DISSERTATION

TITLE OF STUDY

CORRELATING THE SEVERITY OF CONDUCTIVE HEARING LOSS WITH THE SIZE AND SITE OF PARS TENSA TYMPANIC MEMBRANE PERFORATION USING VIDEO-OTOSCOPY.

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A dissertation submitted in part fulfilment of the requirement of the University of Nairobi, for the Award of the Degree of Masters in Medicine in ENT, Head and Neck Surgery 2012.

DECLARATION

This is my original work and has not been presented to the best of my knowledge for a degree in any other university.

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ACRONYMS AND ABBREVIATIONS

COM- Chronic otitis media.

dB - Decibel

dBHL - Decibel hearing level.

ENT - Ear, Nose and Throat.

Hz - Hertz

kHz - Kilohertz

KNH -Kenyatta National Hospital.

MBChB - Bachelor of Medicine and Bachelor of Surgery.

TM - Tympanic membrane

VO - Video otoscope

WHO - World health organization

CORRELATING THE SEVERITY OF CONDUCTIVE HEARING LOSS WITH THE SIZE AND SITE OF PARS TENSA TYMPANIC MEMBRANE PERFORATION USING VIDEO-OTOSCOPY.

ABSTRACT

Background: Pars tensa tympanic membrane perforations are associated with a varying degree of conductive hearing loss which is dependent on variables like size and site. In Kenya, use of video-otoscopy is limited thus the description of size and site of the perforations is subjective.

Objective: To determine the correlation of degree of conductive hearing loss with the size and site of the pars tensa tympanic membrane perforations using video-otoscopy at the Kenyatta National hospital.

Study Design: This was a prospective descriptive study.

Materials and methods: The study was carried out in the ENT department of the Kenyatta National Hospital from April 2011 to January 2012. Video otoscope 426/MP was used to take photographs of the perforations. Dino capture 2.0 version 1.3.2.was used to calculate the perforation area. Pure tone audiometry was carried out and results were analysed.

Data analysis: Data was tabulated into customized Microsoft Office Access 2007 database proformas. Stata V11.2.was used to carry out the analysis and included the ANOVA, Kruskwal-Wallis, Pearson's chi square and linear regression methods.

Results: A total of 80 ears were included with an equal sex distribution and a median age of 14.5 years. The commonest cause of perforation was chronic otitis media (84%). The overall mean percentage perforation size was 31.35%. Kruskwal-Wallis test: p=0.0001 demonstrated a significant correlation between site of perforation and hearing loss.Anteroinferior perforations had an average of 26dBHL and posteroinferior perforations had an average of 44.3dBHL

Conclusion: Variables such as the size and site are important aspects in affecting the degree of hearing loss. The larger the perforation the greater the hearing loss.Posterior perforations and those that have a posterior component had a higher hearing threshold.

INTRODUCTION

Tympanic membrane perforations are a condition as old as the evolution of human species and the incidence of tympanic membrane perforation in the general population is unknown as it has not been studied.[1]

Hearing loss of any degree is sufficient enough to interfere with social and job related communication and hence can be quite debilitating. It is classified as per the World Health Organization audiometric descriptor. It ranges from normal to profound hearing loss based on the pure tone average. [2]

It has been estimated that up to 80% of the tympanic membrane perforations tend to occur in the pars tensa.[3, 4, 5.]These tympanic membrane perforations can be classified into either acute perforations or chronic perforations. Acute perforations can be traumatic or inflammatory. Most of these perforations tend to heal spontaneously. Acute otitis media is defined as any ear discharge less than 2 weeks by the World health organization. [6, 7.] Acute infections of the middle ear cause tympanic membrane perforation by ischemic necrosis. The middle ear infection gives rise to an increase in pressure in the middle ear space and this results in ischemic necrosis which eventually leads to a tympanic membrane perforation.

Chronic perforations are defined as those more than 2 weeks old. They tend to be associated with chronic otorrhoea. Chronic suppuration can occur with or without cholesteatoma or middle ear disease. [6, 7.]

Chronic ear disease may many times not only result in tympanic membrane perforations but also middle ear disease which can be ruled out clinically by the smell and nature of the ear discharge (Cholesteatoma have a foul smelling, scanty ear discharge).

The classification of chronic otitis media is based on the presence of ear discharge, the tympanic membrane and middle ear status. The subtypes include healed chronic otitis media, inactive mucosal chronic otitis media, inactive squamous chronic otitis media, active mucosal chronic otitis media and active squamous chronic otitis media.[6,8,9.]

The old anatomical distinction of either it being a tubotympanic or atticoantral disease has been made redundant with the ability to accurately assess an individual's ear. The terms safe and unsafe ear are also incorrect and misleading as complications are known to arise from any active ear disease irrespective of the pathology.[8,9]

Traumatic perforations of the tympanic membrane can be caused by open-hand blows, injuries by cotton-tipped swabs or foreign bodies, explosions as a result of blast overpressure, welding sparks. [7,10,11.]

Barometric causes due to atmospheric pressure changes like in flying and scuba diving and iatrogenic causes like vigorous syringing of the ear or surgical intervention during insertion of ventilating tubes can cause tympanic membrane perforations.[7,11.]

Fracture injuries to the temporal bone can be associated with conductive hearing loss.The pathophysiology includes ossicular chain disruption or tympanic membrane perforation.[10,12]

Tympanic membrane perforations vary in regards to the subtype of chronic otitis media an individual suffers from. These can include attic perforations, marginal perforations or central perforations.Attic or pars flaccida perforations are almost invariably associated with an invading Cholesteatoma[8]. This is now known as the active squamous epithelial chronic otitis media. These perforations usually tend to occur just above the lateral process of the malleus. Many times retraction pockets which are common in the pars flaccida may be confused to be perforations and this is common with the inactive squamous epithelial chronic otitis media.[8]

Marginal perforations occur at the margin of the tympanic membrane in which the fibrous annulus is involved and usually implies the presence of bony disease. These perforations are inevitably associated with osteitis, granulation tissue and Cholesteatoma formation and are common with the active mucosal chronic otitis media and the active squamous epithelial chronic otitis media.[8]

Perforations involving attic or annulus ring were previously called atticoantral disease or unsafe perforations, as they are usually associated with Cholesteatoma, granulation tissue and osteitis. Now they are classified as either active mucosal chronic otitis media or active squamous epithelial chronic otitis media. These entities are associated with chronic inflammation within the middle ear and mastoid mucosa resulting in edema, submucosal fibrosis, hypervasularity and infiltration of mucosa with inflammatory cells which result in release of inflammatory markers. These inflammatory markers result in resorptive osteitis of the ossicular chain and granulation tissue formation due to blood vessel proliferation by fibroblasts. The hearing assessment in such perforations (e.g. attic, marginal, total) may not correlate directly with the progression of disease due to the middle ear pathology. [8,9]

Central perforations are the pars tensa perforations with intact annulus ring, previously referred to as the tubotympanic type or safe perforations. There are associated with the inactive mucosal chronic otitis media. The perforations have no middle ear or mastoid mucosal involvement. The perforation may be large or small. At times the perforation can be so large that it merits the term-subtotal perforation. Perforations that are associated with acute otitis media are nearly always central.[8]

The pars tensa (central) perforations associated with inactive mucosal chronic otitis media are usually better assessed than perforations associated with the active mucosal and active squamous epithelial chronic otitis media.

Central perforations are classified morphologically according to the tympanic membrane quadrants involved into anterosuperior perforations, anteroinferior perforations, posterosuperior perforations, posteroinferior perforations or combined.[13.]

These perforations can also be classified according to size of the perforation. This includes Pin hole (1-2mm), those that are small (area involving one Quadrant), medium (area involving 2-3 quadrants) and Large perforations (subtotal) [11,13,14,15]

Tubotympanic perforations or perforations secondary to inactive mucosal chronic otitis media can also be coined as anterior central (anterior quadrant perforations),posterior central(posterior quadrant perforations) ,central malleolar (perforations localized near or at the handle of malleus) and big central (all four quadrant perforations).All perforations of the pars tensa with inactive mucosal otitis media are referred to as central. [11,16]

Estimating the size and site of tympanic membrane perforation

In our setting Otologists and otolaryngologists evaluate size, shape and site of the tympanic membrane perforation by simply looking through a hand held otoscope. In some cases an operating microscope is used. These methods are sufficient to characterize shape, site and size but they are subjective.

VO has continued to gain acceptance as an integral component of hearing health care practice today as the technologically advanced video-optical technique has applications in the examination, display and documentation of the external ear canal and tympanic membrane.

It is a simple, compact unit incorporating a rod otoscope with a removable otic speculum, fiber-optic illumination, and a high-resolution colour video camera capable of recording a patient's ear canal and tympanic membrane.

The technology was introduced in the early 1990s. Roy F. Sullivan, PhD, CCC-A, co-owner of Sullivan and Sullivan, Inc., in Garden City, NY, was among the first audiologists to incorporate VO in an audiology practice. By projecting an image onto a video monitor,VO allows comparison of the status of the ear canal and tympanic membrane before and after treatment.

VO helps in objective documentation with the exact dimensions and location of the perforations. Various studies have been carried out to determine how accurate various otolaryngologists are in estimating the size of the perforation subjectively versus using the video-otoscope. These studies show that the VO is far much superior.[17, 18.]

Otorhinolaryngologists use video-otoscopy in numerous key applications of their practice. This includes general examination of the ear canal and tympanic membrane, physician/patient communication, hearing instrument selection and fitting, middle ear and external ear pathology management, professional image enhancement with documentation, patient education and knowledge base and skill growth.

ANATOMY

The tympanic membrane is a thin (approximately 0.08mm) irregularly rounded viscoelastic membrane with a diameter of 10mm[19.]The total surface area of the tympanic membrane is approximately85mm^2 with a physiologically effective area of 55 mm^2 [20.]

The tympanic membrane has 3 layers. The outermost layer is also known as the lateral squamous layer which is continuous with the skin of the external auditory meatus.

The middle layer is a fibrous layer and also known as the lamina propria. The inner most layers is the medial mucosal layer which is continuous with mucosa of the tympanic cavity.

The tympanic membrane is supported around its periphery by a fibrous thickening, called the annulus. This fibrous annulus fits in turn into bony annulus of the tympanic bone.

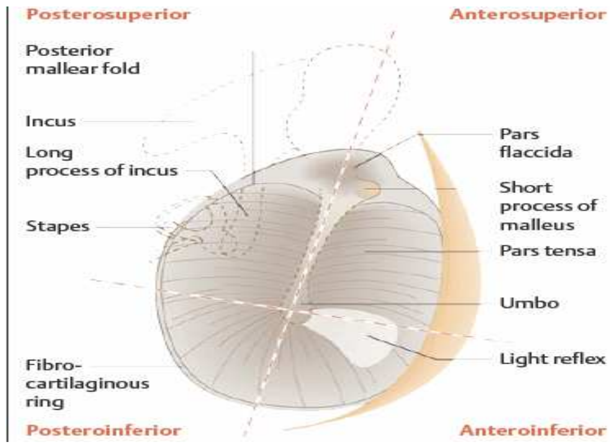
The tympanic membrane is divided into two parts known as the pars tensa and pars flaccida.

Pars flaccida lies superior to the suspensory ligaments of the malleus. In this part of the tympanic membrane the middle layer is comprised of irregular elastic fibers hence the flaccidity. It's usually much smaller and contains the notch of rivinus. It is difficult to visualize and hence called the "attic". It is usually associated with the previously called unsafe "perforations" and attic retraction pockets or inactive squamous epithelial and active squamous epithelial chronic otitis media.

Pars tensa is the zone that consists of a tough and resilient fibrous layer with a mucosal layer inside and squamous epithelium outside. Through the pars tensa one can identify the handle of the malleus and can visualize the round window niche. The posterior and anterior malleolar folds separate it from pars flaccida.

The pars tensa is divided by an imaginary line passing through the handle of malleus and a line perpendicular to the first line through the umbo into four quadrants mainly anteroinferior, anterosuperior, posteroinferior and posterosuperior.

Figure 1:Anatomy of the tympanic membrane and the quadrants.*(adapted from basic otorhinolaryngology.pdf)*



The tympanic membrane is maintained in a state of tension by the in-drawing of the manubrium, which is attained by contraction of the tensor tympani muscle, which is attached to the medial margin of the manubrium. This allows sound vibrations on any portion of the tympanic membrane to be transmitted to the ossicles, which would not be true if the membrane were lax.[20]

The ossicles of the middle ear are suspended by ligaments in such a way that the combined malleus and incus act as a single lever, having its fulcrum approximately at the border of the tympanic membrane. The articulation of the incus with the stapes causes the stapes to push forward on the oval window and on the cochlear fluid on the other side of window every time the tympanic membrane moves inward, and to pull backward on the fluid every time the malleus moves outward.[20.]

PHYSIOLOGY

There are two problems that the ear is faced with during transfer of sound to the inner ear. These include the large impedance difference between the two media (air and fluid) and ability to create a phase difference between the forces that acts at the two windows (round and the oval) in order for the cochlear fluid to move[13].

These problems are solved by presence of an intact tympanic membrane and impedance matching by the middle ear.

The tympanic membrane conducts sound waves across the middle ear and also protects the middle ear cleft and shields the round window from direct sound waves. This shield is necessary to create a phase differential so that sound waves do not impact on the oval and round window simultaneously. This would result in dampening of the flow of sound energy that is being transmitted in a unilateral manner directly from the oval window via the perilymph.

The middle ear overcomes the impedance mismatch between the air filled external auditory canal and the fluid filled inner ear by working as a mechanical transformer. When sound in air strikes a fluid boundary there is a theoretical loss of 99.9% of the energy in a sound wave in air due to reflection. This 99.9% loss is equivalent to 30 dB; a reduction in stimulus intensity of this amount is quite noticeable to a listener. In order to overcome this mismatch in the impedance of air and fluid, the middle ear is interposed between the tympanic membrane and the oval window.

The middle ear acts as a hydraulic press in which the effective area of the eardrum is about 21 times that of the stapes footplate. Thus, the force caused by a given sound pressure in the air acting on the area of the tympanic membrane is concentrated through the ossicles onto the small area of the footplate, resulting in a pressure increase proportional to the ratio of the areas of the two structures, which is about 21:1. It also happens that the lever arm formed by the malleus in rotating about its pivot is somewhat longer than that of the incus, giving another factor of about 1.3 in pressure increase. [21.]

The 21x of the drum/footplate area ratio, multiplied by the 1.3x lever arm factor, yields about a 27.3x increase in pressure, which is 29 dB, thus just about overcoming the theoretical 30 dB loss due to impendance mismatch[13,21.].

In summary the function of middle ear function is to offset the decrease in acoustic energy that would occur if the low impendence ear canal air would directly contact the high impedance cochlear fluid.[13]

Proper impedance matching requires normal anatomy, a functioning external ear, middle ear with an intact tympanic membrane, normal ossicular chain and a well-ventilated middle ear. Any dysfunction of these components results in conductive hearing loss.

PATHOPHYSIOLOGY

The physiology of conductive hearing loss in tympanic membrane perforations can be explained on the basis of the “round window baffle”.[22,23]

The pathophysiology of more severe hearing loss noted in posterior quadrant perforations is thought to be because of direct exposure of the round window to sound waves. This results in cancellation of the phase differential that is generally present at the two windows (round and oval).the sound waves in posterior based perforations reach both windows simultaneously with equal force and hence there is cancellation of vibratory movement of the cochlear fluid.

This purposed pathophysiology for the hearing loss has been disputed by many authors and the studies carried by Voss et al in cadavers where they concluded that the site of the perforation doesn’t affect the degree of hearing loss. They stated that direct stimulation of the oval and round window made little contribution to the degree of hearing loss.[23]

Titus et al attributed a greater hearing loss in posterior based perforations to having a greater risk of underlying middle ear disease such as cholesteatoma or granulation tissue.[15.]

A perforation in the tympanic membrane reduces the surface area of the membrane that is available for sound pressure transmission and allows sound to pass directly into the middle ear[22,23]. Perforations based near or at the manubrium also have a greater conductive hearing loss as it affects the ossicular chain vibratory movement.[23]

It has been proposed that the larger the perforation the greater the decibel loss.[22,23]

LITERATURE REVIEW

Various studies have shown that the range of hearing loss in uncomplicated tympanic membrane perforations can range from being negligible to 50db.

Merchant in his study demonstrated a range of 0-to 40 dBHL in uncomplicated tympanic membrane perforations[24]. Lavy J. found a range of 30-40dBHL[25] and Durko who assessed 145 patients intraoperatively to determine intact ossicular chain found a mean conductive deficit of 30dB in posterior quadrants. The other tympanic membrane quadrant perforations had a conductive hearing loss of an average of 20dBHL.[26]

Mc Ardle showed that tympanic membrane perforations without middle ear involvement could cause hearing loss from negligible to 50dBHL.

He proposed that the hearing loss mechanism was from the reduction in ossicular coupling caused by a loss in sound pressure difference across the tympanic membrane.[27]

Nepal demonstrated that the decibel hearing level in uncomplicated tympanic membrane perforations is from zero to 50dBHL.[28]

Voss demonstrated that with loss of the shielding effect in the tympanic membrane perforation a maximum conductive effect could result in up to 40-50dBHL.[29]

Table 1: summary of studies showing hearing loss range in uncomplicated tympanic membrane perforations.

AUTHOR	HEARING LOSS RANGE IN UNCOMPLICATED TYMPANIC MEMBRANE PERFORATIONS.
Merchant et al	0-40dBHL.
Lavy et al	30-40dBHL
Durko et al.	30dBHL in posterior quadrant perforations. 20dBHL in other quadrant perforations.
McArdle et al.	0-50dBHL.
Nepal et al.	0-50dBHL.
Voss et al.	40-50dBHL.

Different studies over different periods of time have shown that the size of the perforation does affect the degree of conductive hearing loss. These studies all concluded that the larger the perforation of the tympanic membrane the greater the decibel loss in sound perception. [15,16,28,29,30,31,32,33,34,35.]

There are hardly any studies that contradict this popular otological belief.

The site of the perforation still remains a point of contention.

Tympanic membrane perforation site is directly related to the severity of conductive hearing loss.

Mahajan studied 100 patients with 119 tympanic membrane perforations. He demonstrated statistically significant relation between posterior based perforations and degree of hearing loss. In his study the p value obtained for anterior perforations and hearing loss was not significant while the P value for posterior based perforations and degree of hearing loss was significant at 0.24.He also noted that most of his patients had large perforations(4 quadrant involvement):72ears(60.5%) and the posterior superior perforations were least with only 3 ears(2.52%).[16]

Bhusal observed that the greatest hearing loss was found in big central perforations(45dBHL)P(<0.001) and posterior central perforations(43dBHL) (P<0.001).He noted the least hearing loss in anterior central perforations (31dBHL) with an insignificant p value of 0.121) and central malleolar perforations(34dBHL).He concluded that the posterior-central perforations cause more hearing loss than anterior-central ones.

He also noted that the maximum hearing loss was at the lower frequencies. At 500hertz he had an average of 46.4dBH,1000Hz 30.90dBHL,and at 2000Hz hearing loss of 31.9dBHL.[31]

Yung M.W in his study of 100 patients noted that big central and posterior central perforations had the greatest hearing loss compared to other sites of perforation. He also noted a hearing loss of 43 dBHL in the series of big central and posterior central perforations. He concluded that postero-inferior perforations results in larger hearing loss than antero-inferior perforations.[14]

Ahmad and Ramani in their study of hearing loss in perforations of the tympanic membrane also found similar findings. In the 70 ears they found that malleolar perforations cause more hearing loss than non-mallelor unless the perforation involves less than 10 percent of the tympanic membrane surface area.18.5 dBHL was noted in anterior perforation and 29 dBHL was noted in posterior perforation at 500 Hz. They concluded that the difference in hearing threshold between the anterior and postero-inferior perforations was appreciable only at lower frequencies.[32]

Nepal A in his study of assessment of hearing loss in central perforations in 100 patients concluded that posterior perforations resulted in the maximum hearing loss. In frequencies of less than 2000Hz, out of 64 cases involving posterior inferior quadrant perforations 50.0% had mild hearing loss and 39.0% had moderate hearing loss. Of the 62 cases of perforations involving anteroinferior quadrant, 50.0% cases had mild hearing loss, 29.0% had moderate hearing loss .28 cases involving posterosuperior quadrants, 78.0% cases had moderate hearing loss, and mild hearing loss was noted in 11.0% .In 24 cases involving anterosuperior quadrant, 50% had moderate hearing loss and 25.0% each had mild hearing loss. Of the 14 cases of perforations involving all 4 quadrants, 12 had moderate hearing loss and 2 had mild conductive hearing loss. The differences were statistically significant ($p<0.05$).[28]

Table 2: summary of studies showing positive correlation between site of perforation and degree of hearing loss.

AUTHOR	SAMPLE SIZE	CONCLUSION/RESULTS.
Mahajan et al.	119	P value for anterior perforations and degree of hearing loss=0.42. P value for posterior perforations <0.05.
Bhusal et al.	50	Big central and posterior central P< 0.001.
Yung et al.	100	Central and posterior central perforations P<0.001.
Ahmad et al.	70	Posterior perforations=29dBHL Anterior perforations=18.5dBHL.
Nepal et al.	100	Posteroinferior perforations=39% moderate.

The usual explanation for the fact that posterior based perforations are associated with worse off hearing loss is that these perforations are closer to the round window, and thus there is loss of the phase differential. In other words the hydraulic advantage produced by the tympanic membrane on the oval window disappears so that the sound reaches both the windows more or less at the same time with equal force and at nearly equal time. The resultant cancellation of the vibratory movement of the cochlear fluid column results in the maximum hearing loss noted even in small sized perforations located in the postero-inferior quadrants.[14,16,28,31,32.]

In contrast, Voss, from her study in cadavers to determine hearing loss caused by tympanic membrane perforations concluded that the transmission of sound with a tympanic membrane perforation does not depend on the site. Voss used cadavers to determine hearing loss caused by the tympanic membrane perforations. Acoustic transmissions were measured before and after making controlled perforations in the cadaveric ears show that the perforations cause frequency dependent loss that it is largest at low frequency, Increases as the perforation size increases and doesn't depend on the perforation location.[23,29.]

Voss stated that the dominant loss mechanism is the reduction in sound pressure difference across the tympanic membrane .She stated that reduction in the area ratio between the TM and the stapes makes little contribution to the total loss, and direct stimulation of the oval and round windows may limit the loss, but only for perforations greater than 1 to 2 quadrants of the TM[29].

Voss S further carried out studies on non-ossicular signal transmission in the human ear. Direct acoustic stimulation of the cochlea by sound pressure difference between the oval and round windows (called the acoustic route) has been thought to contribute to hearing loss. This has been cited by many authors as an explanation for the greater hearing loss seen in posterior quadrant involvement. Voss study aim was to determine the efficacy of this acoustic route in tympanic membrane perforations. Results of this cadaveric study showed that sound pressure from ear canal to the middle ear depends on the perforation size but not on the location. The sound pressure difference between the windows doesn't depend on the size or the site. In summary it refutes the common otological belief that the site of the tympanic membrane perforation affects the relative phase differential of sound at the oval and round window.[23]

Mehta studied the determinants of hearing loss in tympanic membrane perforations and his results showed that the degree of conductive hearing loss increases with the size of the perforation but the severity of conductive hearing loss is independent of the location. In the 56 ears he analysed, the anterior quadrant perforations versus posterior quadrant perforation showed no statistical significant difference in air-bone gaps at any frequency, although anterior perforations had on average air-bone gaps that were smaller by 1 to 8db at lower frequencies.[35]

Anthony and Harrison in their study showed that there was no significant quantitative correlation between the site of the perforation and the severity of the hearing loss.[36]

Titus S. In his study on correlation of the site of tympanic membrane perforation with the degree of hearing loss using video-otoscopy concluded that in acute tympanic membrane perforations the site of the perforation and the magnitude of hearing loss was insignificant(p=0.244)versus that in chronic perforations(p=0.047).Titus concluded that the posterior superior perforations were most common in chronic perforations and speculated that there was greater hearing loss due to superimposition of diseases to the middle ear diseases like cholestaetoma.[15]

Oluwole also concluded that there was no significant difference in hearing loss in anterior versus posterior quadrant perforations.[33]

Video-Otoscopy

The accuracy of estimating size by standard otoscopy is limited not only by interobserver errors but also by the fact that most perforations are not uniformly round. Thus, their area is not easy to gauge by simple observation or to calculate on the basis of the TM diameter.

The development of computer-based video-otoscopy systems that precisely calculate the size of a perforation relative to the size of the TM has obviated many of these problems[17,18,37,38.]

These systems are accurate and their measurements are reproducible. As such, they provide a standard against which we can measure the accuracy of subjective estimates made by otolaryngologists.

At the University of Ibadan, an assessment of clinical estimation versus video-otoscopic calculations was made and various ENT specialists were asked to estimate the size of 100 tympanic membrane (TM) perforations with standard otoscopy. The specialists included, in descending order of rank, 2 consultant surgeons, 2 senior registrars, and 2 registrars, all of who had confirmed good vision. Their estimates, which were made independently and expressed as a percentage of the total area of the TM, were compared with exact measurements calculated with computer-based video-otoscopy. It was found that the video-otoscopic calculations were far superior to the estimates of the specialists, even the most experienced Consultants ($p < 0.01$) and hence recommend that video-otoscopy be used whenever possible.[39]

These findings were similar to those reported by Hampal and Hsu[18,40.]In both studies, the difference between visual estimates of tympanic membrane perforations and video-otoscopic calculations of these perforations were statistically significant ($p < 0.01$ in both studies) demonstrating the efficacy of video-otoscopy .[18,40.]

JUSTIFICATION OF STUDY

It is recognized that the size of tympanic membrane perforation is proportional to the magnitude of hearing loss. There is no clear consensus on the effect of the site of the perforation on the hearing loss. Many believe posterior based perforations have a greater impact on the degree of hearing loss.

This study was set to investigate the relationship between the site and size of central tympanic membrane perforations and the degree of conductive hearing loss.

No similar study has been carried out in Kenya and hence provides a ground for further studies.

Use of video-otoscopy is limited in Kenya. We rely on subjective measurements of the perforations. Many otolaryngologists remain unclear on how to optimise the benefits of this technology. There is still no graduate or continuing education course, which fully prepares a professional for understanding how to use this technology to its fullest potential. Otolaryngologists who understand the anatomical and medical concepts and can communicate that knowledge to physicians by using the video images or printouts provided by video-otoscopy can gain tremendous respect from referring physicians/patients.

The study incorporated use of video-otoscopy, which provided an opportunity for immediate viewing of the tympanic membrane and its disease on the monitor, not only for the clinician, but also for the patient.

Use of video-otoscopy will also help make Kenyatta National Hospital comparable to other countries' tertiary facilities where it has already been incorporated into the health system. This is the direction otology is heading towards away from the traditional simple methods of otoscopy.

AIMS AND OBJECTIVES

BROAD OBJECTIVE

To determine the correlation of degree of conductive hearing loss with the size and site of pars tensa tympanic membrane perforations using video-otoscopy.

SPECIFIC OBJECTIVES

1. To determine the size of the pars tensa tympanic membrane perforation using a video otoscope and correlating it to the degree of conductive hearing loss.

2. To determine the site of pars tensa tympanic membrane perforation using a video otoscope and correlating it to the degree of conductive hearing loss.

3. To determine the major causes of pars tensa tympanic membrane perforations at the Kenyatta National Hospital.

NULL HYPOTHESIS

The size and site of a perforation does not affect the degree of conductive hearing loss.

MATERIALS AND METHODS

STUDY DESIGN

This was a prospective descriptive study.

SAMPLE SIZE CALCULATION

Sample size was calculated using the yamen formula as follows:

$$n = \frac{N}{1+N(e)^2}$$

Where:

N is the population prevalence.

e is the error margin.

At a confidence interval of 95% and an error margin of 5% the sample size (n) will be based on a previous similar study[28] where 100 cases will be the N (population size).

$$n = \frac{100}{1+100(0.05)^2}$$

n= 80 ears.

SAMPLING METHOD

Consecutive sampling was carried out.

STUDY PERIOD

February 2011-February 2012.

INCLUSION CRITERIA

1. Patients with inactive mucosal chronic otitis media(Central/safe (tubotympanic).
2. Patients with acute otitis media and tympanic membrane perforations.
3. Patients with trauma limited to the external ear and tympanic membrane.

EXCLUSION CRITERIA

1. Patients who declined to participate in the study.
2. Patients who had tympanic membrane perforations with middle ear disease (if the air bone gap is more than 50decibels suggestive of ossicular chain involvement), patients with active mucosal, active squamous epithelial, inactive squamous epithelial chronic otitis media.
3. Patients with sensorineural hearing loss of any cause.
4. Any previous tympanoplasty other than type 1 tympanoplasty.
5. Those below the age of 5years.

CONFOUNDING FACTORS

Tympanosclerosis may affect the degree of hearing loss.

The hearing loss is usually minor if tympanosclerosis simply involves the eardrum; if the middle ear is involved and the ossicular chain becomes fixed, up to 60dB loss may be seen.

CLINICAL EVALUATION

Patient selection was done from the ENT filter clinics that are run by the clinical officers and the consultant clinics at the Kenyatta National Hospital.

The relevant clinical history was taken pertaining to the study and this mainly included hearing loss history; history of ear infections; ear trauma; ear surgery; use of ototoxic drugs, history of dizziness,vertigo and tinnitus.

A physical examination was carried out and the findings were recorded in the proforma. The ear was examined for:

- Any pinna deformities;
- Preauricular or post auricular scars;
- The external auditory meatus and canal abnormalities or infections;
- Characteristics of the tympanic membrane.

MATERIALS AND EQUIPMENT

The materials and equipment that were used for assessing the patients included:

- Tuning fork (512Hz).
- Otoscope-Welch Allyn pocket junior otoscope.
- Video-otoscope (P.C.Werth's digital video otoscope 426/MP model).
- Hp laptop-Vivienne TAM for image visualization.
- Dino capture 2.0 version 1.3.2.
- Diagnostic audiometer- model AC5.

PROCEDURES

The screening tests involved otoscopic examination of the ear canal and the tympanic membrane. The initial assessment was recorded down in the proforma. Video-otoscopy was then carried out to record the images of the pathological tympanic membranes in the Hp laptop for accurate site assessment and size measurement. The size of the tympanic membrane and the size of the perforation were measured by the Dino capture 2.0 version 1.3.2.and documented. The areas were calculated by outlining the shapes of the perforations and the tympanic membranes using the toolbar in the Dino capture 2.0version 1.3.2. Dimensions were measured by the measurement properties in the Dino capture 2.0 version 1.3.2 software. All adult patients were examined with a 7mm aural speculum and children below the age of 12 years were examined with a 5mm aural speculum. The penetration of the aural speculum in the external auditory canal was limited to a premanufactured mark on the speculum. The magnification on the video-otoscope was set at $\times$ 20 for all the patients and this standardization helped exclude intra-examiner bias.

During routine otoscopy any wax present was removed using a Jobson Horne’s probe

Rinnes,weber and absolute bone conduction tests were carried out to help exclude patients with mixed /sensorineural hearing loss.

The pure tone audiometry was carried out using audiometer model AC5 in a sound proof insulated room in the ENT department by a qualified audiologist..

Audiometery was done at 500Hz/1000Hz/2000Hz/4000Hz respectively. Both air and bone conduction thresholds and the pure tone average for each patient was determined and documented for each pathological ear.

The hearing level was based on the average of the pure tone audiometery thresholds at 500/1000/2000 and 4000Hz.The hearing level was then classified as per the WHO audiometric descriptor.

QUALITY CONTROL

- The primary investigator carried out the screening tests for all the patients to prevent inter personal bias and used the same equipment and methods to prevent inter instrument bias.
- All the patients were examined with standardized aural specula as per age and a set magnification on the video-otoscope was used to exclude intra examiner bias.
- The audiometery machine is electrically calibrated yearly and biologically calibrated daily by the audiologists to ensure that the sound quality is correct in both intensity and frequency.
- Only one audiologist carried out the pure tone audiometry to avoid bias.

ETHICAL CONSIDERATIONS

1. The study was carried out only after approval by Kenyatta National hospital and University of Nairobi ethics and research committee(P13/1/2011)
2. Those included in the study were required to give an informed consent either by themselves or their guardians for those below 18 years of age.
3. Patients' incured no extra financial costs and their confidentiality was maintained at all times.
4. Participants reserved the right to withdraw from the study at any time without any penalty.
5. There was no monetary gain by the primary investigator from the study.

DATA ANALYSIS

DATA ENTRY

The biostatistics of the patient, relevant history and the findings on the screening tests were all recorded in the microsoft office access 2007 database proformas.

The data was then separated into different preformatted data sheets under the different titles of age,sex,etiology of the perforation,duration of ear perforation-acute perforations and chronic perforations,site of the perforation,size of the perforation (the area of the perforation over that of the tympanic membrane),degree of hearing loss with the site of perforation.and degree of hearing loss with size of the perforation.

DATA ANALYSIS.

Various patient characteristics were explored by simple tabulation.Analysis was carried out in STATA VII.2. The size and site of perforation were correlated with the magnitude of hearing loss.Analysis of variance- ANOVA- (a parametric method) and Kruskwal-Wallis test(a non parametric method) were used and the results of both approaches qualitatively compared.

Degree of hearing loss according to the WHO audiometric descriptor was also correlated with the site and size of perforation using Pearson's chi square test. A linear regression model was fitted to explore the effect of the site of perforation on the degree of hearing loses, before and after adjusting for the size of perforation. In the model adjusted for size of perforation the percentage of tympanic membrane perforation was centred at the grand mean of the sample; the resulting estimates are therefore the mean hearing threshold in decibels for the various sites of perforations for an individual with an average size of perforation.

RESULTS

Descriptive analysis

A total of 80 ears were included in this study with an equal sex distribution- 40/80 (50%) were male. The patients had a median age 14.5 years (range: 7-57years). Right unilateral perforations were 41/80(51%) and 39/80(49%) left unilateral perforations.

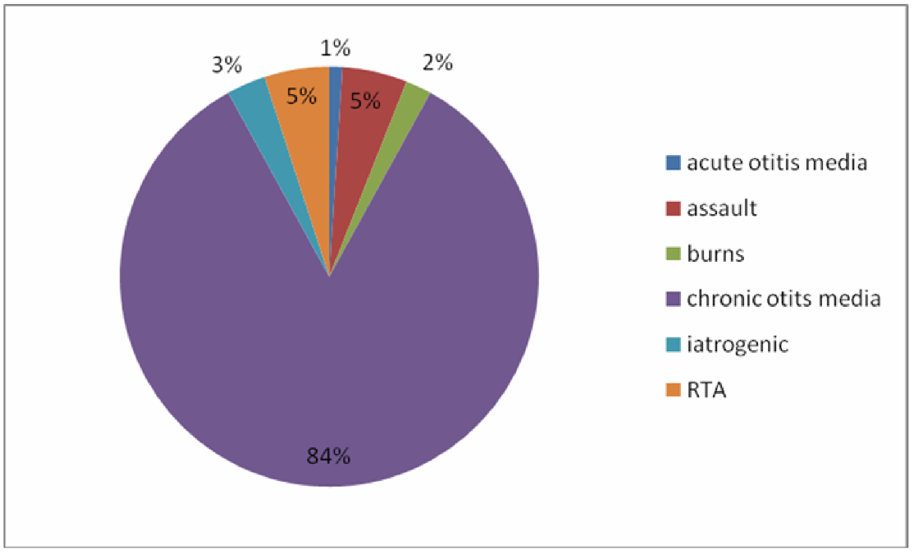
The commonest cause of pars tensa perforations was COM followed by RTA and assault (Table 3/figure 2).

Table 3: Causes of perforation

Cause	Right (n=41)	Left (n =39)	Total (n=80)
Acute otitis media	1(2)	0(0)	1(1)
Assault	2(5)	2(5)	4(5)
Burns	1(2)	1(3)	2(2)
Chronic otitis media	34(83)	33(85)	67(84)
Iatrogenic	1(2)	1(3)	2(3)
RTA	2(5)	2(5)	4(5)
Total	41(100)	39(100)	80(100)

Presented as: number of ears and in brackets the %

Figure 2: Causes of tympanic membrane perforations.



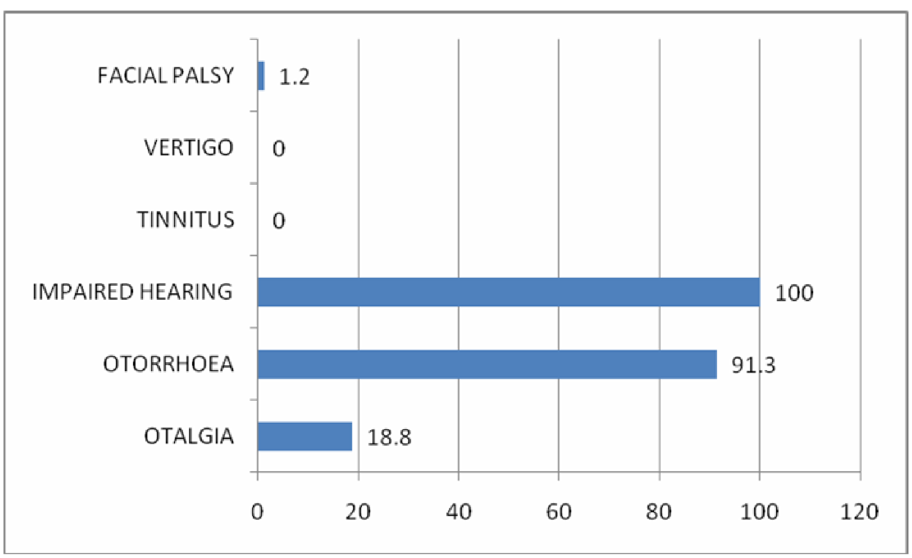
The most prominent symptom was impaired hearing (100%) followed by otorrhoea (91.3%)and Otalgia(18.8%).The other symptoms were encountered less frequently(table 4a and figure 3a).

Table 4a: The presenting symptoms.

Symptom	Right(n=41)	Left(n =39)	Total(n=80)
Otalgia	9(22.0)	6(15.4)	15(18.8)
Otorrhoea	38(92.7)	35(89.7)	73(91.3)
Impaired hearing	41(100.0)	39(100.0)	80(100.0)
Tinnitus	0(0.0)	0(0.0)	0(0.0)
Vertigo	0(0.0)	0(0.0)	0(0.0)
Facial palsy	1(2.4)	0(0.0)	1(1.2)

Presented as: number of ears and in brackets the %

Figure 3a: Distribution of presenting symptoms in percentage.



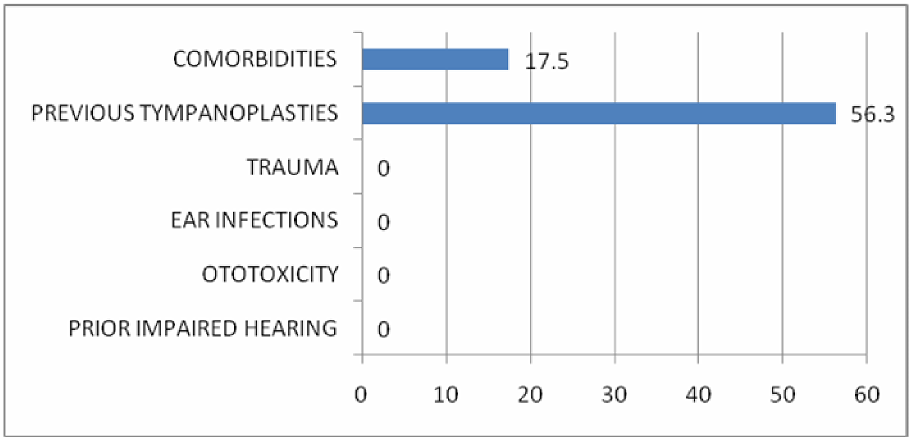
With regards to the past medical history more than 50% of the patients had previous failed type 1 tympanoplasty while 17.5% had co morbidities such as diabetes, hypertension, HIV.(Table 2b and figure3b).

Table 2b: Past medical history.

Past medical history	**Right (n=41)**	**Left (n=39)**	**Total(n=80)**
Prior impaired hearing	0(0.0)	0(0.0)	0(0.0)
Ototoxicity from drugs	0(0.0)	0(0.0)	0(0.0)
Previous ear infection	0(0.0)	0(0.0)	0(0.0)
Trauma	0(0.0)	0(0.0)	0(0.0)
Previous failed type 1 tympanoplasty	24(58.5)	21(53.8)	45(56.3)
Co morbidities	9(22.0)	5(12.8)	14(17.5)

Presented as: number of ears and in brackets the %

Figure 3b:Distribution of relevant past medical history in percentage.



The most common elicited sign was perforation of the tympanic membrane (100%)followed by wax impaction(67.5%) then tenderness(5%).the one patient who had a facial nerve palsy was involved in an RTA.(table 5)

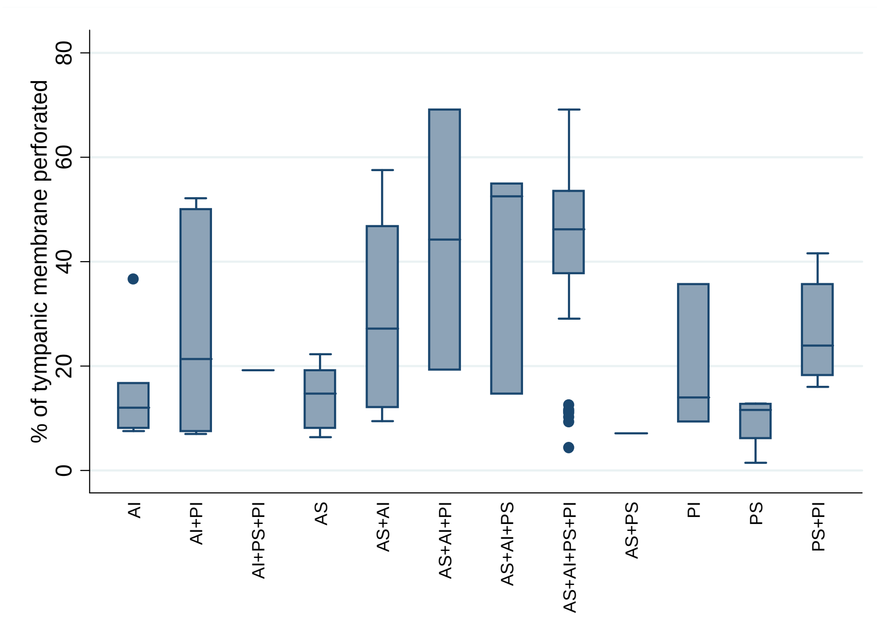
Table 5: Signs on examination.

Sign	Right(n=41)	Left(n=39)	Total(n=80)
Otorrhoea	0(0.0)	0(0.0)	0(0.0)
Tenderness	4(9.8)	0(0.0)	4(5.0)
Wax	24(58.5)	30(73.2)	54(67.5)
Perforation	41(100)	39(100)	80(100)
Palsy	1(2.4)	0(0.0)	1(1.3)

Presented as: number of ears and in brackets the %

The overall mean percentage perforation of the tympanic membrane was 31.35% (95% CI: 26.89%, 35.82%). Note that there were outliers present in the anteroinferior perforations which could be accounted for by the fact that the perforation was involving the entire quadrant hence the size of approximately 38% while majority of the AI perforations ranged between 14% to 18%.Outliers were also noted in the 4 quadrant perforations and this could be accounted for by the fact the outliers were mainly small central perforations traversing all the 4 quadrants.(figure 4).

Figure 4 : Percentage perforation of the tympanic membrane for various sites affected.



Key:AI= Anteroinferior; AS=Anterosuperior; PI=posteroinferior; PS= Posterosuperior. + is used to indicate combinations of positions. (Central line = median of median scores, shaded box = inter-quartile range of median scores, 'whisker' = 95% range of median scores).

Non parametric analysis of association between hearing loss and site of tympanic membrane perforation:

The greatest hearing loss was noted in the posterior perforations include and combinations with a posterior position. PS+PI had the greatest hearing loss (46.2dBHL) followed in a descending fashion by PI(44.3dBHL) ,AS+AI+PI(42.0dBHL), AI+PS+PI(40.0dBHL),AI+PI(39.0dBHL),AS+AI+PS+PI(37.7dBHL),PS(33.3dBHL),AS+AI +PS(32dBHL),AS+AI(28.7dBHL),AI(26dBHL),AS(25.5dBHL) and least in AS+PS (15dBHL) which could not be statistically significant as only one patient was analysed.

On the overall there was a significant association between the site of the perforation and the hearing loss in dBHL (Kruskwal-Wallis test:p=0.0001).(Table 6).

Table 6: Association between the site of the perforation and the degree of hearing loss in dB.

Site	No of ears (%)	mean dBHL (se)
AI	7(8.8)	26.0(3.5)
AI+PI	6(7.5)	39.0(3.7)
AI+PS+PI	1(1.3)	40.0(.)
AS	6(7.5)	25.5(2.8)
AS+AI	7(8.8)	28.7(1.8)
AS+AI+PI	2(2.5)	42.0(0.0)
AS+AI+PS	3(3.8)	32.0(5.0)
AS+AI+PS+PI	35(43.8)	37.7(1.2)
AS+PS	1(1.3)	15.0(.)
PI	3(3.8)	44.3(1.7)
PS	4(5.0)	33.3(5.5)
PS+PI	5(6.3)	46.2(1.3)
K-W test	45.553 with 12 d.f.	
p value	0.0001	

AI= Anteroinferior; AS=Anterosuperior; PI=postreroinferior; PS= Posterosuperior. + is used to indicate combinations of positions. *K-W*= Kruskwal-Wallis. Se (standard error of mean)

There is a strong association between the site of perforation and the degree of hearing loss as measured by the WHO audiometric descriptor (Pearson Chi test: p<0.0001).Patients with posterior based perforations had in majority moderate hearing loss. This result agrees with that of hearing loss measured in dB as in table 6. (figure 5).

Pearson's Chi –Square test for association between site and hearing loss as categorised by the WHO descriptor.

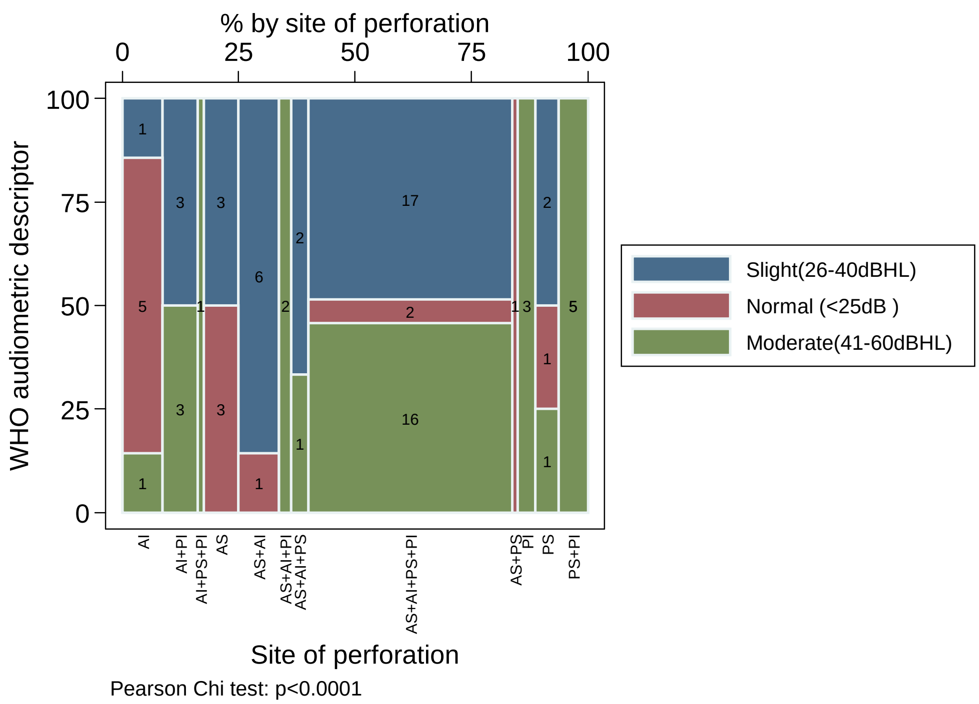


Figure 5: Shows a tabulation of the WHO audiometric descriptor and site of perforation in both counts and proportions. AI= Anteroinferior; AS=Anterosuperior; PI=postreroinferior; PS= Posterosuperior. + is used to indicate combinations of positions (Numbers inside the boxes are the number of ears with a perforation in that particular site).

Analysis Of Variance (ANOVA)

The R-squared is interpreted as the proportion of variation in hearing loss thresholds among the patients explained by the variables (site or size or both) included in the model. A higher value of R-squared also indicates a better fitting model. Site for example explains about 46% of variation in hearing threshold amongst the patients, while size explains 84% of variation. Both Site and Size explain 88% of all variation in hearing thresholds, and is therefore the best fitting model. The f tests shows that there were significant linear associations ($p<0.05$ in all the three models) between the response variable (hearing threshold) and the explanatory variables (site, size and when both are considered). These results are in agreement with those of the non parametric analysis.(Table 7).

Table 7: The results of ANOVA for the effect of size and site of perforation on hearing loss as measured in dBHL.

Model	R-squared	p value*
Site	0.4644	<0.00001
Size	0.8437	<0.00001
Site & Size	0.8844	<0.00001

*based of F test

Linear Regression

Hearing loss and site of perforation:

AI was used as the reference due to the fact that it demonstrated the least hearing loss.For both adjusted and unadjusted estimates positions that are posterior and/or include combinations with a posterior position have in general higher hearing threshold. For example: compared to perforation in the AI sites, those in the P1 are on average 18.33 higher (95 % CI: 8.21,28.45) $p < 0.0001$). A negative value indicates a lower hearing threshold as compared to anteroinferior (AI) perforation.The mean hearing threshold for each (95% CI) are used instead of increments in the hearing thresholds, and plotted in order of increasing hearing threshold. It is evident that those positions that are posterior and/or include combinations with a posterior position have a higher mean hearing threshold.(table 8 and figure 6).

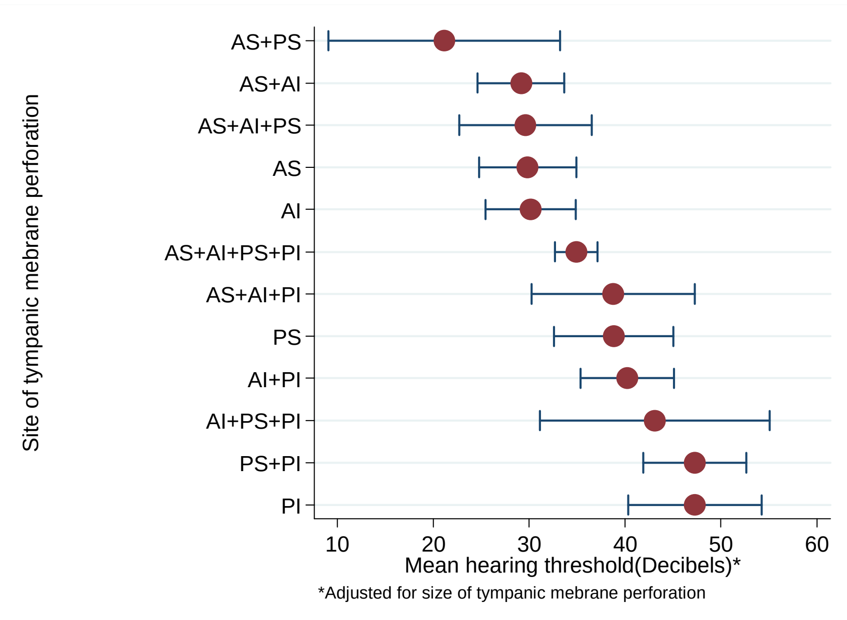
Table 8: Results of the linear regression for the effect of site on hearing loss in dBHL.

MODEL 1 MODEL 2

Site	Mean increment (dB)	95% CI	p	Mean increment (dB)	95% CI	P
AI	Ref	-	-	Ref	-	-
AI+PI	13	4.84,21.16	**0.002**	10.09	3.38,16.79	**0.00**
AI+PS+PI	14	-1.68,29.68	0.079	12.96	0.20,25.72	**0.04**
AS	-0.5	-8.66,7.66	0.903	-0.28	-6.92,6.35	0.93
AS+AI	2.71	-5.12,10.55	0.492	-0.98	-7.47,5.52	0.76
AS+AI+PI	16	4.24,27.76	**0.008**	8.62	-1.26,18.49	0.08
AS+AI+PS	6	-4.12,16.12	0.241	-0.5	-9.01,8.01	0.90
AS+AI+PS+PI	11.71	5.64,17.79	**<0.001**	4.77	-0.68,10.23	0.08
AS+PS	-11	-26.68,4.68	0.166	-8.98	-21.75,3.79	0.16
PI	18.33	8.21,28.45	**0.001**	17.17	8.93,25.41	**<0.0**
PS	7.25	-1.94,16.44	0.12	8.69	1.20,16.18	**0.02**
PS+PI	20.2	11.61,28.79	**<0.001**	17.15	10.09,24.21	**<0.0**
% perforation¶	-	-	-	0.25	0.17,0.34	**<0.0**
Constant	26	20.46,31.54	**<0.001**	30.14	25.42,34.86	**<0.0**

Ref- Reference group (site with which all others are compared to)AI= anteroinferior; AS=Anterosuperior; PI=Posteroinferior; PS= Posterosuperior. + is used to indicate combinations of positions. *K-W*= Kruskwal-Wallis. 95% ,CI= 95 % Confidence interval; * based on a t test; ‡ overall mean hearing threshold adjusted for site alone in the model 1and both site and size in the model 2; ¶ centred at the grand mean .

Figure 6: Estimated mean hearing thresholds for various perforation sites from the linear regression adjusted for the size of the perforation.



DISCUSSION

Tympanic membrane perforations are associated with a varying degree of conductive hearing loss. The size of the perforation has direct correlation with the degree of conductive hearing loss[15,16,28,29,30,31,32,33,34,35.] The site is a subject of controversy especially in relation to the severity of conductive hearing loss and in this study it shows a significant association with posterior perforations ($p<0.0001$).

This study has tried to bring in the use of video otoscopy in Kenya and to give tympanic membrane perforations, a more objective view in terms of size and site.

A total of 80 ears were recruited. The patients were aged between 7-57 years with a median age of 14.5 years indicating a heavy disease burden in the younger age groups.

Only one patient had a perforation due to acute otitis media. The reason for the low number of cases of acute otitis media in this study could be due to the fact that this study was carried out in a tertiary referral hospital and most cases of acute otitis media are treated at the primary setting. The most common cause was chronic otitis media (84%).In Kenya there is a high prevalence of COM and especially in the younger age group. This would explain why 84% of the perforations were secondary due to COM. With a median age of 14.5 years it also shows that it’s a heavy burden in the younger age group.A field study carried out in the Kenyan rural area of kiambu showed a prevelance of chronic otitis media at 1.1% in children .[41.]

Similar finding in studies done by Nepal[28](COM accounted for 85% of the tympanic memebrane perforations)and olowookere[42](COM accounted for 90.90% of the perforations).

COM is the commonest cause of tympanic membrane perforations and this could be accounted for the fact that studies have been carried out in areas which have comparable low socioeconomic status and hence the riskfactors such as overcrowding as common.

Hearing loss in relation with the size of the perforation:

The mean percentage range of the tympanic membrane perforations was from 26.89% to 35.82%.The overall mean was at 31.35%. The tympanic membrane perforation size varied as per the number of quadrants involved. Almost 50% of the tympanic membrane was involved in all four quadrant perforation indicative of large perforations. This could be due to delayed treatment secondary to low awareness among patients in Kenya. Most patients seek medical advice when hearing loss is much more.

On analysis of the size versus the degree of hearing loss a higher R-squared value(R=0.8437) (P=<0.00001) was found .This indicates that size of the perforation does have an impact on the degree of hearing loss and from the unadjusted linear regression of size of perforation on the hearing threshold showed that the one percentage point increase in the area of perforation resulted in 0.27 db increase in the hearing threshold (95% CI 0.19,0 .36). The p value tests, that this value was significantly different from zero; in this case it was less than 0.0001. In other words to increase the hearing threshold by say 10 db (a clinically significant increase) the tympanic perforation needs to be about 37% (10/0.27*1). Adjustment for the site of perforation resulted in similar results of one percentage point increase in the area of perforation resulted in 0.26 db increase in the hearing threshold (95% CI: 0.18, 0.35; p value :< 0.0001). These results are again complementary to those of the ANOVA model.

This confers to the general belief that the larger the perforation the greater the hearing loss and is comparable to other studies done globally [15,16,28,29,30,31,32,33,34,35].

Voss et alconfirmed the above findings in her experimental study where she stated "perforation size is an important determinant of degree of hearing loss".[29]

Nepal in his study classified the perforations into small, medium, large and pinpoint and he noted that the medium and large perforations had the largest hearing loss which ranged from 26-55db(p=<0.05).[28]

Bhusal et al also noted in his study that 17 patients out of 50 had perforations involving all 4 quadrants which he termed as "big central perforations" had the greatest hearing loss with a mean of 49.07db.

This study incorporated the use of Dinocapture software to calculate the dimensions of the perforations giving one a more subjective value to work with. Most of the studies quoted did not carry out this.

Size of the perforation is directly proportional to the degree of hearing loss because with a tympanic perforation there is loss of effective area of the eardrum is about 21 times that of the stapes footplate. This can also result in loss of the lever action especially if the perforation is involving the manubrium and this is common with large perforations. This accounts for a 30dB loss.

There is also loss of the phase differential at the oval and round windows that is created by the tympanic membrane as the sound waves now hit both the windows simultaneously and the larger the perforation the more these windows are exposed.

Hearing loss in relation with the site of the perforation:

A maximum mean hearing threshold was noted in the perforations that were involving the posterosuperior and posteroinferior quadrants(46.2dBHL) and a minimum of 15dBHL was noted in the perforations involving the anterosuperior and posterosuperior quadrants. This could be accounted by the fact that there was only one ear that had this kind of perforation. The site of the perforation has a significant association with the degree of hearing loss(kruskwal-wallis test:p=0.0001).Those perforations with posterior quadrant involvement had a higher hearing loss. This could be due the direct exposure of the round window in the posterior perforations as shown in other studies. This results in loss of the phase differential necessary for one to have perilymph movement.[14,16,28,31,32.]

Both the size and site have a significant effect on the hearing loss(R-Squared-0.8844) and this again is comparable to many studies done globally[14,16,28,31,32.].

Bhusal et al noted that large perforations with 4 quadrant involvements had a hearing loss of 49dbHL and those in the anterior quadrants had hearing loss of at least 31dbHL.[31]

Yung et al found the hearing loss greater in posterior based perforations an average of 43dbHL.[14]

Ahmed also noted a greater hearing loss in posterior based perfroations.He noted a hearing loss of 29db and in anterior perforations noted a hearing loss of 18.5[32.]

Mahajan noted that the posterior based perforations (p=<0.05) had significant hearing loss.[16]

Nepal et al in his 100 cases noted that perforations involving posterior inferior quadrant had a hearing loss of 41-53db.[28]

Durko in the 145 cases he reviewed hearing loss in the posteroinferior quadrants was up to 30dbHL while rest had an average of 20dbHL.[26]

In our study it is noted that the posterior perforations or those with combination of posterior perforations had either slight or moderate hearing loss as indicated in table 6.

Table 9: Summary of studies showing site of perforation and degree of hearing loss.

Author	Site of perforation.	Degree of hearing loss (dBHL).	This study finding.
Bhusal et al	large perforations(4 quadrant involvement.	49dBHL	37.7Dbhl
	Anterior quadrant perforation.	31dBHL	AI=26dBHL AS=25.5dBHL AS+AI=28.7dBHL
Yung et al	Big central/posterior central perforations.	43dBHL	AI+AS+PI+PS=37.7dBHL PI=44.3dBHL PS=33.3dBHL
Ahmad and ramani	Posterior perforations.	29dBHL	PS+PI=46.2dBHL
	Anterior perforations.	18.5dBHL	AS+AI=28.7dBHL
Nepal et al.	Posterior perforations	41-53dBHL	
Durko et al.	posteroinferior quadrants	30dBHL	44.3dBHL
	anterior qua.	20dBHL	

CONCLUSION

Tympanic membrane perforations due to chronic otitis media are common in our setup and these could be attributed to risk factors such as low socioeconomic status which result in poor hygiene, overcrowding.

Overall this study has shown significant correlation between the size and the site of the perforation to the degree of hearing loss. The bigger the perforation the greater the hearing loss ($p<0.00001/R$-squared 84%).The posterior perforations were associated with much more hearing loss than anterior perforationsaffected thus refuting the null hypothesis that site and size of a tympanic membrane perforation does not affect the degree of conductive hearing loss.

This study has also helped introduce the concept of video otoscopy in the Kenyan health system making Kenyatta National Hospital comparable to other countries' tertiary facilities.

RECOMMENDATIONS

1. A study with comparison of degree of hearing loss in acute perforations and chronic perforations should be carried out.
2. Intraoperative examination of ossicular mobility could be incorporated in a future study.
3. The need for training of otolaryngologists in the new and upcoming technology such as video-otoscopy.

STUDY LIMITATIONS

Lack of technical knowledge on how to operate the video-otoscopy to its full capabilities.

Prominent bony overhangs in some of the ear canal walls caused obscuring of the rim of the ear drum hence complete pictures of the tympanic membrane were sometimes difficult.

APPENDIX 1

WHO grades of hearing impairment.

Grade of Impairment.

Audiometric ISO value (average of 500, 1000, 2000,4000 Hz).

Impairment description:

No impairment-25 dBHL or less (better ear): No or very slight hearing problems. Able to hear whispers.

Slight impairment-26-40 dBHL (better ear): Able to hear and repeat words spoken in normal voice at 1 meter.

Moderate impairment-41-60 dBHL (better ear): Able to hear and repeat words using raised voice at 1 meter.

Severe impairment-61-80 dBHL (better ear): Able to hear some words when shouted into better ear.

Profound impairment including deafness-81 dBHL or greater (better ear): Unable to hear and understand even a shouted voice.

APPENDIX 2

GENERAL PATIENT INFORMATION

Perforations (holes in the ear drum) are common due to ear infections or trauma to the ear. This study aims to look at these perforations and to determine degree of hearing loss one suffers in relation to the size and site of the perforation.

It will involve examination of the ear using a headlight. This will help in visualizing the external auditory canal in terms of any wax or debris which if present will be removed using a clean Jobson's probe.

The ear will then be examined with a Welch Allyn pocket otoscope. The ear will be gently pulled outwards and upwards in adults and in children outwards to straighten the ear canal.The otoscope with a clean aural speculum will be introduced gently into the ear canal and in case of discomfort due to presence of trauma or active infections the procedure shall be abandoned.

The ear will then be examined in a similar procedure using a video otoscope.the scope will be fitted with disposable aural speculum.The scope will be attached to a computer in order to visualize the images of the eardrum and the pathologies onto the monitor where they will be recorded as photographs for the purposes of documentation and measurements

The pure tone audiometery test will help determine the degree and type of hearing loss one suffers. It will be carried out in a sound proof room within the ENT department where one

Will be subjected to sounds at different frequencies and the findings will be recorded. It involves no discomfort or pain.

The patient reserves the right to refuse to participate or drop out of the study at any given time without any consequences.

HABARI YA UJUMLA KWA MGONJWA:

Kipenya katika kiwambo cha sikio ni kitu ambacho ina letwa na maambukizi tofauti tofauti ya masikio au kiwewe kwa sikio.

Utafiti huu ni kupima haya kipenya na vile yanaleta kutoweza kusikia vizuri.

Katika utafiti huu kifaa ambacho kina itwa “video-otoscope” ita tumiwa kupima sikio na kipenya katika kiwambo cha sikio.kifaa huu inalinganishwa na kompyuta ili haya kipenya ya weza kuonekana na kupimwa.

Utaratibu huu haina uchungu lakini kama kuna maambukizi inaweza kuleta uchungu kiasi.

Kabla ya kutazama sikio na hii kifaa,sikio ita vurutwa kwa upole juu na nje.Kifaa huu itaingizwa kwa sikio na wakati kipenya itaonekana picha ita chukuliwa. Kama kuna uchufu katika sikio ita tolewa. Kama kuna uchungu sana hii utafiti haita fanywa.

Kupima kiasi ya kutoweza kusikia ina itwa “pure tone audiometery”.Katika upimaji huu uta ambiwa kusikiza sauti kwa kiasi tofauti tofauti,hakuna uchungu and madhara ambayo ina husiana na huu upimwaji.

Mgonjwa ana haki yaku kataza keendelea na utafiti huu wakati wowote.

APPENDIX 3

<u>CONSENT FORM</u>

Patient number:………………………

Consent by patient:

I…………………………………..of………………………………hereby give consent to be included in this study about central tympanic membrane perforations and degree of conductive hearing loss. I understand that photographs of my eardrum will be taken and these photos will be used for documentation and measurements.

The nature of the study has been explained to me by DR. …………………………………….

Date………………. Signed………………..

I Dr.……………………..confirm that I have explained to the patient the nature of the study.

Date………………..signed……………………

Kukubali kwa mgonjwa:

Mimi……………………..……..kutoka…………………….……..ninakubali kushirikisha katika utafiti huu juu ya kutoweza kusikia kwa sababu ya kipenya katika kiwambo cha sikio.

Nina elewa ya kwamba picha ya kiwambo cha sikio langu yata tumiwa kwa usomaji.

Nime elezewa na dakatri……………….

Tarehe:…………………..sahihi……………….

Mimi daktari………………. nahakikisha ya kwamba nimemelezea mgonjwa juu ya utafiti huu.

Tarehe………………. Sahihi………………….

APPENDIX 4

QUESTIONNAIRE ON THE CORRELATION BETWEEN SIZE AND SITE OF CENTRAL TYMPANIC MEMBRANE PERFORATION AND DEGREE OF CONDUCTIVE HEARING LOSS.

SERIAL NO:…………………………………

A. BIODATA

1. Initials:……………………..

2. Sex: Male ☐ Female ☐

3. Age: ☐

B. HISTORY

1. Cause:

a) Infection: Acute ☐ Chronic ☐ Specify ______________

(less than 2 weeks) (more than 2 weeks/recurrent)

b) Trauma: Assault ☐ Iatrogenic ☐

Other ☐ Specify ____________________

2.Symptoms and duration:

	Right		Left		Duration			
	Yes	No	Yes	No	Days	Weeks	Mth	Yrs
Otalgia	☐	☐	☐	☐	☐	☐	☐	☐
Otorrhoea	☐	☐	☐	☐	☐	☐	☐	☐
Impaired hearing	☐	☐	☐	☐	☐	☐	☐	☐
Tinnitus	☐	☐	☐	☐	☐	☐	☐	☐

Vertigo	☐	☐	☐	☐	☐	☐	☐	☐
Facial nerve palsy	☐	☐	☐	☐	☐	☐	☐	☐

Others (please specify)…………………………………………….

C. PAST MEDICAL HISTORY

	Right		Left		
	Yes	No	Yes	No	Specify
Prior impaired hearing	☐	☐	☐	☐	________
Ototoxicity from drugs/chemicals	☐	☐	☐	☐	________
Previous ear infections	☐	☐	☐	☐	________
Previous ear trauma	☐	☐	☐	☐	________
Previous ear surgery	☐	☐	☐	☐	________

Chronic illness Specify __________ Drugs: ______________

D.CLINICAL EXAMINATION

	RIGHT		LEFT	
1. Signs	Yes	No	Yes	No
Otorrhoea	☐	☐	☐	☐
Tenderness	☐	☐	☐	☐
Wax impaction	☐	☐	☐	☐
TM perforation	☐	☐	☐	☐
	☐	☐	☐	☐

Facial nerve palsy

2. Position of perforation:

	Right	Left
Anterosuperior	☐	☐
Posterosuperior	☐	☐
Anteroinferior	☐	☐
Posteroinferior	☐	☐
Central	☐	☐

Photo

3. Area of perforation (P):

4. Area of tympanic membrane (T):

5. Percentage area of perforation (P/T x 100%):

6. Audiometry

Hearing level (dBHL): Right ☐ Left ☐

(Average of 500/1000/2000/4000Hz)

7. Degree of hearing loss (WHO audiometric descriptor)

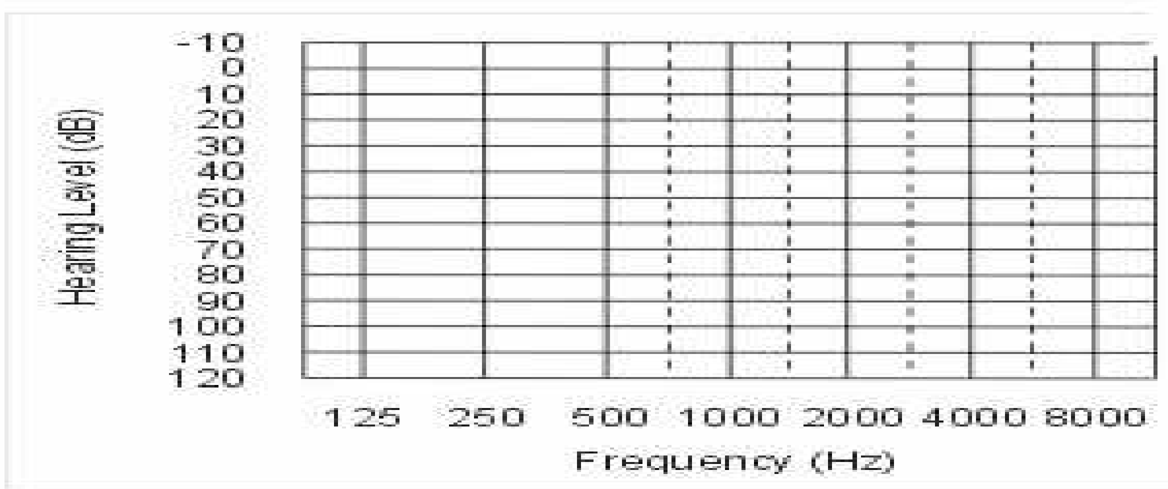
Normal ☐
<25dB

Slight impairment ☐
26-40dBHL

Moderate ☐
41-60dBHL

Severe ☐
61-80dBHL

Profound ☐
>81dBHL



AUDIOGRAM

APPENDIX 5

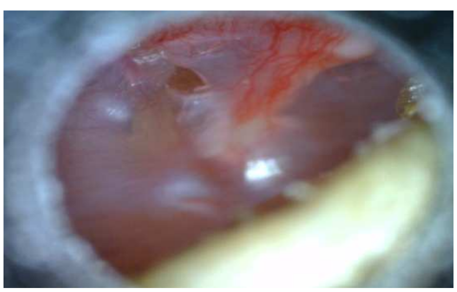


Photo1: left tympanic membrane with a posterosuperior perforation and a prominent bony overhang preventing complete picturization of the anteroinferior and anterosuperior quadrants.

PHOTO 2: right tympanic membrane perforation involving all the 4 quadrants.

PHOTO 3: left tympanic membrane perforation involving anterosuperior and anteroinferior quadrants.

PHOTO 4: right tympanic membrane perforation involving all the 4 quadrants.

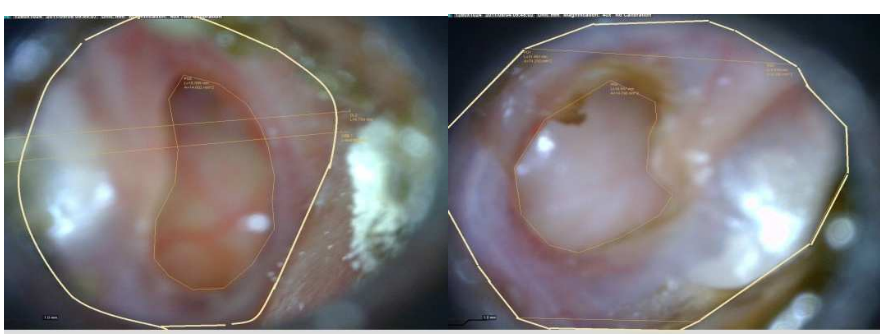


PHOTO 5: calculation of size of the perforation using dino capture *version 2.0* 1.3.2.

PHOTO 6:video otoscope,aural speculum,hand held otoscope.

APPENDIX 6

BUDGET

CONSIDERATION	UNIT	QUANTITY	UNIT COST (Ksh)	TOTAL COST(Ksh)
Biostatician				20,000/=
Video otoscope	1			36,700/=
Stationary/ Printing paper		20	400/-	8,000/=
PTA	80		350/-	28,000/=
Contingency				10,000/=
Total				**102,700/=**

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