PREVALENCE OF OTTIS MEDIA WITH EFFUSION AMONG PRESCHOOL CHILDREN IN KINONDONI DISTRICT DAR ES SALAAM, TANZANIA

by

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A dissertation submitted in partial fulfillment for the degree of Masters of Medicine in Otorhinolaryngology of the Muhimbili University of Health and Allied Science

(August, 2008)



CERTIFICATION

The undersigned certify that he has read and hereby recommends for acceptance by the Muhimbili University of Health and Allied Sciences a dissertation entitled: **"Prevalence of otitis media with effusion among preschool children in Kinondoni district, Dar-es-Salaam"** in partial fulfillment of the requirements for the degree of master of medicine (OTORHINOLARYNGOLOGY) of Muhimbili University of Health and Allied Sciences.

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SUPERVISOR

Date: 27th November, 2008

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DEDICATION

To my husband Kingdom, my parents Richard and Apasiaeli, my parents in law Anderson and Ndeana, my daughter and my sons for their love and encouragements.

ABSTRACT

Introduction: Otitis media with effusion is a common disorder in children which may either resolve spontaneously or cause undesirable complications especially if associated with persistent hearing loss.

Otitis media with effusion contributes to hearing loss, poor speech acquisition and learning difficulties. There has not been any retrievable study done to show the magnitude of otitis media with effusion and its complication in our country.

Aim: This study aimed at determining the prevalence of otitis media with effusion among preschool children in Kinondoni district, Dar-es-salaam.

Materials and Methods: This study was conducted in Kinondoni district, Dar-es-salaam in Tanzania among 541 preschool children aged 2 to 6 years. Random sampling method was used. Otoscopic examination was done by the principal investigator using pneumatic otoscope. Diagnosis of otitis media with effusion was reached by findings of the ear drum with exclusion of features of acute otitis media. Tympanometry was conducted by research assistant and type B curve was regarded as diagnostic for otitis media with effusion.

EPI-INFO version 6.04d computer programme was used to analyze the data and relationships were tested at 5% tolerable error.

Results:

Out of 541 preschool children screened, 24% had otitis media with effusion in one or both ears. Fifteen percent had bilateral otitis media with effusion while 4.8% had right and 4.3% had left otitis media with effusion respectively. Of the screened female children, 26.5% had otitis media with effusion which was slightly higher than males (21.7%). The prevalence of otitis media with effusion was higher (24.5%) among children aged 5 to 6 years as compared to prevalence of 22.5% among children aged 2-4 years.

Both pneumatic otoscopy and tympanometer detected otitis media with effusion in 17.8 % of children aged 2 to 4 years while 14.3% of children aged 5 to 6 years were detected by pneumatic otoscope and 14.1% were detected by tympanometer.

The pneumatic otoscopy was found to be as good as tympanometry in diagnosing otitis media with effusion and it's sensitivity was found to be 97.7% and specificity was 99.5%.

Conclusion: The overall prevalence of otitis media with effusion among preschool children in Kinondoni district in Dar-es-salaam was noted to be high. The prevalence was higher among children aged 5 to 6 years and in females. Pneumatic otoscopy was as good as tympanometry in diagnosing otitis media with effusion.

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DEFINITIONS AND ABBREVIATIONS

Abbreviations:

OME	-	Otitis media with effusion
AOM	-	Acute otitis media
COM	-	Chronic otitis media
HL	-	Hearing loss
SNHL	-	Sensorineural hearing loss
CHL	-	Conductive hearing loss
EAC	-	External auditory canal
URTI	-	Upper respiratory tract infection
ET	-	Eustachian tube
ME	-	Middle ear
ORL	-	Otorhinolaryngology
TM	-	Tympanic membrane.
OM	-	Otitis media
Rt	-	Right
Lt	-	Left
ETD	-	Eustachian tube dysfunction.
dB	-	Decibel
AHCPR	-	American Health Care Policy and Research.
PCR	-	Polymerase Chain Reaction
MUHAS	-	Muhimbili University of Health and Allied Sciences
MNH	-	Muhimbili National Hospital
DSM	-	Dar –as-salaam

Definitions

- Decibel (dB) is a unit used in measuring sound pressure levels.
- Hearing impairment refers to any degree of hearing loss from mild to severe.
- Atelectasis is medial retraction of pars tensa of the tympanic membrane (TM) as a result of otitis media with effusion (OME).
- Adhesive otitis media is fibrous adhehesion between TM and medial wall of middle ear.
- Tympanosclerosis is sub epithelial deposition of calcarious plaques in the middle ear or tympanic membrane (TM).
- A cholesteatoma consists of squamous epithelium that is trapped within the temporal bone, middle ear, or mastoid and can expand only at the expense of the bone that surrounds and contains it.

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CHAPTER ONE

1.0 INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Definition

The OME guidelines define OME as "fluid in the middle ear without signs or symptoms of ear infection." The guideline listed the following synonyms for OME: serous otitis media, secretory otitis media, allergic otitis media, catarrhal otitis media, nonsuppurative otitis media, mucoid otitis media, secondary otitis media, hydrotubotympanum, exudative catarrh, tubotympanitis, tympanic hydrops, glue ear, fluid ear, middle ear effusion, and tubotympanic catarrh [20].
Glue ear is a name given to OME with thick viscous effusion (fluid)
However a better and widely used definition is OME [20].
If OME persist result in decreased mobility of TM and serves as a barrier to sound conduction leading to conductive HL

OME has reached epidemic proportion and can cause deafness at a critical child's language development [12].

OME is common in children with prevalence of about 20% at age of 2-3 yrs [1, 2]
It usually follows unresolved acute otitis media (AOM) and it is asymptomatic in most cases. It's social impact is evident since it is recognized to cause language impairment because it is associated with hearing loss which occurs at a very sensitive age of language acquisition [2,7]. This finding has led to implementation of programmes for earlier detection of OME.

A child with an episode of OME often experiences a mild to moderate fluctuating hearing loss, thus receiving partial or inconsistent auditory cues, which may make speech more difficult to detect and/or to filter from background noise [7].

It has been hypothesized that the resulting misperception or missing of words may affect the input to the knowledge base or to the neural substrate on which language learning is built [5].

Academic skills, particularly in reading and other language based subjects may be affected when there is a high demand for attention to verbally presented information [6].

This study focused the first six years of life because this is the age at high risk of acquiring OME and yet is the period of most rapid language development. In addition children of this age group are least likely to be able to report or seek help for impaired hearing, particularly if these problems have a slow onset and are subtle.

Persistent OME may be associated with physical or behavioral symptoms including hyperactivity, poor attention and behavior problems and reduced child gravity of life in some studies [6].

Early interventions have been shown to minimize the complications.

Children with chronic OME are also at risk of structural tympanic membrane damage such as retraction pocket, ossicular chain erosion, adhesive otitis media, cholesteatoma and atelectasis.

Children who experience persistent or repeated OME and associated with HL during early childhood may be at a disadvantage of learning speech and language [7].

1.2 BACKGROUND

1.2.1 ANATOMY

MIDDLE EAR or TYMPANIC CAVITY

The middle ear or tympanic cavity is an irregular, laterally compressed space within the temporal bone. It is filled with air, which is conveyed to it from the nasal part of the pharynx through the auditory tube. It contains a chain of movable bones, which connect its lateral to its medial wall, and serve to convey the vibrations communicated to the tympanic membrane across the cavity to the internal ear [30].

The tympanic cavity consists of two parts: the tympanic cavity proper, opposite the tympanic membrane, and the attic or epitympanic recess, above the level of the membrane; the latter contains the upper half of the malleus and the greater part of the incus. Including the attic, the vertical and antero-posterior diameters of the cavity are each about 15 mm. The transverse diameter measures about 6 mm. above and 4 mm. below; opposite the center of the tympanic membrane it is only about 2 mm.

The tympanic cavity is bounded laterally by the tympanic membrane; medially, by the lateral wall of the inner ear. It communicates, behind, with the tympanic antrum and through it with the mastoid air cells, and in front with the auditory tube [30].

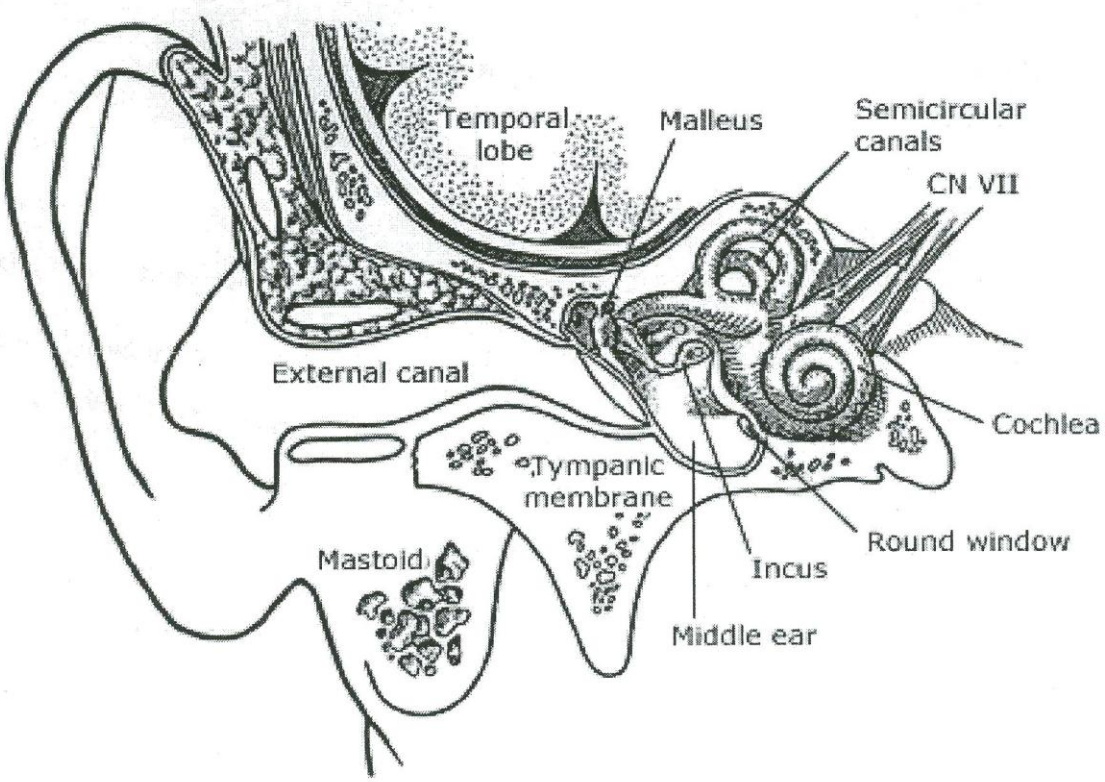
The auditory tube (*Eustachian tube*) is the channel through which the tympanic cavity communicates with the nasopharynx. Its length is about 36mm in adults and in children is 21mm, and its direction is downward, forward, and

medialward, forming an angle of about 45 degrees in adults with the sagittal plane and one of from 30 to 40 degrees with the horizontal plane.

It is formed partly of bone cartilage and fibrous tissue .There is slight anatomical variation between adults and children in terms of length and angulation [30].

The tympanic membrane separates the tympanic cavity from the external acoustic meatus. It is a thin, semitransparent membrane, nearly oval in shape, somewhat broader above than below, and directed very obliquely downward and inward so as to form an angle of about fifty five degrees with the floor of the meatus. Its longest diameter is downward and forward, and measures from 9 to 10 mm; its shortest diameter measures from 8 to 9 mm (in adults) [30].

FIGURE 1: ANATOMY OF THE EAR



1.2.2 EPIDEMIOLOGY

In a study of 208, three years old children, it was found that in higher SEC groups OME in early life is associated with significant language delays and lower intelligence quotient scores[11].

The last two decades of the 20th century saw a dramatic rise in OME, largely due to increased pollution and increased use of early childhood day care (where children are exposed to many respiratory infections).

Rosenfield in 1994 noted that about a quarter of OME cases are discovered incidentally during well-child examinations. About 60 percent of children would have OME by the age of two years and 80 percent before school entry [62].

The Agency for Healthcare Research and Quality 1994 OME guideline reported that in one study of children two to six years old in group child care, 53 percent had at least one episode of OME during the first year of the study, 61 percent had at least one episode during the second year of the study, and 30 percent had recurrent OME [24].

There is evidence that OME has a retarditive effect on development. Therefore more effective strategies to encounter this effect in areas where OME is present need to be established [11].

1.2.3 DIAGNOSTIC TESTS

Various methods have been proposed for the diagnosis of OME. The OME guideline panel drew several conclusions regarding diagnosis of OME [24]. They recommended the use of pneumatic otoscopy as the primary diagnostic method with tympanometry as a confirmatory diagnostic method.

OTOSCOPY

The normal TM is gray, concave and translucent and moves briskly on pneumatic otoscopy. In AOM the classic signs are redness and bulging of the TM with associated symptoms and signs of fever,otalgia/irritability etc[8].

Pneumatic otoscopy is examination of the ear where the TM is viewed under illumination with small amounts of positive and negative air pressure in external auditory canal (EAC).The TM should move inward and outward in synchrony with pressure changes.

In healthy ear, pressure as low as 1 to 2 daPa result in detectable motion of drum head [21].

Use of operating microscope improves the ability to make these subtle judgments.

Pneumatic otoscopy is performed with a handheld unit that consists of a light source, a magnifying lens, and a speculum. The otoscope allows visual inspection of the tympanic membrane as well as the external ear canal. With the speculum securely in place, the degree of movement of the tympanic membrane in response to pneumatic pressure may be observed. Decreased tympanic membrane mobility in response to pneumatic pressure is believed to be related to the presence of middle ear effusion [21].

Other classic findings of OME are tracted, hypomobile or immobile TM and a dark fluid filled tympanum that obscures visualization of the long process of the incus. There may be increased vascularization of the radial vessels, with or without increase in malleolar vessels.

Fluid levels and air bubbles may be seen within the middle ear cleft. Atelectatic change may be present to a variable degree [21].

TUNING FORK TESTS

These have limited value in diagnosing OME. They are also unreliable in children [21].

TYMPANOMETRY

The handheld tympanometer is a device that provides quantitative information on the function of structures and the presence of fluid in the middle ear. The graphic display of this data is the tympanogram. A pneumatic otoscopic examination of the tympanic membrane should be performed before tympanometry. Using pneumatic otoscopy with tympanometry improves the accuracy of diagnosis because many abnormalities of the eardrum and ear canal that might cause an abnormal tracing can be visualized.

Tympanometry is performed by inserting into the ear a probe that emits a tone and measures the amount of sound energy reflected from the tympanic membrane as a function of ear canal air pressure [4].

The instrument may or may not be handheld. The output of tympanometric measurement may be qualitative, that is, tympanogram patterns, or quantitative, for example static admittance, equivalent ear volume, tympanometric width, tympanometric peak pressure, or acoustic reflex.

Tympanometry has an important place in the evaluation of children with middle ear disorders. Ease of use, acceptance by patients, and reproducibility of results and availability of low cost machines has led to wide use of tympanometry in physicians offices [4].

By plotting the amount of acoustic energy reflected from the TM as the pressure in the EAC is varied from -400daPa to -100daPa, a tympanogram is obtained, the shape of which provides considerable information about the status of the middle ear.

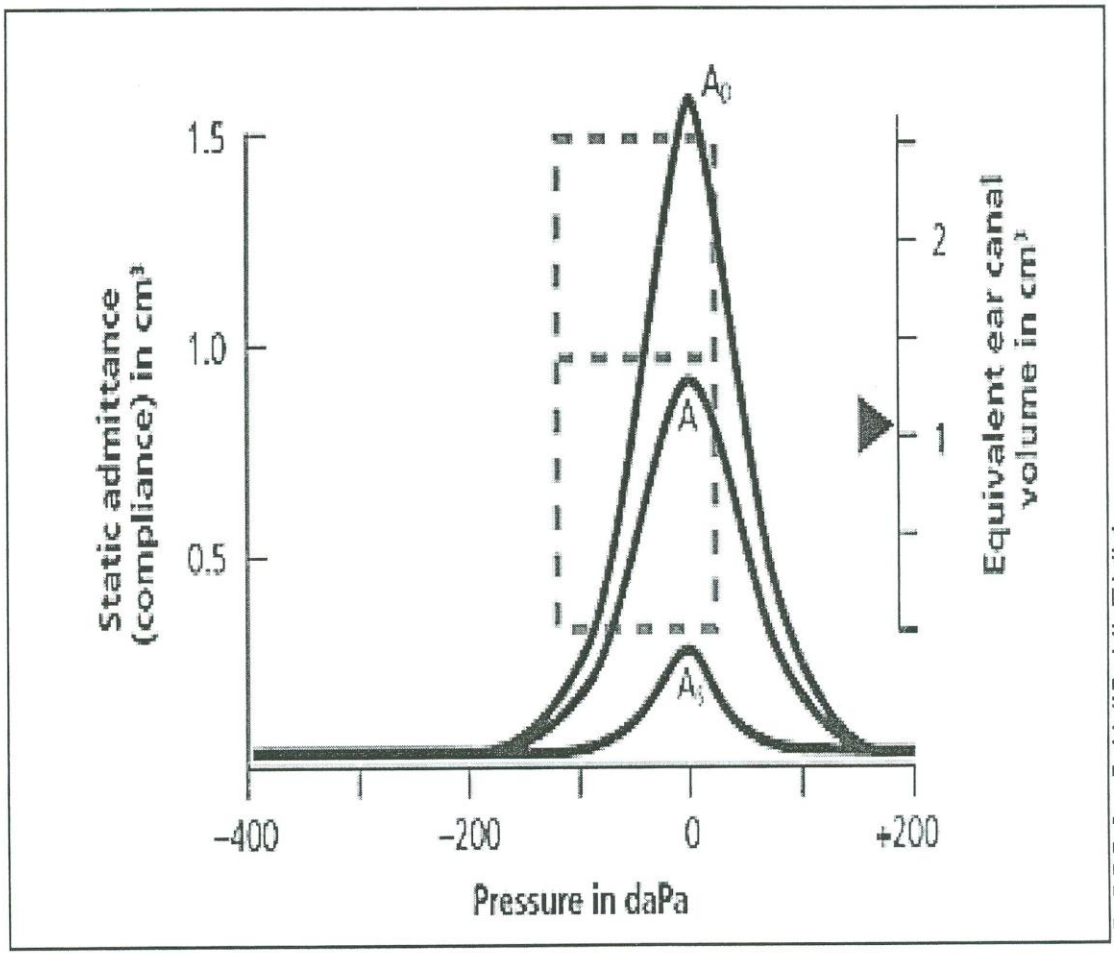
The flat or type B tympanogram is believed to be associated with the presence of middle ear effusion. The type A tympanogram is believed to indicate normal middle ear status. The relationship of the type C tympanogram to middle ear status is less clear [4].

When the tympanogram is completely filled or impacted with effusion, compliance is low and the tympanogram is flat, which signify that reflected energy does not vary with the pressure change. This shape was labeled type B by Jerger [22].

Type B curves may be completely flat or have rounded compliance peak, which is often below -300daPa.

Figures 2 and 3 depict various tympanogram tracings based on variations of the original Liden and Jerger classifications [5] . The middle curve in *Figure 2* is from a normal ear. The tympanogram curve has a normal maximum height that occurs at a pressure close to zero and the width of the curve is normal. This is referred to as a type A tracing. In this figure, the ear canal volume is normal. *Figure 2* also has a curve that demonstrates a high peak height, labeled as type AD. High static admittance can result from an overly mobile tympanic membrane caused by disarticulation with the bony structures of the middle ear, or a tympanic membrane that has healed over a perforation but is thinner and more compliant than expected [23].

The lowest curve in *Figure 2* is a type AS tracing, with a reduced peak height, recorded from middle ears with some fluid or ossicular fixation that partially decreases mobility [43]



The right vertical axis represents the equivalent ear canal volume measured in cm3 and is indicated with a triangle in each tympanogram. The left vertical axis represents the static admittance (or compliance) measured in cm3. Static admittance and peak pressure are normal for adults (older than 10 years) if the curve crosses into either of the two stacked interrupted-line rectangles. They are normal for children if the curve crosses into the lower of the two rectangles.

Figure 2. Type A tympanogram. Type AD has a high peak height. The middle curve is normal. Type AS has a reduced peak height.

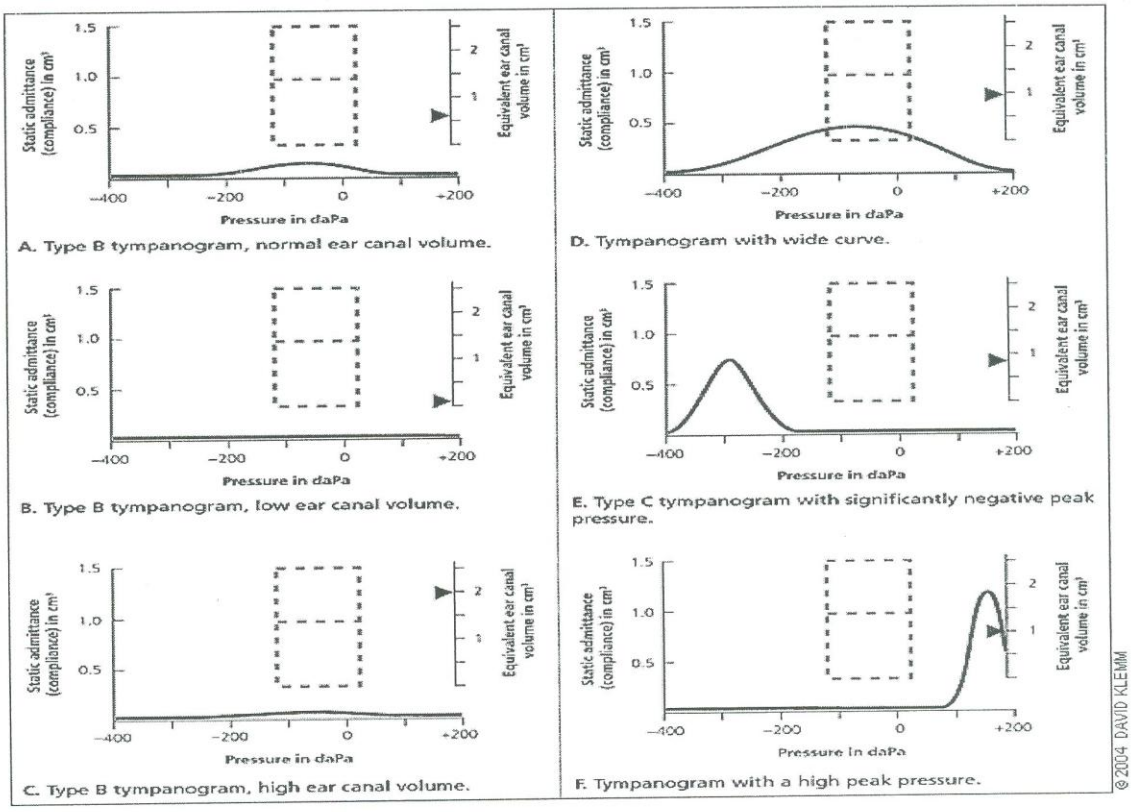


Figure 3A is a flattened, or type B tracing, with a low static admittance. The ear canal volume is normal. The most common cause of this pattern is decreased mobility of the tympanic membrane secondary to middle ear fluid (OME). Other causes are increased stiffness of the eardrum (from scarring), tympanosclerosis (the formation of dense connective tissue around the auditory ossicles), cholesteatoma, or middle ear tumor [43]. When evaluating the efficacy and clinical usefulness of tympanometry, many studies consider only a type B tracing as definitely abnormal [77].

PURE TONE AUDIOMETRY

Effusion that completely fills the middle ear cleft usually results in a moderate conductive hearing loss, however small amount of effusion may not alter hearing sensitivity.

Audiometry is impractical in children less than 2 years old but it is recommended in decision algorithm for electing surgical drainage of middle ear. It is recommended by the Agency of American Health Care Policy and Research (AHCPR) guidelines [24].

The acoustic middle-ear muscle reflex, either ipsilateral or contra lateral, may also be measured by acoustic emittance instruments and represents the contraction of the stapedius and tensor tympani in response to sound stimulation. Its absence may be related to the presence of middle ear effusion depending on the clinical situation [6].

ACOUSTIC REFLECTOMETRY

Acoustic reflectometry is performed using a handheld instrument that measures the response of the tympanic membrane to a frequency-sweep sound spectrum. The spectral gradient angle, which is a function of the frequency and amplitude, may be related to middle ear effusion presence [3].

Distinguishing features between AOM and OME is that children with OME present no evidence of acute inflammation despite visible fluid or reduced mobility on pneumatic otoscopy.The ear is not acutely painful, but the child may have ear discomfort and/or hearing loss.

Children with AOM present with combination of ear pain (otalgia) loss of landmarks and an opaque bulging, inflamed TM on direct otoscopy [6].

1.2.4 RISK FACTORS

Various risk factors have been implicated but to date only a few have been proven.

The incidence declines with age except for slight upward trend between 5 and 6 years since this is the age where most of children start kindergarten.
The age specific incidence of OME parallels that of acute infection; the peak was at age of 6 to 13 months in Boston children and 10 to 12 months in Nashville children. Persistence effusion of the middle ear was more likely in young children i.e. between 2 to 5 years of age [11].

Reton et al found that approximately 50% of children of 2 years of age or younger had effusion that lasted for 4 weeks only, 20% of children older than 2 years had OME of this duration similar findings were noted in Danish surveys of healthy children [2]. OME and high negative pressure were more frequent in children 1 – 4 years of age than in children aged 7 years and older.

Studies done in Boston revealed that about 50% of children aged 2 years or less had OME secondary to AOM, another study was done by Pelton et al which showed that 20% of children older than 2 years had OME which persisted for 1 month or more [9,11] .

In Dannish studies of healthy children the findings were similar with high incidence of OME between 1 to 4 years than in those older than 7 years [2].

SEX:

Males have a higher incidence of AOM than females. In the Boston study, males had significantly more single and recurrent episodes [11]. In Finnish males had significantly more episodes than did female in the study done June 1978 [33]. Another Finnish study done showed that males had more episodes than females [30].More males undergo myringotomies and tympanoplasties than females a fact that shows that chronic or severe infections of ME are common among males [33].

RACE:

Eskimos, America Indians and Hispanic children have high incidence than America white, Blacks have a lower incidence of OME than whites. These differences may be due to anatomical differences in ET in term of length and width .Socioeconomic and racial differences may also play role [9].

SOCIAL/ECONOMIC CONDITION

OME is common in low socioeconomic classes.

Factors e.g crowding, poor hygiene, inadequate nutrition, delay in medical services and poor compliance with treatment increase the occurrence of OME.

In some studies done in Pittsburgh children revealed that children living in urban areas have higher incidence of OME than those leaving in rural areas. The reason is considered to be the higher density of population in urban area especially those with day care centers[11].

Cambon et al noted a strong association between OME and poor social economic conditions among native Americans of British Colombia [33].

In the Boston study children living in overcrowded household were more likely to have OME than the children living in household with few members [11].

DAY CARE CENTER

The setting for child day care in the preschool years (child's home, other home, family based care or large center facility) is an important factor in the incidence of OME. The more the respiratory pathogens the higher rate of respiratory infection including AOM which is a precursor of OME.

Studies done in Dannish revealed that children cared outside the home have higher incidence of OME than those cared at home [2].

Early placement of the child out of home, group day care may discourage breast feeding hence increasing the risk of OME

Current estimates are that more than 11 Million children receive full or part- time day care. More than 50% of mother who have children < 6 years of age work outside the home [11].

Day care centers vary in size and others are crowded and poorly ventilated. Therefore there is opportunity for spread of respiratory infection among the children attending day care than those receiving care at home. Day care attendance has increased substantially in the last 25 years [11].

SEASON

Studies done in Pittsburgh revealed OME occurring in winter months persisted longer than effusion occurring in summer months[11].

SMOKING

Smoke exposure can result in structural and physiological changes in respiratory tree such as goblet cell hyperplasia and mucus hypersecretion, ciliostasis and decreased mucociliary transport [49].

Etzel et al demonstrated high incidence of AOM and increased duration of OME in children exposed to smoke [49].

GENETIC FACTORS

Genetic predisposition to ME infection as well as OME has been documented. This is related to the genetic anatomical abnormalities in skull,nasopharynx,eustachian tube and immune response [39] .

BREAST FEEDING

Breast feeding has preventive factors against URTI including AOM and therefore OME [69].

ALTERED HOST RESPONSES AND UNDERLYING DISEASES

- These include immunodeficiencies (congenital or acquired)
  Drugs which suppress immunity
- Anatomical defect
  -Cleft palate ,cleft uvula,
  -Sub mucus cleft
- Patulous Eustachian tube
- Down syndrome.

ANTIBIOTICS

Wide spread use of antibiotics has been implicated, resulting in either incomplete resolution of AOM, or a change in virulence of organisms. It has been postulated that antibiotics interfere with local IgM production in the middle ear [17].

RECURRENT ATTACKS OF AOM

OME may follow recurrent attacks of AOM. Merchant et al (1984) in a study of 70 babies followed from birth to one year showed that 54% had one or more episodes of AOM, 10 of whom developed bilateral middle ear effusions[17].

VIRAL RESPIRATORY INFECTION

Acute OME is increased in children with history of viral respiratory infection. The viruses which have been implicated are;influenza virus,adenovirus,respiratory syncyntial virus and rarely parainfluenza and rhinovirus[17].

1.2.5 AETIOLOGY

The aetiology and pathogenesis of OME are not yet fully understood, however, multiple factors and complex interaction of biochemical, immunologic and inflammatory mediators in the middle ear cavity have been documented in various studies. Among these factors abnormal function of the ET, mucosal changes, presence of microorganisms, and the effect of inflammatory cells seem to have the most influence on the etiology and pathogenesis of OME [35-39].

EUSTACHIAN TUBE

The ET has at least three physiologic functions with respect to the ME which are:

1. Protection from nasopharyngeal secretions and pressure. Experimental studies done revealed that there is surfactant protein in the middle ear cleft which is similar to the one found in the alveoli and have immunoreactive properties [35].
2. Clearance of secretion from ME into the nasopharynx [36-39].
3. Ventilation of the ME to equilibrate air pressure with atmospheric pressure [36,38].

If any of above mechanisms is impaired OME can result.

The factors which may affect eustachian tube may be considered under three main groups.

i. **Factors causing basic Eustachian tube malfunction** e.g cleft palate. This is related to abnormal patency of Eustachian tube followed by unwanted nasopharyngeal secretions which may enter the middle ear, with or without negative pressure[38].

ii. Factors leading to altered mucociliary systems

Examples are infections of the sinuses, nose, postnasal spaces, tonsils and pharynx, allergy; altered immunological factors; surfactant deficiency; ultrastructural changes in cilia; fibrocystic disease; hormonal factors such as high oestrogen levels and hypothyroidism. These lead to poor clearance of middle ear fluid with resultant accumulation of fluid in the middle ear[38].

iii. Factors leading to nasopharyngeal disproportion

These include craniofacial abnormalities as found in Down's syndrome, Hurler syndrome and Hunter's syndrome, and tumor of the postnasal space. These pose a mechanical disadvantage to clearance of the middle ear fluid. Adenoid hypertrophy has been incriminated[38].

1.2.6 PATHOGENESS

Infection or allergic reaction resulting in congestion of the respiratory mucosa of the nose, nasopharynx and ET obstructs the narrowest portion of the tube, the isthmus. This obstruction causes negative middle ear pressure followed by OME.

Anatomic or physiologic abnormality of the ET can cause recurrent episodes of AOM or persistent OME.

The hypothesis that abnormal function of ET is important factor in the pathogenesis of ME disease was first suggested more than 100 years ago by Politzer [36].

Studies done revealed that inflammation due to infection or allergy may cause intrinsic mechanical obstruction of the ET [37-39].

A much smaller proportion of children have mucosal disease of middle ear as a result of allergy itself [37-38].

The structural TM damage which can occur is due to the reason that effusion contains leukotrienes, prostaglandings and arachidonic acid metabolites that invoke a local inflammatory response. Reactive changes may occur in the adjacent TM and mucosal linings. A relative under ventilation of the middle ear produce a negative pressure that predispose to focal retraction pockets, generalized atelectasis of the TM and cholesteatoma[38].

After blockage of ET, reaction in the mucosal lining develops in phases as follows:

1. Lack of ventilation creates a "hydrops ex vacuo".Fluid is sucked into the tympanic cleft. The mucosa becomes swollen, hyperaemic and oedematous. The basal membrane thickens and its fiber network is altered. Therefore the middle ear is filled with effusion. Anaerobic conditions, due to oxygen resorption by the mucosa, favor epithelial metaplasia.The flat epithelium becomes higher and ciliated.Secretory elements and goblet cells develop, and gland-like structures are build up.Mucous is produced as an important component of the effusion[39].

2. Blocked ET with intact ear drum membrane prevents the clearance of effusion away from the tympanum. This brings to the whole elaboration of the middle ear content to the mucosa. Finger like projections and connective tissue buds plunge into the effusion, starting a tissue proliferation. Various granulomas are built up, for example cholesterol granulomas. Enzyme production helps to digest this mass of fatty degenerated or mucoid discharge. A lot of microphages can be seen, overloaded with debris, like lipophagocytes or foam cells [39].

3. The reticulohistiocytic system of the middle ear lining also proliferates. A mononuclear diffuse cellular infiltration can be seen locally around the vessels. Focus –like aggregations are seen, similar to lymphocytic nodules [39].

4. Epitheloid cells and giant cells surrounded by lymphocytes can be seen, which is a sign of special irritation. Without restoration of tubal function, the abilities of the mucosa are overcharged and defective healing results. Effusion under organization. Fatty deposits, hyalinization, dystrophic calcification and strands of scar tissue narrow the tympanic cleft. Also there is proliferation of collagen fibers in the submucous connective tissue. These will end up in the atelectasis of the middle ear [39].

MICROBIOLOGY

In the past OME was thought to be non infective condition [53]. Recently Rainsanem, Stenfors and Senturia et al identified bacteria by means of smear and culture and by Polymarase Chain Reaction (PCR) in about 42 % of children with OME [32].

Bacteria,mycoplasma and viruses have all been shown to be present in some samples The type of microorganisms isolated are similar to those isolated in AOM predominantly B- hemolytic streptoccocci and H.infuenza[32].

1.2.7 CLINICAL PRESENTATION

OME in its quiescent phase has none of the symptoms and signs attributed to the infection of the middle ear. Therefore the most frequent presentation is fluctuant, latent or overt hearing loss. When latent in infants and young children, it may present with impaired speech and language development. There may be behavioral difficulties and scholarstic retardation. Children rarely complain of hearing difficulty. In the western world it is frequently first detected on routine screening tests, either clinically, audiometrically or by impendence studies.

Commonly found are indirect symptoms such as shouting, insularity, increasing the volume of the television or delay in reading development[6].

Recurrent otalgia usually results from secondary infection of the middle ear fluid and so frequently coincides with a cold or URTI, sinusitis or an episode of allergic rhinitis or following swimming.

Tinnitus is another feature of OME. The patient may complain of presence of flies and bees in the ear.

Dizziness is another reported symptom. OME is the commonest cause of vertigo in children. The affected child is noted to hold onto his seat momentarily during a spell of vertigo[6].

DIAGNOSIS

Diagnosing OME correctly is fundamental to proper management; moreover OME must be differentiated from AOM.

OME may be asymptomatic or patients may experience ear discomfort, hearing loss, tinnitus, possibly vertigo, feelings of ear fullness most of these vague presentation can be noted and expressed by adult but in young children the features frequently noted are hearing loss, unstable gait and language problems. Often the child with OME is so accustomed to reduced hearing sensitivity that parents become aware of the problems only after the child turns up the volume of the radio or television or is not attentive during conversation[8].

1.2.8 COMPLICATIONS OF OME

Persistent or fluctuating HL is present in most of children who have OME

A. CONDUCTIVE HL

Usually mild to moderate in the range of 20 and 30 dB where the softer speech sound and voiceless consonants may be missed. The HL is influenced by quantity and quality of fluid in the middle ear, i.e. ears with thin fluid are not as impaired as ears with glue like fluid and ears that are partially filled with fluid have less hearing impairment than ears that are completely filled with fluid.

Permanent CHL can occur secondary to irreversible changes that result from recurrent acute a chronic inflammation (e.g. adhesive OM or ossicular discontinuity)[59].

B. SENSORINEURAL HL

This can be attributed to effect of increased tension or stiffness of round window membrane. Permanent SNHL may occur presumably due to spread of infection or products of inflammation through round window membrane [36,59] .

C. LINGUISTIC AND LEARNING EFFECTS

Impaired cognitive, language and emotional development in children. When effusion is chronic, surgical intervention should be considered especially when antimicrobial therapy fails.

Untreated OME, especially if it is bilateral, has been associated with delayed language development and poor learning. It is especially significant in children with many episodes of OME during the language formative years and is due to the prolonged periods of hearing loss.

Those children with recurrent episodes have been found to perform poorly compared to their counterparts. In contrast to adults, a 25 dB hearing loss is catastrophic for children's speech development and learning. Fluctuating hearing loss is also confusing to children[7,59,63,68,70,73].

D. ATELECTASIS, RETRACTION AND CHOLESTEATOMA

Atrophy of the tympanic membrane can follow long standing negative middle ear pressure. The atrophy can be localized or generalized. Since the lamina propria is very thin, even minor pressure can cause retraction. Localized atrophy frequently occurs in combination with tympanosclerosis. Perforation of the atrophic region may occur following a slap or blow to the ear, ear syringing, diving, or following episode of acute suppurative otitis media. Following perforation the chances of spontaneous healing are minimal.

Retraction pockets may occur on the retracted TM. In the attic, the formation of attic cholesteatoma may occur.

In diffuse atrophy, there may be large perforation of the TM that does not heal. A tensa retraction may progress to cholesteatoma involving the incus and malleus, and atelectasis. The atelectasis is extremely difficult to arrest or correct and may lead to erosion of the outer attic wall and ossicles[8].

E. TYMPANOSCLEROSIS

Long standing OME may be associated with tympanosclerosis. This has been associated with TM perforation and interferes with hearing. However it is commoner following ventilation tube insertion[8].

1.2.9 MANAGEMENT OF OME

Management of OME is still controversial. Correct management approach remains to be defined, although there are many forms of treatment for this condition. However we now have some evidence based information to make some important decision regarding treatment or no treatment and which therapeutic options are effective and which ones are not [6].

Management of the effects of the effusion on hearing thresholds varies according to the duration and severity of the hearing loss. Many cases of OME resolve spontaneously without treatment, while a significant number require intervention.

Since this condition shows seasonal variation, and that relapses and remissions may occur several years after the prescribed treatment has been completed, it is therefore difficult to formulate an empirical approach to management of this condition.

OME in most children will need treatment if it persists for two or 3 months, but treatment may be indicated in some children because there are possible complications and sequelae associated with this condition [46].

Since impairment of hearing of some degree usually accompanies OME, treatment may be warranted when long standing HL is present. This is because such a loss may impair cognitive and language development function and result in disturbances in psychosocial adjustment. Important factor which should be considered when deciding to treat or not to treat are:

- Significant conductive HL
- Occurrence in young infants, since they are unable to communicate about their symptom and may have suppurative disease
- An associated acute suppurative URTI
- Concurrent permanent conductive or SNHL
- Presence of speech or language delay associated with effusion or HL.
- Alteration of TM such as retraction pocket.
- Middle ear changes e.g adhesive OM or osscicular involvement
- Previous surgery for OM e.g Typanostomy tube placement or adenoidectomy
- When episodes occur frequently
- When effusion last for 3 months or longer both ears or 6 or more months in one ear[24].

MEDICAL TREATMENT

Use of decongestants and antihistamine have failed to demonstrate efficacy in eliminating OME in children .However they can be used in children with recurrent episodes with evidence of upper respiratory allergy [40,58.]

Inflation of the ET middle ear using Politzer's method or the valsava maneuver has been advocated for more than a century for OME however studies by Chan and Bluestone found lack of efficacy and therefore not recommended except in adults with barotrauma[4].

Of the medical treatment advocated antimicrobial agent can be helpful in those children who have not received antibiotic recently.

There is no convincing evidence to recommend the use of steroids in the management of OME [24, 90.]

A study reported by Rosenfeld and Post J C, confirmed efficacy, particularly when the effusion is chronic, surgical intervention should be considered especially when antimicrobial therapy fail [23].

Recent guideline has recommended either antimicrobial therapy or tympanostomy Tube insertion for bilateral, chronic effusion (i.e. 3-4 months) associated with HL [90] .

SURGICAL TREATMENT

Myringotomy with tympanostomy tube placement

The potential benefits of prolonged ventilation of the middle ear were first recognized by Politzer (1867) and Hinton (1860) who created a permanent perforation by burning a hole in the TM using galvano-cautery,and inserting foreign materials such as catgut or silver canulae to maintain patency [36].There efforts had little success until 1954 when Amstrong succeeded in maintaining a plastic tube in position.

The ventilation tube acts as temporary substitute for the eustachian tube. The ventilation of the middle ear therefore improves and the epithelium gradually reverts to normal. Glandular activity is reduced and ciliary activity resumes to normal. During this period the restoration of normal ET should be the objective, failure of which will result into recurrence of effusion when the ventilation tube ceases to function.

A neat radical incision is made through TM in the anteroinferior or anterosuperior quadrant. The fluid is aspirated and the ventilation tube is inserted where it is found necessary to prevent early closure of the incision[24].

Immediate hearing improvement is achieved by this procedure. The mean duration of the survival of functioning ventilation tube is around 6 to 12 months. This depends on many factors including the epithelial migration of the TM and external auditory meatus, the tube design, size of myringotomy incision and the size of middle ear cavity on the face of atelectatic tympanic membrane.

Ventilation tubes are associated with more complications compared to myringotomy alone. These include short-lived otorrhoea, scarring and tympanosclerosis of the TM and rarely the persistent TM perforation. Extrusion of the tube is also a complication which requires re-insertion of the ventilation tubes on one or more occasions until spontaneous resolution occurs[27].

ADENOIDECTOMY AND ADENOTONSILLECTOMY

Myringotomy and adenoidectomy with or without tympanostomy tube insertion have been demonstrated to be effective in children with chronic OME who are unresponsive to antibiotic.

Adenotonsillectomy as practiced to date is based on indications other than OME.A study done by Bluestone et al demonstrated radiographically retrograde obstruction of the eustachian tube in relation to OME and adenoids hypertrophy [34].

Paradise et al carried out a well controlled prospective study which confirmed improvement in recurrent otitis media and OME following adenoidectomy [34].Other studies demonstrated disagreement.

OTHER SURGICAL MEASURES

Surgical intervention can be done in the other obvious cause affecting the eustachian tube function, example earlier closure of cleft palate which results to improvement of aural condition. Other measures such as turbinate resection may reduce obstruction due to hypertrophic turbinates in indicated cases[6].

SUMMARY OF MANAGEMENT OF OME

i. OME without significant hearing loss, which is hearing of more than 20 dB in speech frequencies, requires no intervention. These cases require watchful waiting and close follow up.

ii. Bilateral OME with significant hearing loss require observation and follow up for three months. If no spontaneous recovery myringotomy and aspiration of fluid is indicated at the first instance. If fluid recurs, myringotomy with ventilation tube insertion is done. This may be repeated if needed.

iii. Unilateral OME with or without significant hearing loss, surgical intervention is deferred after special consideration of other factors such as speech, language development and learning.

iv. If there is specific underlying cause of OME, example cleft palate should be managed accordingly.

v. Adenoidectomy should only be done selectively after careful investigations.

vi. Tonsillectomy is not recommended unless there are very specific indications for tonsillectomy in children with OME.

vii. Parents should be made aware of the possibility of ventilation tube extrusion after 6 to 12 months which may need re-insertion in about 25% of cases.

viii. The status of the TM with respect to the degree of atelectasis will indicate the need for bilateral tube insertion. Limitation of tube insertion to one ear for bilateral cases greatly reduces the complication rates.

1.3 LITERATURE REVIEW

Prevalence of OME

Approximately 2.2 million diagnosed episodes of OME occur annually in US [24].

OME may occur spontaneously because of poor ET function or as an inflammatory response following AOM.

Approximately 90% of children (and 98% of individual ear) have OME at some time before school age. Most common between 6 months and 4 years.

In the 1st year of life, >50% of children will experience OME, increasing to >60% by 2 years [24].

Many episode resolve spontaneously within 3 months, but 30% - 40% of children have recurrent OME and 5% - 10% of episodes last 1 year or longer.

Children get more OME than older children or adults due to several reasons.

- The Eustachian tube is shorter, more horizontal and straighter (quick and easy trip for the bacteria)
- The tube is floppier with a tinier opening (easily to block)
- Young children get more colds and takes time for immature immune system to be able to recognize and ward off cold viruses.

Many children with OME do not have past histories of AOM but it is suggested that in them there may have been a sub clinical infection [21].

Otitis media with effusion is among the most common pediatric health problems especially among young children [8].

It appears to be the most common precursor of chronic OM and may lead to SNHL [8]

Inspite of the association between OM and OME no previous studies have been done in our set up, which show the magnitude of OME.

From the studies done in United States one third of children with AOM were found to have OME that persisted for 4 or more weeks [9].

Another study done in Boston children showed persisted OME after AOM which showed persistent OME in 10% of children after 3 months following episode of AOM.

In a Boston study, persistent OME in the middle ear was found in 70% of children 2 weeks after 1st episode of OM, 40% at 1 month, 20% at 2 months and 10% at 3 months [11].

Studies done by Weichbold and Rohrer in Germany in 2004 in forty seven nursery schools where total of 183 children were screened for the presence of OME,63% aged between 3 to 5 years and among them 64% had temporary CHL due to external or middle ear problems (glue, ETD, OM, or cerumen).[13]

In 1998 Lyn and Jadusingh studied 2202 Jamaican children aged 5 to 7 years old. 4.9% had hearing impairment and OME was present in 2%, which was less than in developed countries [14].

Another study done by Kramer AH, Mc Cullongh among 126 Inuit children the prevalence of OME was studied.4% had OME causing significant HL, 17% had OME with minimal or no detectable HL. Therefore prevalence of OME was between 4% to 21% [15].

Total of 284 children between 3 to 8 years of age in Southern India were studied in 1997 for the overall prevalence of otological abnormality (excluding wax)which was 21.5%.Hearing impairment was detected in 34 children (11.9%).Otitis media was noted in 17.6 %.Therefore the importance of including tympanometry as part of screening protocol was highlighted [16].

In the study done at Turkey in Kindergartens, day care centers in rural and central areas of Trabzon revealed that prevalence of OME was 11.14% and the risks factors noted were low socioeconomic factors, URTI, AOM and recent antibiotic use [9].

Another study done in hospitalized patients at Dannish in 1988 revealed a prevalence of 68 % of OME in children 0-6 yrs of age [17].
Study done in Malaysia revealed prevalence of OME amongst preschool children between 5-6 yrs was 13.8% [25].

In 1985, 480 children between 0 to 23 months were studied in Venda South Africa for the presence of ME pathology by pneumatic otoscopy, tympanometry and contralateral acoustic reflex [25]. Prevalence of OM was 8.2%.Among those with OM 3.8% had OME which was different from the study done in Nigeria.
Study done at Lagos teaching hospital in Nigeria between January 2002 to June 2003 among children aged 6 months to 15 years those presented in ENT clinic , Among 184 patients HL was documented in 120 (65.2%) children, speech disorders in 56 (30.4%) ,of those with HL, 70% had delayed speech and language. Etiological factors recorded for communication disorders were among others OME contributed 4.3%.Others were meningitis, seizures, congenital etc. Early detection and follow up was recommended in early years of life[18].

In Tanzania, Bastos I,Mallya J and Andreasson L.in 1995 studied 854 school children from urban and rural in northern Tanzania.HL within speech frequency range was found in 55%.Prevalence of OM was 1.6%,scarred sclerotic TM`s were found in 26%[19].
A pilot study done by the researcher revealed that out of ~105 children who attended our ORL, OPD Clinic at Muhimbili National Hospital (MNH) per month, 31 (29%) have OM.

1.4 STATEMENT OF PROBLEM

OME appears to be most common precursor of chronic otitis media and may lead to SNHL[61].

The magnitude of OME in Tanzania is not well understood. However the pilot study done by the author revealed that OM is a common problem in children who attend ORL OPD clinic. Since MNH is a tertiary referral hospital, this indicates that AOM is common in our children but they are managed at private hospitals, district hospitals and others are given local herbs until the complications arise.
Otitis media with effusion is a common illness in childhood and is often preceded by an attack of AOM.

The risk factors for OME are also present in Tanzania e.g overcrowding, URTI, attendance to day care centers, passive smoking, not breast feeding and low social economic factors.

OME has been noted to cause deafness at critical time in a child's language and speech development [7].

Hearing loss, language and speech delay are problems evident in some children in Tanzania although the etiological factors are not clearly known.
There are very few studies which have been done to show the magnitude of OME in most of developing country such as Tanzania.

This study will therefore be the beginning of other studies in Tanzania which will initiate strategies of screening children for presence of OME and its complications and therefore promote early intervention to prevent complications which follows OME.

1.5 STUDY RATIONALE

This study is intended to evaluate the magnitude of OME in DSM which will alert the clinicians and other health care providers to develop the habit of screening children at risk and hence early intervention so as to prevent the possible complications.

Monitoring and intervention of persistent OME is important so as to prevent the complications which may follow OME such as HL, delayed language development and impaired cognitive perception.

Establishing prevalence of OME is important in determining whether it poses sufficient health risks to the population to warrant allocation of scarce resources to address it to the appropriate institutes and the public in general.

The study will also identify important areas for the need of future researches.
This study will also be done as a requirement of the partial fulfillment of the Master Degree in ORL in Muhimbili University of Health and Allied Sciences. .

CHAPTER TWO

2. AIM AND OBJECTIVES OF THE STUDY

2.1 Aim

To determine the prevalence of OME in preschool children in Kinondoni District, Dar es Salaam.

2.2 Specific objectives

1. To determine the prevalence of OME according to age and sex.
2. To determine the prevalence of OME by otoscopic examination.
3. To determine the prevalence of OME by tympanometry
4. To determine the validity of pneumatic otoscopy in diagnosing OME as compared to tympanometry.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study location

The study was conducted in Dar-es-salaam city in Tanzania in day care centers in Kinondoni District.

3.2 Study population

The study population included preschool children aged between two to six years of age in selected schools. Those who were aged 2 to 4 years and six months were grouped under 2 to 4 age group while those who were aged above 4 years and six months to 6 years and six months were grouped under 4 to 6 age group.

A list of all private and government owned schools was obtained from the Kinondoni education offices in Dar-es-salaam. The schools were divided into two groups, depending on whether the owner is government or private. Using simple random sampling seven schools were selected from each group.

The schools selected included, Filbert Bay, Kwanza Academy, Mount Kibo, EDP Royal, Alliance, Gift Skilful, St Anne which were private preschools. The government schools selected included, Mburahati, Kimara Baruti, Ubungo Kisiwani, Mianzini, Tandale, Mwananyamala Kisiwani and Kibo preschools.

Inclusion criteria

All children aged between two to six years old.

Children whose parents consented for the study.

Exclusion criteria

- Children younger than two years and those older than six years.
- Children with craniofacial malformations and those with Downs syndrome.
- Children with symptoms and signs of AOM or COM.
- Children whose caretakers did not consent.

3.3 Study design

This was quantitative cross sectional study.

3.4 Study duration

The study duration was 10 months, from February 2007 to October 2007.

3.5 Sampling Method and Sample size Determination

All preschools in Kinondoni District in DSM were listed. Thirty six preschools were government while 22 were private owned. Seven schools were selected by shuffling papers with names of schools listed in two separate groups and picking seven schools randomly in the same manner. Each child who fulfilled the inclusion criteria in the selected schools was included in the study.

Sample size was calculated using the sample size calculator developed by the Creative Research system [www.surveysystem.com/sscalc.htm (13/09/ 2003)].

The formula used was:

$$n = \frac{z^2pq}{d^2}$$

Where:

z = Percentage point of normal distribution corresponding to the level of significance (1.96).

p = Expected prevalence of OME in a population of preschools (~20%)

q = 100-p

d = maximum likely error taken to be 5%

Design effect = 2

$$n = \frac{1.96 \times 1.96 \times 20 \times (100-20)}{2 \times 2} = 492$$

The sample size of 541 was therefore adequate.

3.6 Data collection techniques and Tools

After obtaining the relevant research clearance, the author went to the Kinondoni District education office. The education officer gave the author the introduction letters to the head teachers in the selected schools. At the schools the author introduced herself to the heads together with the research assistant and explained clearly what was intended to be done.

The heads were cooperative and they allocated assistants from member of staff to work with the researcher. They selected one room where the test was conducted. During the exercise the children were grouped into ten until they were all screened.

Data collected i.e dermographic,otoscopic and tympanometric was entered into a data collection form. The principle investigator did otoscopic examination and research assistant (audiometrist) did the tympanometry and all the findings were recorded.

Equipments

i. Diagnostic set which included an otoscope with various sizes of aural specula.
ii. Pneumatic otoscope
iii. Tympanometer
iv. Siegle`s pneumatic speculum
v. Cotton wool, spirit and Boric acid ear drop

Otoscopic examination:

Each ear was examined by the researcher who is a resident in ORL.Otoscopic examination was done using battery hand handled otoscopy and the wax or foreign bodies which were encountered were removed at Muhimbili national

hospital and thorough re-examination of TM by pneumatic otoscopy was done and documented.

The pneumatic otoscopy was used to inspect for the mobility of TM and its colour, position,light reflex ,retraction pockets and any other abnormalities were recorded.

Tympanometry

Bilateral tympanograms were recorded by the research assistant (specially trained audiometrist) at each preschool selected using a calibrated Kamplex AT2 tympanometer with a 220-Hz probe tone. The lower pressure limit of this machine is − 300 daPa. The tympanogram traces were categorized by using Fiellau-Nikolajsen's modification of Jergers classification: [27].

A = Peak at + 100 daPa to – 100 daPa1 C = Peak at – 101 daPa to – 200 daPa 2 C = Peak at – 201 daPa to – 300 daPa B = Flat (compliance < 0.2 ml) U = Unclassified (e.g. child refused test, incomplete trace, ear blocked by wax)

Data collection form

Data collected (demographic,otoscopic, and tympanometry) was entered into data collection form by principal investigator (Appendix 1).

3.7 Data processing and Analysis

Data was entered after cleaning for accuracy, completeness and internal consistency using EPI-INFO version 6.04d computer programme. Data was summarized in frequency distributions and proportions after coding. Relationships were tested using statistical significance x^2 test at 5% level of significance.

3.8 Ethical consideration

Ethical clearance was obtained from MUHAS Ethical Committee. The principal investigator went to Kinondoni District education office. The investigator therefore introduced herself to District Education officer who wrote acceptance letter to conduct research which was addressed to the head teachers of the preschools selected. The main aim of the study was explained to the head teachers who agreed and were cooperative. They allocated assistants from member of staffs to work with the researcher. A written consent was sought from the parents of all children involved in the study. All children who were found with ear diseases during screening were advised and managed accordingly after notification of the parents or the caretakers by school teachers.

POSSIBLE CAUSES OF BIAS

1. **Sample size**

   Since this was population based study large sample size would have represented the whole population, but due to time limit and financial constraint a limited study sample was used. However the sample taken is acceptable according to the calculated sample size.

2. **Sample selection**

   Simple random sampling was used throughout the study to avoid selection bias. Since this was aprevalence study in the area that had not been studied for similar problem before it was important that the sampling was as unbiased as possible.

3. **Non response**

   Some of the parents did not respond to the informed consent, therefore their children were dropped from the study. Some children who had wax impaction were not brought to the hospital for removal.

4. **Reliability of instrument used**

The tympanometer was tested and calibrated prior to the beginning of the test. It was transported with care to avoid damage.

3.9 Study Limitations

Study area accessibility

Since the study area was urban there was good accessibility.

Finance

The sample size was limited so as to have reliable results. This was due to limited finances.

Time

Since the study was for award of a Master's Degree, it was designed in the way that it could be conducted and finished within ten months.

Seasonal variation

Studies done revealed that OME shows seasonal variation. The intention was to carry out all necessary field work during same seasons, which was somehow difficult to collect all the data within same season.

CHAPTER FOUR

4.0 RESULTS

Total of 556 children were recruited for study. Out of these 15 were dropped from the study because of the following reasons;

a) Presence of features of AOM or perforated tympanic membrane.

Six (6) children were noted to have features of AOM while four (4) had perforated TM bilaterally.

b) Poor compliance

Four children out of 39 children who had wax impaction were lost from the study .Children who had wax impaction in either ear, their parents were informed by schools head teachers to bring the child to Muhimbili national hospital for removal. Four children did not turn up. Those (35) children who turned up, wax removal was done followed by re-evaluation for the presence of OME.

c) One child had features of Downs syndrome and was also dropped from the study.

Therefore at the end 541 preschool children who fulfilled the inclusion criteria were included in the study.

The diagnosis of OME was made by either pneumatic otoscopy or tympanometry. The later was regarded as gold standard.

4.1 DEMOGRAPHIC CHARACTERISTICS OF THE STUDY POPULATION.

TABLE 1: Demographic characteristics of study population.

SEX	NO OF CHILDREN SCREENED	%
M	277	51.2
F	264	48.8
TOTAL	541	100
AGE (YRS)		
2-4	129	23.8
5-6	412	76.2
TOTAL	541	100

Among the 541 children screened, 277 (51.2%) were males and 264 (48.8%) were females.

Of the screened children, 129 (23.8%) were aged 2-4 years, while 412 (76.2%) were aged 5-6 years [Table 1].

TABLE 2: Age and sex distribution of the study population

	SEX					
AGE (yrs)	M	%	F	%	TOTAL	%
2-4	59	(21.3)	70	(26.5)	129	(23.8)
5-6	218	(78.7)	194	(73.5)	412	(76.2)
TOTAL	277	(100)	264	(100)	541	(100)

Of the 277 screened male children, 59 (21.3%) were aged 2-4 years and 218 (78.7%) were aged 5 to 6 years. Among 264 screened female children, 70(26.5%) aged 2 to 4 years and 194 (73.5%) aged between 5 to 6 years (Table 2).

4.2 OVERALL PREVALENCE OF OTITIS MEDIA WITH EFFUSION

TABLE 3: Prevalence of OME by age

	OME				
AGE	**YES**	**%**	**NO**	**%**	**TOTAL**
2-4	29	(22.5)	100	(77.5)	129
5-6	101	(24.5)	311	(75.5)	412
TOTAL	130	(24)	411	(76)	541

The overall prevalence of OME was 24%.This included the children who had OME in either or both ears. Of these 29 (22.5%) were aged 2 to 4 years while 101(24.5%) were aged 5 to 6 years
[Table 3].

TABLE 4: Prevalence of OME by sex

	OME				
SEX	**YES**	**%**	**NO**	**%**	**TOTAL**
M	60	(21.7)	217	(78.3)	277
F	70	(26.5)	194	(73.5)	264
TOTAL	130	(24)	411	(76)	541

Out of 130 children who had OME, 60 (21.7%) were males while 70(26.5%) were females [Table 4].

4.3 PREVALENCE OF OTITIS MEDIA WITH EFFUSION BY PNEUMATIC OTOSCOPY

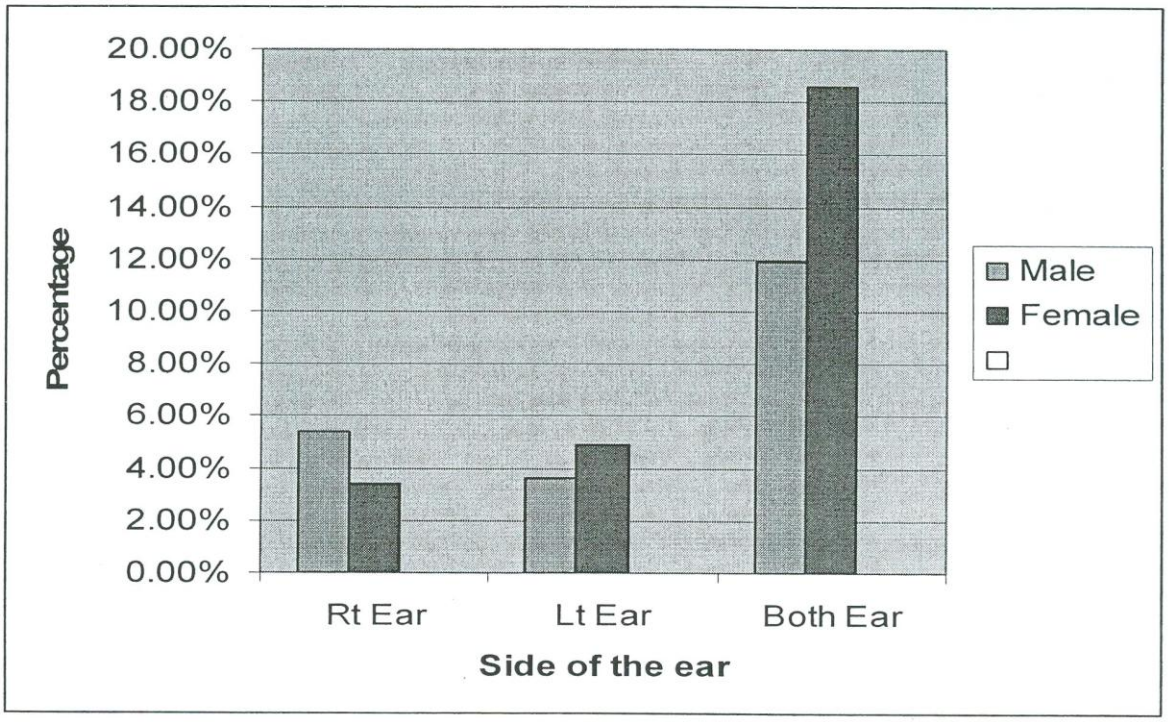
TABLE 5: Overall prevalence of OME by sex according to pneumatic otoscopy

	OME				
SEX	YES	%	NO	%	TOTAL
M	58	(20.9)	219	(79.1)	277
F	71	(26.9)	193	(73.1)	264
TOTAL	129	(23.8)	412	(76.2)	541

Among the 129 children diagnosed to have OME by pneumatic otoscopy, 58 (20.9%) were males and 71 (26.9%) were females [Table 5].

FIGURE 4

Prevalence of OME by sex according to pneumatic otoscopy



Among the 277 male children screened, 33 (11.9%) had bilateral OME and 15 (5.4%) had OME in the right ear only while 10 (3.6%) had OME in the left ear only.

Of the 264 female children screened 49 (18.6%) had bilateral OME and 9 (3.4%) had right sided OME while 13 (4.9%) children had left sided OME. The p-value was 0.154 and chi square was 3.74 which was statistically not significant. [Figure 4].

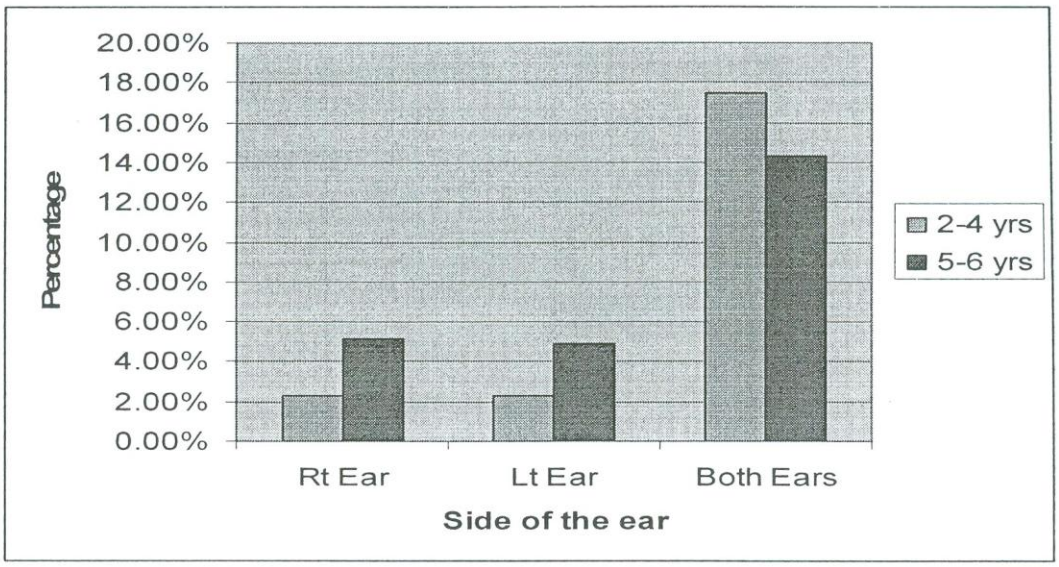
TABLE 6: Prevalence of OME by age according to pneumatic otoscopy

	OME				
AGE (in yrs)	**YES**	**%**	**NO**	**%**	**TOTAL**
2-4	29	(22.5)	100	(77.5)	129
5-6	100	(24.3)	312	(75.7)	412
TOTAL	129	(23.8)	412	(76.2)	541

Out of the screened children 129 (23.8%) were diagnosed to have OME by pneumatic otoscopy of which 29(22.5%) were aged 2 to 4 years while 100(24.3%) were aged 5 to 6 years [Table 6].

FIGURE 5

Prevalence of OME by age according to pneumatic otoscopy



Among the 129 children studied who were aged 2-4 years, 23 (17.5%) had bilateral OME, 3 (2.3%) had right OME and other 3 (2.3%) had left OME by pneumatic otoscopy.

Of the 412 children who were aged 5-6 years, 59 (14.3%) had bilateral OME,and 21 (5.1%) had right OME while 20 (4.9%) had left OME. The chi square was 3.98 and p-value was 0.263 which was not significant statistically [Figure 5].

4.4 PREVALENCE OF OTITIS MEDIA WITH EFFUSION BY TYMPANOMETRY

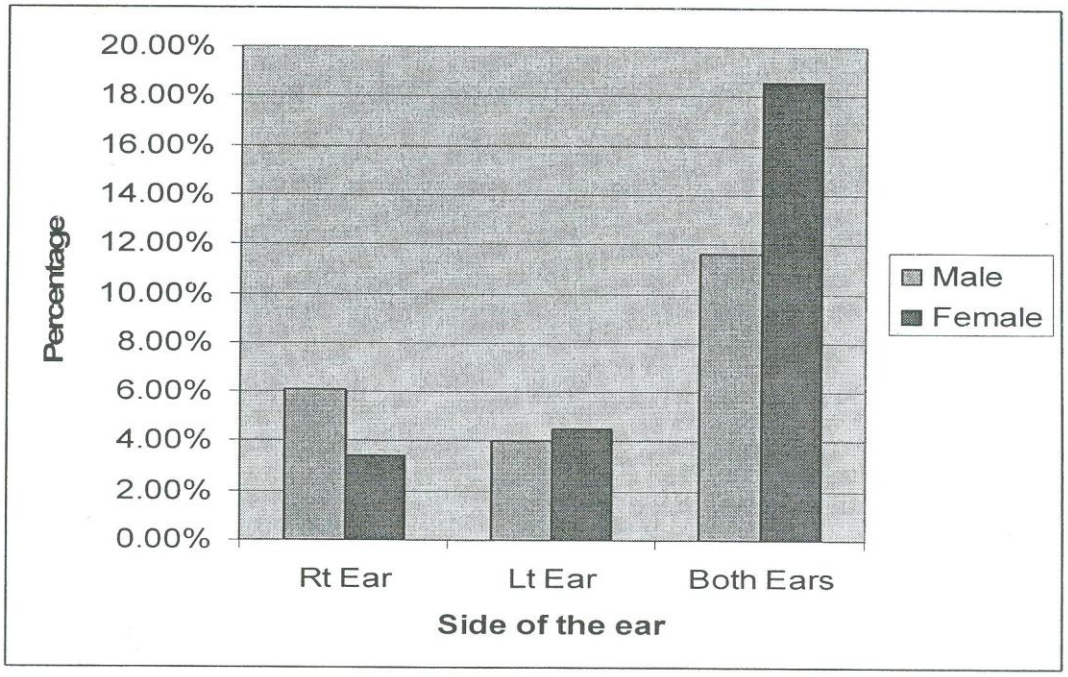
TABLE 7: Prevalence of OME by sex according to tympanometry

	OME		
SEX	**YES %**	**NO %**	**TOTAL**
M	60 (21.7)	217 (78.3)	277
F	70 (26.5)	194 (73.5)	264
TOTAL	130 (24)	411 (76)	541

Out of the 130 children diagnosed to have OME by tympannometry,60 (21.7%) were males while 70 (26.5%) were females[Table 7]

FIGURE 6

Prevalence of OME by sex according to tympanometry



Out of 277 screened male children, 32 (11.6%) had bilateral OME and 17(6.1%) had right OME while 11 (4%) had left OME by tympanometer. Among the 264 female children screened 49 (18.6%) had bilateral OME while 9 (3.4%) and 12 (4.5%) had right and left OME respectively. The chi square was 5.34 and p-value was 0.07 which was insignificant statistically. [Figure 6]

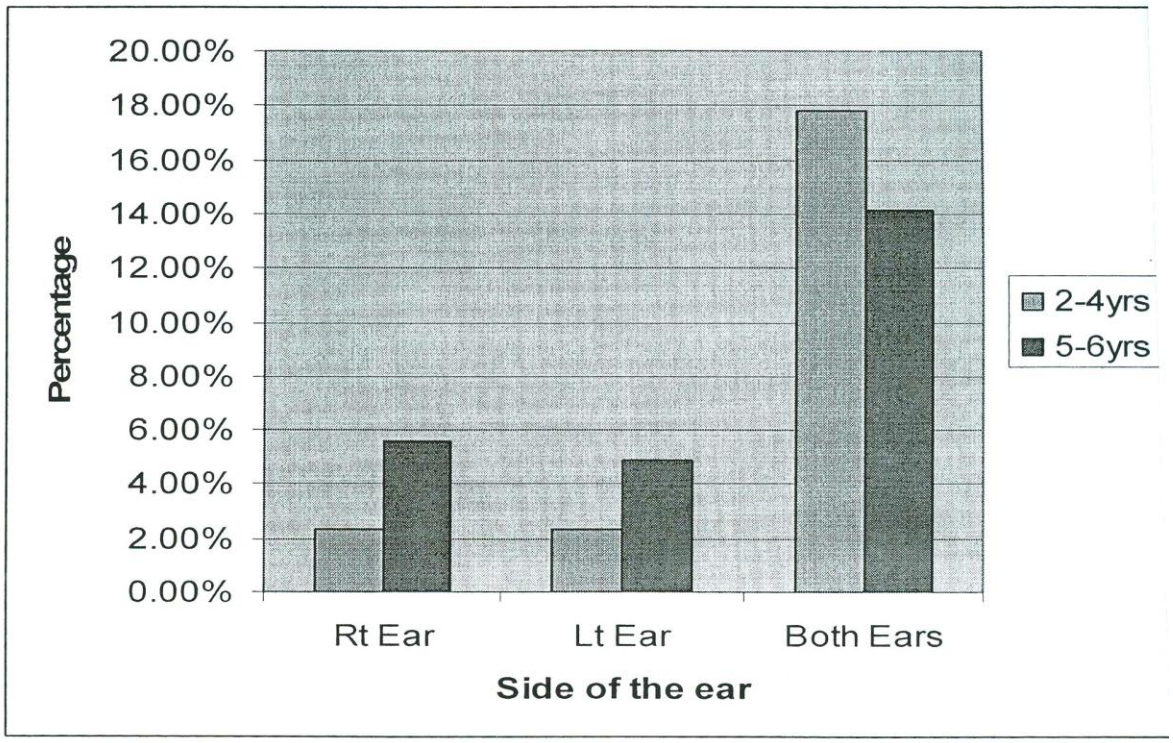
TABLE 8: Overall Prevalence of OME by age according to tympanometry

	OME		
AGE (YRS)	YES %	NO %	TOTAL
2-4	29 (22.5)	100 (77.5)	129
5-6	101 (24.5)	311 (75.5)	412
TOTAL	130 (24)	411 (76)	541

Out of 130 children who had OME by tympanometry, 29 (22.5%) were aged 2 to 4 years while 101 (24.5%) were aged 5-6 years [Table 8].

FIGURE 7

Prevalence of OME by age according to tympanometry



Out of 129 screened children who were aged 2-4 years 23 (17.8%) had bilateral OME while equal number of children 3 (2.3%) had isolated right and left OME by tympanometry. Among those who were aged 5 to 6 years, 58 (14.1%) had bilateral OME while 23 (4.8%) and 20 (4.9%) had right and left OME respectively. Chi square was 4.58 and the p-value was 0.263 which was not statistically significant [Figure 7].

4.5 VALIDITY OF SCREENING TEST

In this study the screening test was regarded as pneumatic otoscopy while the tympanometry was regarded as the gold standard. The sensitivity and specificity of the screening test was therefore calculated.

TABLE 9: Validity of screening test

		TYMPANOMETRY		TOTAL
PNEUMATIC OTOSCOPY		+	-	
	+	127	2	129
	-	3	409	412
TOTAL		130	411	541

Sensitivity = Children positive on screening test / Total positive by gold standard = 127 / 130 x 100

=97.7% [This is the probability that a child with OME had a positive test result]

Specificity = Children negative for OME on the screening test / Total negative by gold standard = 409 / 411 x 100

=99.5% [This is the probability that a child without OME had a negative test result] [Table 9]

CHAPTER FIVE

5. DISCUSSION

5.1 OVERALL PREVALENCE OF OME

The prevalence of OME and its complications is not well known in Tanzania. Most of the studies done are on chronic otitis media, hearing impairment, and cerumen impaction. Example is the study done in northern Tanzania (Moshi and Monduli) by Mallya J and Bastos on middle ear diseases and hearing impairment which showed the prevalence of COM to be 1.6%, scarred and sclerotic tympanic membrane 10.9%[19].

This study revealed the overall prevalence of OME to be 24% which included OME in either or both ears. Prevalence of bilateral OME was 15%.This finding is different from the study done in Nigeria in 1988 by Oqis and others where by the prevalence of OME was 50% in the 5 to 23 months, 28.1% in the 2-5 years age group, and 7.1% in the children aged 5 to 6 years [65].

Another study done in Kenya by Kabahuma in 1990 found point prevalence of 21.9% among children aged 6 to 10 years (unpublished study)[84].

In Malaysia a study done by Saim.A (1997) whereby preschool children were screened, the prevalence of OME was 13.8% which is also different from this finding [86].

In Southern Vietnam study by Dang H and others in children between 6-10 years noted overall prevalence of OME to be 7.1% while prevalence in 2 years children was 22% and prevalence increased during rainy seasons [87].

Prevalence of OME in Greece was found to be 6.5% between 6-8 years and it was found that the prevalence decreases as the age increases.

In Kuwait ,a study done by Holmquist J and others in 1987 revealed prevalence of OME of 31.3% in either or both ears [85]

5.2 PREVALENCE OF OME BY AGE

In this study the prevalence of bilateral OME was 22.5% in children aged 2-4 years and 24.5% in those aged 5-6 years.

Most of other studies done were between 1 month to 15 years, therefore comparison may be difficult.

The prevalence of OME in 5-6 years age group is comparable to the

Kenyan study done by Kabahuma in 1990, where the prevalence of OME in 6 years old was 28.8%, this decreased to 2.7% in 10 years children (unpublished study) [84].

The prevalence of OME was noted to be higher in 5 to 6 years old (24.5%) compared to 2 to 4 years age group (22.5%).This is different from the study done in Turkey which revealed the prevalence rate of OME which decreases as the age increases [88].

A study done in southern Vietnam showed significant changes of prevalence of OME by age whereby the prevalence of OME at 2 years was 22% while among 6-10 years was 7.1% [87].

5.3 PREVALENCE OF OME BY SEX

The study showed low prevalence of OME in males as compared to females M.21.7% F. 26.5%.That of Kenya also showed similar trend M:18.7% F:25.4% (unpublished) [84].

Even though the findings are not statistically significant, it showed an apparent higher prevalence in females than males.

Reasons for variation in these prevalence rates may be attributed to different climatic conditions, sample size used, environmental factors or methods used. Also most of the studies did not specify lateralization of OME.

5.4 LATERALIZATION OF OME

In this study it was found that, among the 541 screened preschool children the prevalence rate of unilateral OME was 9.1% while bilateral OME was 15%.This was not statistically significant (p-value 0.07).This was different from another study done in Riyadh whereby the rates of unilateral OME was 5.7% compared to 8.1% of bilateral OME, however both were not statistically significant [89].

5.5 PREVALENCE OF OME ACCORDING TO DIAGNOSTIC CRITERIA

Among the 541 screened children 129 (23.8%) were diagnosed to have OME in either or both ears by pneumatic otoscopy which is almost similar to those diagnosed by tympanometry, which was 130 (24%).A similar number 22.5% of children aged 2 to 4 years were diagnosed by both tests.

The prevalence of bilateral OME diagnosed by tympanometry was 15% compared to 15.2% diagnosed by pneumatic otoscopy.

This was almost similar to the other studies done in Nigeria where the two tests were used i.e. pneumatic otoscopy and tympanometry whereby the prevalence of OME by tympanometry was 8% and 7.6% by pneumatic otoscopy [65].

Another study done in Kuwait in 1987 revealed prevalence of OME by tympanometry of 31.3% compared to 30% by pneumatic otoscopy [85].

In 2004,American Academy of Otolaryngology, Head and Neck surgeons made recommendations on use of pneumatic otoscopy as the primary diagnostic test for OME and can also differentiate between OME and AOM [90].

In this study the pneumatic otoscopy was regarded as screening test while the tympanometry was regarded as gold standard. After calculation the sensitivity of pneumatic otoscopy was 97.7% and the specificity was 99.5%.This shows that pneumatic otoscopy is almost just as good in diagnosing OME as is tympanometry.

This finding is similar to that of another study done in United States by Hurris and others in 1998 which evaluated validity of tympanometry and pneumatic otoscopy and it was found that the diagnosis provided by both tests were similar, agreeing in diagnosis 80-100% of the time [91].

Another study done by Toner J G revealed no significant difference between predictive value of pneumatic otoscopy (88%) and tympanometry (89%).When both were used in conjunction the predictive accuracy did not increase significantly [89].

Takata G S in 2003 did a study which showed that pneumatic otoscopy had best apparent performance with sensitivity of 94% and specificity of 80% .Examiner qualification is also a factor which can increase the accuracy. The conclusion made from the study was that pneumatic otoscopy can do just as well as or better than tympanometry and acoustic reflectometry in diagnosing OME [17].

Study done by Markiz and others in 1998 on clinical importance of pneumatic otoscopy in the diagnosis of OME showed sensitivity of 96% which was in agreement with this study [21].

The differences noted could be due to various factors, such as:

a) Different study settings. Some studies were done in rural area while this study was done in urban area. Since it has being documented that environmental factors may be predisposing factor for development of OME, study setting may influence the results.

b) Diagnostic algorithm used differs. This study used pneumatic otoscopy and tympanometry while others used either or both of the mentioned plus acoustic reflectometry.

c) Sample size was different, example this study's sample size was 541 while in the study done, example in Malaysia sample size was 1199 children.

d) Different age groups were studied; this study screened preschool children between 2 to 6 years of age while in the Southern Vietnam study, children between 6-10 years of age were screened. This may lead to different results since age is another predisposing factor in the development of OME.

e) Years of study also can influence, since some studies were done in 19^{th} centuries, the results may differ from this study due to industrialization and environmental changes.

Therefore standardization of results will not be possible.

CHAPTER SIX

6. CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

1.This study clearly show that OME is prevalent in Tanzanian preschool children where by the prevalence rate was 24%.

2. It was noted that the prevalence rate of OME was higher between 5-6 years of age (24.5%) than in the children 2-4 years of age (22.5%).

3. The study showed that the prevalence of OME is higher in females (26.5%) than in males (21.7%). This was not statistically significant.

4. In this study OME was noted to be bilateral in 15% ,and unilateral in 9.1% of the cases. This is important documentation because if only one ear is affected, the outcomes, complications and management differ from those of bilateral OME. In most other studies done, there was no documentation on lateralization of OME.

5. Pneumatic otoscopy showed high sensitivity (97.7%) and high specificity (99.5%).This shows that pneumatic otoscopy is as good as tympanometry as a primary diagnostic tool in diagnosing OME. This finding is similar to other studies [89,91].

6.2 RECOMMENDATIONS

1. Screening of preschool children for presence of OME should be introduce in our country to enable early detection and therefore prevention of complications which will improve children's language acquisition and academic performance.

2. Clinicians and other health care providers should build the habit of evaluating children at risk of developing OME and promptly referring those found to have OME.

3. Further studies are important so as to address the magnitude of OME in other areas of Tanzania. Follow up studies are also indicated so as to see the regression rate of OME in Tanzania.

4. A study to evaluate predisposing factors and complications of OME is also recommended.

5. Pneumatic otoscopy is as good as tympanometer in diagnosing OME. It is cheap, easy to use, causes less discomfort to children and it can differentiate OME from AOM.

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