.</i> Transnasal esophagoscopy. <i>Otolaryngology-Head and Neck Surgery</i> .2001; 125:588-589 |
| Study type | <p>Cross sectional study conducted at the Centre for Voice Disorders of Wake Forest University, U.S.A.</p> <p>The aim was to report the author's experience in using TNE.</p> <p>Retrospective review of 100 consecutive patients undergoing TNE between October 1, 2000 and February 28, 2001. TNE was conducted with patient sitting in an examination chair cross from the endoscopist. The patient's more patent nasal cavity is first sprayed with 1.1 oxymetazoline 0.05% and lidocaine 4%. Two Tessalon Perles (benzonatate) are given to the patient. Two sprays of 20% benzocaine are then administered to the oropharynx. The endoscope (VE-1530, Pentax Precision Instrument Corporation, Orangeburg, NY) is lubricated with 2% viscous lidocaine. The endoscope is then passed into the nasal cavity either along the floor of the nose or between the middle of inferior turbinates.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>100 consecutive patients who underwent TNE between October 2000 to February 2001 for various indications;-</p> <ul style="list-style-type: none"> - 79 as a screening examination for evaluation of reflux, globus, and/or dysphagia - 8 for biopsy of known lesions in laryngopharynx - 5 as screening examination in head and neck cancers patients - 4 for tracheoscopy - 2 for evaluation of possible foreign body - 1 for dilatation of oesophageal stricture - 1 for replacement of trachea-oesophageal puncture under direct vision |
| Intervention | Transnasal oesophagoscopy (TNE) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Safety</p> <p>Minor complications occurred in 4 patients:-</p> <ul style="list-style-type: none"> • 3 of 96 patients (3.1%) had self limited epistaxis, bleeding controlled with direct pressure and no packing. One patient had self-limited vasovagal reaction that required no treatment. <p>Authors conclusion</p> <p>TNE is safe and well tolerated by patients with topical anaesthesia alone. TNE may replace radiographic imaging of the oesophagus in otolaryngology patients with reflux, globus and dysphagia.</p> |
| General comments | |

Evidence Table : Safety
Question : Is TNE / transnasal flexible laryngo-oesophagoscopy oesophagoscopy (TNFLO) safe?

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|---|---|
| Bibliographic citation | 7. Price T, Sharma A, Snelling J <i>et al.</i> How we do it: The role of trans-nasal flexible laryngo-oesophagoscopy (TNFLO) in ENT: one year's experience in a head and neck orientated practice in the UK. <i>Clinical Otolaryngology</i> . 2005.30;551-556 |
| Study type | <p>Cross sectional study conducted at the Norfolk and Norwich University Hospital, UK.</p> <p>The aim was to report the experience of using transnasal flexible laryngo-oesophagoscopy TNFLO in the UK and Europe.</p> <p>A prospective review of patients undergoing transnasal flexible laryngo-oesophagoscopy (TNFLO) at the Norfolk and Norwich University Hospitals from January 1, 2004 to January 1, 2005. Information was gathered on patient demographics, symptoms, indications and therapeutic procedures performed. A Pentax 80K series Digital Video Endoscope (EE 1580K; Pentax, Slough, UK) was used.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>116 TNFLO procedures</p> <p>Indications for TNFLO:-</p> <ul style="list-style-type: none"> - 56 patients for screening examination for symptoms of globus pharyngeus - 5 patients for acute dysphagia - 18 patients with chronic dysphagia - 14 patients with dysphonia - 16 patients as part of surveillance of their head and neck cancer |
| Intervention | Transnasal flexible laryngo-oesophagoscopy (TNFLO) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Patient tolerance</p> <p>Pain scores</p> <ul style="list-style-type: none"> • Average score on visual analogue scale, of 0-10, were < 1 for all types of discomfort <p>Complications</p> <ul style="list-style-type: none"> • The procedure had to be abandoned in one patient (0.9%) because of uncontrolled retching • There were no significant complications in any of the patients • One patients (0.9%) suffered a minor anterior epistaxis which was controlled within minutes by simple pressure alone • No patients suffered any syncopal events |
| General comments | |

Evidence Table : Safety
Question : Is transnasal oesophagoscopy (TNE) safe?

| | |
|---|--|
| Bibliographic citation | 8. Belafsky PC, Allen K, Rosario LC, Roseman D <i>et al.</i> Wireless pH testing as an adjunct to unsedated transnasal esophagoscopy: The safety and efficacy of transnasal telemetry capsule placement. <i>Otolaryngology-Head and Neck Surgery</i> .2004;131(1):26-28 |
| Study type | <p>Cross sectional study conducted at the Scripps Centre for Voice and Swallowing, La Jolla, California, U.S.A.</p> <p>The aim was to describe the authors experience with transnasal wireless pH capsule placement.v</p> <p>All patients undergoing unsedated TNE and wireless pH capsule placement between January 1, 2003 and July 31, 2003 were prospectively evaluated. The Medtronic wireless Bravo pH telemetry capsule was placed transnasally in all cases through the same nare as the TNE immediately after completion of the endoscopy. Data concerning patient tolerance, success of capsule placement and function, complications, and pH recordings were collected. Any study with less than 36-hours of data recording was considered a failure.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>46 patients:-</p> <ul style="list-style-type: none"> • equal number of males and females • Mean age = 52 years <p>Indications for oesophagoscopy and pH testing was:-</p> <ul style="list-style-type: none"> • Oesophageal reflux disease (18/46) • Chronic cough (18/46) <p>Laryngopharyngeal reflux (10/46)</p> |
| Intervention | Unsedated transnasal oesophagoscopy and wireless pH capsule placement |
| Comparison | |
| Length of follow up | 48 hours |
| Outcome measures/ Effect size | <p>Safety</p> <ul style="list-style-type: none"> • Patient tolerance was excellent. • Complications included self limiting epistaxis in 4.3% (2/46), laryngospasm in 4.3% (2/46), and vasovagal reaction in 2.2% (1/46). <p>Authors conclusion</p> <p>The transnasal placement of a wireless pH capsule is a safe and effective diagnostic adjunct to unsedated transnasal oesophagoscopy.</p> |
| General comments | |

Evidence Table : Safety
Question : Is transnasal oesophagoscopy (TNE) safe?

| | |
|---|--|
| Bibliographic citation | 9. Rees CJ, Fordham T, Belafsky PC. Transnasal Balloon dilation of the Esophagus. <i>Arch Otolaryngol Head Neck Surg.</i> 2009;135(8): 781-783 |
| Study type | <p>Cross sectional study conducted at University of California Davis School of Medicine (UCD) and Wake Forest University School of Medicine (WFU), U.S.A.</p> <p>The aim was to evaluate the safety and efficacy of transnasal balloon dilation of the oesophagus.</p> <p>A retrospective chart review of all persons undergoing transnasal balloon dilation of the oesophagus at the UCD and WFU from January 1 2007 to December 31, 2008. The Pentax VE-1530 transnasal oesophagoscope (Pentax Precision Medical Co, KayPentax, Lincoln Park, New Jersey) and multidiameter hydrostatic wire-guided controlled radial expansion oesophageal dilators (Boston Scientific, Natick, Massachusetts) were used in all procedures. Transnasal balloon dilation of the oesophagus can be performed with topical anaesthesia or with the patient under conscious sedation, at the preference of the patient.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>38 patients:-</p> <ul style="list-style-type: none"> - mean age was 65.3 years (range, 13-88 years) - 29/38 (76.0%) males and 9/38 (24.0%) females <p>Indications for dilation:--</p> <ul style="list-style-type: none"> - Cricopharyngeal dysfunction - Benign stricture - web - Schatzki ring. |
| Intervention | Transnasal oesophageal balloon dilations |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Safety</p> <ul style="list-style-type: none"> • No major complications or oesophageal perforations • No patients were hospitalised after the procedure • Two minor complications (3.7%) resulting in the procedures being aborted. These were self limited laryngospasm in one patient and intractable gagging in a second patient. Both of these aborted procedures were attempted under topical anaesthesia only. <p>Authors conclusion</p> <p>Transnasal oesophagoscopy balloon dilation can be performed in unsedated or sedated patients with low complications rate. This technique, formerly available only through larger calibre oral gastroscopes and under sedation, allows for office-based oesophageal balloon dilation in an otolaryngology practice.</p> |
| General comments | |

Evidence Table : Economic evaluation
Question : Is transnasal oesophagoscopy (TNE)/ transnasal flexible laryngo-oesophagoscopy (TNFLO) more cost saving compared to rigid oesophagoscopy?

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|---|--|
| Bibliographic citation | 1. Price T, Sharma A, Snelling J <i>et al.</i> How we do it: The role of trans-nasal flexible laryngo-oesophagoscopy (TNFLO) in ENT: one year's experience in a head and neck orientated practice in the UK. <i>Clinical Otolaryngology</i> . 2005.30;551-556 |
| Study type | <p>Cross sectional study conducted at the Norfolk and Norwich University Hospital, UK.</p> <p>The aim was to report the experience of using transnasal flexible laryngo-oesophagoscopy TNFLO in the UK and Europe.</p> <p>A prospective review of patients undergoing transnasal flexible laryngo-oesophagoscopy (TNFLO) at the Norfolk and Norwich University Hospitals from January 1, 2004 to January 1, 2005. Information was gathered on patient demographics, symptoms, indications and therapeutic procedures performed. A Pentax 80K series Digital Video Endoscope (EE 1580K; Pentax, Slough, UK) was used.</p> |
| LE | II-3 |
| Number of patients & Patient characteristics | <p>116 TNFLO procedures</p> <p>Indications for TNFLO:-</p> <ul style="list-style-type: none"> - 56 patients for screening examination for symptoms of globus pharyngeus - 5 patients for acute dysphagia - 18 patients with chronic dysphagia - 14 patients with dysphonia - 16 patients as part of surveillance of their head nad neck cancer |
| Intervention | Transnasal flexible laryngo-oesophagoscopy (TNFLO) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Cost implication</p> <p>Improved efficiency in management of certain patients with fewer steps involved. This translate to monetary saving in terms of :-</p> <ul style="list-style-type: none"> • reduction in the reliance of radiological investigations (barium swallow ± £150); • reduced follow-up clinic appointments (± £80) • reduced in cost of inpatient investigation with reduced admissions and use of in-patient theatres (general anaesthetic oesophagoscopy (± £450) <p>Resource savings apply not only to the hospital but also to the patient.</p> <p>Authors conclusion</p> <p>The impact of the TNFLO within the authors' department has been a very substantial shift from investigation and treatment in the operating theatre, to a procedure room based practice under local anaesthesia. The TNFLO enables the provision of an economical 'one stop service', is well tolerated by patients and has opened a door to a wealth of novel therapeutic procedures.</p> |
| General comments | |

Evidence Table : Economic evaluation
Question : Is transnasal oesophagoscopy TNE /TFO more cost saving compared to Barium swallow?

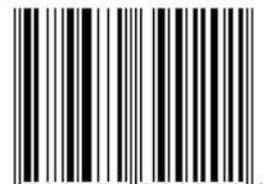
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|---|--|
| Bibliographic citation | 2. McPartlin DW, Nouraei SA, Tatla T <i>et al.</i> How do we do it: Transnasal fiberoptic oesophagoscopy. <i>Clinical Otolaryngology</i> . 2005;30:547-550 |
| Study type | Cross sectional study conducted at the Charing Cross Hospital, London, UK. Patients presenting to the outpatients department with symptoms of globus pharyngeus or mild dysphagia were investigated with TFO, excluding from the experience those patients with symptoms suggestive of malignancy. The endoscope (Vision Sciences® TNE-2000D with Slide-On™ TNE sheath), comprised of a flexible fiberoptic endoscope of 4 mm diameter with a working length of 665 mm. At the end of the procedure patients completed a questionnaire incorporating two separate visual analogue score (VAS), one for procedural pain and one for unpleasantness /discomfort. In addition, the examiner filled out an assessment form including the indication for the examination, the clinical findings, and assessment of ease of use of the equipment and the quality of views obtained. |
| LE | II-3 |
| Number of patients & Patient characteristics | 16 patients with symptoms of globus pharyngeus or mild dysphagia. Age range, 35 to 68 years 7/16 (44.0%) males and 9/16 (56.0%) females |
| Intervention | Transnasal fiberoptic oesophagoscopy (TFO) |
| Comparison | |
| Length of follow up | |
| Outcome measures/ Effect size | <p>Economic analysis:-</p> <p>Cost implications of employing TFO/TNE as a standard care. Cost for Barium swallow investigations:-</p> <ul style="list-style-type: none"> • Average 84 barium swallow investigations requested annually for globus pharyngeus and mild dysphagia at the cost of £240 for investigation and £40 for a follow-up appointment (source: Trust's finance department). • Cost per annum = £23,520 <p>Capital cost of purchasing naso-oesophagoscope is around £20,000, with disposable sheaths costing £50 each. Using these assumptions, the capital cost of purchasing a naso-oesophagoscopoe will be fully met after 86 investigations, over 1 year of use. After that the technology leads to savings of £230 (82%) per patient investigated for symptoms of upper aerodigestive tract pathology.</p> <p>Authors conclusion Our findings suggest that TFO is well tolerated under local anaesthesia, without the need for sedation. As such it is a useful diagnostic tool for use in the outpatients setting. It is quick and easy to perform and yields good views of the mucosal surfaces, from nasal vestibule to the gastric cardia. It is a highly viable economic option and be valuable addition to the diagnostic of the ENT clinic.</p> |
| General comments | |

LIST OF EXCLUDED STUDIES

1. Amin MR, Postma GN, Setzen M *et al.* Transnasal esophagoscopy: A position statement from the American Bronchoesophagological Association (ABEA). *Otolaryngology-Head and Neck surgery*.2008;138:411-414
2. Mokhashi MS, Wildi SM, Glenn TF *et al.* A prospective, blinded study of diagnostic esophagoscopy with a superne, battery powered esophagoscope. *American Journal of Gastroenterology*.2003;98(11):2383-2389
3. Catanzaro A, Faulx A, Isenberg GA *et al.* Prospective evaluation of 4-mm diameter endoscopes for esophagoscopy in sedated and unsedated patients. *Gastrointestinal Endoscopy*.2003;57(3):300-304
4. Postma GN. Transnasal esophagoscopy. *Current Opinion in Otolaryngology & Head and Neck Surgery*.2006;14(3);156-158
5. Doctor VS. In-office unsedated tracheoesophageal puncture. *Current Opinion in Otolaryngology & Head & Neck Surgery*.2007;15(6):405-408
6. Thota PN, Zuccaro G Jr, Vargo JJ 2nd *et al.* A randomized prospective trial comparing unsedated esophagoscopy via transnasal and transoral routes using a 4-mm video endoscope with conventional endoscopy and sedation. *Endoscopy*.2005;37(6):559-565
7. Rees CJ. In-office transnasal esophagoscope-guided botulinum toxin injection of the lower esophageal sphincter. *Current Opinion in Otolaryngology & Head & Neck Surgery*. 2007;15(6):409-411
8. Jobe BA, Hunter JG, Chang EY *et al.* Office-based unsedated small-caliber endoscopy is equivalent to conventional sedated endoscopy in screening and surveillance for Barrett's esophagus: a randomized and blinded comparison. *American Journal of Gastroenterology*.2006;101(12):2693-703
9. Rees CJ. In-office unsedated transnasal balloon dilation of the esophagus and trachea. *Current Opinion in Otolaryngology & Head & Neck Surgery*.2007;15(6):401-404

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