THE PREDICTIVE VALUE OF TYMPANOMETRY IN OTITIS MEDIA WITH EFFUSION

A PROSPECTIVE CROSS-SECTIONAL STUDY
OF 92 EARS IN
HOSPITAL UNIVERSITI SAINS MALAYSIA
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By

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Table Of Contents

TABLE OF CONTENTS

Sections		Page
Acknowledgement		i
Table of contents		ii
Abbreviations		iii
Abstract:	English Version	iv-vi
	Versi Bahasa Malaysia	vii-ix
Introduction		1-37
Objectives of the study		38
Methodology		39-46
Results of the study		47-75
Discussion		76-103
Conclusion		104-106
References		107-114
Appendix		115-116

Abbreviations

ABBREVIATIONS

cc	=	cubic centimeters
cm3	=	cubic centimeters
C3a	=	complement anaphylatoxin 3
C5a	=	complement anaphylatoxin 5
daPa	=	decapascals
dB	=	decibel
Hz	=	hertz
HUSM	=	Hospital Universiti Sains Malaysia
IL	=	interleukin
mmH2O	=	milimetres of water
mohms	=	milliohms
OME	=	otitis media with effusion
OR	=	Odds ratio
PTA	=	pure tone audiometry
ROC	=	receiver operating characteristic
SPL	=	sound-pressure level
Std Dev	=	standard deviation
TNF	=	tumour necrosis factor

Abstract

ABSTRACT

Study of The Predictive Value of Tympanometry in Otitis Media with Effusion in Hospital Universiti Sains Malaysia

This study was aimed to determine the correlation between tympanogram types and myringotomy findings, the predictive value of various tympanogram types in otitis media with effusion, to observe the correlation between otoscopy and some predisposing factors of otitis media with effusion with myringotomy findings.

A prospective cross-sectional study was conducted on 92 ears presumed to have otitis media with effusion from history, otoscopy, tympanometry and audiometric assessment among patients attending the Otorhinolaryngology clinic Hospital Universiti Sains Malaysia from June 1999 till May 2001. All ears fulfilled at least two out of five criteria i.e. symptoms of reduced hearing, fullness, recurrent otitis media or nasal congestion, otoscopic appearance of dullness, retraction or fluid level, reduced tympanic membrane mobility, conductive hearing loss from audiogram and type B (flat) tympanogram. A repeat tympanometry was done 24 hours prior to myringotomy. Myringotomy procedure was performed under local or general anaesthesia.

The highest number of cases (72.8%) was in the age group of 4 to 13 years old with mean age of 15.5. Majority was Malay (93.5%) while 72.8% (67) of cases were males. All symptoms of reduced hearing, ear fullness, chronic nasal

congestion and recurrent otitis media showed slightly higher risk of fluid in the middle ear with Odds ratio of 1.83, 1.41, 1.67 and 1.47 respectively. Cigarette smoking (OR = 1.65), passive smoking (OR = 1.65) and allergy (OR = 2.22) also showed higher risk of fluid in the middle ear although not statistically significant. In this study, tympanic membrane retraction was found to be highly and significantly associated with presence of fluid at myringotomy with Odds ratio of 3.35 and P = 0.046. There was no statistically significant association of otoscopic appearance of bubbles or fluid level with fluid at myringotomy (P = 0.20) most likely due to the small samples having these features. Tympanic membrane immobility showed no significant association with presence of fluid in this study (P = 0.20). Adenoid hypertrophy was found to have higher risk of fluid in the middle ear (OR = 2.77).

Audiogram with conductive hearing loss was found to be significantly correlated with presence of fluid, with Odds ratio of 3.89 and P value 0.044.

Type B tympanogram was found to be significantly associated with presence of fluid at myringotomy. (OR = 3.63, P = 0.035). The positive predictive value of type B tympanogram was 86.5% with sensitivity of 78.4% and specificity of 50%. Type A tympanogram had a high specificity (94%) but low sensitivity (22.2%) in predicting a dry middle ear and this correlation was statistically significant (OR = 0.20, P = 0.044). Type C1 tympanogram had less risk of fluid in the middle ear (OR = 0.23) and this was statistically significant (P = 0.036). Type C2

tympanogram although not statistically significant (P = 0.59), had slightly higher risk of fluid in the middle ear (OR = 1.27). The combination of type B and C2 tympanogram improved the positive predictive value (87.7%) and sensitivity (86.5%) in predicting presence of middle ear fluid. Type A tympanogram was found in all ears without sign and symptoms of otitis media with effusion.

In conclusion, this study showed a reasonable correlation of tympanogram types with myringotomy findings but the use in screening and diagnosis of otitis media with effusion should be in combination with other parameters i.e. symptoms, otoscopy and audiogram.

ABSTRAK

<u>Kajian Mengenai Nilai Jangkaan Timpanometri dalam Diagnosa Radang Telinga Tengah dan Efusi di Hospital Universiti Sains Malaysia</u>

Objektif kajian ini adalah untuk mengetahui hubungan di antara jenis timpanogram dengan keputusan miringotomi, nilai jangkaan pelbagai jenis timpanogram dalam diagnosa radang telinga tengah berefusi, menentukan hubungan antara otoskopi dan beberapa factor penyebab radang telinga tengah berefusi dengan keputusan miringotomi.

Kajian keratan lintang prospektif telah dijalankan ke atas 92 telinga yang dijangka mengalami radang telinga tengah dan efusi daripada simptom, otoskopi, timpanometri dan audiometri dari pesakit yang datang ke Klinik Telinga, Hidung dan Tekak Hospital Universiti Sains Malaysia dalam tempoh dari Jun 1999 hingga Mei 2001. Semua telinga memenuhi sekurang-kurangnya dua dari lima kriteria iaitu; simptom kurang pendengaran, sakit telinga, kekerapan jangkitan telinga tengah akut, kongesi hidung, otoskopi menunjukkan "dullness", retraksi, paras air, kurang mobiliti gegendang telinga, kurang pendengaran konduktif dari audiogram dan timpanogram jenis B. Ujian timpanogram dibuat dalam masa 24 jam sebelum prosedur miringotomi. Prosedur miringotomi dilakukan dengan buis sepenuh atau setempat.

Kebanyakan kes dalam kajian ini (72.8%) adalah dalam kumpulan umur 4 hingga 13 tahun dengan purata umur 15.5. Kebanyakan pesakit adalah berbangsa Melayu (93.5%) sementara 72.8% (67) kes adalah lelaki. Kesemua simptom iaitu kurang pendengaran (OR = 1.83), sakit telinga (OR = 1.41), kongesi hidung berpanjangan (OR = 1.67) dan kekerapan jangkitan telinga tengah akut (OR = 1.47) menunjukkan risiko yang lebih tinggi untuk kewujudan efusi dalam telinga tengah. Faktor merokok (OR = 1.65), merokok pasif (OR = 1.65) dan alahan (OR = 2.22) juga menunjukkan risiko lebih tinggi kewujudan efusi telinga tengah walaupun kurang signifikan secara statistik. Di dalam kajian ini, retraksi gegendang telinga didapati mempunyai hubungan yang tinggi dan signifikan dengan kewujudan efusi semasa miringotomi (OR = 3.35, P = 0.046). Di dalam kajian ini, mungkin disebabkan saiz sampel yang terhad, gegendang telinga yang menunjukkan ciri "bubbles" atau paras air tidak didapati mempunyai hubungan yang signifikan dengan kewujudan efusi semasa miringotomi. Begitu juga dengan gegendang yang menunjukkan kurang mobiliti. Bengkakan tisu adenoid didapati mempunyai risiko lebih tinggi kewujudan efusi (OR = 2.77).

Audiogram yang menunjukkan kurang pendengaran konduktif didapati mempunyai hubungan yang signifikan dengan kewujudan efusi (OR = 3.89, P = 0.044).

Timpanogram jenis B didapati mempunyai hubungan yang signifikan dengan kewujudan efusi semasa miringotomi (OR = 3.63, P = 0.035). Nilai jangkaan *positif timpanogram jenis B ialah 86.5% dengan nilai sensitiviti 78.4% dan spesifisiti 50%. Timpanogram jenis A mempunyai spesifisiti yang tinggi (94%) tetapi sensitiviti yang rendah (22.2%) dalam menentukan ketiadaan efusi dan hubungan ini adalah signifikan (OR = 0.20, P = 0.044). Timpanogram jenis C1 menunjukkan kurang risiko bagi kewujudan efusi telinga tengah (OR = 0.23, P = 0.036). Timpanogram jenis C2 menunjukkan risiko yang agak tinggi bagi kewujudan efusi (OR = 1.27) walaupun tidak signifikan (P = 0.59). Kombinasi timpanogram jenis B atau C2 meningkatkan nilai jangkaan positif (87.7%) dan sensitiviti (86.5%) dalam menentukan kewujudan efusi telinga tengah. Semua telinga yang tidak mempunyai simptom dan ciri-ciri radang telinga tengah berefusi menunjukkan timpanogram jenis A.*

Kesimpulannya, kajian ini menunjukkan hubungan yang agak ketara di antara jenis timpanogram dengan efusi semasa miringotomi. Walau bagaimanapun, kegunaannya di dalam penyaringan dan diagnosa radang telinga tengah dan efusi perlu disertai dengan parameter lain seperti simptom, otoskopi dan audiometri.

Introduction

INTRODUCTION AND THEORETICAL ASPECTS OF TYMPANOMETRY AND OTITIS MEDIA WITH EFFUSION

TYMPANOMETRY

Introduction

Admittance measurements of the ear form the most commonly used set of tests in clinical audiology after pure tone audiometry. They provide a simple and rapid method for obtaining objective information in a normal clinical environment using relatively simple equipment (Lutman, 1986). Acoustic immittance is the term to describe the transfer of acoustic energy. It can be measured in terms of acoustic impedance, which is the opposition to flow of energy, or acoustic admittance, which is the ease of energy flow (Bluestone, Klein, 1995). The term 'acoustic admittance' as applied to the ear describes the mobility of the vibrating structures. It is the ratio of the velocity of middle ear displacements to the applied sound pressure and it is measured at a low audiofrequency, typically 220Hz. (Lutman 1985). The function of the aural acoustic immittance instrument depends on the principles of sound in relation to the physiological characteristics of the ear. The most effective transfer of energy occurs when energy flows from one medium of similar impedance i.e. with similar mechanical properties of stiffness, mass and friction. The middle ear facilitates the transfer of sound energy from an air medium with low impedance to a liquid medium with a relatively high impedance i.e. the cochlea. The tympanic membrane and middle ear act as an impedance matching transformer. Abnormalities that interfere with this function impair hearing. Three basic observations about acoustic immittance can be made with aural acoustic immittance instruments: i) tympanogram

ii) acoustic stapedial reflex

iii) equivalent ear canal volume

This instrument is currently used in a wide variety of clinical settings for both diagnosis and screening. A tympanic membrane-middle ear system that has an increase in one or more of the components of impedance will not transfer sound energy efficiently to the cochlear fluids. In such an instance, acoustic impedance is increased, or acoustic admittance is reduced. A greater amount of sound energy will be reflected from the tympanic membrane-middle ear region and a smaller amount of sound energy will be transmitted to the cochlea and excellent example of this type is a middle ear that contains an effusion. Conversely, the tympanic membrane and middle ear may have a decrease in impedance or increase in admittance in which case an increased amount of sound energy is received by the middle ear but is not transmitted to the cochlea example being ossicular chain disarticulation (Bluestone, Klein, 1995).

History

The development of impedance audiometry during the past decade has added new scope and dimension to clinical audiology. Based on the pioneering efforts of Metz (1946), subsequent workers have refined instrumentation, technique and interpretation to produce an invaluable tool for differential diagnosis. The development of contemporary instrument for impedance audiometry has in the main followed two essentially parallel paths. In the United States, Zwislocki and his colleagues (1961-1969) developed an electromechanical bridge. In Europe, Thomsen (1955), Terkildsen (1960), Moller (1960) and others pioneered the application of the electroacoustic approach, culminating in the present commercially available electroacoustic bridge.

In a study by Jerger J. (1970), impedance audiometry was performed as part of the routine clinical examination in a consecutive series of more than 400 patients with various types and degrees of hearing impairment. An electroacoustic bridge (Madsen, ZO 70) was used to carry out the measurement of tympanometry, acoustic impedance, and threshold for the acoustic reflex. Results indicate that, while individual components of the total impedance battery lack diagnostic precision, the overall pattern of results yielded by the complete battery can be of great diagnostic value.

A number of terms have been used to describe the various measurements made in the plane of the tympanic membrane. ASHA (1978) has recommended the word immittance as an all-encompassing term to describe measurements made of tympanic membrane impedance, compliance or admittance. The American National Standards Institute (ANSI, 1987) has adopted a set of standards that define both the characteristics of instruments used in the measurement of acoustic immittance and the associated terminology (Martin, 1994).

Instrumentation-Method and Principles

Tympanometry is an important test of middle ear function, in which the compliance of the tympanic membrane is measured as a function of the mechanically varied air pressure in the external canal (Ludman, 1998).

Tympanometry is an objective assessment. The most important aspect of tympanometry is its ability to measure tympanic membrane mobility. The probe for the tympanometer needs three openings to detect the tympanic membrane. One is for the sound that is introduced into the ear, which is called the probe tone. A second is for a microphone to listen to the resulting sound intensity. A third opening is for a pressure pump that can increase and decrease the air pressure in the external canal (Pender, 1992).

The electrical signal converted by the microphone is amplified and rectified to direct current and represents the sound pressure level in the external meatus. It is compared with a reference meter, and the comparison registered on a balance meter. By adjusting the intensity of the probe tone, it is possible to produce a voltage of the reflected sound equal to that of the reference voltage. A rigid air-containing cavity acts as a pure acoustic compliance of a magnitude that depends on the volume of the cavity. Measures of compliance may be expressed as the volume of air in a rigid chamber that would have an equal compliance. Most clinical instruments use the unit of an equivalent volume in cubic centimeters as the unit of compliance. The total compliance obtained is the sum of that contributed by the volume of air in the meatus beyond the probe (Ludman, 1998).

The tympanic membrane vibrates most efficiently when the pressure on both sides is equal. It is generally conducted with a low frequency probe tone of 220 or 226 Hz. The use of higher frequency probe tones or a succession of different frequencies can modify results in a variety of ways, making the test much more valuable diagnostically (Shanks et al., 1988).

The ear insert is placed in the external auditory meatus so as to make an airtight seal and the air pressure within the canal slowly raised to 200 mmH2O and then gradually reduced to –200 mmH2O. Impedance or admittance values are recorded manually or automatically at various pressures to produce a graph of compliance against air pressure with an XY plotter. By varying the external canal pressure, the tympanic membrane is stiffened and little energy is admitted and transmitted to the inner ear. In patients with normal middle ears the compliance rises and reaches a maximum value at or near atmospheric pressure. The magnitude of the maximum compliance allows calculations of the compliance attributable to the middle ear mechanism by subtraction of that attributable to the air in the external canal measured during pressure immobilization of the tympanic membrane. The tympanogram describes the flexibility of the tympanic membrane, which is of utmost importance as almost all middle ear disorders influence this function (Ludman1998).

Interpretations of results and use in diagnosis of Otitis media with effusion

The immittance measurement is recorded on a graph called a tympanogram, which show compliance on the Y axis and pressure on the X axis (Martin, 1994). It is a graphic display of the changing relationship of the probe tone to the sound pressure level in the canal. In the impedance instrument, the abscissa of the tympanogram records air pressure in millimeters of water, and the ordinate records compliance, an arbitrary unit. The tympanogram obtained from an admittance instrument is measured in absolute units. The ordinate records admittance (Y) of a volume of air in cubic centimeters (cc or cm3), or milliliters (ml) that has equivalent acoustic admittance or in units called milliohms, and the abscissa records air pressure in decapascals, daPa (1daPa=1.02 mm H2O).

Since the tympanic membrane compliance is maximum when the air pressure on both sides of the drum is equal, the peak of the normal tympanogram tracing occurs at approximately 0 mmH2O. If pressure within the middle ear is negative, the tympanometric peak will be in the negative pressure zone of the tympanogram. Thus, the position of the peak of the trace along the horizontal axis is indicative of middle ear pressure (Hergils et al., 1990; Renvall et al., 1975). The height of the peak is normally between half and full scale on the ordinate. Conditions that increase the impedance of the tympanic membrane-middle ear system (e.g. middle ear effusion) can result in a tympanogram peak that is less than half scale, showing decreased or low compliance. Conditions that decrease the impedance of the system e.g. flaccid tympanic membrane elevate the peak to exceed full-scale deflection. The shape of the peak or more specifically the gradient (slope) is also important. A peak that has a gradual slope (rounded) rather than steep one is usually associated with some degree of tympanic membrane-middle ear disorder.

The height of the peak varies with age, with values ranging from a mean of 0.5 (90% range of 0.22 to 0.8) in children three to five years to a mean of 0.7 (90% range of 0.3 to 1.4) in adults (Morgolis and Heller, 1987).

Jerger (1970) has categorized typical tympanometric results into different type (Martin 1994). This categorization is with respect to shape, location of peak and middle ear admittance. These patterns are only applicable to low-frequency probe tones and are designated types A, B and C with some subclassifications of the A type. Some have the opinion that the use of such classification is unhelpful as it tends to camouflage the underlying dimensions which the tympanogram describes (Lutman, 1987).

Type A curves are seen in patients who have normal middle ear function. The point of greatest compliance is at 0 daPa (usually +/- 50 daPa) and the curve is characterized by a rather large inverted V. Some consider values up to –100 daPa to represent a Type A.

Type As curves show the same characteristic "spike" at or near 0 daPa, suggesting normal middle ear pressure. However the dip is much shallower than that of the usual Type A. Type As curves are often seen in patients in whom the stapes has become partially immobilized.

Type A(D) preserves the general type A pattern but with unusually high amplitude of the curve or in some cases, the positive and negative sides of the spike do not meet at all. Such curves may be associated with flaccidity of the tympanic membrane or separation of the chain of middle ear ossicles.

Type B curves are seen when the middle ear space is filled with fluid. Because even wide variations in pressure in the ear canal can never match the pressure of fluid behind the tympanic membrane, the point of greatest compliance cannot be found. Type B curves can also be seen when a small amount of earwax or other debris occludes one of the tiny tubes within the probe, a wax plug blocks the external ear canal, or when there is a hole in the membrane so that the meter measures the compliance of the rigid walls of the middle ear. These factors should be excluded whenever type B curves are evident.

In certain conditions, the pressure in the middle ear falls below normal. In such cases the tympanic membrane becomes most compliant when the pressure in the ear canal is negative, thus equaling the atmospheric pressure, which brings the tympanic membrane to its normal position producing type C curve. When maximum membrane compliance occurs at a negative pressure of -100 daPa or greater, middle ear pressure is considered to be negative (Martin, 1994).

At times, it may erroneously appear that a tympanogram is flat, missing a peak pressure point. This can be due to negative middle ear pressure that is so extreme that the peak pressure point does not appear. In cases of "flat" tympanogram it is often advisable to make immittance measures as low as –400 daPa (Roeser et al., 1978). The tympanogram will also be flat in an ear with tympanic membrane perforation due to lack of compliance change in response to the pressure change in the external auditory meatus (Kobayashi, Okitsu, 1986). A number of factors may influence the outcome of tympanometry. When pressure is varied from positive to negative, the peak of the wave is lower than when pressure is changed from negative to positive, although this rarely affects the interpretation of results. Performing tympanometry with different probe tone frequencies and multifrequency testing can yield vastly different results, as well as small changes in the shape of the tympanogram when the rate of pressure is varied. The shape of tympanogram or gradient is a ratio between the height and width (width over height). The steeper the ratio, the greater the amplitude of the peak and the greater the inferred acoustic compliance (Martin, 1994). Five typical tympanograms illustrating various conditions of the middle ear are shown in Figure 1.

Results of impedance audiometry were analyzed in 454 consecutive patients with conductive hearing loss and completely successful results were obtained on 428 patients (94%). Type A pattern were usually associated with otosclerosis or other ossicular chain fixation and type B and C were usually found in otitis media. Maximum static compliance values had only limited diagnostic value due to overlap between conductive and normal groups. Stapedial reflex could not be elicited in most patients (James Jerger, 1973).

Jerger's nomenclature has been modified by Fiellau-Nikolajsen (1983) producing four subgroup of tympanogram as in Table 1. (Richard Maw, 1998)

Table 1: Tympanogram types after Fiellau-Nikolajsen (1983)

Type A	Middle ear pressure +200 to –99 daPa
Type C1	-100 to –199 daPa
Type C2	-200 to –400 daPa
Type B	Flat trace without well defined compliance peak

An evaluation of the applicability of tympanometry in the younger age groups and an epidemiological study of the distribution of tympanogram types in a group of preschool children was made. A total of 456 ears in 230 children were completely investigated with tympanometry and otoscopy. Of these, 54.5% showed type A curves, 32.1% showed type B and 12.4% showed type C curves. In 112 (46.6%) children, bilateral type A tympanograms were found. This showed that prevalence of abnormal tympanometry prove to be unexpectedly high in both sexes (Ivanovska et al., 2000).

OTITIS MEDIA WITH EFFUSION

Definition and clinical entity

Chronic secretory otitis media is synonymously referred to as catarrhal, exudative, seromucinous or non-suppurative otitis media. The term secretory is appropriate in that it reflects a particular aspect of the pathological changes. The term otitis media with effusion (OME) allows differentiation of the type of effusion and facilitates distinction between acute and chronic forms. Chronic secretory otitis media may be defined as the prolonged presence within the middle ear cleft of an effusion that may be serous or mucoid but is not purulent (Richard Maw, 1998).

Otitis media with effusion is defined as fluid in the middle ear without signs and symptoms of ear infection (Otitis Media Guideline Panel, Stool et al., 1994) as opposed to acute otitis media in which fluid in the middle ear is accompanied by signs and symptoms of ear infection i.e. bulging eardrum, pain and when perforated, with drainage of purulent material.

Previously also known as glue ear, some defined it as a condition in which non-purulent fluid accumulates in the middle ear causing some conductive deafness (Black, 1985).

Reported studies show data for incidence and prevalence, including point and period prevalence rates vary in relation not only to the method of detection of effusion but also to the ages of the children and whether it is the child or an individual ear that is assessed. It also reflects whether high or low risk groups are investigated and finally there may be differing threshold for diagnosis.

Generally speaking, incidence of the disease fits a logarithmic regression curve with an annual incidence of 40 per cent in 2 year old and 2 per cent in 11 year old. The combined results of selected published studies showed a bimodal prevalence curve with peaks of 20 per cent at age 2 years and 15 per cent at age 5 years. Relapses and remissions occur and the median duration is less than 3 months. Ninety per cent of post-infective middle ear effusions are said to resolve within 3 months (Richard Maw, 1998).

Stool et al (1994) estimated otitis media with effusion as to represent 25 to 35 per cent of all otitis media cases. In a prospective longitudinal study, prevalence rates of OME analyzed in 150 healthy-born and 100 high-risk born infants, aged 0-2 years, showed strong association of prevalence with age ($P<0.001$). During the first months of life, OME prevalence rates increased rapidly in both groups, but did not differ significantly. From the age of 6 months onward, OME prevalence rates of the high- risk group became significantly higher ($P<0.05$). The peak prevalence of OME (59% in the high-risk group versus 49% in the normal group) was observed around the age of 10 months (Engel et al, 1999).

Little has been published with regard to OME and its aetiology in adults. It is considered rare in adults and deserves a thorough examination especially of the nasopharynx (Shimotakahara et al., 1989).

Aetiology and Predisposing Factors

There are various theories on causes of OME although the exact pathogenesis still remains unknown. (Harada et al., 1985).

High and low risk cases are recognized; the high risk constitute an otitis-prone group. Most risk factors represent associations and not causality. The factors are interrelated and there is comorbity and can be divided into those that are accepted as definite and proven and those that are still unproven.

Out of proven risk factors, age and gender are without doubt. Few children acquire clinical signs of OME after age of 5 or 6 years and boys more often affected. Syndromic conditions such as Hurler, Hunter and Down syndromes are predisposed due to infective and skull based cofactors. Children with palatal abnormalities and structural cilia abnormalities are also predisposed. A family history of otitis media and early episode of acute suppurative otitis media can identify increased susceptibility probably indicate early colonization of the nasopharynx. The type of daycare and age commenced relates to frequency of exposure to upper respiratory infections. Unproven but possible factors include low birth weight, parental smoking, bottle feeding and daycare, maternal alcohol, effect of sleeping position and atopy is associated but need confirmation of their causal role (Maw, 1998).

Several factors in aetiology:

i) initial upper respiratory tract viral infection

ii) secondary bacterial colonization of middle ear cleft

iii) a tubal component although obstruction and dysfunction as a principle primary cause is questionable

iv) reduced nasopharyngeal dimension

v) adenoid tissue and other lymphoid tissue as a source of infection

vi) pressure changes and partial pressure of carbon dioxide linked with tubal dysfunction

vii) cellular or humoral immune deficiency example to haemophilus influenzae infection in otitis-prone child.

A study demonstrated that interleukin-8 (IL-8) is consistently present in the middle ear effusion of children with OME and is strongly correlated with levels of IL-1 beta and TNF-alpha both known inducers of IL-8 production. These cytokines is intimately involved in the inflammatory cascade in the middle ear (Maxwell et al., 1994).

Evidence is accumulating of a substantial risk of OME from passive exposure to tobacco smoke (Kraemer et al., 1983; Black, 1985; Hinton and Buckley, 1988; Strachan et al., 1989). Maw and Bawden (1994) suggested that passive smoking might increase likelihood of OME based on evidence from cohort studies despite inconclusive data. It is estimated that 8% of the cases of OME and 17.6% of days with OME may be attributable to tobacco smoke exposure (Etzel et al., 1992).

Harada et al (1985) found extremely high values of C3a and C5a in middle ear fluids revealing intensive inflammatory reaction and that complement anaphylatoxin play an important role as a delayed factor in OME.

Sakurai et al (1985) in his study concluded the primary pathology involved obstructive lesion in tubotympanic cleft resulting in negative middle ear pressure with subsequently eustachian tube dysfunction.

Risk factors other than nasopharyngeal carcinoma and irradiation in the development of OME in adults have not been established. Shimotakahara et al (1989) in his study suggested relations of OME in adults to previous middle ear surgery in contralateral ear, history of childhood middle ear disease, chronic nasal obstruction, cigarette smoking and family history of middle ear disease.

Diagnostic criteria and role of tympanometry in OME

Diagnosis and screening involve assessment of hearing ability, middle ear mechanical function, aspects of cochlear and possibly vestibular function (Maw, 1998).

History:

The symptoms differ with age. In young children, attention to possibility of fluid in middle ear is drawn by hearing loss that may cause effect on speech, language, cognition and behaviour. It may follow acute and recurrent episodes of otitis media or secondary acute infection may lead to otalgia, sometimes otorrhoea.

Hearing loss was reported in 97% of adults, either as recurrent subjective loss, or longstanding greater than five years, 69% have unilateral complaints, ear fullness in 77%, and tinnitus in 60% (Shimotakahara et al., 1989).

Otoscopy:

Pneumatic otoscopy combining visualization of the tympanic membrane (otoscopy) with test of tympanic membrane mobility, if performed by experienced examiner, may produce accuracy for diagnosis of OME between 70% and 79% (Stool et al., 1994). Specificity of 75% and sensitivity of 90% have been quoted which need interobserver validation (Maw, 1998).

Several authors have studied observer variability in simple otoscopy and interobserver agreements ranging between 51% and 85% have been reported. A prospective study designed to assess the relative merits of pneumatic otoscopy and tympanometry in predicting presence of middle ear effusion using an immobile tympanic membrane on otoscopy, or a Jerger type B curve on tympanometry as an indicative of effusion, found no significant difference (P>0.05) between predictive value of pneumatic otoscopy (88%) and tympanometry (89%) (Toner, Mains, 1990).

The diagnosis of OME is obvious in the presence of an air fluid level or bubbles behind the tympanic membrane. But these findings are absent in majority of cases where the middle ear is nearly or completely filled by the effusion. Other otoscopic signs of effusion such as retraction, dark or dull color are considered nonspecific (Gates et al., 1986).

Jaisinghani et al (1999) in his study showed a normal appearing tympanic membrane does not exclude the possibility of middle ear pathology suggesting the need for other diagnostic tools such as multifrequency tympanometry.

The Maastricht Otitis Media with Effusion Study (MOMES) algorithm was used to standardized diagnosis in a prospective longitudinal study of prevalence rates of OME in 150 healthy-born and 100 high risk born infants aged 0 to 2 years. Otoscopic findings were described and categorized in terms of normal (I), indefinite (II) which include dullness, atelectasis and OME (III) which include 'glue', fluid lines/bubbles, hyperaemia and otorrhoea (J.Engel et al., 1999).

Pneumatic otoscopy can suggest the presence of effusion even when otoscopy alone gives no indication of middle ear pathology (Stool et al., 1994). Even experienced otoscopists have a sensitivity rate (detection of fluid when truly present) of no more than 94% and a specificity (detection of no fluid when truly there is no fluid present) of between 74% and 78%; the sensitivity and specificity were improved to 97% and 90% respectively when combined with tympanometry (Gates et al., 1986).

Otoscopy is not an exact method of determining presence or absence of OME. Study by Paradise of a number of individuals who were involved in paediatric otoscopy on a regular basis found 15-20% of effusions were missed (Brooks, 1982).

Tympanometry:

It provides an indirect measure of tympanic membrane compliance and an estimate of middle ear pressure. The positive predictive value of an abnormal (type B, flat) tympanogram is between 49% and 99% that is few as half of ears with abnormal tympanograms may have OME. The negative predictive value is better; the majority of middle ear with normal tympanograms will in fact be normal (Stool et al., 1994).

Maw et al (1998) described a positive predictive value of 84% with a simple peak versus no-peak classification. Such qualitative measures are sufficient for clinical needs but quantitative measurements of tympanometric peak, width, height and equivalent volume may allow severity to be assessed by measuring these continuous variables. Type B traces are highly sensitive in detecting effusions with a greater than 25 dB hearing loss on pure tone audiogram but are only 75% specific. Only 2% of children with a bilateral hearing loss greater than 25 dB do not have type B tympanograms. Multifrequency tympanometry may further increase diagnostic ability. The inclusion of acoustic reflex measurements does not increase the ability of tympanometry to predict clinically significant hearing thresholds (Maw et al., 1998).

In infants less than 7 months of age, many of the ears with effusion had "normal" tympanograms, presumably because external auditory canal walls in such infants tend to be highly distensible (Paradise, Bluestone, 1976). Reliability improves with age (Maw, 1998). Curves suggesting normal (high) compliance in atmospheric or near atmospheric middle ear air pressure were rarely associated with effusion. Conversely, curves suggesting low tympanic membrane compliance were highly correlated with presence of effusion. Curves suggesting intermediate or reduced middle ear air pressure were also correlated with effusion but the degree of correlation was dependent on the shape of the curve (Paradise et al., 1976).

Some reported tympanometry to be accredited with sensitivity rates varying between 83% and 98% (Toner, Mains, 1990). They however found in their study that when pneumatic otoscopy and tympanometry were used in conjunction, the predictive accuracy did not increase significantly.

Bluestone et al (1973) grouped tympanograms into five types on the basis of prediction of middle ear effusion. An even more detailed classification was developed by Paradise et al (1976) who described 15 tympanograms profiles. They pointed out the usefulness of the gradient of the curve in typing. Rounded curves or shallow gradient are more likely to be associated with fluid than sharply peaked curves (steep gradient). Addition of acoustic reflex threshold to the immittance test may be helpful occasionally in screening but adds little to the identification of effusion in general clinical use (Gates et al., 1986).

The Maastricht Otitis Media with Effusion Study (MOMES) diagnostic algorithm using a Grason-Stadler 1723 Middle Ear Analyzer and a modified Jerger classification categorized tympanograms type A and C1 as aerated/normal (I), type C2 or indefinite as indefinite (II), and type B as OME (III) (Engel et al., 1999).

Impedance measurement specificity compared well with otoscopy but less well with myringotomy. The probable explanation is that both otoscopy and impedance tend to classify as outside normal limits a number of ears that do not have frank OME (Brooks, 1982). It is also emphasized that the one-time finding of a flat tympanogram does have the correlation but no congruence with OME and several studies retesting the same patients some days or weeks apart have shown great variability from test to test and conclusions from a point prevalence on the basis of a single tympanometry test therefore are questionable; which could only be confirmed by paracentesis (Wolthers, 1990).

Bluestone, Beery and Paradise (1973) attempted to relate tympanograms patterns to the presence or absence of effusion at myringotomy but found a high percentage of false positive results (i.e. the tympanometric patterns indicated the presence of an effusion but none was found at myringotomy). In a later study, Paradise, Smith and Bluestone (1976) proposed a pattern classification with the same type of instrument for the identification of middle ear effusion based on otoscopy and in many instances the myringotomy findings and the accuracy of