ASSESSMENT OF THE EFFICACY OF VIDEO ENDOSCOPY OF THE EUSTACHIAN TUBE AS A TEST OF EUSTACHIAN TUBE FUNCTION

A dissertation submitted in part fulfilment of MS Branch IV, ENT examination of the Tamil Nadu Dr. MGR Medical University, to be held in March 2010

CERTIFICATE

This is to certify that the dissertation entitled '**ASSESSMENT OF THE EFFICACY OF VIDEO ENDOSCOPY OF THE EUSTACHIAN TUBE AS A TEST OF EUSTACHIAN TUBE FUNCTION**' is the bonafide original work of **Dr Ann Mary Augustine**, submitted in partial fulfilment of the rules and regulations for the MS Branch IV, Otorhinolaryngology examination of The Tamil Nadu Dr. M.G.R Medical University, to be held in March 2010.

Dr Achamma Balraj
Professor and Head
Department of ENT,
Christian Medical College,
Vellore.

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Dr Anand Job
Professor
Department of ENT,
Christian Medical College,
Vellore.

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CONTENTS

INTRODUCTION

The eustachian tube is the only communication between the middle ear air system and the atmosphere and has long been recognized to play a vital role in maintaining the homeostasis of the middle ear, thereby aiding in normal middle ear function. Abnormalities of eustachian tube function have therefore been implicated in most cases of middle ear disease[1]. In children, eustachian tube dysfunction can result in poor speech and language development and poor scholastic performance secondary to conductive hearing loss due to glue ear. In adults, chronic eustachian tube dysfunction triggers a wide range of middle ear diseases including cholesteatoma. A normally functioning eustachian tube is also well proven to be a good prognostic indicator in the management of various middle ear pathologies[1].

Eustachian tube dysfunction can be due to anatomical obstruction of the lumen, functional obstruction or the eustachian tube may be patulous. Anatomical obstruction may be in the form of mucosal swelling, polyps or mass lesions. Functional obstruction refers to failure of eustachian tube opening in the absence of anatomical obstruction which is the most common cause of eustachian tube dysfunction.

Studies on the eustachian tube have been difficult due to its inaccessible location in the skull base and the multiplicity of factors involved in normal function and dysfunction. Over the years many tests have been devised to assess the functional status of the eustachian tube. These tests have greatly enhanced our knowledge and understanding of the functioning of the eustachian tube and its significance in various pathological processes affecting the middle ear. However, so far none of the available tests of eustachian tube function can be considered as a gold standard.

With the advent of diagnostic endoscopic techniques, attempts have been made to study eustachian tube function using endoscopes. Dynamic slow motion video endoscopy of the eustachian tube has been recently evaluated as a method of functional assessment of the eustachian tube and has shown promising results. This test has been recommended for its simplicity and can be easily performed as an outpatient procedure. The efficacy of the test as a diagnostic tool for functional assessment of the eustachian tube however has so far not been studied.

AIMS AND OBJECTIVES

1) To study the pattern of eustachian tube function in individuals having clinically normal middle ears (normal tympanic membrane on otoscopy), with normal audiogram and ‘A’ type curve on tympanometry using digital slow motion video endoscopy of the eustachian tube

2) To study in these patients, the degree of correlation between digital slow motion video endoscopy and Eustachian Tube Swallow Test (ETST), as tests of eustachian tube function

LITERATURE REVIEW

ANATOMY OF THE EUSTACHIAN TUBE

The eustachian tube also known as pharyngotympanic tube or auditory tube connects the middle ear cavity with the nasopharynx. It is named after the sixteenth century anatomist Eustachius who in 1563 first described the membrano-cartilaginous part of the pharyngotympanic tube. The term eustachian tube was introduced by the Italian anatomist Antonio Maria Valsalva (1666-1723), professor of Anatomy at Bologna, who in 1717 established the concept of the bony part of the tube. In 1862 Ruedinger described the definite division of the tube into the bony and cartilaginous-membranous parts.[2]

The eustachian tube in the adult is approximately 36 mm long, a size that is attained at the age of 7 years. It is directed downward from the middle ear at an angle of 45° and runs forward and medially from the middle ear. It consists of 2 portions, a lateral third (12 mm), which is a bony portion arising from the anterior wall of the tympanic cavity, and a medial two thirds (24 mm), which is a fibro-cartilaginous portion entering the nasopharynx. The tube opens about 1-1.25 cm behind and slightly below the posterior end of the inferior turbinate.

The bony portion also called Ruedinger canal[3] is widest at its tympanic end. It passes through the squamous and petrous portions of the temporal bone but narrows gradually to the isthmus, which is the narrowest part of the eustachian tube. The diameter at the isthmus is 0.5 mm or less. A thin plate of bone separates it from the tensor tympani muscle superiorly. The carotid canal lies medial to the bony part of the eustachian tube.

The cartilaginous portion consists of a plate of cartilage posteromedially. The cartilage bends forward to form a short flange. The rest of the anterolateral wall is formed by fibrous tissue. The apex or lateral end of the cartilaginous part joins the bony portion at the isthmus; the wider medial end lies under the mucosa of the nasopharynx and raises the mucosa to form the torus tubaris. Just behind this elevation is a recess called the pharyngeal recess or fossa of Rosenmuller, which is a common site of origin for nasopharyngeal carcinoma and occult primary tumours. Lymphoid tissue is present around the tubal orifice and in the pharyngeal recess. The cartilaginous eustachian tube is attached to the skull base in a groove between the petrous part of the temporal bone and the greater wing of the sphenoid. [4]

Ostmann fat pad

This fat pad is located in the inferolateral aspect of the eustachian tube and is thought to be an important contributing factor in closing the tube. It is also quite likely to contribute in the protection of the eustachian tube and the middle ear from retrograde flow of nasopharyngeal secretions.

Epithelial lining

The eustachian tube is lined by respiratory type of epithelium with goblet cells and mucous glands. A carpet of ciliated epithelium is seen lining the floor of the tube. The mucosa at the nasopharyngeal end of the tube is truly respiratory type but on passing along the tube towards the middle ear, the number of goblet cells and mucous glands decrease and the ciliary carpet becomes less dense. [4]

Muscles acting on the Eustachian tube

The muscles of the eustachian tube system help open and close the tube, thus allowing it to perform its function. These muscles are the (1) tensor veli palatini, (2) levator veli palatini and (3) salpingopharyngeus. Huang et al,[5] performed dissection studies on 15 fresh cadaveric head specimens (30 samples) and presented the following description of the 3 muscles acting on the eustachian tube:

Tensor veli palatini

The tensor veli palatini muscle originates from the bony wall of the scaphoid fossa and from the whole length of the short cartilaginous flange that forms the upper portion of the front wall of the cartilaginous tube. The muscle is triangular, its anterior border being directly vertical, while its posterior border slopes downward, forward, and medially, thus forming a narrow tendon inferiorly at the apex of the triangle. The axis of the tensor veli palatini is oblique to that of the tube, the angle between the two being 30 to 45 degrees. The tendon turns medially around the pterygoid hamulus at an angle of 90 degrees. It then fans out within the soft palate and mingles with the fibres from the opposite side in the midline raphe. Within the soft palate, the tendinous fibres spread out to become a horizontal, sheet like aponeurosis occupying the anterior quarter of the velar length and extending from the posterior nasal spine to the tip of the uvula. The aponeurosis is attached anteriorly to the posterior nasal spine in the midline and to the curved crest of the palatine bone on either side of it, extending to the inferior margin of the medial pterygoid plate laterally. The muscle is usually fleshly along its middle 50 percent and tendinous in its upper and lower 25 percent.[5] The tensor veli palatini separates the eustachian tube from the otic ganglion, the mandibular nerve and its branches, the chorda tympani, and the middle meningeal artery. It is supplied by the mandibular nerve.

Salpingopharyngeus

The salpingopharyngeus is a delicate muscle that is attached to the inferior part of the cartilage at the pharyngeal end of the eustachian tube. It then descends in a posterior direction and blends with the palatopharyngeus muscle. The salpingopharyngeus may be vestigial, comprising more of a fibrous than muscular element.[5] Its nerve supply is from the pharyngeal plexus.

Levator veli palatini

The levator veli palatini has 2 origins: the lower surface of the cartilaginous tube, the lower surface of the petrous bone and from the fascia of the upper part of the carotid sheath as described by Rohan and Turner[6]. However Huang et al[5] found the superior attachment of the levator to be at the posteromedial aspect of the eustachian tube at the junction of its cartilaginous and bony parts. At first, the levator is inferior to the tube; it then crosses to the medial side and passes between the superior constrictor muscle and cranial base to merge with the soft palate. The extravelar part of the levator veli palatini was consistently cylindrical and of fairly uniform size from its origin to its point of entry into the velum, the mean diameter being 7.96 mm at the cranial base and 8.13 mm at the torus tubaris. The levator palatini is also supplied from the pharyngeal plexus.

Blood vessels

The arterial supply of the eustachian tube is derived from the ascending pharyngeal artery (branch of external carotid artery), middle meningeal artery (branch of the maxillary artery) and ascending palatine artery (branch of the facial artery). The venous drainage is carried to the pharyngeal and pterygoid plexus of veins. The lymphatics drain into the retropharyngeal lymph nodes.[4]

Nerves

The pharyngeal branch of the sphenopalatine ganglion derived from the maxillary nerve (V2) supplies the ostium. The nervus spinosus derived from the mandibular nerve (V3) supplies the cartilaginous part, and the tympanic plexus derived from the glossopharyngeal nerve supplies the bony portion of the eustachian tube.[4]

Development of the Eustachian tube

The eustachian tube develops as a persistence of the first pharyngeal pouch. The tympanomastoid compartment appears at the 3-week stage as an outpouching of the first pharyngeal pouch known as the tubotympanic recess. The endodermal tissue of the dorsal end of this pouch eventually becomes the eustachian tube and tympanic cavity. Hammar, (as cited in Proctor),[7] described 3 stages in the development of the eustachian tube: a) the anlage period, b) the demarcation period and c) the transformation period.

In the first stage which occurs between 3 to 7 weeks of gestation, a slit-like pouch develops from the first visceral groove for the pharyngeal wall and extends through the undifferentiated mesenchyme to make contact with the ectoderm of the 1^{st} branchial cleft.

In the second stage which occurs between the 7^{th} to 9^{th} weeks of intrauterine life, the branchial arch grows rapidly and constricts the mid portion of the tubotympanic recess, the lateral part giving rise to the primary tympanic cavity and the medial part forming the anlage of the Eustachian tube.

In the first part of the third stage which extends from the 9^{th} week till birth, the mesenchyme surrounding the primitive tympanum is replaced by loose connective tissue, which later is absorbed resulting in enlargement of the tympanic cavity. By the 4^{th} month the tube enlarges and the lumen becomes slit like. The cartilaginous portion develops by chondrification in four centres of the surrounding mesoderm. By the 5^{th} month demarcation between the tube and the middle ear becomes distinct.

Between the 10th and 12th weeks post conception the levator veli palatini and tensor veli palatini muscles develop. At 14 weeks the tensor tympani muscle becomes apparent and rugae begin to develop within the tube. The tube increases in length from 1 mm at 10 weeks post conception to 13 mm at birth. Also, the angle between the eustachian tube and the skull base is 10 degrees at birth. This is in contrast to the adult length of 36 mm and angle of 45 degrees in adults. Vertical development of the skull, and increase in the angle of the skull base, allow the eustachian tube to reach its adult length and angle by age 7.

The mucous glands of the eustachian tube develop between the 13th and 26th week of fetal life, appearing first on the medial and then on the lateral wall. The glands develop earlier at the pharyngeal orifice and the spread towards the middle ear.[8]

Having studied 12 autopsy specimens of temporal bones ranging in age from 39 weeks gestation to 19 years of age, Kitajiri [9] described the postnatal development of the eustachian tube. He found that the area of the tubal lumen increased to 4.7 times the area at birth, to its adult size at 19 years. The maximum increase in size was at the midcartilaginous portion. The cross-sectional length and width of the medial lamina of the eustachian tube cartilage increases more than that of the lateral lamina.

PHYSIOLOGY OF THE EUSTACHIAN TUBE

The functions of the eustachian tube include a) Aeration or pressure regulation of the middle ear, 2) clearance of secretions from the middle ear by means of the ciliary epithelium and 3) protection of the middle ear from the secretions and sound pressures in the nasopharynx.

Protective Function

The eustachian tube is usually closed at rest. Sudden loud sounds are therefore dampened before reaching the middle ear through the nasopharynx. The middle ear is also protected by the local immunologic defence of the respiratory epithelium of the eustachian tube. A pulmonary immunoreactive surfactant protein has been isolated from the middle ears of animals and humans and is thought to have some protective function in the middle ear [10]

Clearance Function

Drainage of secretions and occasional foreign material from the middle ear is achieved by the mucociliary system of the eustachian tube and the middle-ear mucosa, muscular clearance of the eustachian tube and surface tension within the tube lumen.

The flask model proposed by Bluestone and his colleagues[11] helps to better explain the role of the anatomic configuration of the eustachian tube in the protection and drainage of the middle ear. In this model, the eustachian tube and middle ear system is likened to a flask with a long narrow neck. The mouth of the flask represents the nasopharyngeal end, the narrow neck represents the isthmus, and the middle ear and mastoid air cell system represents the body of the flask.

Fluid flow through the neck depends on the pressure at either end, the radius and length of the neck and the viscosity of the liquid. When a small amount of liquid is instilled into the mouth of the flask, the flow of the liquid stops in the neck. This is due to the narrow diameter of the neck and the relative positive air pressure in the chamber of the flask. However, this does not take into consideration the dynamic role of the tensor veli palatini muscle in actively opening the nasopharyngeal orifice of the eustachian tube. In children the eustachian tube has a much shorter neck. As a result, less pressure is required at the nasopharynx to force fluid and pathogens into the middle ear of children.

The flask model can be used to illustrate another difference between a child's anatomy and that of an adult. In an erect adult the eustachian tube inclines about 45 degrees to the horizontal plane. In a child, the eustachian tube inclines only about 10 degrees. An erect adult gains the benefit of gravity which acts to increase resistance to fluid entering the middle ear. Conversely an infant gains little benefit from gravity because the tube is nearly perpendicular to the force of gravity. Moreover, a child feeding in the supine position actually has the full force of gravity driving fluid into the middle ear.

Pressure Regulation Function

Of the three functions of the eustachian tube, the pressure regulation or ventilatory function of the middle ear is considered the most important. This is because hearing is optimal when the middle ear gas pressure is relatively the same as the air pressure in the external auditory canal, since the tympanic membrane and middle ear compliance is optimal in this situation. The continuous absorption of air through the mucosal lining in the middle ear cleft, together with the variations of the ambient barometric pressure, constitute the basic need for intermittent air exchange through the eustachian tube. This is accomplished by opening the tube, which admits air to pass either from or into the middle ear space.

Tubal Opening Mechanism

As a result of muscular activity, the cartilaginous portion of the tube opens. The tensor palatini muscle is considered the main dilator, but the tensor tympani muscle may also play a role in tubal-opening mechanism.[12] The tensor tympani is attached to the neck of the malleus and contraction of the muscle may slightly increase the middle ear pressure by medial displacement of the tympanic membrane when contracted. The origin of this muscle from the cartilage of the tube as from the adjoining bone may well influence the opening of the tube at the isthmus (Ingelstedt and Jonson, 1966[13]). Thus contraction of the tensor tympani may play an important role in the tubal opening mechanism.

Another mechanism for opening the eustachian tube must also be taken into account. If the intratympanic air pressure for some reason exceeds 100-150 mm H_2O above the ambient air pressure, the eustachian tube may open spontaneously without any muscular activity involved. This demonstrates the effect of continuous increase of intratympanic air pressure. Also when increased pressure is applied from the nasopharyngeal end, the eustachian tube opens. This is exemplified in tubal catheterizing or in applying high pressure in the nasopharynx as in Valsalva's manoeuvre. The importance of small air pressure differences across the tube for a complete separation of the mucous surfaces and a breaking of the mucous film was discussed by Perlman et al in 1967[14]. In pressure chamber experiments performed by Ingelstedt and co-workers in 1963[15] and 1967[13], it was shown that the tube did not open on swallowing until the chamber reached +150 mm H_2O relative to the ambient pressure. This demonstrates the effect of step by-step increases of negative pressure in the middle ear. Not until the pressure reaches -150 mm H_2O is the patient able to change the pressure by swallowing. This means that it is easier to equalize a pressure of -150 mm than that of -100 mm H_2O. This has been shown repeatedly when testing eustachian tube function in ears with chronic otitis media (Flisberg, 1966[16]; Miller, 1965[17] ; Holmquist, 1969[18]), but will supposedly hold also for normal ears.

Tubal Closing Mechanism

In contrast to opening of the tube, closure is exclusively a passive phenomenon. When the muscles relax or when a static pressure no longer keeps the tubal walls separated, the tubal lumen collapses. Closure of the tube proceeds from distal to proximal, i.e. from the valve area to the nasopharyngeal end. This mechanism is hypothesised to have a protective effect against reflux.[43]

Tubal Opening Time

The equalization capacity of the tube is influenced by many factors, among which the most critical seems to be the time the tube stays open as a result of muscular activity or air pressure influence. According to many investigators (Perlman, 1951[19]; Miller, 1965[17]; Flisberg, 1966[16]), the opening time varies between 0.1-0.9 sec. Depending on the pressure difference across the tube, the width and length of the narrowest part, together with the opening time, the air volumes passing through the tube may vary. This explains the great differences in tubal ventilating functions even among normal persons. More basic data elucidating the inter and intra-individual variations are important for our understanding of the ventilating function of the eustachian tube.

Eustachian Tube Function at Changing Ambient Pressure

The response of the eustachian tube to changes in the ambient pressure has been studied by many authors (Thomsen, 1958[20]; Ingelstedt et al., 1967[21]). When the ambient air pressure decreases, as during flight ascent, the intratympanic air pressure increases. Opening of the eustachian tube is now facilitated on swallowing, or the tube may even open spontaneously as a response of the air pressure force on the tubal walls. The situation is more complex when the relative intratympanic air pressure is decreasing, as during descent. As mentioned earlier, increased negative middle ear pressure up to at least -150 mm H_2O facilitates tubal opening. More complicated conditions occur at higher negative intratympanic air pressure levels, which influences tubal opening. It seems clear that negative middle ear pressure impairs tubal opening by a suction effect on the mucosal walls in the tube (Flisberg, 1966[16]). It has also been shown that a negative middle ear pressure of about -1100 mm H_2O may make it impossible for the tubal opening muscles to overcome the collapsing force. These observations are especially relevant for divers and pilots exposed to rapid and great changes of the ambient air pressure.

EUSTACHIAN TUBE FUNCTION IN THE ELDERLY

In a study on 36 human temporal bones Takasaki et al[22] established that there is a significantly higher degree of calcification of the eustachian tube cartilage in the elderly along with a significant atrophy of the tensor veli palatini muscle making the elderly more prone to eustachian tube dysfunction. However, on functional testing using tympanometry by Chermak et al[23] there was no significant difference between young and older adults in peak pressure and peak amplitude. The pressure change and function change on William's test also showed no significant difference in the elderly in comparison to young adults.

EFFECTS OF EUSTACHIAN TUBE DYSFUNCTION

Eustachian tube dysfunction has been implicated as the primary pathophysiological factor in the development of various middle ear diseases including acute suppurative otitis media, chronic suppurative otitis media, otitis media with effusion and middle ear atelectasis. Eustachian tube dysfunction also predisposes an individual to the development of barotrauma. Patulous eustachian tube is an abnormal condition in which the tube is abnormally patent. The patient often complains of autophony, as well as ear fullness. Rapid weight loss may lead to decreased size of the Ostmann fat pad, which is thought to contribute to this condition.

TESTS OF EUSTACHIAN TUBE FUNCTION

A functional and patent eustachian tube is necessary for ideal middle ear sound mechanics. A fully patent eustachian tube may not necessarily have perfect functioning, as is the case with the patulous eustachian tube or with mucociliary abnormalities. Testing of both eustachian tube patency and function are therefore important.

A self-described method by patients with perforated tympanic membranes is the bitter taste of ear drops in the mouth when used topically. This indicates a patent eustachian tube.

Pneumatic Otoscopy

Permeatal examination of the tympanic membrane assesses the patency and perhaps the function of the tube. A normal appearing tympanic membrane usually indicates a normally functioning eustachian tube, although this does not preclude the possibility of a patulous tube. Otoscopic evidence of tympanic membrane retraction or fluid in the middle ear indicates eustachian tube dysfunction but cannot be used to differentiate between functional impairment and mechanical obstruction of the tube. Normal tympanic membrane mobility on pneumatic otoscopy (siegalization) indicates good patency of the eustachian tube. Roeser et al.[24] compared pneumatic otoscopy with tympanometry and demonstrated inefficiencies in using this technique as the only assessment of abnormal middle ear pressure. Pneumatic otoscopy moreover, cannot quantify eustachian tube function.

Valsalva test

In the Valsalva test, the eustachian tube and middle ear are inflated by a forced expiration with the mouth closed and the nose pinched by the thumb and forefinger. The effect of high positive nasopharyngeal pressures at the proximal end of the eustachian tube system can be evaluated qualitatively. When the tympanic membrane is intact, the overpressure in the middle ear can be observed by otoscopy as a bulging tympanic membrane. When the tympanic membrane is perforated, the sound of the air escaping from the middle ear can be heard with a stethoscope or with the Toynbee tube.

Politzer Test

The Politzer test is similar to the Valsalva test, but instead of positive nasopharyngeal pressure being generated by the patient, the nasopharynx is passively inflated. This is achieved by compressing one nostril into which the end of a rubber tube attached to an air bag has been inserted while compressing the opposite nostril by finger pressure. The subject is asked to swallow or to elevate the soft palate by repeating the letter "k."

Both the Valsalva and Politzer tests are outdated and rarely used clinically for assessment of eustachian tube function. These manoeuvres may be more beneficial in the management of some patients. Nevertheless, the efficacy of these procedures for treatment of middle ear effusion is controversial, and they are not without potential risks.

Toynbee test

This test is considered more reliable than the Valsalva and Politzer tests in the assessment of eustachian tube function. On closed nose swallowing, negative middle ear pressure develops in healthy persons. In an intact tympanic membrane, pneumatic otoscopy or tympanometry can be used to measure changes in middle ear compliance. In a perforated tympanic membrane, the manometer of the impedance bridge can be used to measure middle ear pressure changes.

Eustachian tube catheterization

Catheterization of the eustachian tube with a curved metal cannula via the transnasal approach has been used to assess tubal function for more than 100 years. It can be done blindly, with the help of a nasopharyngoscope, or transorally with a 90° telescope. The catheter is passed along the floor of the nose until it touches the posterior wall of the nasopharynx. The catheter is then rotated 90° medially and pulled forward until it impinges on the posterior free part of the nasal septum. The catheter is then rotated 180° laterally, so that its tip lies at the nasopharyngeal opening of the eustachian tube. A Politzer bag is attached to the outer end of the catheter, and an auscultation tube with 2 ear tips is used with one tip in the patient's ear and the other in the examiner's ear. Air is pushed into the catheter by means of the Politzer bag. The examiner hears the rush of air as it passes through the catheter into the eustachian tube and then into the middle ear.

Successful transferring of applied positive pressure from the proximal end of the cannula into the middle ear suggests tubal patency. Normal blowing sounds mean a patent eustachian tube and bubbling indicates middle ear fluid. Whistling suggests partial eustachian tube obstruction while absence of sounds indicates complete obstruction or failed catheterization.

Tympanometry

Measuring middle ear pressure with an electro acoustic impedance meter helps to assess eustachian tube function. High negative middle ear pressure (>-100 dPa) indicates eustachian tube dysfunction.

Bluestone[25] provided a nine-step inflation-deflation eustachian tube assessment procedure for intact tympanic membranes. This procedure involves swallowing manoeuvres at both positive and negative pressures. One's ability to cause at least a 20-mm pressure change, as measured on the tympanogram was the criterion for adequate tuba1 patency. This technique also has a modification for nonintact tympanic membranes. The procedure is based upon the application of positive pressure to the middle ear until the eustachian tube spontaneously opens. The manometer is then stopped and observed regarding the pressure at which the eustachian tube passively closes. The patient is then asked to swallow to equilibrate the remaining pressure. The procedure may also be used with negatively induced pressure by asking the patient to equilibrate the pressure with swallows. This inflation-deflation technique described by Bluestone has provided a vehicle for numerous researchers and clinicians in the study of eustachian tube patency.

The Williams test[26] used in this study is a modification of the inflation-deflation test designed to assess the eustachian tube function in individuals with normal tympanic membranes.

EUSTACHIAN TUBE SWALLOW TEST (WILLIAM'S TEST)

William's proposed a pressure-swallow technique for the assessment of eustachian tube patency to be used in patients with intact tympanic membranes. Williams's technique involves the measurement of an initial tympanogram after which the external canal pressure is induced to positive 400 mm of H_2O. The patient is then asked to swallow several times after which a second tympanogram is traced. This procedure can also be used with the induction of negative pressure. William observed that a shift of tympanometric peak of 25 to 30 mm indicated adequate eustachian tube patency. In an attempt to further quantify immittance measurements of the eustachian tube, Givens et al,[27] Seidemann et al[28] and Seifert et al.[29] devised a bivariate assessment technique of eustachian tube assessment. This procedure involved the analysis of implied middle ear pressure and compliance changes as the result of a pressure-swallow procedure. This procedure is a modification of the Bluestone and Williams procedures. Studies using this procedure observed that the middle ear compliance change was found to be a sensitive indicator of eustachian tube patency in addition to the measurement of middle ear pressure change alone.

A study done by Schuchman et al[30] on divers showed that 82.26% of normal ears pass the test when a peak pressure shift of ≥ 5 dPa after swallowing in either positive or negative canal pressure condition was considered as evidence of a functional eustachian tube.

Similarly the shift in peak amplitude, or function change (FC) may also be used for quantification of eustachian tube function. As suggested by Seidemann and Givens,[28] FC data are reported in percent according to the following equation:

$$\% FC = \frac{FD2 - FD1}{FD1} \times 100$$

FD1 represents the difference between peak amplitude and the +200 mm point on the baseline tympanogram. FD2 is the difference in amplitude between peak pressure and +200 mm in the positive canal pressure or negative canal pressure conditions.

Schuchman et al used six different criteria in his study on divers and assessed the percentage of normal eustachian tubes that pass the test based on each criterion. These criteria were as follows:

1) Pressure change of ≥5 dPa in the positive or negative EAC pressure situation
2) Pressure change of ≥5 dPa in the positive and negative EAC pressure situation
3) Pressure change of ≥15 dPa in the positive or negative EAC pressure situation
4) Pressure change of ≥15 dPa in the positive and negative EAC pressure situation
5) Functional change of ≥ 5% in the positive or negative EAC pressure situation
6) Functional change of ≥ 5% in the positive and negative EAC pressure situation

The percentage of tubes that passed the test in criteria 1 to 6 as described above were 82.26%, 66.13%, 55.65%, 21.77%, 87.90% and 57.25% respectively.

Sonotubometry

Sonotubometry measures the function of the eustachian tube using sound. A constant sound source is applied to the nostril while a microphone in the external auditory canal records the transmitted sound pressure level. The test is started with a constant sound signal in the nostril. The subject is asked to swallow (drink water); when the eustachian tube opens, an increase in sound level is measured. Thus, the active ventilatory function of the eustachian tube can be measured noninvasively. The measurements take place under physiological circumstances, without the use of extreme pressures and without the need for tympanic membrane perforation. Thus, sonotubometry has several advantages and can be considered an appropriate method to measure ventilatory eustachian tube function.

The procedure described by Virtanen in 1978[31] became standard in subsequent studies, with a few minor adaptations. He used an earphone that could generate a continuous sound of 6, 7, or 8 kHz and be inserted into the nostril of the test subject. This sound source was fixed tightly within the nostril to minimize sound leakage. A microphone embedded in a circumaural ear muff was placed in the ipsilateral external auditory canal to protect against ambient noise. The microphone and insert earphone were connected to a heterodyne analyser that consisted of an analyser and a frequency oscillator. A continuous tone generated by the oscillator was transmitted to the earphone inserted into the nose. A filter set was used to filter out any ambient noise. Test sound that reached the external auditory canal was picked up by a calibrated condenser microphone connected to a preamplifier. A sound level recorder measured the signal. The test subject sat in a quiet room with his or her mouth closed and without moving the head. He or she was asked to swallow water while the sound signal in the external ear was being recorded continuously. Opening of the tube was reflected by a sudden increase in signal in the external ear canal (5 dB).

In a literature review on sonotubometry, van der Avoort et al[32] concluded that sonotubometry is inexpensive, painless and easy to perform in both adults and children and therefore, it has great potential value as a diagnostic tool for individuals with suspected eustachian tube disease. The technique of sonotubometry has gradually been improved over the years. The results of sonotubometry are at least as good as those of other function tests. However, because the results still tend to be ambiguous in children and because otitis media is most common in this population, the reproducibility and application of sonotubometry require further evaluation. Sonotubometry has great advantages over other function tests, but it is not used routinely to assess eustachian tube ventilatory function because its value for clinical practice has not yet been adequately demonstrated.

Imaging

The eustachian tube may be radiologically viewed using ultrafluid lipiodol as a contrast medium.[33,34] The dye is injected through an intact tympanic membrane or through a previously present perforation or tympanostomy tube. X rays may be taken immediately and after 10 minutes of instillation in Stenver's, frontal and submentovertex positions.

Three dimensional Computed Tomography scans with multiplanar reconstruction have also been used to assess the tube in normal individuals, in patients with patulous eustachian tube,[35] and in otitis media.[36] It has also been used in studying eustachian tube clearance. Fluoroscopy with contrast provides dynamic evaluation of mucociliary clearance.

Functional Magnetic Resonance Imaging (MRI)[37] is yet another innovation in the assessment of eustachian tube function. For anatomical evaluation of the auditory tube and its surrounding structures a T2-weighted turbo spin echo sequence (axial orientation, TR/TE 3194/100 ms; coronal orientation TR/TE 3993/100 ms, NEX: 4) and a T1-weighted 3D gradient echo sequence (TR/TE: 42/4.6 ms, slice thickness 1 mm, axial orientation pre and post i.v. injection of contrast material) were carried out. In order to assess the opening of the auditory tube a single slice dynamic turbo gradient echo sequence (TR/TE 15/6.5 ms, flip angle 15°, SPIR pulse, matrix 256 x 256, FOV 240 mm, slice thickness 5 mm, NEX: 2) was performed while the patient performed valsalva manoeuvre. Duration of one dynamic scan was 4 sec.

EUSTACHAIN TUBE ENDOSCOPY

History

Kimura et al. were the first authors to introduce trans–eustachian tube endoscopy in 1989.[38] In 1994, Edelstein et al.[39] passed a flexible, micro-fiberoptic endoscope (0.55 mm with 2,000 pixels, 0.8 mm with 6,000 pixels, and 1.0 mm with 10,000 pixels) through the eustachian tube via its pharyngeal orifice for the purpose of evaluating middle ear status. Their approach required eustachian tube cannulation. Significant instrument failure from internal breakage of the fibres was encountered.

Klug et al.[40] employed trans–eustachian tube endoscopy (endoscope was passed from the pharyngeal orifice into the middle ear) in 40 temporal bone–

eustachian tube specimens of recently deceased persons, which lacked visible abnormalities. The data presented were obtained with a flexible, articulating micro-fiberoptic endoscope (0.8 mm diameter, 3,000 pixels), which was passed from the pharyngeal orifice through a tube catheter into the middle ear. Klug et al. did not describe eustachian tube status in these specimens, except to indicate that the endoscope successfully negotiated the isthmus in 92.5% of the specimens.

Su[41] was the first author to employ flexible, microfiberoptic, trans–eustachian tube endoscopy (0.85mm diameter) for the purpose of examining eustachian tube status in awake patients under local anaesthesia. The approach to endoscopic insertion was transtympanic. The endoscope was passed from the middle ear to the pharyngeal orifice. Of the 18 patients, 13 had otitis media with effusion, 3 had chronic otitis media, and 2 had traumatic eardrum perforation. In 9 of the 18 patients, the endoscope successfully negotiated the isthmus section of the eustachian tube; the eustachian tube status in relation to its valve mechanism was described for these 9 patients.

Linstrom et al[38] performed trans-tympanic eustachian tube endoscopy on patients with chronic ear disease, using flexible fibreoptic endoscopes of 0.5 mm and 1.0 mm diameter and recorded that the lumen at the isthmus was substantially narrowed in those with chronic middle ear disease.

Poe et al[42] in their experience with the 1.6mm and 0.6mm fiberoptic endoscopes to assess the eustachian tube lumen felt that, though the resolution was adequate to enable visualization of gross structures, analysis of fine motion was not possible. The endoscope immediately became fogged with any contact with the mucosal wall, and examination of the lumen was difficult.

They found that the optimal procedure was to place a scope with a larger diameter at the correct angle to allow one to look superiorly and laterally up the eustachian tube orifice and observe it during active dilation. Contact with the lumen walls was avoided, and the endoscopes did not interfere with the eustachian tube motion. The 4mm fiberoptic endoscope yielded a far superior view capable of some slow-motion video analysis and was easier to position into the eustachian tube orifice than a rigid scope of comparable size. The 4mm fiberoptic scope was easier to insert when compared with the smaller 2.7mm and 1.9mm rigid endoscopes. However, the best optics were definitely provided by the 4mm rigid endoscopes, which yielded clear large images that were well suited to examination of fine muscular movements in the lumen as it opened up during manoeuvres. They recommended looking initially with the 4mm rigid scope, but if there is insufficient room in the nasal cavity to pass it, or if the angulation to the eustachian tube orifice is not suited to a 30° view angle, then a 4mm nasopharyngoscope may be the next best option.

Procedure

Patients are examined in the sitting position in an office setting. Topical spray anaesthetic and decongestant, lidocaine 4% topical mixed with equal parts of phenylephrine hydrochloride 0.5% solution, is applied to both nasal cavities while the patient sniffs. Endoscopes are introduced into the nasal cavity and advanced up to the nasopharyngeal orifice of the eustachian tube, just posterior to the inferior turbinate and identified by the torus tubaris. It is easy to pass by the torus and examine the fossa of Rosenmuller, believing it to be the eustachian tube orifice.

The endoscopes that are used are usually either a 4mm diameter steerable flexible fiberoptic nasopharyngoscope or a 4mm diameter, 30-degree view angle, Hopkins Rod rigid sinus surgery endoscope. The rod endoscopes have high-resolution images, but the fiberoptic endoscopes are easier to pass and can be steered deeper into the eustachian tube lumen if desired. The 30-degree rigid endoscope is introduced with the view angle looking directly laterally and passed along the nasal floor, following the inferior turbinate until reaching the nasopharyngeal orifice and eustachian tube. Once at the orifice, the endoscope is rotated slightly to look superiorly toward the long axis of the eustachian tube. If the rigid endoscope will not easily pass through a narrow nasal cavity, then a flexible fiberoptic endoscope can usually be admitted. The optimal fiberoptic view is most commonly obtained by introducing the endoscope along the floor of the contralateral nasal cavity and passing the tip behind the vomer. This brings the tip into the proper angle to view up the long axis of the eustachian tube when it dilates. Occasionally, the lumen may be successfully viewed with a fiberoptic scope from the ipsilateral nasal cavity.

The endoscopes are used with a charge-coupled device (CCD) camera in place, and images are viewed on a video monitor. Video recordings are made with an s-VHS video recorder. The patient is asked to vocalize “K-K-K” repeatedly to isolate the action of the levator veli palatini (LVP) from the tensor veli palatini (TVP). The “Ks” stimulate palatal elevation and posteromedial rotation of the medial cartilaginous lamina and posteromedial wall of the eustachian tube. Swallows are done to induce normal physiologic tubal dilations, and forced yawns are performed to cause maximal sustained dilation. The procedure is repeated from the contralateral eustachian tube orifice. The video of tubal dilations is then reviewed and analyzed in normal time, slow motion, and even stepping through single frames that are captured at a rate of 30 frames per second.

Normal Eustachian Tube Opening on Endoscopic evaluation

Normal dilation and opening were observed to have four consistent sequential phases during a normal swallow[43]:

1. The soft palate elevates with simultaneous medial rotation of the posteromedial wall. The lateral pharyngeal wall also medialises, causing transient constriction of the nasopharyngeal orifice despite the medial rotation of the eustachian tube medial wall. One hypothesis for this contrary movement could be to provide momentary protection of the eustachian tube against reflux at the initiation of swallow.
2. The palate remains elevated, and the posteromedial wall remains medially rotated as the lateral pharyngeal wall displaces laterally to begin the dilation of the nasopharyngeal orifice.
3. The tensor veli palatini begins to contract, causing dilation of the lumen to propagate from the nasopharyngeal orifice toward the bony isthmus. The dilation occurs by displacement of the anterolateral tubal wall laterally and away from the already contracted and medially rotated posteromedial wall.
4. Tubal opening occurs as the functional valve of the cartilaginous tube dilates into a roughly rounded aperture. The convex bulge seen in the resting

anterolateral valve wall becomes visibly flattened to produce the final opening.

5. Closure of the tube begins with closure of the valve area and propagates proximally toward the nasopharyngeal orifice. This distal to proximal closure has been hypothesized to have a pumping action that may protect against reflux.

On video endoscopic assessment of the pharyngeal opening of the eustachian tube of 34 adults Poe et al[42] found that normal subjects showed significant variations in several static and dynamic properties of the eustachian tube. There was a wide range in the mucosal thickness, mucosal folds, patency of the pharyngeal orifice at rest, and thickness of the isthmus valve convexity, most likely due in part to Ostmann's fat pad. Thin subjects had consistently thin mucosa and obese subjects had significant thickening of the lumen walls. During active swallowing or yawning, there were large variations between patients in the degree of motion of the medial cartilaginous lamina, lateral excursion of the lateral pharyngeal wall, and height of palatal elevation. Mucosal and muscular motion variations became minimal moving from proximal to distal and approaching the region of the isthmus.

Recent studies of the peritubal musculature show that opening occurs principally by the coordinated action of the tensor veli palatini and a group of adjacent muscle fibres called the dilator tubae muscle.[44] The dilator tubae muscle originates primarily on the lateral membranous wall of the eustachian tube, intermingles with the more medial tensor veli palatini fibres, courses adjacent to the tensor veli palatini tendon, and then loosely wraps around the middle third of the hamulus and inserts beyond the hamulus into the velum. The dilator tubae has no bony insertion and is completely dependent on tensor veli palatini contraction as a platform against which the dilator can open the tube. The tensor veli palatini, therefore, has significant control over the efficiency of tubal dilation.

Poe et al observed consistent patterns of muscular contraction during swallows and yawns, which normally often open the eustachian tube. The action of the levator veli palatini is to elevate the palate and medially rotate the medial cartilaginous lamina. These actions begin the distal dilation of the eustachian tube and set the stage for the subsequent tensor veli palatini contraction. The tensor veli palatini can be seen to contract by the ripple of tension that lateralizes the lateral membranous wall. Once the entire distal tube is open, the final act appears to be the dilator tubae muscle pulling the valve like convexity of the lateral wall at the isthmus laterally to open the full length of the tube. The bony portion is normally patent at all times. The dilator tubae contraction in many normal subjects was sufficient to completely straighten the lateral wall convexity or make it transiently concave during maximal opening. The lumen of the maximally dilated tube appeared nearly circular. The relaxation sequence in normal subjects consistently began with closure of the isthmus convex valve, and then closure of the tube from distal to proximal, but the final relaxation of the levator veli palatini and lateral pharyngeal wall, and lateral rotation of the medial cartilaginous lamina, occurred in various orders.

In a further study by Poe et al[45] on slow-motion video endoscopic assessment of the eustachian tube in sixty-four ears and eustachian tubes with pathologic changes, tubal function was graded on (a) the extent of lateral excursion and progression of dilatory wave as estimates of tensor veli palatini and dilator tubae muscle function, (b) the degree of mucosal disease, (c) obstructive mucosal changes, (d) ease and frequency of tubal dilation with manoeuvres and (e) patulous tubes. All tubes with active pathologic conditions of the ear (otitis media with effusion, tympanic membrane retraction, draining ear, cholesteatoma) had significant abnormalities. However, correlation could not be made between the severity of middle ear disease and the severity of observed eustachian tube dysfunction. They concluded that slow-motion video endoscopic analysis is a potentially useful technique in classifying types of pathologic changes in the eustachian tube.

Mathew, G. A. et al[46] in a study done at CMC, Vellore, on 61 normal ears and 63 ears with middle ear disease, classified patterns of eustachian tube function on video endoscopy as follows –

Grade 0 – normal eustachian tube with no mucosal edema or congestion. Medial cartilaginous lamina and lateral wall movements are normal. Tubal lumen opens well on swallowing.

Grade 1 – edema and congestion of mucosa limited to the pharyngeal orifice of eustachian tube. Normal lateral wall motion and tubal lumen opens with swallowing

Grade 2A – Reduced lateral wall motion secondary to edema and congestion involving lumen. Tubal lumen opens partly with swallowing

Grade 2B – Reduced lateral wall motion secondary to abnormal tubal muscle contraction. Tubal lumen opens partly with swallowing

Grade 3A – Tubal lumen fails to open with swallowing secondary to gross edema

Grade 3B – Tubal lumen fails to open with swallowing secondary to abnormal tubal muscle contraction.

Patulous (P) – Noticeable concavity in the superior portion of the lateral wall of the lumen, with persistent patency of the lumen, extending towards the isthmus, with medial and lateral cartilaginous walls remaining separate even at rest.

The study showed a significantly higher prevalence of eustachian tube dysfunction among individuals with middle ear disease compared to the control group and significant correlation between manometric studies (positive pressure equalization test and tympanometry) and eustachian tube video endoscopy.

MATERIALS AND METHODS

The sample size was calculated as follows

Formula:

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2}{\pi(1-\pi)(\rho_1-\rho_0)^2\left\{\frac{1}{\pi^2+\pi(1-\pi)\rho_0} + \frac{2}{\pi(1-\pi)(1-\rho_0)} + \frac{1}{(1-\pi)^2+\pi(1-\pi)\rho_0}\right\}}$$

Ref: Donner A, Eliasziw M. Statistical implications of the choice between a dichotomous or continuous trait in studies of inter-observer agreement. Biometrics June 1994; 550 – 555.

The prevalence of eustachian tube dysfunction among individuals with normal middle ears was 39% and the agreement between DSVE and positive pressure equalization test was 0.3 based on the study done by Mathew et al.[46] For a population agreement of 0, power of 80% and 5% level of significance, the sample size calculated from the above formula was 84 ears.

100 ears of adults undergoing rigid nasal endoscopy (RNE) for various indications, in the ENT outpatient department, who satisfy the following criteria, were included in the study.

Inclusion criteria:-

1) absence of ear symptoms
2) normal otoscopy findings
3) pure tone audiogram thresholds lesser than 20dB HL
4) ‘A’ type curve on tympanometry

Exclusion criteria:-

1) Gross deviated nasal septum
2) Gross nasal polyposis
3) Nasopharyngeal pathology (adenoid hypertrophy, nasopharyngeal tumours etc.)
4) Evidence of middle ear disease on otoscopy or tympanometry
5) Very ill or debilitated individuals

Subjects who satisfied the above criteria were then subjected to the reference test (Eustachian tube swallow test) and the index test (Digital slow motion video endoscopy) as described below:

Reference Test:

<u>The Eustachian Tube Swallow Test (ETST)</u>

A baseline tympanogram (T1), using the GSI Tympstar middle ear analyzer was obtained from the subject while seated in an upright position after being cautioned to avoid extraneous jaw movements, throat clearing, or swallowing while the probe tip is in place. The external auditory canal (EAC) air pressure is then increased to +400 mm of H_2O and the subject is instructed to take three hard swallows of water, after which a second tympanogram (T2) was recorded. Canal pressure is returned to 0 mm of H_2O and the subject swallows, thereby returning middle ear pressure to the baseline condition. Finally, pressure in the ear canal was decreased to – 400 mm of H_2O, the subject again swallowed thrice, and a third tympanogram (T3) was traced.

Positive external auditory canal pressure produces a mean shift of the tympanometric peak in the negative direction, while negative canal pressure causes the tympanometric peak to shift in the positive direction. A reverse shift may also be encountered and was considered a normal variant.

Similarly the shift in peak amplitude, or function change (FC) was also used for quantification of eustachian tube function. As suggested by Seidemann and Givens,[28] FC data are reported in percent according to the following equation:

$$\% \text{ FC} = \frac{\text{FD2} - \text{FD1}}{\text{FD1}} \times 100$$

FD1 represents the difference between peak amplitude and the +200 mm point on the baseline tympanogram. FD2 is the difference in amplitude between peak pressure and +200 mm in the positive canal pressure or negative canal pressure conditions.

Six different criteria used by Schuchman et al[30] were used in this study to interpret the results of the eustachian tube swallow test and for comparison with the digital slow motion video endoscopy grading of eustachian tubes. These criteria were as follows:

1) Pressure change of ≥5 dPa in the positive or negative EAC pressure situation
2) Pressure change of ≥5 dPa in the positive and negative EAC pressure situation
3) Pressure change of ≥15 dPa in the positive or negative EAC pressure situation
4) Pressure change of ≥15 dPa in the positive and negative EAC pressure situation
5) Functional change of ≥ 5% in the positive or negative EAC pressure situation
6) Functional change of ≥ 5% in the positive and negative EAC pressure situation

Index test:

Digital Slow motion Video Endoscopy (DSVE)

All subjects were examined in the outpatient setting. A cottonoid soaked in 4% lignocaine was placed along the floor of the nasal cavity for 5 minutes for local anaesthesia. The endoscope used was a rigid Hopkins rod 4 mm in diameter, angled 45° (Karl Storz). Endoscopes were fitted with a Serwell video camera head and processor. An Olympus CLK 4 halogen light source was used for the endoscope. The image processor was connected to and images viewed on a Benq 17 inch colour LCD video monitor. The images were recorded digitally in a computer using the software Imimo Version 7 (Avanttec). The images were analyzed by POWER DVD software (Cyberlink Corp) on a 17 inch colour monitor in real time, slow motion and frame by frame for assessing eustachian tube dynamics.

Once anesthetized, a nasal endoscope was introduced along the floor of the nasal cavity with the 45° viewing angle facing superiorly and advanced just beyond the posterior end of inferior turbinate and rotated laterally to face the nasopharyngeal orifice of the eustachian tube. The scope was then positioned as close as possible to the nasopharyngeal orifice of the eustachian tube, avoiding contact with the mucosa and angled to view as far down the lumen of the tube as possible.

The pharyngeal orifice of the eustachian tube was assessed for mucosal congestion, edema, discharge, and polyps at the mouth of the eustachian tube. The subjects were asked to do several swallows to induce normal physiologic tubal dilatations. They were then asked to perform forced yawning to cause sustained tubal dilatation. The movements of medial cartilaginous lamina, lateral excursion, and dilatory wave of the lateral pharyngeal wall and tubal lumen opening were inspected. The process was repeated for the opposite eustachian tube through the contralateral naris. The video recordings of tubal dilatations were viewed in normal time, slow motion, and frame by frame 3 independent observers who were blinded to the results of the eustachian tube swallow test. The eustachian tube function was graded as follows –

Grade 0 – normal eustachian tube with no mucosal oedema or congestion. Medial cartilaginous lamina and lateral wall movements are normal. Tubal lumen opens well on swallowing.

Grade 1 – oedema and congestion of mucosa limited to the pharyngeal orifice of eustachian tube. Normal lateral wall motion and tubal lumen opens with swallowing

Grade 2A – Reduced lateral wall motion secondary to oedema and congestion involving lumen. Tubal lumen opens partly with swallowing

Grade 2B – Reduced lateral wall motion secondary to abnormal tubal muscle contraction. Tubal lumen opens partly with swallowing

Grade 3A – Tubal lumen fails to open with swallowing secondary to gross oedema

Grade 3B – Tubal lumen fails to open with swallowing secondary to abnormal tubal muscle contraction.

Patulous (P) – Noticeable concavity in the superior portion of the lateral wall of the lumen, with persistent patency of the lumen, extending towards the isthmus, with medial and lateral cartilaginous walls remaining separate even at rest.

In the interpretation of Digital slow motion video endoscopy for comparison with eustachian tube swallow tests, the grade given by 2 out of 3 observers was taken. In the event of all 3 observers giving 3 different grades, the grade assigned by the most senior observer was considered.

RESULTS

100 eustachian tubes in 54 subjects were included in the study (Table 1). In 8 subjects only one eustachian tube was included in the study due to selection criteria, while both eustachian tubes were included in the remaining 46 individuals.

Table 1: Clinical profile of eustachian tubes

Parameter	Groups	Frequency	Percentage
Age	≤ 25 years	27	27
	26-40 years	59	59
	> 40 years	14	14
	Total	100	100
Sex	Males	65	65
	Females	35	35
	Total	100	100
Indication for RNE	Allergic rhinitis	58	58
	Chronic sinusitis	5	5
	Headache	20	20
	Epistaxis	5	5
	Polyps	1	1
	Others	11	11
	Total	100	100
Side	Right	49	49
	Left	51	51
	Total	100	100
Bilateral/ Unilateral	Bilateral	46	85.2
	Unilateral	8	14.8
	Total subjects	54	100

The age range was from 18 years to 62 years with a mean age of 31.24 and a standard deviation of 9.36. Of the 100 eustachian tubes, 65 tubes were of male subjects while 35 were of female subjects. 49 were right side tubes and 51 were left side tubes. The indication for rigid nasal endoscopy in 58 eustachian tubes was allergic rhinitis, the other common indications being evaluation for head ache, chronic sinusitis, epistaxis etc.

Table 2: Tympanometric profile on William's test.

Parameters	**Minimum**	**Maximum**	**Mean**	**SD**
Age	18	62	31.24	9.357
Baseline Middle ear Pressure	-100	35	-0.90	21.758
Middle ear pressure in +ve EAC pressure	-100	45	-8.25	21.572
Pressure change with +ve EAC pressure	0	55	10.95	12.179
Middle ear pressure in -ve EAC pressure	-105	95	16.30	35.181
Pressure change with -ve EAC pressure	0	115	22.70	23.066
Baseline Middle ear Volume	0.1	5.9	1.063	0.9511
Middle ear volume in +ve EAC pressure	0.2	5.9	1.145	0.9747
Volume change with +ve EAC pressure	0	0.7	0.104	0.1399
Middle ear volume in -ve EAC pressure	0.2	5.9	1.193	0.9810
Volume change with -ve EAC pressure	0	1.3	0.150	0.1624
Functional Change% in +ve EAC pressure	0	100	12.716	15.706
Functional Change% in -ve EAC pressure	0	100	18.101	15.398

Table 2 describes the profile on performance of the William's test on the 100 eustachian tubes. The mean base line pressure was – 0.9 dPa, while the mean baseline middle ear volume was 1.063 ml. The mean pressure in the positive external auditory canal (EAC) pressure situation was -8.25 dPa, the mean absolute change in pressure from the base line being 10.95 dPa. The mean middle ear volume in the same situation was 1.145ml with a mean change in volume of 0.104 ml. Similarly, in the situation of negative EAC pressure, the mean pressure was 16.3 dPa, the mean absolute change in pressure being 22.7 dPa. The mean middle ear volume in this setting was 1.193 ml, the mean change being 0.15 ml. The mean functional change in the positive EAC pressure situation was 12.72% while that in the negative pressure situation was 18.1%.

Various criteria have been used to diagnose eustachian tube dysfunction using the William's test. The following criteria were used in this study to classify the eustachian tube as functional or dysfunctional.

1) Pressure change of ≥5 dPa in the positive or negative EAC pressure situation
2) Pressure change of ≥5 dPa in the positive and negative EAC pressure situation
3) Pressure change of ≥15 dPa in the positive or negative EAC pressure situation
4) Pressure change of ≥15 dPa in the positive and negative EAC pressure situation
5) Functional change of ≥ 5% in the positive or negative EAC pressure situation
6) Functional change of ≥ 5% in the positive and negative EAC pressure situation

The percentage of eustachian tubes that were classified as functional and dysfunctional based on each of these criteria is shown in Table 3.

Table 3: Percentage of functional and dysfunctional tubes based on various tympanometric criteria on William's test.

Criteria	Dysfunctional (%)	Functional (%)
1 (Pr change ≥5mm in +ve or –ve)	1	99
2 (Pr change ≥5mm in +ve and –ve)	30	70
3 (Pr change ≥15mm in +ve or –ve)	41	59
4 (Pr change ≥15mm in +ve and –ve)	72	28
5 (FC% ≥5% in +ve or –ve)	16	84
6 (FC% ≥5% in +ve and –ve)	44	56

It can be seen that the percentage of eustachian tubes that pass the test based on the various criteria steadily decreases as the criteria becomes more stringent from 99% in criteria I to 28% in criteria IV.

Table 4: DSVE grade profile

DSVE Grade	Frequency	Percentage
Grade 0	24	24
Grade 1	30	30
Grade 2a	10	10
Grade 2b	13	13
Grade 3a	7	7
Grade 3b	7	7
Patulous	9	9

The profile of eustachian tube grading based on Digital slow motion video endoscopic assessment of the eustachian tube showed that 24% tubes were normal both structurally and functionally. 30% of the tubes opened fully with swallowing but were oedematous. 23% of the tubes opened partially while 14% failed to open with swallowing. 9% of the tubes were patulous.

Among the eustachian tubes that opened partially or failed to open, 5 tubes were found to have a floppy medial cartilaginous lamina which seemed to contribute to the partial opening or failure to open with swallowing. 3 of these 5 tubes opened partially with swallowing and were graded as 2a while 2 failed to open with swallowing and were graded as 3a.

The results of dynamic assessment of the eustachian tube function based on various criteria on William's test were then correlated with the grading of eustachian tube function based on digital slow motion video endoscopy.

Table 5: Correlation between Tympanometric grade and DSVE grading (Chi Square/ Fisher's exact test), for the various tympanometric criteria

Key

Tymp Grade: Tympanometric Grade

0 – Dysfunctional

1 – Functional

Table 5: Correlation between Tympanometric grade and DSVE grading

Tympanometric Criteria	Tymp Grade	DSVE Grading 0	1	2a	2b	3a	3b	P	p Value
1	0	0 0%	1 3.3%	0 0%	0 0%	0 0%	0 0%	0 0%	1.000
	1	24 100.0%	29 96.7%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	
	Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	
2	0	10 41.7%	10 33.3%	0 0%	2 15.4%	1 14.3%	3 42.9%	4 44.4%	0.112
	1	14 58.3%	20 66.7%	10 100.0%	11 84.6%	6 85.7%	4 57.1%	5 55.6%	
	Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	
3	0	11 45.8%	17 56.7%	0 0%	3 23.1%	4 57.1%	5 71.4%	1 11.1%	0.002
	1	13 54.2%	13 43.3%	10 100.0%	10 76.9%	3 42.9%	2 28.6%	8 88.9%	
	Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	
4	0	18 75.0%	25 83.3%	3 30.0%	9 69.2%	6 85.7%	6 85.7%	5 55.6%	0.048
	1	6 25.0%	5 16.7%	7 70.0%	4 30.8%	1 14.3%	1 14.3%	4 44.4%	
	Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	
5	0	4 16.7%	4 13.3%	1 10.0%	2 15.4%	0 0%	3 42.9%	2 22.2%	0.521
	1	20 83.3%	26 86.7%	9 90.0%	11 84.6%	7 100%	4 57.1%	7 77.8%	
	Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	
6	0	11 45.0%	12 40.0%	4 40.0%	6 46.2%	2 28.6%	5 71.4%	4 44.4%	0.819
	1	13 54.2%	18 60.0%	6 60.0%	7 53.8%	5 71.4%	2 28.6%	5 55.6%	
	Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	

Statistically significant correlation was seen between William's test and the digital slow motion video endoscopy results when criteria 3 and criteria 4 were used to assess the eustachian tube on William's test. The P values were 0.002 and 0.048 respectively. There was no significant correlation between the two tests when other tympanometric criteria were used.

Table 6: Age, sex and side related correlation with DSVE Grade

Parameter	Group	DSVE							p value
		0	**1**	**2a**	**2b**	**3a**	**3b**	**P**	
Age	≤ 25 yrs	8 33.3%	8 26.7%	1 10.0%	4 30.8%	2 28.6%	2 28.6%	2 22.2%	0.930
	26-40 yrs	14 58.3%	18 60.0%	6 60.0%	8 61.5%	3 42.9%	4 57.1%	6 66.7%	
	> 40 yrs	2 8.3%	4 13.3%	3 30.0%	1 7.7%	2 28.6%	1 14.3%	1 11.1%	
	Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	
Sex	Male	10 41.7%	21 70.0%	9 90.0%	9 69.2%	6 85.7%	5 71.4%	5 55.6%	0.108
	Female	14 58.3%	9 30.0%	1 10.0%	4 30.8%	1 14.3%	2 28.6%	4 44.4%	
	Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	
Side	Right	14 58.3%	13 43.3%	6 60.0%	7 53.8%	1 14.3%	3 42.9%	5 55.6%	0.501
	Left	10 41.7%	17 56.7%	4 40.0%	6 46.2%	6 85.7%	4 57.1%	4 44.4%	
	Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	

As seen in Table 6, when correlated with age, sex and side of the eustachian tube, DSVE showed no significant correlation. The p values obtained were 0.930, 0.108 and 0.501.

The indication for which rigid nasal endoscopy (RNE) was performed for each of the subjects was categorised into 2 groups. Those with allergic rhinitis or infective pathology were grouped together while the others that included epistaxis, evaluation of headache etc were considered together. A chi square/ Fisher's exact test was performed to look for any correlation between the indication for nasal endoscopy and the DSVE grading.

Table 7: Correlation between DSVE grading and Indication for rigid nasal endoscopy

Indication for RNE	**DSVE grade**							**P value**
	0	**1**	**2a**	**2b**	**3a**	**3b**	**P**	
Allergic/infective pathology	17 70.8%	16 53.3%	8 80.0%	10 76.9%	4 57.1%	5 71.4%	4 44.4%	0.469
Others	7 29.2%	14 46.7%	2 20.0%	3 23.1%	3 42.9%	2 28.6%	5 55.6%	
Total	24 100.0%	30 100.0%	10 100.0%	13 100.0%	7 100.0%	7 100.0%	9 100.0%	

There was no significant correlation between the indication for nasal endoscopy and the endoscopic grading of the eustachian tube. The p value obtained was 0.469.

Further analysis was done to ascertain if the presence of oedema or congestion of the eustachian tube correlated with the indication for nasal endoscopy. The eustachian tubes with oedema or congestion were grouped together (i.e. Grade 1, 2a and 3a), and compared with those with no oedema or congestion (i.e. Grade 0, 2b, 3b and P).

Table 8: Correlation between the indication for RNE and the presence or absence of oedema or congestion of the eustachian tube.

Indication for RNE	**Eustachian tube status**			**p value**
	Oedematous	**Non Oedematous**	**Total**	
Allergic/infective pathology	28 59.6%	36 67.9%	64 64%	0.385
Others	19 40.4%	17 32.1%	36 36%	
Total	47 100%	53 100%	100 100%	

As seen in Table 8, there was no significant difference in the occurrence of eustachian tube oedema or congestion between those with allergic or infective pathology and those with non allergic and non-infective nasal pathology.

The Grading on DSVE was then regrouped into 3 functional grades as follows:

Modified Grade 1 = DSVE grade 0, 1 and P

Modified Grade 2 = DSVE grade 2a and 2b

Modified Grade 3 = DSVE grade 3a and 3b

Modified Grade 1 therefore includes all eustachian tubes that open fully, Grade 2 includes all partially opening eustachian tubes and Grade 3 includes all eustachian tubes that failed to open. Results of video endoscopy using this modified grading were then correlated with the results on tympanometry using the various tympanometric criteria as described above.

Table 9: Correlation between Tympanometric grade and Modified DSVE grading (Chi Square/ Fisher's exact test)

Tympanometric grade:

0 – Dysfunctional 1 - Functional

Table 9: Correlation between Tympanometric grade and Modified DSVE grading

Tympanometric Criteria	Tympanometric grade	Modified grade 1	Modified grade 2	Modified grade 3	p value
1	0	1 1.6%	0 0%	0 0%	1.000
	1	62 98.4%	23 100.0%	14 100.0%	
	Total	63 100.0%	23 100.0%	14 100.0%	
2	0	24 38.1%	2 8.7%	4 28.6%	0.009
	1	39 61.9%	21 91.3%	10 71.4%	
	Total	63 100.0%	23 100.0%	14 100.0%	
3	0	29 46.0%	3 13.0%	9 64.3%	0.001
	1	34 54.0%	20 87.0%	5 35.7%	
	Total	63 100.0%	23 100.0%	14 100.0%	
4	0	48 76.2%	12 52.2%	12 85.7%	0.102
	1	15 23.8%	11 47.8%	2 14.3%	
	Total	63 100.0%	23 100.0%	14 100.0%	
5	0	10 15.9%	3 13.0%	3 21.4%	.527
	1	53 84.1%	20 87.0%	11 78.6%	
	Total	63 100.0%	23 100.0%	14 100.0%	
6	0	27 42.9%	10 43.5%	7 50.0%	1.000
	1	36 57.1%	13 56.5%	7 50.0%	
	Total	63 100.0%	23 100.0%	14 100.0%	

The Chi square or Fisher's exact test was performed and it was found that there was a statistically significant correlation between the modified video endoscopy grading and the eustachian tube swallow test results when criteria 2 and 3 were used. The P values were 0.009 and 0.001 respectively. The P values when other criteria were used were > 0.05.

Tympanometric parameters namely pressure change, volume gain and functional change in both the positive and negative external auditory canal pressure situations were then compared with the modified video endoscopy grading to look for any significant correlation.

Table 10: Correlation between tympanometric parameters and modified DSVE grading.

Parameter	Mod Grade	Mean	SD	p value
Pressure Change in +ve EAC pressure	1	8.97	10.278	0.015
	2	17.38	15.702	
	3	10.91	12.413	
Pressure Change in -ve EAC pressure	1	20.37	23.552	0.005
	2	31.43	17.113	
	3	20.45	27.609	
Volume gain in +ve EAC pressure	1	0.113	0.1535	0.694
	2	0.095	0.1203	
	3	0.064	0.0674	
Volume gain in -ve EAC pressure	1	0.166	0.1882	0.257
	2	0.129	0.0845	
	3	0.091	0.0539	
Functional Change in +ve EAC pressure	1	13.890	17.300	0.727
	2	9.881	10.788	
	3	10.868	13.194	
Functional Change in -ve EAC pressure	1	19.298	16.986	0.550
	2	16.481	10.847	
	3	13.794	11.964	

It was found that there was a statistically significant correlation between the mean pressure change (in both the positive and negative canal pressure situations) and the modified video endoscopy grading, the p values obtained being 0.015 and 0.005 respectively. However there was no significant correlation between the volume gain or the functional change and the video endoscopy grading. On further analysis, the mean pressure change was more in the partially obstructed tubes compared to the fully obstructed and the fully patent tubes.

DISCUSSION

Eustachian tube dysfunction is well known to play a key role in the etiopathogenesis of various diseases of the middle ear including acute suppurative otitis media, chronic suppurative otitis media both atticoantral disease and tubotympanic disease, otitis media with effusion and middle ear atelectasis[1]. Eustachian tube status is also an important prognostic indicator in the management of chronic suppurative otitis media and middle ear atelectasis[1]. The assessment of eustachian tube function although difficult, is well known to be vital in otological practice.

In the search for an ideal tool for the assessment of eustachian tube function, various diagnostic tests have been devised to assess the anatomic and functional patency of the eustachian tube either directly or indirectly. Tests that measure functional patency assess pressure regulation, mucociliary clearance or protective function of the eustachian tube. Of these, the pressure regulatory function is of prime importance. While each of the tests of eustachian tube function has its own merits and demerits, most tests are not used in routine clinical practice for various reasons such as the unavailability of equipment and expense of tests like sonotubometry, MRI and CT scan. Moreover, a gold standard test for the assessment of eustachian tube function is yet to be devised.

Digital slow motion video-endoscopy of the eustachian tube is a recently described method of dynamic assessment of eustachian tube function. It is simple to perform and can be done along with a diagnostic nasal endoscopy in the outpatient setting. Poe et al[42] were the first to devise this modality of eustachian tube assessment. They described in detail the pattern of normal eustachian tube movement on slow motion video endoscopy. After further studies on patients with middle ear disease, Poe et al[43] described abnormalities of the eustachian tube as assessed by slow motion video endoscopy. Mathew et al[46] devised a grading system for the eustachian tube on slow motion endoscopy and showed a higher prevalence of dysfunctional tubes in those with middle ear disease in comparison to those with normal middle ears. DSVE has been recommended as a new tool to identify structural abnormalities and to assess the functional status of the eustachian tube.

This study aimed to assess the profile of eustachian tube function using DSVE in those with normal middle ears and to assess the efficacy of this test by comparing it with yet another modality of dynamic assessment namely, the Eustachian Tube Swallow Test or William's test. The study was carried out in patients with nasal pathology requiring diagnostic nasal endoscopy as a part of their evaluation. Considering ethical factors, nasal endoscopies on normal individuals for the study was not considered.

While analysing the results of the eustachian tube swallow test, various criteria described by Schuchman et al[30] in their study on divers were applied. The various criteria used were as follows –

1) Pressure change of $\geq$5 dPa in the positive or negative EAC pressure situation
2) Pressure change of $\geq$5 dPa in the positive and negative EAC pressure situation
3) Pressure change of $\geq$15 dPa in the positive or negative EAC pressure situation

4) Pressure change of ≥15 dPa in the positive and negative EAC pressure situation
5) Functional change of ≥ 5% in the positive or negative EAC pressure situation
6) Functional change of ≥ 5% in the positive and negative EAC pressure situation

The eustachian tubes were classified as functional or dysfunctional based on each of the above criteria. The results thus obtained were comparable to the results obtained by Schuchman et al[30]. The percentage of functional tubes obtained in their study using criteria 1 to 6 as described above were 82.26%, 66.13%, 55.65%, 21.77%, 87.90% and 57.25% respectively. In this study the percentage of functional tubes obtained was 99%, 70%, 59%, 28%, 84% and 56% respectively for criteria labelled 1 to 6 (Table 3).

On the eustachian tube swallow test, when the tympanometric criteria of ≥5dPa pressure change in the positive or negative external auditory canal pressure situation is used to classify the eustachian tube as functional or dysfunctional, it is seen that 99% of the tubes pass the test (Table 3). As all the middle ears included in this study were normal both otoscopically and on the basis of the audiogram and tympanogram, it may be assumed that a pressure change of ≥5dPa on the Williams test is adequate to consider the eustachian tube as functional for hearing and middle ear aeration.

On video-endoscopy, 24% tubes were found to be completely normal with no evidence of any structural or functional abnormality and were hence graded as 0 (Table 4). In the grading system proposed by Mathew et al[46], Grade 0, 1 and P comprised of tubes where the tubal lumen opened fully during swallowing. Grade 1 consisted of oedematous tubes while grade P referred to patulous tubes. When considering only the functional status and ignoring structural abnormalities such as oedema or patulous tubes (i.e. considering grade 0, 1 and P together), 63% of the tubes were found to open fully on video endoscopic assessment.

Grade 2 referred to eustachian tubes that opened partially on swallowing, where grade 2a referred to tubes that opened only partially due to oedema and grade 2b tubes were those that opened only partially due to a muscle dysfunction. 23% of the tubes in our study opened partially (grade 2a and 2b) on DSVE grading (Table 4). Considering fully opening and partially opening tubes together, it is seen that 86% of the tubes were functional thereby maintaining the homeostasis of the middle ear.

Grade 3 referred to tubes that failed to open on swallowing, 3a referring to failure to open secondary to oedema and 3b referring to failure to open due to muscle dysfunction. In spite of a normal audiogram and tympanometry 14% of the eustachian tubes in this study failed to open on swallowing (grade 3a and 3b) (Table 4). These apparently dysfunctional tubes probably equalize middle ear pressure by spontaneous opening, secondary to the development of a pressure differential across the two ends of the eustachian tube thereby maintaining the normalcy of the middle ear[20,21].

In the study done by Mathew et al[46], among the control group consisting of normal individuals, 61% of the tubes were normal structurally and functionally (Grade 0). 13% of the tubes were grade 1, 11% were grade 2 and 10% were grade 3. 5% patulous tubes were found among normal individuals. In this study, the percentage of tubes belonging to Grade 0, 1, 2 and 3 were 24%, 30%, 23% and 14% respectively

(Table 4). 9% of the tubes in our study were patulous. However, none of these individuals had any symptoms of a patulous eustachian tube.

A significant observation was the presence of a floppy medial cartilaginous lamina in 5 eustachian tubes, 3 of which opened partially on swallowing and 2 failed to open on swallowing. This floppy cartilaginous lamina appeared to contribute significantly to the dysfunctional status of the eustachian tube. The grading system proposed by Mathew et al[46] does not however include this factor in the criteria for eustachian tube assessment. The following modification of the grading system proposed by Mathew et al[46] may be considered in order to include eustachian tube dysfunction secondary to a floppy cartilaginous lamina.

Grade 0 – normal eustachian tube with no mucosal oedema or congestion. Medial cartilaginous lamina and lateral wall movements are normal. Tubal lumen opens well on swallowing.

Grade 1 – oedema and congestion of mucosa limited to the pharyngeal orifice of eustachian tube. Normal lateral wall motion and tubal lumen opens with swallowing

Grade 2A – Reduced lateral wall motion secondary to oedema and congestion involving lumen. Tubal lumen opens partly with swallowing

Grade 2B – Reduced lateral wall motion secondary to abnormal tubal muscle contraction. Tubal lumen opens partly with swallowing

Grade 2C – Floppy medial cartilaginous lamina. Tubal lumen opens partly with swallowing

Grade 3A – Tubal lumen fails to open with swallowing secondary to gross oedema

Grade 3B – Tubal lumen fails to open with swallowing secondary to abnormal tubal muscle contraction.

Grade 3C – Tubal lumen fails to open secondary to a floppy medial cartilaginous lamina.

Patulous (P) – Noticeable concavity in the superior portion of the lateral wall of the lumen, with persistent patency of the lumen, extending towards the isthmus, with medial and lateral cartilaginous walls remaining separate even at rest.

In the grading of eustachian tubes, grade 1, 2a and 3a referred to tubes that had features of oedema or congestion of the mucosa and opened fully, partially or did not open on swallowing respectively. Of the 100 eustachian tubes included in this study, 30% of the eustachian tubes were graded as Grade 1, 10% of the tubes were grade 2a and 7% of the tubes were grade 3a (Table 4). 47% of the eustachian tubes therefore showed evidence of oedema or congestion. 64% of the eustachian tubes were of subjects with allergic or infective nasal pathology which are known to predispose the eustachian tube to structural changes such as oedema or congestion. However, on statistical analysis there was no significant difference in the occurrence of oedema and congestion between those with allergic or infective nasal pathology and those with non-allergic, non-infective pathologies (Table 8). The presence of oedema and congestion of the eustachian tube in those with non-allergic, non-infective nasal pathologies may be due to factors such as gastro-oesophageal reflux disease[47] which is known to cause eustachian tube dysfunction. Assessment of these factors was not included in the present study.

The results of the tests of correlation showed statistically significant correlation between digital slow motion video endoscopy results and dynamic tympanometry when a pressure change of at least 15 dPa in the positive and/or negative canal pressure situation (i.e. criteria 3 and 4) is considered as the criteria for passing the test (Table 5). However there was no correlation between the DSVE grading and dynamic tympanometry when other criteria using 5 dPa pressure change (criteria 1 and 2) or functional change (criteria 5 and 6) were used. This requirement of a higher pressure change on dynamic tympanometry for correlation with DSVE may be due to the fact that DSVE assesses the structural and functional status of the eustachian tube, while dynamic tympanometry assesses only the functional status. An oedematous eustachian tube which opens partially on swallowing may be able to produce a pressure change of 5 dPa and therefore is classified as functional on dynamic tympanometry using the criteria of 5 dPa pressure change in the positive and / or negative EAC pressure situation. However on DSVE, such a tube is classified as partially functional. When the dynamic tympanometric criteria of at least 15 dPa pressure change is used these partially functional tubes are more likely to be classified as dysfunctional on tympanometry and therefore correlates better with DSVE grading.

There was statistically significant correlation between the mean pressure change in the positive and negative canal pressure situation and the modified video endoscopic grading (Table 10). Maximum pressure change however, was seen among the partially obstructed tubes, which is contrary to our understanding of eustachian tube function. Using the absolute value of pressure change instead of the various criteria on William's test therefore did not show a relevant correlation with video-endoscopy.

Mathew et al[46] in their study on digital slow motion video endoscopy showed a significantly higher incidence of eustachian tube dysfunction in those with middle ear disease when compared with normal individuals. While a partially functional eustachian tube can maintain middle ear pressure, digital slow motion video endoscopy has the advantage of revealing structural abnormalities like oedema of the eustachian tube, tubal muscle dysfunction etc. which can be treated and followed up to prevent the onset of middle ear disease. Tympanometry when done alone does not pick up such structural abnormalities. Thus, digital slow motion video endoscopy when performed in addition to dynamic tympanometry adds valuable information regarding the structural aspects of the eustachian tube.

The use of digital slow motion video endoscopy of the eustachian tube is recommended along with other tests such as tympanometry for the evaluation of all middle ear pathologies to obtain a better understanding of the structural and functional status of the eustachian tube. This study dealt with eustachian tubes of patients with normal middle ears. Studies to correlate dynamic tympanometry with digital slow motion video-endoscopy in patients with middle ear abnormality or barotrauma will further consolidate the correlation between the two tests.

CONCLUSIONS

Digital Slow motion Video-Endoscopy(DSVE) of the eustachian tube as a test of eustachian tube function, is a simple outpatient procedure that can be done while performing a diagnostic nasal endoscopy. DSVE showed significant correlation with the William's test (Eustachian tube swallow test) when a pressure change of at least 15mm is considered as the criteria for eustachian tube function in either the positive or negative canal pressure situation or in the positive and negative canal pressure situation. A 5dPa pressure change in the positive or negative canal pressure situation however seems adequate to maintain normal pressures in the middle ear.

In patients with normal middle ears who show normal eustachian tube function on tympanometry, DSVE identifies early structural abnormalities. While the eustachian tube swallow test assesses the functional status of the eustachian tube only, digital slow motion video endoscopy provides information about both the structural and functional status of the eustachian tube. Recognition of such abnormalities would aid in early diagnosis of eustachian tube dysfunction and in instituting appropriate treatment.

A modification of the grading system introduced by Mathew et al[46] has been proposed in order to include those eustachian tubes having a floppy medial cartilaginous lamina contributing to abnormal eustachian tube dynamics.

DSVE can be considered a potential tool in the armamentarium of the otologist and can be done while performing a diagnostic rigid nasal endoscopy. When used along with tympanometry, DSVE can provide vital information for the prevention and management of middle ear disease and for prediction of outcomes in ear surgery.

Further studies, to compare and correlate digital slow motion video endoscopy results with tympanometry in patients with abnormal types of curves on tympanometry are recommended to gain a better understanding of the efficacy of this test in the assessment of eustachian tube function.

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APPENDIX – A

INFORMED CONSENT

ASSESSMENT OF THE EFFICACY OF DIGITAL SLOW MOTION VIDEO ENDOSCOPY (DSVE) AS A TEST OF EUSTACHIAN TUBE FUNCTION

Information Sheet

The Eustachian tube is a communication between the ear and the air passage behind the nose. It is responsible for equalizing the air pressure between the air passage and that of the ear, thereby facilitating the normal functioning of the ear. Blockage of this tube can result in various types of ear diseases. People with problems related to the upper airway are more prone to have abnormal functioning of the Eustachian tube.

A new test has been devised to assess the functioning of the Eustachian tube which involves the use of an endoscope in the nose and obtaining video recording of the opening of this tube during rest, swallowing and yawning. The video recording is then analyzed to study the Eustachian tube. A study is being conducted in our hospital, in order to assess the usefulness of this new test. The study is being done on people with no ear problems, who are to undergo an endoscopy of the nose as part of the routine evaluation process for their problems.

Subjects who agree to participate in this study will undergo examination of their ears followed by an audiogram (a test of hearing) and tympanometry (a test of the status of the middle ear). The special test will be done as a part of the routine endoscopy when a video recording of the Eustachian tube opening will be made at rest, while swallowing and yawning.

The special procedure is not associated with any added risks or complications, apart from those normally associated with the endoscopy and you will not have to bear any additional cost.

The recordings will be stored for assessment by three different ENT surgeons and will be accessible to all those involved in the execution and monitoring of the present study. The recordings may also be used for further studies on the same subject at a later date. No recording will be made available to the subject, but the result of the test may be verbally informed to the subject at request.

If you are willing to participate in this study you will be required to sign in the following consent form.

Informed Consent form to participate in a clinical trial

ASSESSMENT OF THE EFFICACY OF DIGITAL SLOW MOTION VIDEO ENDOSCOPY (DSVE) AS A TEST OF EUSTACHIAN TUBE FUNCTION

Subject's Initials: __________ Subject's Name: _________

Date of Birth / Age:________

Please initial box

(Subject)

(i) I confirm that I have read and understood the information sheet dated __________ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_______________

Date: _____/_____/______

Signatory's Name: ___________________________________

Signature of the Investigator: _________________________

Date: _____/_____/______

Study Investigator's Name: ___________________________

Signature of the Witness: _____________________________

Date:_____/_____/_______

Name of the Witness: ________________________________

APPENDIX – B

PROFORMA

ASSESSMENT OF THE EFFICACY OF DIGITAL SLOW MOTION VIDEO ENDOSCOPY (DSVE) AS A TEST OF EUSTACHIAN TUBE FUNCTION

Name: Hospital No:
Age: Sex:
Address:

Phone No: email:
Indication for endoscopy:

	Right ear (S. No.)	Left ear (S. No.)
Otoscopy		
PTA		
Tympanometry		
ETST		

DSVE RESULTS: Right ear (S. No)

	Observer 1	Observer 2	Observer 3
ET function grade			
Anatomic abnormalities			
Other remarks			

DSVE RESULTS: Left ear (S. No)

	Observer 1	Observer 2	Observer 3
ET function grade			
Anatomic abnormalities			
Other remarks			

APPENDIX – C

DATA SHEET

APPENDIX – A

INFORMED CONSENT

ASSESSMENT OF THE EFFICACY OF DIGITAL SLOW MOTION VIDEO ENDOSCOPY (DSVE) AS A TEST OF EUSTACHIAN TUBE FUNCTION

Information Sheet

The Eustachian tube is a communication between the ear and the air passage behind the nose. It is responsible for equalizing the air pressure between the air passage and that of the ear, thereby facilitating the normal functioning of the ear. Blockage of this tube can result in various types of ear diseases. People with problems related to the upper airway are more prone to have abnormal functioning of the Eustachian tube.

A new test has been devised to assess the functioning of the Eustachian tube which involves the use of an endoscope in the nose and obtaining video recording of the opening of this tube during rest, swallowing and yawning. The video recording is then analyzed to study the Eustachian tube. A study is being conducted in our hospital, in order to assess the usefulness of this new test. The study is being done on people with no ear problems, who are to undergo an endoscopy of the nose as part of the routine evaluation process for their problems.

Subjects who agree to participate in this study will undergo examination of their ears followed by an audiogram (a test of hearing) and tympanometry (a test of the status of the middle ear). The special test will be done as a part of the routine endoscopy when a video recording of the Eustachian tube opening will be made at rest, while swallowing and yawning.

The special procedure is not associated with any added risks or complications, apart from those normally associated with the endoscopy and you will not have to bear any additional cost.

The recordings will be stored for assessment by three different ENT surgeons and will be accessible to all those involved in the execution and monitoring of the present study. The recordings may also be used for further studies on the same subject at a later date. No recording will be made available to the subject, but the result of the test may be verbally informed to the subject at request.

If you are willing to participate in this study you will be required to sign in the following consent form.

Informed Consent form to participate in a clinical trial

ASSESSMENT OF THE EFFICACY OF DIGITAL SLOW MOTION VIDEO ENDOSCOPY (DSVE) AS A TEST OF EUSTACHIAN TUBE FUNCTION

Subject's Initials: _________ Subject's Name: ________
Date of Birth / Age:_______
Please initial box
(Subject)
(i) I confirm that I have read and understood the information sheet dated _________ for the above study and have had the opportunity to ask questions. [ ]
(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]
(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]
(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]
(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____________
Date: _____/_____/______
Signatory's Name: ___________________________________

Signature of the Investigator: _________________________
Date: _____/_____/______
Study Investigator's Name: __________________________

Signature of the Witness: ____________________________
Date:_____/_____/_______
Name of the Witness: _______________________________

APPENDIX – B

PROFORMA

ASSESSMENT OF THE EFFICACY OF DIGITAL SLOW MOTION VIDEO ENDOSCOPY (DSVE) AS A TEST OF EUSTACHIAN TUBE FUNCTION

Name: Hospital No:
Age: Sex:
Address:

Phone No: email:
Indication for endoscopy:

	Right ear (S. No.)	Left ear (S. No.)
Otoscopy		
PTA		
Tympanometry		
ETST		

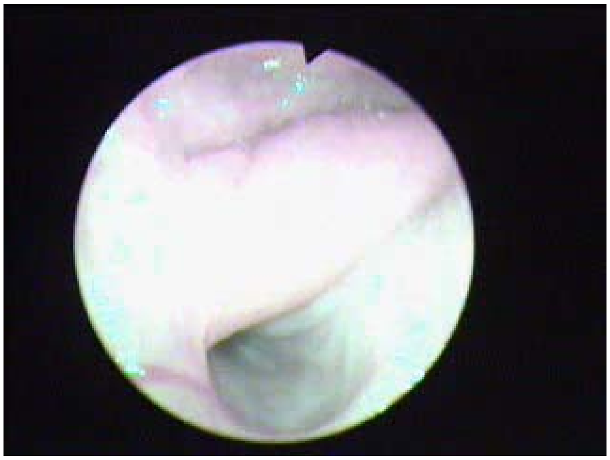
DSVE RESULTS: Right ear (S. No ______)

	Observer 1	Observer 2	Observer 3
ET function grade			
Anatomic abnormalities			
Other remarks			

DSVE RESULTS: Left ear (S. No ______)

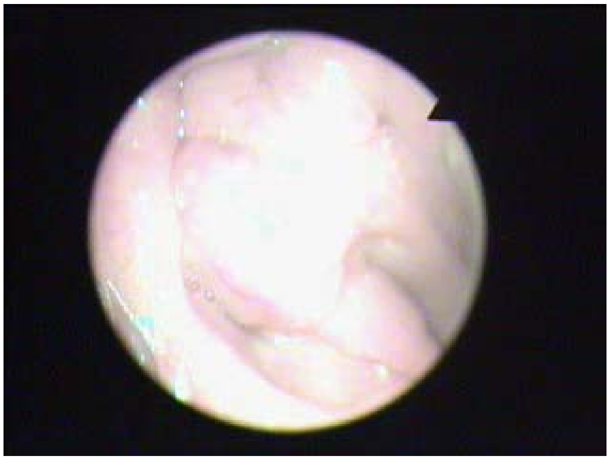
	Observer 1	Observer 2	Observer 3
ET function grade			
Anatomic abnormalities			
Other remarks			

Endoscopic Grading of the Eustachian Tube



Grade 0 – Normal right eustachian tube

Grade 1- Right eustachian tube with oedema but opening fully on swallowing



Grade 2a – Oedematous right eustachian tube opening partially on swallowing

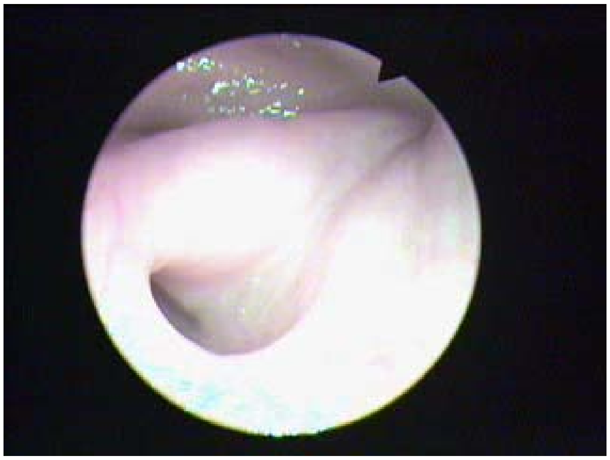
Endoscopic Grading of the Eustachian Tube

Grade 2b – Right eustachian tube opening partially, with a muscular ridge due to muscle dysfunction

Grade 3a – Oedematous right eustachian tube which fails to open on swallowing

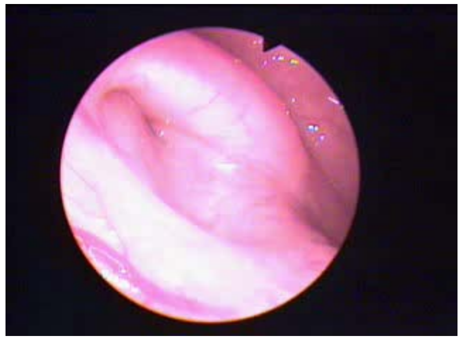
Endoscopic Grading of the Eustachian Tube

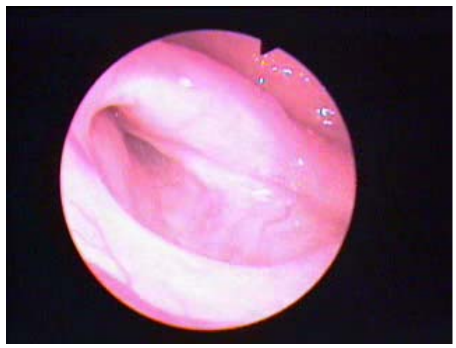
Grade 3b – Left eustachian tube that fails to open on swallowing with a muscular ridge due to muscle dysfunction

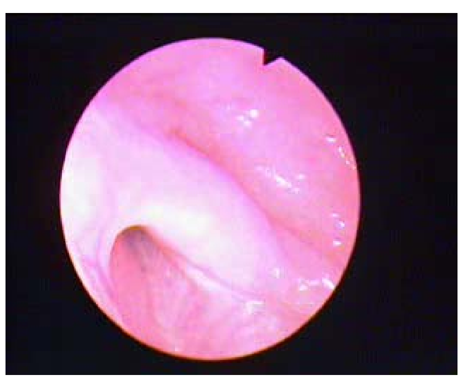


Patulous eustachian tube

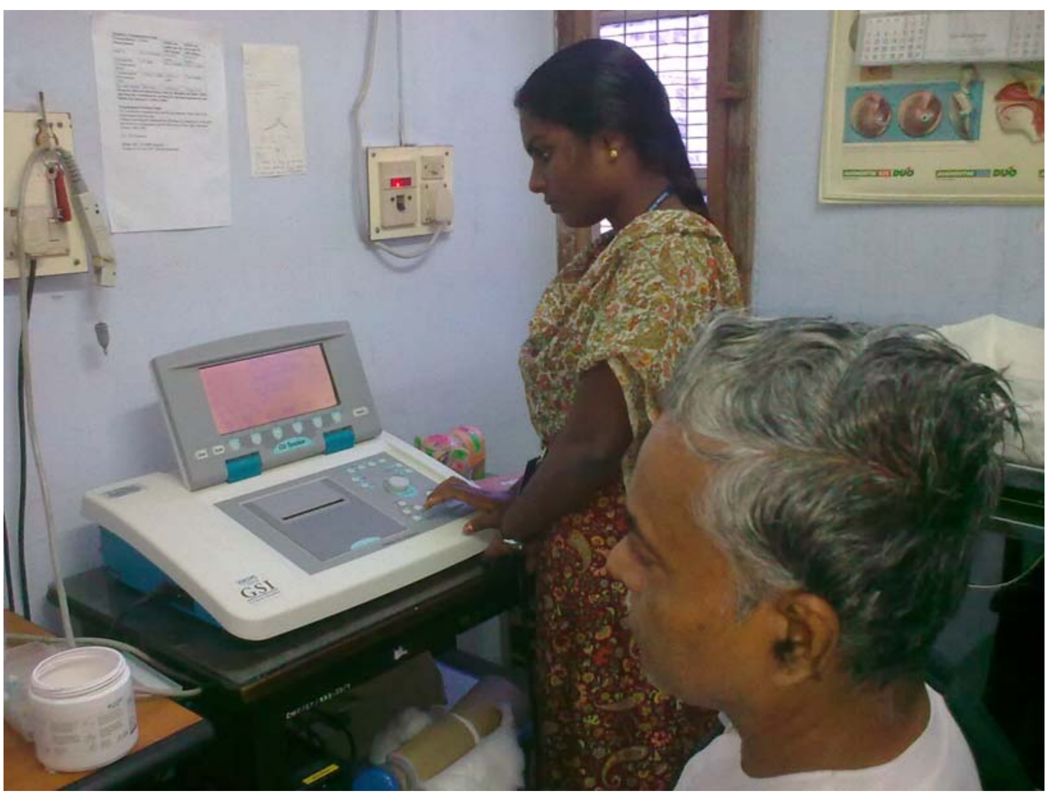
Eustachian Tube Opening Sequence

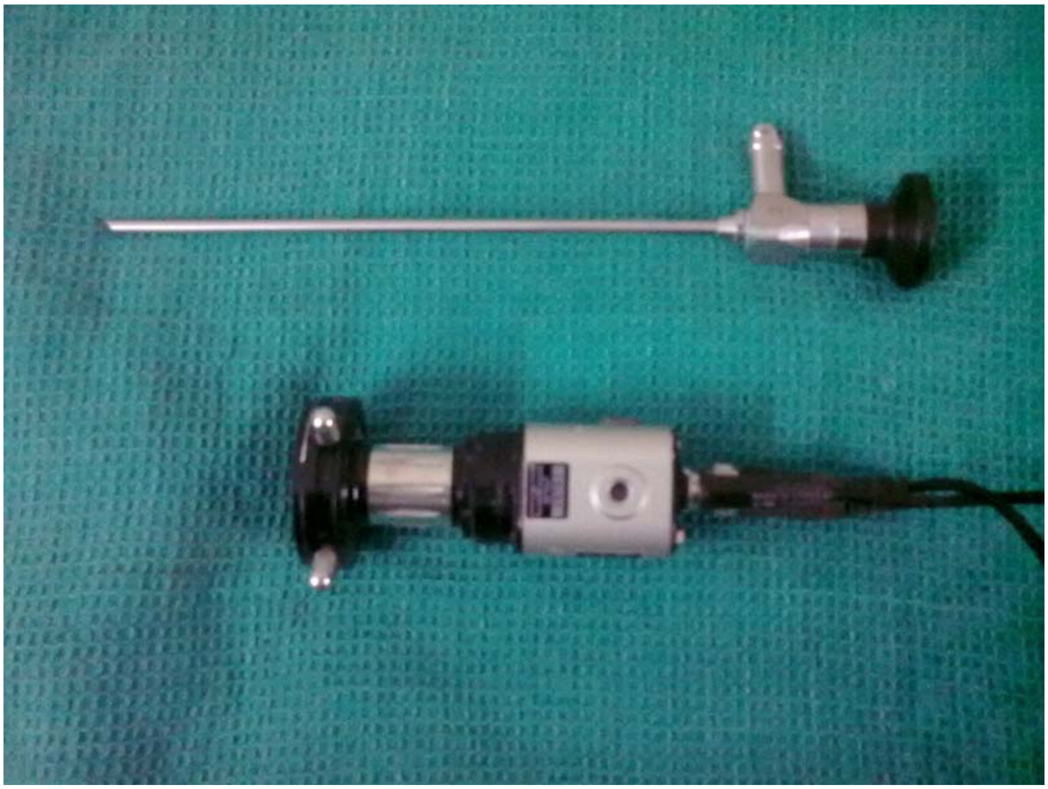






Eustachian Tube Swallow Test being performed on a patient





45° rigid nasal endoscope and Camera head used for the Video endoscopy of the eustachian tube

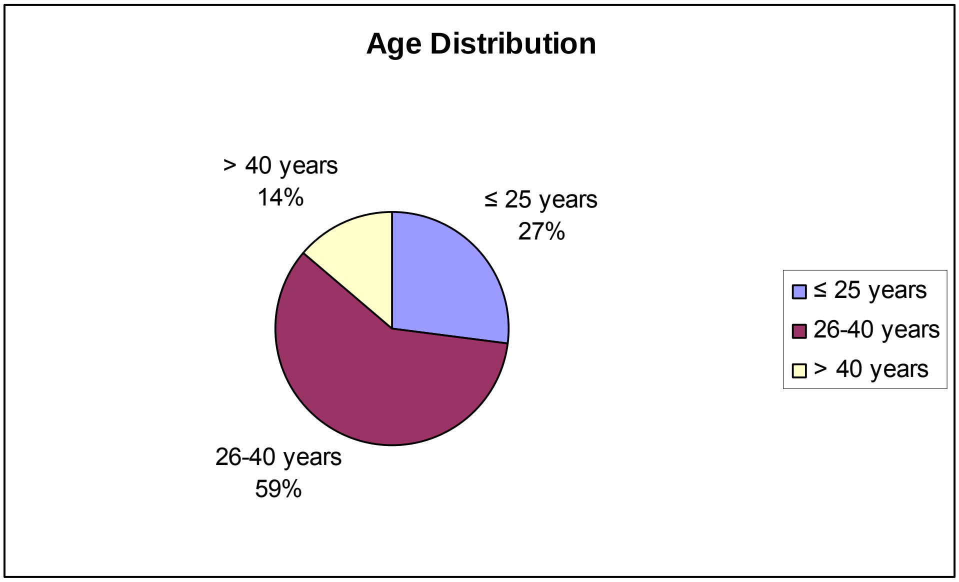


Figure 1: Pie chart showing the age distribution of the eustachian tubes included in the study

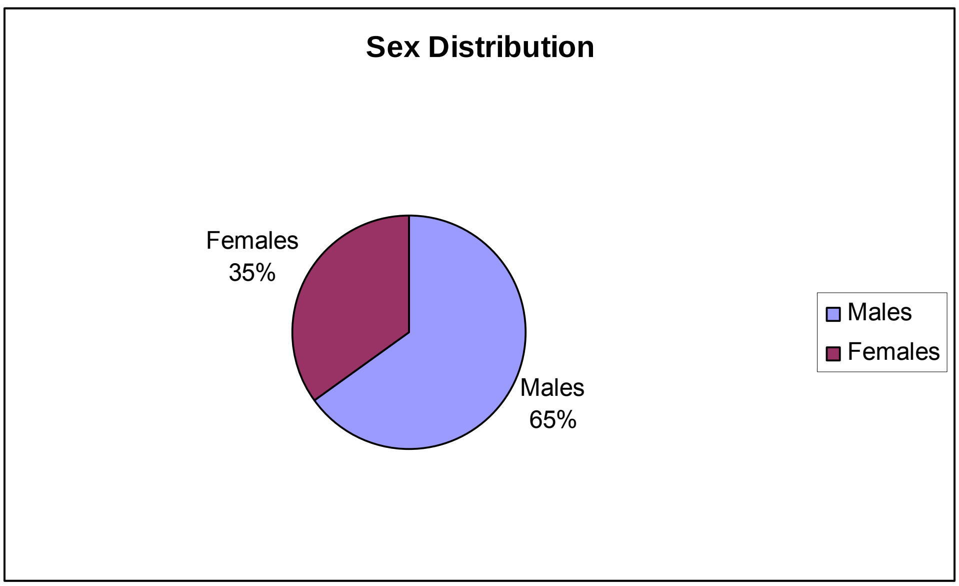


Figure 2: Pie chart showing the sex distribution of eustachian tubes included in the study

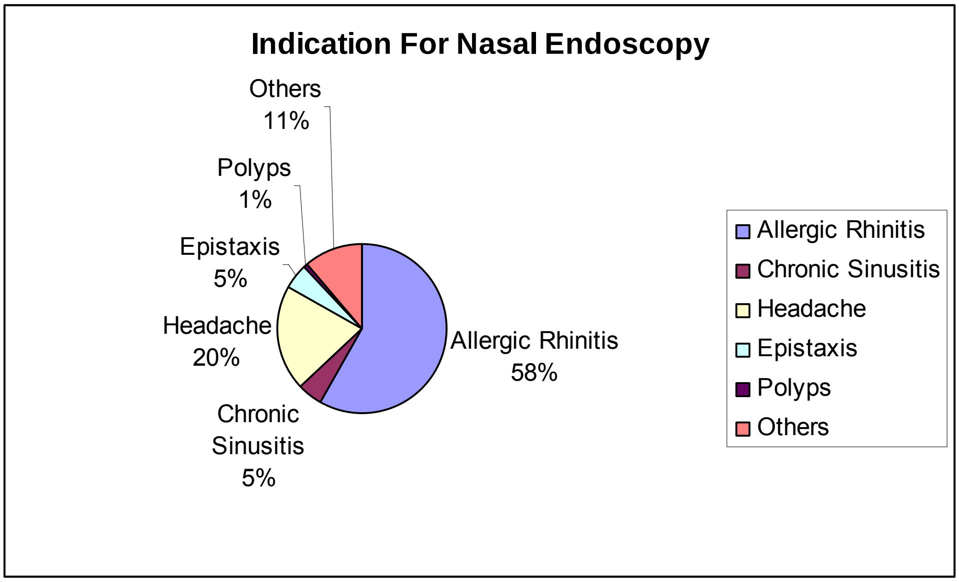


Figure 3: Pie chart showing the various indications for which rigid nasal endoscopy was performed for the eustachian tubes included in the study.

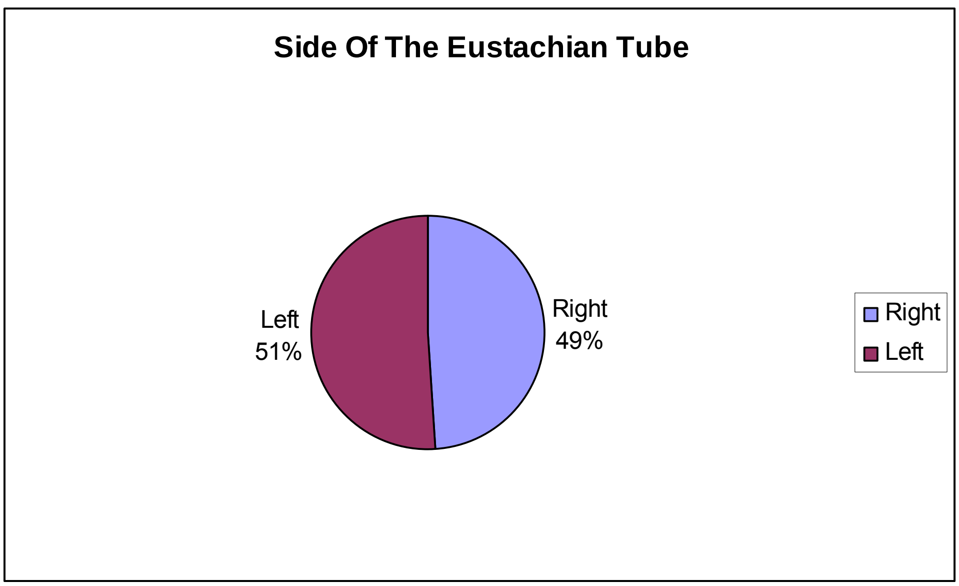


Figure 4: Pie chart showing the sex distribution of the eustachian tubes included in the study.

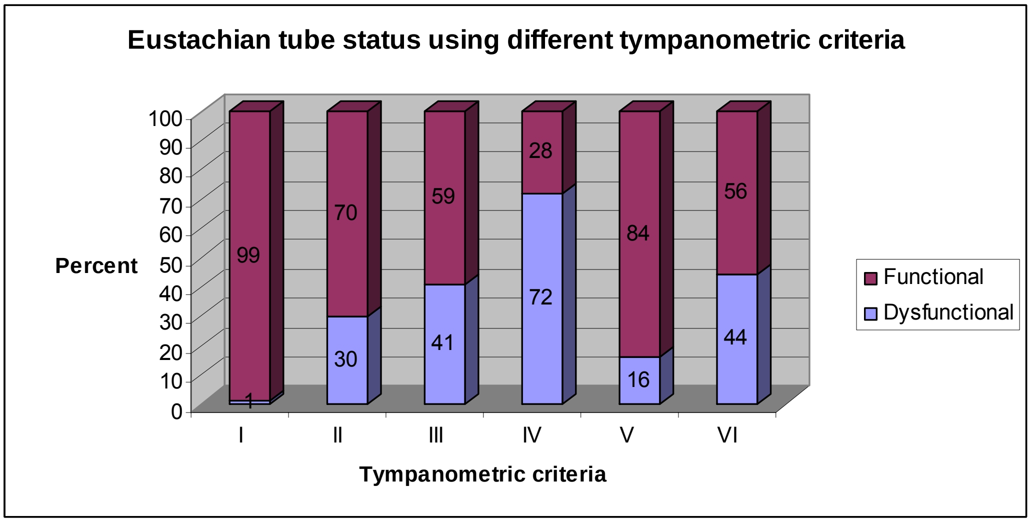


Figure 5: Bar diagram showing the percentage of tubes that were classified as functional or dysfunctional using different tympanometric criteria

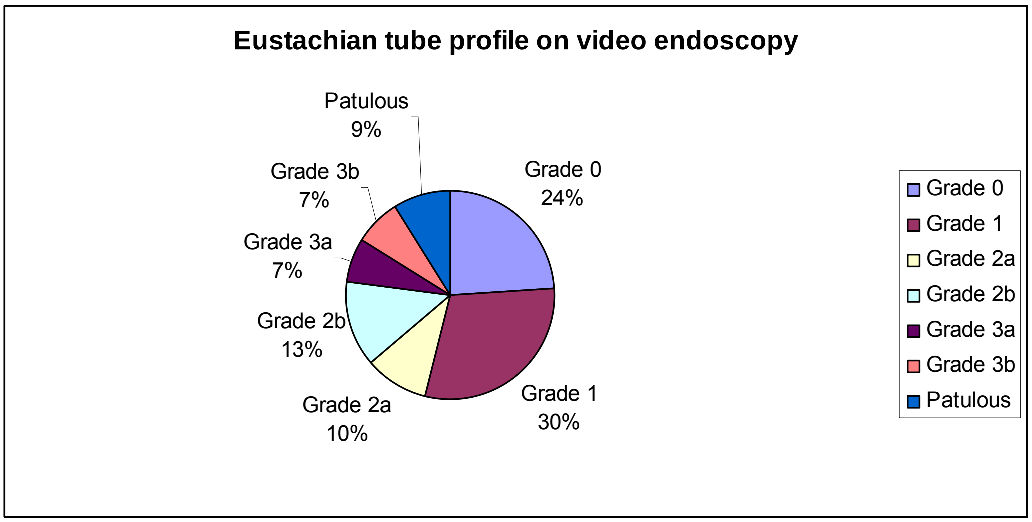
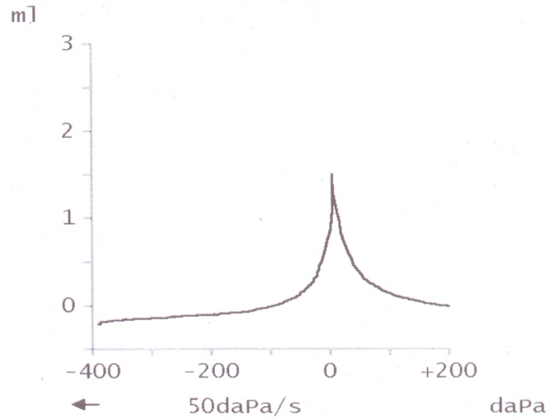


Figure 6: Pie chart showing the profile on DSVE grading of the 100 eustachian tubes included in the study.

ETF - INTACT TM TEST 13

Ytm 226 Hz L

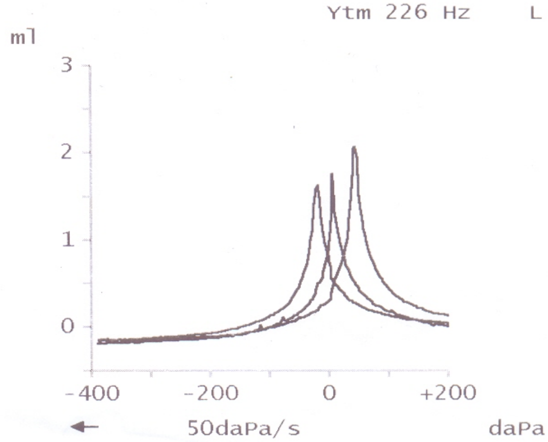


EARCANAL VOLUME: 1.2

	daPa	ml
TYMP 1:	5	1.5
TYMP 2:		
TYMP 3:		

ETF - INTACT TM TEST 14

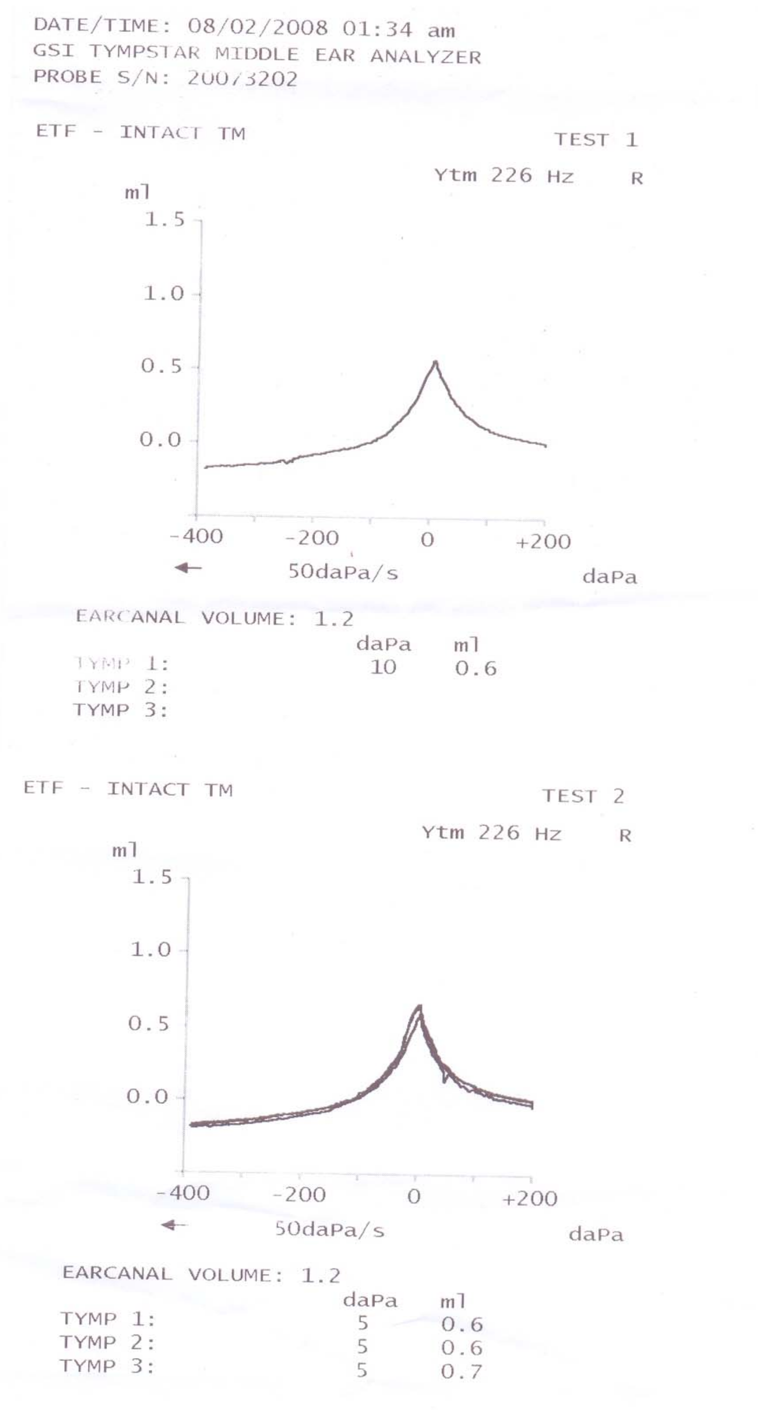
Ytm 226 Hz L



EARCANAL VOLUME: 1.0

	daPa	ml
TYMP 1:	5	1.8
TYMP 2:	-20	1.6
TYMP 3:	45	2.1

Eustachian Tube Swallow Test (William's Test) showing a functional eustachian tube



Eustachian Tube Swallow Test (William's Test) showing a dysfunctional eustachian tube