TIME TO SUCCESS & ITS PROGNOSTIC FACTORS AMONG PATIENTS UNDERWENT MYRINGOPLASTY IN KELANTAN

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by

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LIST OF ABBREVIATIONS

A	Accrual time
CI	Confidence interval
df	degree of freedom
F	Additional follow-up
Hospital USM	Hospital Universiti Sains Malaysia
HRPZ II	Hospital Raja Perempuan Zainab II
LML	Log minus log
OR	odds ratio
PH	proportional hazard
PS	power and sample size calculation
HR	hazard ratio
IQR	interquartile range
LR	Likelihood ratio
m	ratio of control to experiments patients
m_1	median survival time in first group
m_2	median survival time in the second group
SD	standard deviations
WHO	World Health Organisation
SPSS	Statistical Package for Social Science
t	time
AOM	Acute otitis media
CSOM	Chronic suppurative otitis media
TM	Tympanic membrane

dB	Hearing decibel
PTA	Pure tone audiogram
CHL	Conductive hearing loss

LIST OF SYMBOLS

n	sample size
%	percentage
<	Less than
>	More than
≤	Less than or equal
≥	Equal than or more
=	equal
α	Alpha (type I error)
b	regression coefficient
β	Beta (type II error)
R2	regression correlation

ABSTRAK

TEMPOH MENCAPAI KEJAYAAN & FAKTOR PROGNOSTIK DI KALANGAN PESAKIT YANG MENJALANI MYRINGOPLASTY DI KELANTAN

Pengenalan: Myringoplasty merupakan prosedur pembedahan bertujuan untuk membaiki penembusan pada membran timpanum. Indikasi utamanya adalah untuk mencegah daripada infeksi kanal auditori luar dan untuk pemulihan pendengaran. **Objektif**: Kajian ini dijalankan untuk menentukan median masa kejayaan dalam myringoplasty serta membandingkan masa untuk berjaya di antara kumpulan dan mengenalpasti faktor prognostik kejayaan dalam myringoplasty di kalangan pesakit di Kelantan. **Kaedah:** Kajian retrospektif telah dilaksanakan melibatkan 215 pesakit yang mengalami penembusan membran timpani dan menjalani myringoplasty dalam tempoh Januari 2006 hingga Disember 2015. Susulan semula ke atas pesakit dilakukan pada bulan ke 3, 6, 9, 12 dan 24 bermula dari hari pertama pembedahan dilakukan. Semua maklumat yang diperlukan diambil dari nota pembedahan dan juga borang perkembangan pesakit. Masa pesakit mencapai penutupan penuh membrane timpani serta pendengaran yang normal dikira sebagai berjaya manakala pesakit yang gagal untuk dijejaki atau gagal dalam pembedahan dipertimbangkan sebagai *censored*.

Keputusan: Analisis Kaplan Meier mendapati keseluruhan median masa untuk berjaya dalam myringoplasty adalah 19.9 (95%CI: 13.6, 44.0) bulan. Terdapat perbezaan masa untuk berjaya yang signifikan bagi pembolehubah umur, pekerjaan, status perkahwinan, URTI, tympanosclerosis dan status merokok. *Multiple Cox Proportional Hazard Regression* mendapati bahawa umur, jantina, status merokok, URTI, saiz penembusan, sisi yang terlibat, jenis graft dan rank pakar bedah mempunyai hubungan yang

signifikan dengan kadar kejayaan myringoplasty. **Kesimpulan:** Kadar kejayaan dalam myringoplasty didapati lebih rendah berbanding kadar yang biasa dinyatakan kepada klien semasa mengambil persetujuan disebabkan perbezaan dari aspek kriteria pemilihan pesakit, definisi kejayaan serta tempoh *follow up* selepas pembedahan. Tempoh untuk berjaya, hasil yang dijangkakan dan faktor prognostik perlu diterangkan dengan baik kepada klien dengan mengambilkira pelbagai definisi kejayaan dimana ekspektasi klien yang tidak realistik merupakan kontraindikasi bagi memperbaiki penembusan membran timpani melalui myringoplasty.

Kata kunci: myringoplasty, penutupan perforasi, kejayaan, pelekatan graft, pemulihan pendengaran

ABSTRACT

TIME TO SUCCESS AND ITS PROGNOSTIC FACTORS AMONG PATIENTS UNDERWENT MYRINGOPLASTY IN KELANTAN

Introduction: Myringoplasty is a surgical procedure which is use to repair a perforation in the tympanic membrane. Most common indications are to prevent further infection of the ear via external auditory canal and to improve hearing. **Objectives**: This study was conducted to determine the median time to success in myringoplasty as well as to compare the median time to success in myringoplasty between groups and also to identify the prognostic factors of success in myringoplasty among patients in Kelantan. **Methods:** A retrospective cohort study was carried out on 215 patients having tympanic membrane perforations and underwent myringoplasty within the period of January 2006 to December 2015. From the day of surgery patients were retrospectively followed up at 3, 6, 9, 12 and 24 months. All the information needs had been retrieved from the operation's note and patient's progress sheet. Time when patients achieved complete closed of perforation with normal hearing was considered as time to success while those who were lost to follow up as well as failure case were censored observation. **Results**: Kaplan Meier analysis showed that overall median time to success in myringoplasty was 19.9 (95%CI: 13.6, 44.0) months. There were significant different of time to success between groups for variable age, occupation, marital status, smoking status, postoperative URTI, tympanosclerosis and smoking status. Multiple Cox Proportional Hazard Regression revealed that age, gender, smoking status, upper respiratory tract infection, size of perforation, affected side, graft used and rank of surgeon were significantly associated with success rate of myringoplasty. **Conclusion:** Success of a

myringoplasty appeared to be lower than commonly quoted success rates to the clients in taking consent due to different of patient's selection criteria, the definition of success used as well as the duration of follow up time after surgery. Time to success, postoperative expected outcome & the prognostic factors should be properly counselled when taking into account of various definitions of success as unrealistic patient expectation is the contraindications for repairing tympanic membrane through myringoplasty.

Key words: myringoplasty, surgical success rate, graft uptake, hearing improvement

CHAPTER 1: INTRODUCTION

1.1 Background of study

Tympanic membrane perforations result mainly from infectious and traumatic aetiologies. Perforations resulting from acute otitis media and traumatic heal spontaneously in most cases (Athanasiadis-Sismanis, 2010). However, persistent perforation with otorrhea commonly associated with hearing loss.

From 2015 recently updated World Health Organization media centre's information, it is stated that over 5% of the world's population has disabling hearing loss consisting 328 million adults and 32 million children with majority comes from low and middle income countries (WHO, 2015). Dhingra, PL. (2007) explained that there are three types of hearing loss; conductive hearing loss, sensorineural hearing loss and both conductive and sensorineural hearing loss.

Chronic suppurative otitis media can be differentiates from other chronic forms of otitis media with the presence of a persistent tympanic perforation and middle ear discharge (WHO, 2004). Disruption of the eardrum and ossicles assembly (conductive hearing loss) or hair cell damage by bacterial infection that has penetrated the inner ear (sensory hearing loss), or both (mixed hearing loss) had produces mild to moderate conductive hearing loss in more than 50% of cases (Chao and Wu, 1994).

Myringoplasty is a simple repair of tympanic membrane perforation without ossicular reconstruction (Manolidis, 2003). It is a special procedure indicates for tympanic membrane perforations and associated hearing loss, with or without middle ear pathology. The aims of this surgery is to restore the integrity of the tympanic

membrane, avoid possible otological or intracranial effects or complications and improve the sound transmission mechanism (Ordonez-Ordonez *et al.*, 2008). Many study showed that the success rate of myringoplasty varies with different factors were found influencing the outcome of the surgery. However, a few study reported the median time to success or time when 50% of the patient's success in the surgery after considering loss to follow up and failure cases.

1.2 Problem statement

Many studies reported different success rate of myringoplasty with varies definition of postoperative success at different follow-up times. Some researchers interested in anatomical success and some interested in both anatomical and pathological success together with hearing outcomes. It is important to use the correct definition of successful treatment as many studies reported the differences of success rate when it is defined as anatomical success only or anatomical with functional success.

Karela *et al.*, (2008) defined the successful operation achieved when the patient had intact tympanic membrane at three and six months follow-up period respectively (Karela *et al.*, 2008). Their research also considers on hearing outcomes which is improvement of postoperative air conduction by 10 dB hence was accepted as hearing improvement but this parameter was not in the postoperative success definition. Triolo, R., and O'Leary, S., (2009), stated that surgical outcomes in their study are expressed in terms of successful closure of the tympanic membrane, improvement in air conduction (AC) PTA and in terms of the number of patients who achieved normal or mildly impaired hearing (AC PTA $\leq$ 40 dB). But similarly like the previous study mentioned,

the hearing gain outcomes variable has been analyzed separately. Same goes to Joshi *et al.,* (2013) whose defined successful surgery achieved when ear was dry and the tympanic membrane intact and mobile at the end of three months' follow-up with separately analyze pure tone audiograms at three months' post-operative.

More briefly, the operation was considered failed if perforation were still present at three months postoperatively (Becker and Lubbe, 2011). On the contrary, it was mentioned that success of myringoplasty was defined according to two distinct anatomical and audiological criteria (Knapik and Saliba, 2011). It was achieved when ear with grade I tympanic membrane retraction and myringosclerosis were considered intact postoperatively together with postoperative difference of no more than 10 dB in the mean bone conduction threshold. The outcomes were measured at 6, 12 and 24 months postoperatively. Similarly, previous study defined the true success rate of myringoplasty as an intact tympanic membrane at 12 months post-surgery without evidence of effusion together with preservation of hearing at 12 months (Kumar *et al.*, 2010)

However, the definition of true success rate in this study are much more similar to the study carried in Japan whose defined successful of treatment as an intact tympanic membrane without evidence of adhesion, retraction or effusion at the 12 months' postoperative visit together with hearing preservation (Takahashi-Tatsumi *et al.*, 2013).

Furthermore, a few studies have discussed about the optimal time to achieve the postoperative success. They only report the variation of follow-up period without describing the median time to achieve the event which can be finding through survival analysis. Some studies report only on descriptive data which is not giving so much benefit to the treatment. For an example, a study conducted in Melaka had reported the

number of cases achieved closure of perforation and numbers of patients had reduced in size of perforation postoperatively (Subramaniam and Abdul, 2006).

Pertaining to the grade of surgeon conducting the procedure, most studies were carried out with same surgeon conducting the surgery. A study conducted by Karela *et al.,* (2008) represented a single experienced ear surgeon who either performed or supervised all procedures leads to a homogeneous approach which in contrary a more heterogeneous group of surgeons of different grades using different techniques or variations of similar techniques could eventually lead to different results. Therefore, this study is to look on the outcomes when considering for three levels of surgeon; consultant, specialist and residents.

1.3 Justification to conduct the study

WHO (2010), further highlights that the major preventable causes of hearing impairment in low and middle-income countries are middle ear infections, excessive noise, inappropriate use of certain drugs, problems during childbirth and vaccine-preventable infections. The burden of otitis media occurs overwhelmingly in the developing world with almost nine times more cases reported compare to developed countries (Smith and Mathews, 2006). Otitis media with effusion (OME) in children is one of the most common condition encountered by the practising otorhinolaryngologists in Malaysia (Abdullah *et al.*, 2007). According to the researchers, no proper study on the clinical and audiology profiles on chronic otitis media with effusion in the Northeast of Malaysia since the patients who attended the public hospital generally are from a relatively poorer socioeconomic background with predominance of the Malay race (Abdullah *et al*., 2007).

Hearing loss may be perpetuated in these sub-urban communities because of the exposure to more risks of hearing loss, such as unhygienic living conditions, disease outbreaks, lack of access to healthcare, and poorer knowledge about prevention (Swanepoel *et al.*, 2010). Thus, a cycle of hearing loss contribute to poverty and poverty contributing to hearing loss may be perpetuated in the developing world (Swanepoel *et al.*, 2010). According to Albera *et al.,* (2006), myringoplasty is a common procedure in otology practice to surgically repair the tympanic membrane which is indicates for infections, social reasons and hearing improvement. However, this treatment is a challenging procedure with some great variations in outcomes among various surgeons and institutions.

In Malaysia, a few studies had been carried out to identify the true time to success of myringoplasty and the prognostic factor of the postoperative success. In 2005, the efficacy of preserved human amniotic membrane as an alternative graft material were evaluated in terms of its anatomical and functional outcomes to repair tympanic membrane defects during myringoplasty (Harvinder *et al.*, 2005). In the following year, Subramaniam and Abdul had done a descriptive study on day care myringoplasty in Hospital Melaka. They did include data as side and size of perforation, grade of surgeon, surgical approach, graft material, postoperative dressings, and the need for overnight admission, complication and outcome without analysing the relationship among them (Subramaniam and Abdul, 2006).

Furthermore, a few studies include patients smoking status as one of the prognostic factor for the outcomes. Recently study in Bangladesh shows that smoking cigarettes significantly increase the risk of hearing impairment especially at higher frequency, compare to the non-smoker group. The smoker group was found at higher risk of developing hearing loss due to showing higher hearing thresholds at various frequencies tested (Sumit *et al.,* 2015). Therefore, variable smoking status has been included in this study.

1.4 Benefits of the study

This study conducted to identify the predictive factors for total closure of perforation with normal hearing after surgery as well as the median time of the event after surgery as it is very important in patient's post-surgery management to ensure complete healing and to avoid any complications accordingly. Findings of the associate factors for the interest outcome is useful for any precaution in order to optimized the healing improvement progressing time as speedy recovery will provide more benefits to the patients. Besides, the findings on optimal healing can be apply in giving consent to patients before undergoing the treatment as well as identifying the clinical progression of disease with intervention.

1.5 Research questions

i. What is the socio-demographic & clinical characteristic of patients undergoing myringoplasty in Kelantan?

ii. What is the median time to success among patients underwent myringoplasty in Kelantan based on socio-demographic and clinical factors?

iii. Is there any differences of time to success between groups based on socio-demographic and clinical factors?

iv. What is the prognostic factor for success of myringoplasty among patients in Kelantan?

1.6 Research objectives

1.6.1 General objective

To determine median time to success and its prognostic factor among patients underwent myringoplasty in Kelantan, Malaysia.

1.6.2 Specific objectives

i. To describe the socio-demographic and clinical characteristic of patients underwent myringoplasty in Kelantan.

ii. To determine the overall median time to success in myringoplasty among patients in Kelantan.

iii. To compare the median time to success in myringoplasty between groups based on socio-demographic and clinical factors.

iv. To identify the prognostic factors of success in myringoplasty among patients in Kelantan.

1.6.3 Research hypotheses

Hypothesis Alternative (H_a):

i. There is a difference of median time to success in myringoplasty between groups based on socio-demographic and clinical factors.

ii. There is an association between identified prognostic factors with success of myringoplasty among patients in Kelantan.

CHAPTER 2: LITERATURE REVIEW

Mainly all the literature search pertaining to myringoplasty, tympanoplasty type I, hearing loss, tympanic membrane perforation, chronic suppurative otitis media, trauma perforation, upper respiratory tract infection and hearing test was widely done by search engines such as Google Scholar, Science Direct, MedLINE and EBSCOhost. The title divided into search concepts and a few of alternative keywords were identified for each concept. For example, the concept of "hearing outcome in myringoplasty" were alternatively search as "audiological result in myringoplasty" and concept of "prognostics factors of success in myringoplasty" alternatively searches by "factors influencing outcome in myringoplasty / tympanoplasty type I". Various searching strategy had been applied such as combination of terms with the used of Boolean connectors (AND, OR and NOT). Other search strategies used were searching by phrase and using truncation or synonyms words. The entire literature search were published from 2006 to 2016 was included as clinically up to date. However, scoping reviewed on books was not limited to the date published.

2.1 Anatomy of the Ear

The human ear consists of three parts; external ear, the middle ear, and the inner ear (Yueh *et al.*, 2003). The anatomy structure of the three parts viewed in figure 1.0 (Dale and Kerr, 1989).

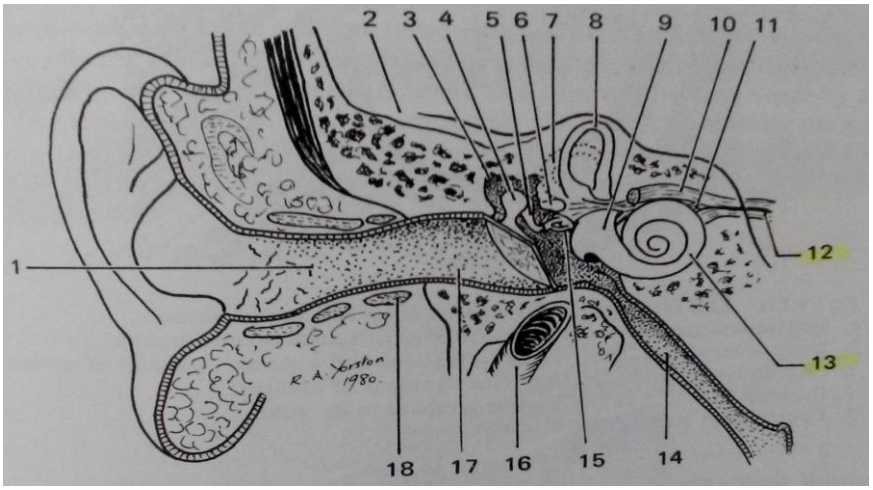

Figure 2.0 Vertical coronal diagrammatic section through right ear

1. External meatus, cartilaginous part
2. Middle cranial fossa
3. Attic
4. Malleus
5. Incus
6. Position of semicircular canal
7. Position of posterior semicircular canal
8. Superior semicircular canal
9. Vestibule
10. Facial nerve
11. Vestibular nerve
12. Cochlear nerve
13. Cochlea
14. Eustachian tube
15. Stapes
16. Internal carotid artery
17. Bony part of external meatus
18. Cartilage

2.1.1 The External Ear

The external ear consists of the pinna (auricle) and the external auditory canal, and it is immediately accessible to physical examination. Its function is thought to be largely protective, although its physical configuration may provide moderate (5 – 15 dB) passive augmentation of sounds at the upper range of speech processing frequencies (Yueh *et al.*, 2003). Figure 1.1 showed the lateral view of left auricle (Dale and Kerr, 1989).

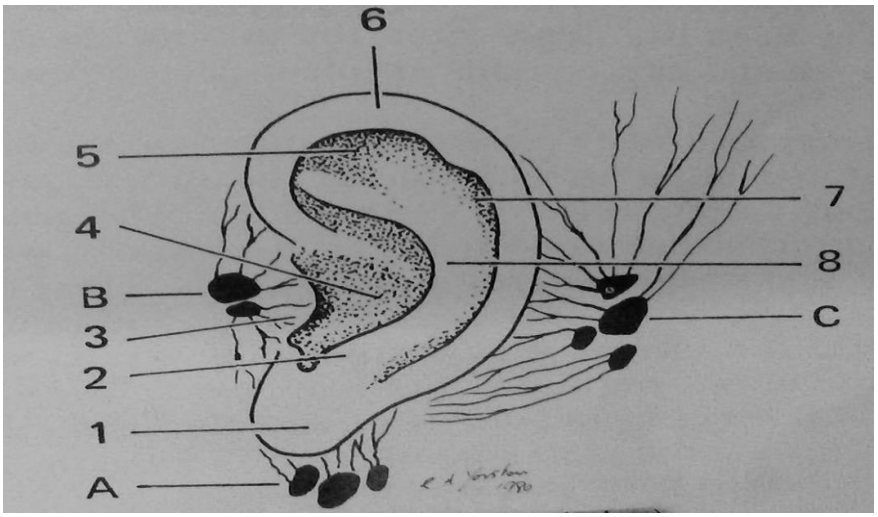

Figure 2.1 Lateral view of left auricle

1. Lobule
2. Antitragus
3. Tragus
4. Cavum conchae
5. Fossa triangularis
6. Helix
10. Facial nerve
7. Scapha
8. Antihelix lymp nodes:
   - A. Superficial cervical
   - B. Preauricular
   - C. Postauricular

2.1.2 The Middle Ear

The middle ear is bounded laterally by the tympanic membrane (eardrum) and medially by the osseous labyrinth, which is the bone-encased structure that houses the end organs of hearing (cochlea) and balance (semicircular canals). The healthy middle ear is an air-filled cleft that contains the three ossicles (malleus, incus, and stapes) that transduce vibrations from the tympanic membrane to the oval window of the fluid-filled cochlea. The substantially larger area of the tympanic membrane, compared with that of the oval window, and the relatively minor mechanical gain from the ossicular configuration combine to amplify sound pressures by 20 to 30 dB (approximately the difference between a whispered voice and normal conversational speech) (Yueh, B. *et. al*, 2003).

The middle ear consists of the tympanic membrane that terminates the ear canal

and the three small bones (ossicles), the malleus, the incus and the stapes together with tensor tympany muscle and the stapedius muscle as shown in figure 1.2 (Dale and Kerr, 1987). The manubrium of malleus is embedded in the tympanic membrane and the head of the malleus is connected to the incus that in turn connects to the stapes, the footplate of which is located in the oval window of the cochlea. The chorda tympani are a branch of the facial nerve (the nervous intermedius) that travels across the middle ear cavity which carries taste fibres and probably also pain fibres. The Eustachian tube connects the middle ear cavity to the pharynx (R.Moller, 2006).

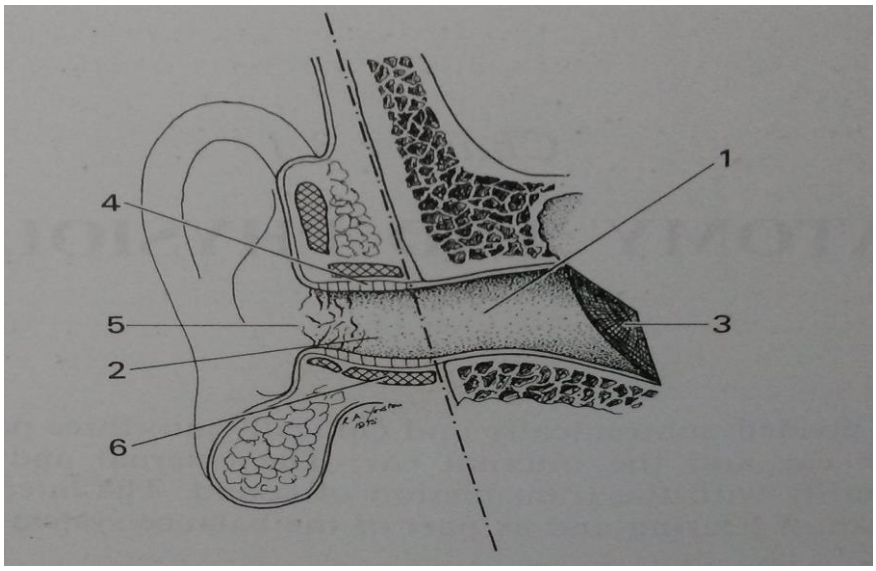

Figure 2.2 Right external auditory meatus

1. Bony part
2. Cartilaginous part
3. Tympanic membrane
4. Hair follicles and ceruminous glands
5. Introitus
6. Meatal cartilage

2.1.2.1 Tympanic Membrane

The tympanic membrane is a slightly oval, thin membrane that terminates the ear canal. It is cone-shaped, with an altitude of two mm with the apex pointed inward. Seen from the ear canal, the membrane is slightly concave and is suspended by a bony

ring. Normally it is under some degree of tension. Its surface area is approximately 85 mm^2. The main part of the tympanic membrane, the pars tensa with an area of approximately 55 mm^2, is composed of radial and circular fibres overlaying each other. These fibres are composed of collagen and they provide a lightweight stiff membrane that is ideal for converting sound into vibration of the malleus. A smaller part of the tympanic membrane, the pars flaccida, located above the manubrium of malleus, is thicker than the pars tensa and its fibres are not arranged as orderly as the collagen fibres of the pars tensa.

The tympanic membrane is covered by a layer of epidermal cells, continuous with the skin in the ear canal. This outer layer of the tympanic membrane migrates from its center outwards and this moves small injuries and scars and transports small foreign bodies out in to the ear canal. Small holes in the tympanic membrane usually heal spontaneously (Moller, A.R., 2006). For purpose of description the membrane is divided into four quadrants by imaginary lines, one drawn horizontally through the umbo while the other bisects this line at right angles as shown in Figure 1.3(Dale and Kerr, 1987)

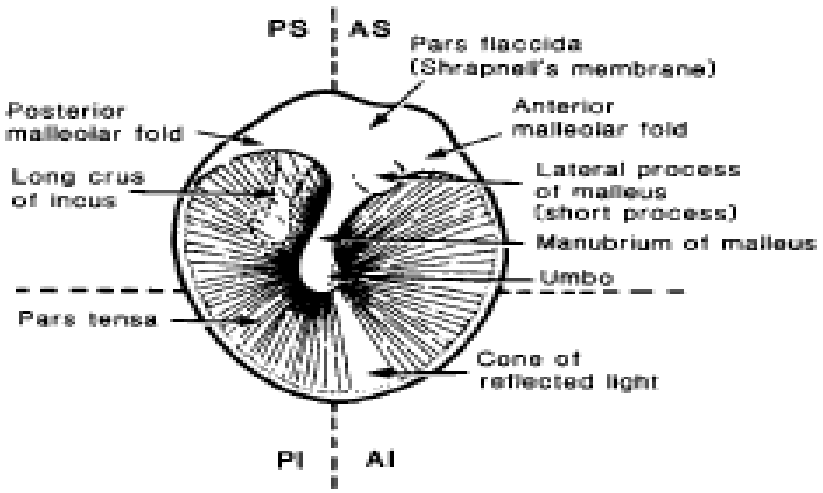

Figure 2.3.Right Tympanic membrane with four quadrants:
PS=posterior-superior, AS=anterior-superior,
PI=posterior-inferior, AI=anterior-inferior

2.1.2.2 Middle Ear Cavities

The middle ear cavities consist of the tympanum (the main cavity) that lies between the tympanic membrane and the wall of the inner ear (the promontorium), a smaller part (the epitympanum) that is located above the tympanum, and a system of mastoid air cells. The head of the malleus is located in the epitympanum. The middle-ear cavity and the eustachian tube are covered with mucosa. The total volume of the middle-ear cavities is often given to be approximately 2 cm^2, but the size of the middle ear cavities varies considerably from person to person and if the volume of the mastoid air cells is included, the total volume can be as large as 10 cm^3 (R.Moller, 2006).

2.2 Tympanic Membrane Perforation

Tympanic membrane perforations are a common case that is due to infection, ventilation tube insertion or trauma (Saliba *et al.*, 2011).

2.2.1 Traumatic Perforations

Traumatic perforations are referring to tears in the tympanic membrane and considers significant when involved a large section of the membrane (Carrasco, V., 1998). Large traumatic tympanic membrane perforations can heal without any intervention in approximately three to six weeks and additional time may be allotted if the significant healing is not complete while repairing is recommended if there is no sign of healing or the quality of new membrane is poor. Traumatic perforations with

tympanic membrane flaps that extend into the middle ear heals poorly and were treated immediately by bringing the flap out into position and approximating the edges with either a paper patch (Carrasco, V., 1998).

2.2.2 Infective Perforations

Klien J.O., (2000) stated that acute otitis media (AOM) is a very common condition and a leading cause of health care visits and antibiotic prescription. WHO estimated that 50% of people who suffer from hearing impairment were those among 65 and 330 million individuals who suffer from chronic suppurative otitis media (Acuin, 2004). Otitis media effusion can be define as the presence of middle ear effusion without signs of acute infection (Takata *et al.,* 2002). It is stated that the presence of bubbles in the middle ear cavity is a reliable sign of middle ear effusion but their absence does not reliably exclude effusion. CSOM is persistent discharge of pus through a perforated tympanic membrane (Gunasekera *et al.,* 2009). The duration of 'persistent' varies in different studies. The World Health Organization, 2004 uses a definition of two weeks. If the discharge is of shorter duration, the child would be considered to have AOM with perforation.

2.3 Effect of Tympanic Membrane Perforations on Hearing

The tympanic membrane (TM) serves as a key component of the tympano-ossicular system for sound transmission. Perforation of the TM is common in an otologic practice and can result from various causes such as trauma and chronic otitis media. Perforations of the TM can result in a conductive hearing loss (CHL) that ranges

from negligible to 50 dB and the effects of TM perforations on middle-ear sound transmission were not well characterized (Mehta *et al.*, 2006). The primary mechanism of conductive hearing loss due to perforation is a reduction in ossicular coupling caused by a loss in the sound pressure difference across the tympanic membrane (Merchant and Rosowski, 2010).

In the experimental approach, measurements of middle-ear sound transmission were made in cadaveric temporal bones before and after controlled TM perforations of various sizes and locations. In the theoretical approach, a quantitative, physics-based model of the human middle-ear was used to understand the mechanisms of hearing loss resulting from a TM perforation. The dominant mechanism causing hearing loss in ears with TM perforations is a reduction in the sound pressure difference across the TM and not the phase cancellation at the round window (Mehta *et al.*, 2006).

2.4 Hearing Loss

The causes of hearing loss and deafness can be divided into congenital and acquired causes. Congenital cause can be hereditary and non-hereditary genetic factors or by certain complications during pregnancy and childbirth including maternal rubella, syphilis or certain other infections during pregnancy, low birth weight, lack of oxygen at the time of birth, inappropriate use of particular drugs during pregnancy and also by severe jaundice during neonatal period while acquired causes were due to infectious diseases, chronic ear infections, collections of fluid in the ear, drugs reaction, injury to the head or ear, excessive noise, ageing and also wax or foreign bodies (WHO, 2015). Hearing loss also results from pathologic conditions along the sound transduction pathway. The cochlea and to a lesser extent, the middle and external ear are commonly

involved; pathologic conditions of the auditory nerve or brainstem rarely manifest as hearing loss (Agrawal *et al.*, 2008).

Hearing loss is a societal problem. It is known to be highly prevalent, and the cost of needs increased and diminished autonomy associated with hearing loss is shared by society. The prevalence of hearing loss in the United States is predicted to rise significantly because of an aging population and the growing use of personal listening devices. Indeed, there is concern that we may be facing an epidemic of hearing impairment (Agrawal *et al.*, 2008). In one study conducting by Marke Trak Survey, the incidence of hearing loss per 1000 households increased to 283 from 266 in 1989. In 2004, this equates to 31.5 million people reporting a hearing difficulty. Hearing loss population grew 9.9% compared to a 6.8% increase in US households (Kochkin, 2005).

2.5 Myringoplasty

Perforations due to otitis media heal spontaneously in the majority of cases and perforations due to traumatic etiologies also heal spontaneously within 4 to 6 weeks (Athanasiadis-Sismanis, 2010). However in certain cases these perforations may remains and associated with hearing loss. Myringoplasty is a surgical procedure introduced by Berthold in 1878 but was only in 1956 when Wullstein and Zoellner developed some fundamentals principles in modern practice (Wullstein, H., 1956). It is said to be the surgical restoration of the perforated tympanic membrane by grafting, with the principal goals being a ‘dry ear’ and improved hearing (Merchant *et al.*, 2003). The principal indication of myringoplasty are recurrent otorrhea, the desire to swim without having to waterproof the ear and to improve conductive hearing loss (Sergi *et al.*, 2011).

2.5.1 Expectation of Myringoplasty

The aim of the myringoplasty is to produce a safe, dry ear and if possible to restore or improve the hearing which depends upon the nature and extent of the disease (Dale and Kerr, 1988).

2.5.2 Indications of Myringoplasty

2.5.2.1 Protection

Closing tympanic membrane perforations isolated the middle ear from external environment and prevent contamination by exposure to pathogens introduced via the external auditory canal. Repeated exposure to pathogens can lead to recurrent, acute otitis media with consequent permanent alteration of the middle ear and its sound transmitting mechanism or active chronic otitis media with otorrhea that is refractory to the treatment (Athanasiadis-Sismanis, 2010).

2.5.2.2 Auditory

Closure of TM perforation restores the vibratory area of the membrane and affords round window protection, thus improving hearing and decreasing tinnitus. Therefore, patients with tympanic membrane perforation associated with hearing loss with or without middle ear pathology such as tympanosclerosis, small retraction pockets

and choleastetoma were indicated for the treatment (Manolidis, 2003).

2.5.3 Contraindications of myringoplasty

Poor general health, malignant tumors of the outer and middle ear, uncontrolled cholesteatoma, unusual infection, complications of chronic ear disease and non-functioning Eustachian tube were reported as contraindications for myringoplasty. Furthermore, a patient with tympanic membrane perforation on the only better hearing ear was also contraindicated for this procedure. However, exacerbation of chronic otitis media, chronic mucoid discharge associated with allergic rhinosinusitis or chronic otitis externa should be controlled with appropriate treatment prior to the surgery (Dale and Kerr, 1988).

2.5.4 Patients Selection in Myringoplasty

The following intervention should be thoroughly practice to achieve the target of the treatment and in identifying risk factors for failure of the proposed myringoplasty.:

i. A proper history of the patients relates to the tympanic membrane perforation and a complete head and neck assessment should be taken
ii. The clinical assessment should include diagram of the perforation which can be obtain by high quality photograph of the otoscopic findings.
iii. Patient should undergo pure tone air and bone conduction audiometry testing along with speech discrimination evaluation.
iv. Patient should be explain on the nature of the problem, the proposed treatment

and alternatives therapies, expected outcome and potential complications either in verbal or written explanations (Manolidis, 2003).

2.5.5 Factors considered preoperatively

2.5.5.1 Eustachian Tube Function

A normal contralateral ear indicates a proper of Eustachian tube function. Success of surgery associated with bilateral pathology especially in children (Caylan *et al.*, 1998) but it should not prevent the surgical intervention (Manolidis, 2003).

2.5.5.2 Control of infection

Proper aural toilet, improvement monitoring in otorrhea, ear irrigation and antibiotic administration has been practicing in infection control of the affected ear. The effectiveness of control intervention is depends on patient compliance and consideration on mastoid involvement, severe allergies and incomplete treatment of the offending organism (Manolidis, 2003).

2.5.5.3 Allergies

Coexistent inhalant allergies as well as environmental allergies prior to surgery should be identifying before performs the treatment. The status of the upper respiratory tract influences the Eustachian tube function thus affect the outcome of surgery.

2.5.5.3 Age of the Patient

Previous study reported variations result of myringoplasty among different age of patients. Consensus stated that myringoplasty among children are not encourage for as many reported a lower success rate compared to adult patient. However, the reasons of the differences are not clear and commonly related to higher incidence of otitis media and its predisposing factors among children (Knapik and Saliba, 2011).

2.5.5.4 Status of Contralateral Ear

The choice of which ear to repair is depends on hearing status which the worse hearing ear should be operated first. However, a better hearing contralateral ear that threatens health such as choleasteatoma and active infection should be consider to operate first (Wasson *et al.,* 2009).

2.5.6 Surgical Technique

2.5.6 Grafting Techniques

There are two types of grafting techniques in myringoplasty, which are underlay and overlay. Graft placement in the underlay technique is medial to the tympanic membrane remnant and manubrium of the malleus while in the overlay technique graft placement is lateral to the tympanic membrane remnant and medial to the manubrium.

Both techniques give excellent results as long as properly performed by experienced surgeons. Figure 2.4 (a) and (b) shows the grafting procedure with underlay technique (Athanasiadis-Sismanis, 2010).

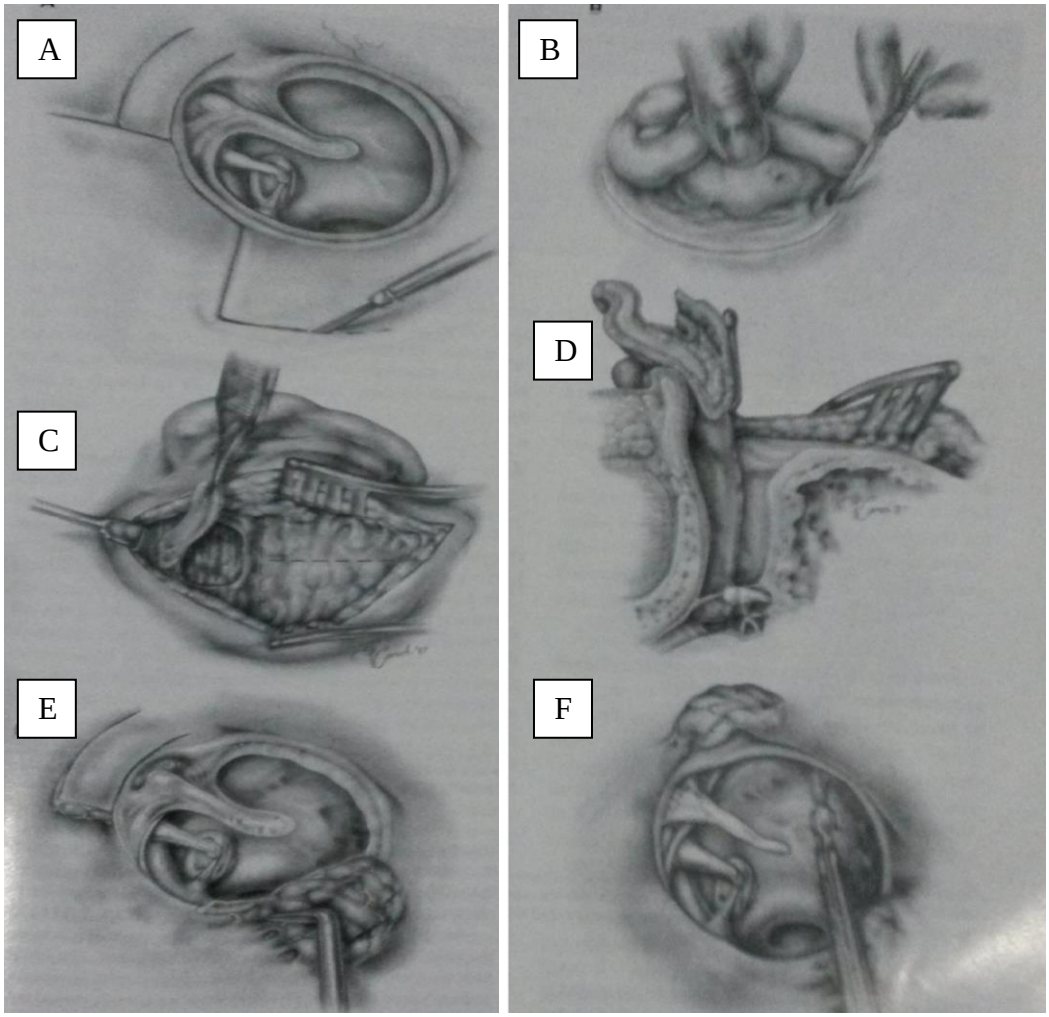

Figure 2.4 (a) The underlay technique with grafting by temporalis fascia
A: The Vascular strip is outline with a no.67 Beaver blade
B: standard postauricular incision is used to exposed the temporalis fascia
C: Larger piece of loose areolar temporalis fascia is removed, pressed and dried under a heat lamp
D: The vascular strip is lifted out of the external auditory canal and placed under the anterior blade of a self retaining retractor
E: The inferior flap is elevated to the fibrous annulus with a House No.2 knife
F: Cup forceps remove mucosa from under the fibrous annulus

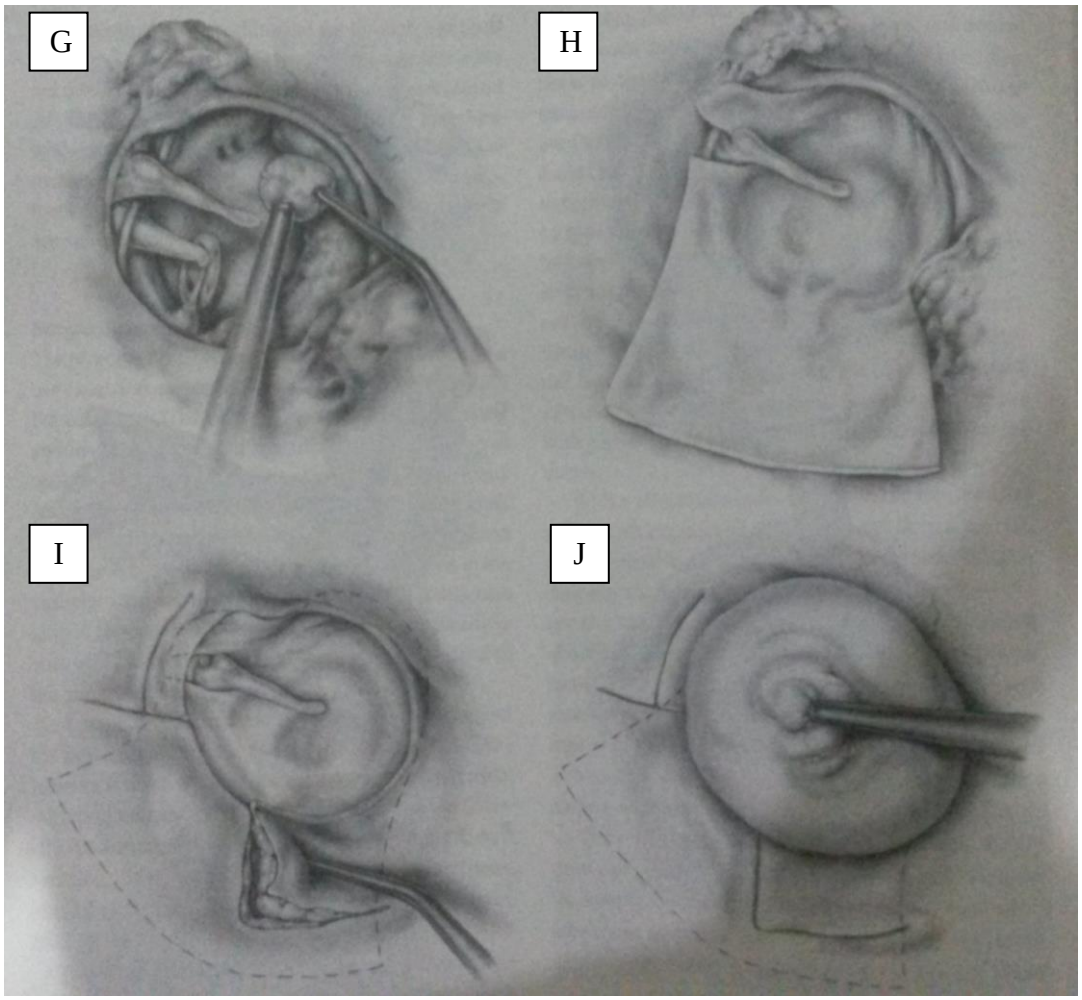

Figure 2.4 (b) The underlay technique with grafting by temporalis fascia
G: Moist absorbable gelatine sponge (Gelfoam) is packed into the entire middle ear space, starting in the Eustachian tube orifice
H: The graft is placed into the middle ear so that it lies under the annulus anteriorly.
I: When the inferior and superior flaps are replaced, the graft is held securely in position
J: The ear canal is filled with polymixin B and polysporin ointment instead of packing at the end of the procedure

2.6 Postoperative Outcomes Assessment

2.6.1 Otoscopy

Otoscopy is the clinical examination of the external auditory meatus especially the tympanic membrane perforation closure and the passage leading to it from the

external meatus using an instrument that magnifies thru lenses and lights the area, known as otoscope. The important of performing otoscopy is to identify several common problems that preclude sound from entering the ear as well as to identify the abnormalities compared to the known norm (Oxford Press, 2007).

2.6.2 Pure Tone Audiometry

Pure tone audiometry is the common behavioural procedure used to determine both the degree and aetiology of hearing loss. Pure tone audiogram is a measure of threshold of hearing by air and bone conduction and thus the degree and type of hearing loss (Oxford Press, 2007). An audiometer is an electronic device which produces pure tones, the intensity of which can be increased or decreased in 5 dB steps. The amount of intensity that has to be raised above the normal level is a measure for degree of hearing impairment at that frequency and is recorded in the form of a graph called audiogram. The threshold of air and bone conduction (A-B gap) is a measure of the degree of conductive deafness. It may be noted that audiometer is so calibrated that the hearing of a normal person, both for air and bone conduction is at zero dB and there is no A-B gap.

2.6.3 Hearing Thresholds

According to Trudgen R., 2008, hearing threshold were classified into six categories that is normal hearing (-10 to 25 dB), mild hearing loss (26 to 40 dB), moderate hearing loss (41 to 55 dB), moderately severe hearing loss (56 to 70 dB), severe hearing loss (71 to 90 dB) and profound hearing loss (≥ 91 dB). Conductive