THE EFFECT OF MIDDLE EAR VOLUME ON HEARING IMPROVEMENT POST MYRINGOPLASTY

DR ASFA NAJMI BINTI MOHAMAD YUSOF

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LIST OF ABBREVIATIONS

ABG	Air bone gap
ANOVA	Analysis of variance
CSOM	Chronic suppurative otitis media
CT	Computed tomography
dB	Decibel
ORL	Otorhinolaryngology
MEV	Middle ear volume
PTA	Pure tone audiometry
TMP	Tympanic membrane perforation
WHO	World Health Organization

ABSTRAK

TAJUK: KESAN ISIPADU BAHAGIAN TELINGA TENGAH TERHADAP PENDENGARAN SELEPAS PEMBEDAHAN TAMPALAN GEGENDANG TELINGA

Pengenalan

Kebocoran gegendang telinga (TMP) adalah salah satu ciri-ciri penyakit telinga bernanah kronik (CSOM). Ia dirawat dengan pembedahan tampalan gegendang telinga (myringoplasty). Kejayaan myringoplasty merujuk kepada penyembuhan sepenuhnya tampalan gegendang telinga dan juga pemulihan pendengaran selepas pembedahan. Selain TMP, jumlah isipadu telinga tengah (MEV) merupakan faktor lain yang telah memberi kesan kehilangan pendengaran dalam kajian terkini, oleh itu ia dianggap memainkan peranan dalam peningkatan pendengaran selepas myringoplasty. Kajian ini bertujuan untuk menentukan sama ada MEV mempunyai peranan yang penting dalam peningkatan pendengaran selepas myringoplasty.

Seramai 72 pesakit CSOM yang menjalani myringoplasty dan TMP yang sembuh sepenuhnya telah dinilai. Ujian pendengaran telah dijalankan sebelum dan 3 bulan selepas pembedahan. Pure tone audiometry (PTA) telah dilakukan untuk menentukan tahap pendengaran dan peningkatan pendengaran dicatatkan sebagai perbezaan purata pendengaran (ABG) sebelum dan selepas pembedahan. Manakala tympanometry telah digunakan untuk menentukan MEV. Purata MEV telah dikira dan isipadu telinga tengah dibahagikan kepada kumpulan kecil dan besar. TMP telah diperiksa dan direkod sebagai gambar melalui sistem 'endoscopic' atau lukisan. Saiz TMP direkodkan dalam peratusan dan kemudian dibahagikan kepada 3 kumpulan; kecil

<50%, sederhana 50-75% dan > 75%.

Analisis data menunjukkan peningkatan pendengaran selepas myringoplasty dalam semua frekuensi, terutamanya pada frekuensi rendah. Purata pendengaran sebelum pembedahan adalah 27.58 dB dan selepas pembedahan adalah 14.33 dB. Perbezaan ABG menunjukkan peningkatan 13.25 dB selepas myringoplasty. MEV dalam kajian ini adalah 2.83 ml. MEV didapati tidak memberi kesan pada peningkatan pendengaran selepas myringoplasty. Selain itu, saiz TMP sebelum pembedahan juga tidak memberi kesan kepada peningkatan pendengaran selepas myringoplasty. Akhir sekali, tiada hubungan yang signifikan antara 2 faktor tersebut terhadap peningkatan pendengaran selepas myringoplasty.

Objektif

Untuk mengetahui sama ada isipadu telinga tengah memberi kesan terhadap pendengaran selepas myringoplasty.

Bentuk kajian

Kajian ini dilakukan secara pemerhatian prospektif di Klinik Otorinolaringologi Hospital Universiti Sains Malaysia dan Hospital Raja Perempuan Zainab II.

Metodologi

72 subjek yang mengalami CSOM telah memenuhi kriteria dipilih untuk menyertai kajian ini. Pesakit berumur 15 tahun ke atas, kehilangan pendengaran konduktif serta merancang untuk pembedahan myringoplasty telah dipilih. Walaubagaimanapun, pesakit yang mempunyai tahap pendengaran sederhana (lebih dari 50 dB), mempunyai telinga bernanah dan tampalan gegendang telinga tidak sembuh sepenuhnya selepas pembedahan telah dikecualikan dalam kajian ini. Kebenaran bertulis untuk kajian ini diperolehi daripada pesakit. Segala maklumat tentang pesakit, ujian fizikal dan ujian pendengaran telah direkodkan. PTA telah dilakukan untuk mengetahui tahap ABG dan tympanometry untuk mengetahui jumlah isipadu telinga tengah sebelum dan 3 bulan selepas pembedahan. Peningkatan pendengaran direkodkan perbezaan purata ABG sebelum dan selepas pembedahan pada frekuensi 250, 500, 1000, 2000 dan 4000 Hz. Purata isipadu telinga tengah (2.8 ml) digunakan untuk menentukan kumpulan isipadu kecil dan besar. Gegendang telinga yang berlubang diperiksa dan diambil gambar menerusi sistem ‘endoscopic’ ataupun dalam bentuk lukisan. Saiz kebocoran gegendang telinga direkodkan dalam bacaan peratus. Saiz gegendang telinga yang berlubang dibahagikan kepada 3 kumpulan; kecil < 50%, sederhana 50 – 75% dan besar > 75% direkod.

Kesimpulan

Tampalan TMP telah menyebabkan peningkatan pendengaran yang ketara dalam semua frekuensi. Walau bagaimanapun, kedua-dua saiz TMP dan MEV menunjukkan tiada kesan kepada peningkatan pendengaran selepas myringoplasty dan tiada hubung kait antara kedua faktor tersebut.

ABSTRACT

TITLE: THE EFFECT OF MIDDLE EAR VOLUME ON HEARING IMPROVEMENT POST MYRINGOPLASTY

Tympanic membrane perforation (TMP) is one of the features of CSOM. It is surgically corrected with myringoplasty. Successful myringoplasty referred to a completely healed tympanic membrane and may resulted in hearing improvement post operatively. Besides TMP, middle ear volume (MEV) is another factor that has been shown quite recently to affect hearing loss and thus is thought to play a role in hearing improvement post myringoplasty. This study aims to determine whether MEV does have an important role in the hearing improvement post myringoplasty.

A total of 72 CSOM patients who underwent myringoplasty and resulted with healed TM were evaluated. Audiometric tests were performed pre- and 3 months post-operatively. Pure tone audiometry (PTA) was done to determine the level of hearing improvement and improved hearing was recorded as average difference air bone gap (ABG) pre and post-operatively. While tympanometry was done to determine the MEV. The mean MEV was measured and divided into small and large groups.

Perforated eardrums were examined and photographed through a system of 'endoscopic' or drawing. The size of TMP was recorded in percentage and then divided into 3 groups; small <50%, moderate 50-75% and > 75%.

Data analysis showed hearing improvement post myringoplasty in all frequencies, particularly at low frequencies. ABG pre-operative was 27.58 dB and post-operative was 14.33 dB. The ABG difference showed hearing improvement of 13.25 dB. Mean MEV in this study was 2.83 ml. MEV was found not to have any affect on the hearing improvement post myringoplasty. Moreover, the size of perforated tympanic membrane measured pre-operatively also did not affect hearing outcome post myringoplasty. Lastly, there was no significant correlation between those 2 factors on hearing improvement post myringoplasty.

Objective

To determine whether the middle ear volume affecting hearing improvement post myringoplasty.

Study design

This is a prospective observational study in Otorhinolaryngology Clinic and Hospital Universiti Sains Malaysia Hospital Raja Perempuan Zainab II.

Methodology

72 subjects of CSOM patients who fulfilled the criteria were selected to participate in this study. Patients aged 15 years and above, conductive hearing loss and surgical planning for myringoplasty were included in this study. However, we excluded patients with hearing loss greater than 50 dB, mucopurulent ear discharge and unhealed tympanic membrane after surgery. Written consent for this study were obtained from the patient. All information regarding the patient’s detail, physical examination and hearing tests were recorded. PTA was performed to determine the level of hearing improvement and tympanometry to determine the MEV before and 3 months after surgery. Improved hearing recorded is the average difference ABG pre and post-operatively in 250, 500, 1000, 2000 and 4000Hz frequencies. The mean MEV divided the volume into small and large groups. A perforated eardrum examined and photographed through a system of 'endoscopic' or drawing. Percentage of size of TMP was recorded and divided into 3 groups; small <50%, moderate 50-75% and > 75% were recorded.

Conclusion

Closure of TMP had resulted in significant hearing improvement in all frequencies. However, both size of perforation and MEV showed no effect on hearing improvement post myringoplasty. There is no correlation between them.

CHAPTER 1 : INTRODUCTION AND LITERATURE REVIEW

1.1 INTRODUCTION

Chronic suppurative otitis media (CSOM) is one of the commonest ear diseases in the developing countries (Sangavi, 2015). It forms due to irreversible sequel of unresolved otitis media that presented with ear discharge and conductive hearing deafness beyond 3 months period (Sangavi, 2015). In addition, this middle ear disease leads to tympanic membrane perforation (TMP) and has different degrees of hearing loss (Rasha & Ahmed, 2015). CSOM is the major contributor to TMP (Kurkjian, 1993).

A simple central TMP with absence of other middle ear lesion is indicated for myringoplasty (Das *et al.*, 2015). Myringoplasty or tympanoplasty type I is a surgical closure of TMP without ossicular chain reconstruction. The graft material that is most commonly accepted for the surgery is temporalis fascia via underlay technique (Browning *et al.*, 2008). Occasionally the graft can be harvested from tragal perichondrium or cartilage (Rasha & Ahmed, 2015).

The primary aim of myringoplasty is to protect the middle ear from external pathogen (Sangavi, 2015). Apart from that, the closure of TMP restores the vibratory area of the tympanic membrane therefore improves hearing (Das *et al.*, 2015).

1.2 LITERATURE REVIEW

Chronic suppurative otitis media (CSOM) is defined as long standing inflammation of the middle ear and mastoid cavity, which manifest otorrhoea through tympanic membrane perforation (TMP) (Acuin, 2004). It is a sequelae of acute or untreated otitis media (Kamath *et al.,* 2013). The duration of CSOM is controversial. The most accepted duration is more than 3 months of ear discharge (Goycoolea *et al*., 1991), despite World Health Organization (WHO) requirement, which only need 2 weeks of ear discharge (Smith *et al*., 1996).

According to WHO, the approximate worldwide prevalence rate ranging between 1% to 46%. There are 65 to 330 million people who had experienced ear discharge and 60% of them suffered from hearing impairment (Acuin, 2004). CSOM incidence rate is 4.76%, equating to 31 million cases, with 22.6% cases occurring annually under five years of age (Monasta *et al*., 2012). It is a major ear problem in developing countries (Aoyogi *et al.,* 1994). Moreover, the CSOM cases are mostly encountered in Asia, Africa and Latin America (Acuin, 2007). Among the Indian population, it is estimated that 6% suffers from chronic ear disease (Smyth, 1976). In Malaysia 4.36% of school children presented with CSOM (Elango *et al.*, 1991). This is quite a disturbing number considering the conductive hearing loss that associated with.

CSOM (90.9%) is the major contributor to TMP other than acute suppurative otitis media (6.1%) and trauma (3%) (Olowookere *et al.*, 2008). Besides, TMP can also be the result from other middle ear diseases and iatrogenic causes (Sarker *et al*., 2011; Bhusal *et al*, 2007).

Inactive CSOM or dry perforation is a subtype of chronic otitis media, which is defined as a permanent perforation of the pars tensa without inflammation of the middle ear and mastoid mucosa. The perforation can be completely surrounded by a remnant of pars tensa or extend to the fibrous annulus (Browning *et al.,* 2008).

Surgical treatment is the well accepted management for TMP to close the perforation and thus, obtain a permanent dry ear (Kamath *et al*., 2013). Tympanoplasty is the reconstruction of the tympanic membrane, and also deals with middle ear pathology (Hirsh, 2008). Tympanoplasty type I or myringoplasty is closure of TMP without ossiculoplasties (Pfammatter *et al.*, 2013 and Said *et al.,* 2007). According to Hirsh (2008), myringoplasty is referred to the reconstruction of a perforated tympanic membrane, which assumes that the middle ear space, mucosa and the ossicular chain are free of active infection. Surgical closure of TMP can be considered in any patient with dry ear (Kurkjian, 1993). Myringoplasty or tympanoplasty type I can be performed via permeatal, endaural or post aural approach (Pfammatter *et al.*, 2013; Sharma *et al.*, 2009). The technique can be underlay or overlay and the materials used are fascia, perichondrium and cartilage (Pfammatter *et al.*, 2013).

Tympanic membrane is important for tympano-ossicular system for sound transmission (Mehta *et al.*, 2006), however the effects of TMP on middle ear sound transmission are not well characterized. This is due to ears with perforations usually had additional pathological changes (Park *et al*., 2015). Perforated tympanic membrane can lead to conductive hearing loss that is not exceeded more than 50 dB (Mehta *et al.,* 2006). The conductive hearing loss in central perforation is result from loss of pressure difference across TMP thus reduced the tympanic membrane and ossicular motion (Merchant *et al.,* 1997). In addition, this middle ear chronic infection may produce chemical inflammatory cells that pass through the round window and cause damage of hair cells in cochlea thus result in sensory hearing loss (Mittal *et al.*, 2015).

TMP results in conductive hearing loss with the influence of several factors such as size and site of perforation, malleus involvement and middle ear volume (MEV) (Lerut *et al.*, 2012). A few studies reported that the size of perforated tympanic membrane and MEV can affect degree of hearing loss. The hearing loss is greater with larger perforation or smaller MEV (Park, 2015; Mehta *et al*, 2006; Voss *et al.*, 2001) The level of hearing impairment is directly related to size of perforation and greater in low frequencies (Lerut *et al.*, 2012; Kurkjian, 1993).

Majority of the studies showed that size of TMP is one of the main factors that can determine the hearing loss. The air bone gap (ABG) is larger as the size of TMP increases (Sangavi, 2015; Mehta *et al.*, 2006; Voss *et al.*, 2001). Yung (1983) discovered that greater hearing loss was found in big central perforation and central malleolar perforation were due to exposure to the round window. The bigger the perforation the greater hearing loss in sound perception and it is frequency dependent. The greatest decibel loss is noted at the lowest frequencies (Saliba *et al.*, 2011). Hearing loss at lower frequency can be explained by the ability of the low frequency sounds to bend and escape via the TMP thus will not vibrate the tympanic membrane. If the size of perforation is greater, it also can permit high frequency hearing loss (Zakaria *et al.*, 2016).

Some researchers thought that the site of perforation has significant effect on hearing loss. The hearing loss is worse when the perforation site is at the posterior half of the tympanic membrane (Lerut *et al.*, 2012; Yung, 1983; Ahmad & Ramani, 1979).

Round window and oval window are located at the posterior part of medial wall of the middle ear. Thus, perforation at posterior part of tympanic membrane will allow sound wave to strike directly at the round window and oval window that will cancel the sound wave to each other. This mechanism is also known as “phase-cancellation effect” that contributed to the hearing loss. (Schuknecht, 1993). However in recent studies, the site of TMP has no effect on hearing loss (Zakaria *et al*., 2016; Mehta *et al.,* 2006; Voss *et al.,* 2001)

Few journals reported that MEV is another factor that can contribute in perforation induced hearing loss (Zakaria *et al*., 2016; Mehta *et al.,* 2006; Voss *et al.,* 2001). MEV refers to the volume of air contained within the tympanic cavity (epitympanum, hypotympanum and protympanum) and the mastoid collectively (Mehta *et al.,* 2006). Normal MEV is 2 - 20 ml (Molvaer *et al.*, 1978). It is important for ossicular coupling where the aeration of middle ear allows tympanic membrane, ossicles and round window to move (Merchant *et al.,* 2010). Mehta *et al* (2006) mentioned the changes in the MEV might be due to mucosal oedema or accumulation of fluid in the middle ear.

Mehta *et al* (2006) did a prospective study regarding determinants of hearing loss in perforations of the TM. Besides size of TMP, he stated that the MEV also contribute to hearing loss. Mean MEV in his study was 4.3 ml and he divided into 2 subgroups: small (≤ 4.3 ml) and large (>4.3 ml). He concluded that the conductive hearing loss increase varies inversely with the volume of middle ear and mastoid air space. The hearing loss is greater in small MEV. The small volume leads to middle ear stiffness thus result in low frequency hearing loss (Mehta *et al.,* 2006).

Voss *et al* (2001) did a cadaveric experimental study and he discovered that 2 identical perforations showed different hearing loss up to 30 dB due to different MEV. He concluded that hearing loss depends on both, size of TMP and MEV (Voss *et al*., 2001).

A study done by Ahn *et al* (2008), to compare MEV on 44 patients who had unilateral chronic otitis media with TMP and contralateral normal tympanic membranes. The MEVs were measured by tympanometry and CT scan. He concluded that chronic otitis media caused reduction in the MEV compared to the contralateral normal ears (Ahn *et al*, 2008).

Hearing improvement post myringoplasty is still debatable however, several studies showed that there are significant hearing improvement following closure of TMP (Pfammatter *et al*. 2013; Karela *et al.,* 2008; Said *et al.,* 2007) The hearing improvement post myringoplasty was dependant on several factors such as size and site of perforation, ossicular status, surgical technique, type of graft and the functional status of eustachian tube (Black & Wormald, 1995; Blakley *et al*, 1999). Hearing improvement can be assessed either by hearing gain method or mean ABG for every frequency (Sarker *et al*., 2011).

Sarker *et al* (2011) found that the hearing gain was greater after closure of larger perforation compared to smaller perforation. Improvement of ABG closure post myringoplasty in small, medium and large size perforation was 10.45 dB, 19.24 dB and 18.67 dB respectively (Sarker *et al.*, 2011). These findings were also supported by Thiel *et al* (2013) who claimed that greater hearing improvement was noted postoperatively if the initial TMP is more than 50%. In Pfammatter study, the ABG improvement was significantly seen in 500, 1000, 2000 and 4000 Hz and it also showed linear correlation between the pre-operative size of TMP and ABG post myringoplasty (Pfammatter *et al.*, 2013). The hearing improvement is significant even though there is incompleted closure of TMP (Said *et al.*, 2007).

This differs from study by Karela *et al* (2008) who concluded that hearing improvement post myringoplasty was independent to the size and site of perforation, gender and age. Also in a study of 9 patients and paper patching on the TMP showed that the ABG result was independent to perforation size (Röösli *et al.*, 2012). Pfammatter *et al* (2013) found the size of TMP affect hearing improvement post operatively, while other factors such as MEV, temporal bone pneumatization and mucosal condition did not affect the hearing outcome.

There are few ways to measure MEV. Linderman and Holmquist (1981) stated that the impedance audiometry or tympanometry is a rapid and valuable estimation of MEV compared to conventional mastoid X-ray. According to Ahn *et al* (2008), he used tympanometry and temporal computed tomography (CT) scan to measure MEV in unilateral chronic otitis media. Similarly, Park *et al* (2015) also used temporal bone CT scan to measure volume of middle ear and mastoid pneumatisation. Ahn *et al* (2008) concluded that the MEV measured by tympanometry was significantly larger than the MEV measured by CT scan.

Tympanometry is an objective measurement to test the mobility of tympanic membrane and to detect the underlying middle ear problem. It can measure compliance of the tympanic membrane, pressure, ear canal volume, acoustic reflex and gradient (Kiefer and O'donoghue, 2010). Tympanometry is a method to measure the volume contained within a closed air space by sealing the probe tip (Ahn *et al.*, 2008). However, the commercial tympanometry is not sensitive to volumes greater than 7 ml (Mehta *et al.,* 2006). It tends to overestimate MEV result when compared to CT scan measurement (Ahn *et al*, 2008).

There were studies of status of mastoid air cell pneumatisation to the result of hearing gain post myringoplasty which still has been a debate. A well pneumatized mastoid showed post-operative hearing gain from 10-30 dB in 95% cases (Mishra *et al*., 2007). While in other study, the pneumatization of mastoid had no correlation with post-operative result (Sethi *et al.,* 2005).

Lerut *et al* (2012) proposed to use endoscopic photographs or drawing to document preoperative perforation size. The size of TMP can be measured in several ways. Saliba *et al* (2011) compared two methods in his study; the estimation of size perforation was expressed in percentage and in millimeter. Pars tensa of TM can be divided anatomically into 4 quadrants with 25% for each quadrant (Browning *et al.*, 2008). Even though the quadrant is used to estimate the size, it can provide a visual template to assist in the estimation of small or large perforation with good agreement between observers. This visual estimation method is cost effective, simple and quick compared using calculation from complex software computer. Thus, there was no need for a complicated computer based programme to calculate perforation size in relative to the tympanic membrane area (Saliba *et al.,* 2011). Therefore, the clinical description in percentage is preferred in several studies (Naderpour *et al*., 2016; Sarker *et al.*, 2011).

Post-operative surgical outcome was measured by the condition of graft taken and post-operative hearing gain. The audiometric assessment was done at 12 weeks after the operation in view of complete graft healing (Said *et al.,* 2007).

There are various methods to assess hearing improvement post operatively that have been reported in many studies including hearing gain method and mean ABG post operatively. The hearing gain was assessed by closure of ABG (Sarker *et al.,* 2011). Said *et al* (2007) used mean gaps at frequency 500, 1000, 2000 Hz pre myringoplasty minus post operative mean gap to get hearing gain more than 10 dB. Similarly, hearing gain of at least 10 dB from different ABG before and after operation was used in previous study (Sergi *et al.,* 2011). Shetty (2012) in his study mentioned, to assess the hearing outcome by the standard parameters examples gain in ABG within 20 dB, gain in air conduction and gain in hearing more than 15 dB post-operative.

Japan Clinical Otology Committee used 3 criteria to measure hearing outcomes that are; post-operative hearing within 40 dB, hearing gain more than 15 dB or ABG post operatively within 20 dB (Thiel *et al.,* 2013). Moreover, most authors reported as hearing improvement if the air conduction hearing level was up to 30 dB or ABG closure within 20 dB (Sangavi, 2015).

Karela *et al* (2013) reported on a study of 211 patients with underlay myringoplasty, achieved hearing gain by 14.67 dB in 91.5% of patients. There was also other study showed significant reduction of air conduction threshold up to 3 months post myringoplasty (Kamath *et al.,* 2013). A study of 115 patients, who underwent underlay and overlay myringoplasty showed result of significant hearing improvement in both groups but better hearing gain in underlay group (Sergi *et al.,* 2011).

The success rate to achieve complete closure of tympanic membrane by expert surgeons is around 95%. The graft take rate was 100% for small, 80% for medium perforation and 72.73% for large perforations (Sarker *et al.*, 2011). Some report stated that large perforations are more prone to get reperforation (Wielinga, 1995).

From the literature, the size of TMP and MEV play an important role on hearing loss pre-operatively. However, there were limited studies regarding MEV on hearing improvement after successful myringoplasty. In our study, we focus on MEV as well as size of TMP on hearing outcome post myringoplasty. Thus, the result from our study will determine whether the MEV has important role in hearing outcome post-operatively. The MEV will become one of the prognostic factors of successful myringoplasty in hearing outcome in future.

CHAPTER 2 : OBJECTIVES

2.1 GENERAL OBJECTIVE

To study the effect of MEV toward hearing improvement post myringoplasty.

2.2 SPECIFIC OBJECTIVES

1. To estimate MEV in patient with inactive CSOM.
2. To determine the association between the size of TMP with hearing improvement post myringoplasty.
3. To determine the association of MEV with hearing improvement post myringoplasty .
4. To determine the correlation between the size of perforation and MEV with hearing improvement post myringoplasty.

2.3 SIGNIFICANCE OF STUDY

Several studies had shown that the size of TMP and MEV are hearing loss dependent in perforated tympanic membrane. The bigger the perforation, the larger the hearing loss. Post myringoplasty with bigger size of TMP repaired showed larger hearing improvement. While small MEV showed inversely to hearing loss. However there were limited previous studies regarding MEV on hearing outcome post myringoplasty. Thus, the purpose of this study was to determine whether MEV can be one of the prognostic factors on hearing improvement post-operatively. Therefore, the results of this study may help in predicting the possible hearing outcome post myringoplasty in future.

2.4 NULL HYPOTHESIS

2.4.1 There is no association of size of TMP on hearing improvement post myringoplasty.

2.4.2 There is no association of MEV on hearing improvement post myringoplasty.

2.4.3 There is no correlation between the size of perforation and MEV with hearing improvement post myringoplasty.

CHAPTER 3 : METHODOLOGY

3.1 STUDY DESIGN

The study was a prospective observational study. It was conducted at Otorhinolaryngology (ORL) Clinic Hospital Universiti Sains Malaysia (HUSM), Kubang Kerian and Hospital Raja Perempuan Zainab II (HRPZ II), Kota Bharu from January 2016 to December 2016.

3.2 INCLUSION CRITERIA

CSOM patients with permanent TMP, patients age more than 15 years and above as well as conductive hearing loss were recruited in this study.

3.3 EXCLUSION CRITERIA

Patients with hearing loss greater than 50 dB, active mucopurulent ear discharge and unhealed tympanic membrane after surgery were excluded from this study.

3.4 SAMPLE SIZE CALCULATION

One sample mean formula was used to calculate the sample size. Standard deviation, SD was cited from Mehta *et al*, 2006.

$$n = \left(\frac{Z_{\alpha/2}\sigma}{\Delta}\right)^2$$

$Z\alpha$ = critical value for α

α = population SD in previous study

Δ = estimated different from population mean (detectable difference)

Zα = 1.96

α = 5.0%

Δ = 1.5

σ = 4.3

Adjusted n= 36

The sample size calculated was 72 ears (including 10% dropout)

3.5 ETHICAL CONSIDERATION

In this study, all the patients that fulfilled the criteria were given thorough explanation regarding the purpose and benefit of the study. Written consent was taken from the patients before any procedure done. Participation in this study was voluntary and patients can withdraw any time from this study. Patient's identification was not revealed to the rest of the researcher team members. The ethical approval was obtained from Ethics Committee Hospital Universiti Sains Malaysia and Medical Research and Ethic Committee Kementerian Kesihatan Malaysia.

3.6 STUDY CONDUCT

Samples were selected via purposive sampling method**.** CSOM patients who attended ORL clinic at HUSM and HRPZ II that underwent myringoplasty were screened for inclusion and exclusion criteria. Myringoplasty was performed under general anaesthesia with underlay technique by using temporalis fascia graft 70 subjects and the other 2 subjects were using tragal perichondrium. Total of 72 subjects were selected in this study with one subject contributing one ear.

Informations regarding patient's history, clinical examination and audiometric test; pure tone audiometry (PTA) and tympanometry were performed and documented during preoperative visit as well as consent was taken for research. Endoscopic picture or drawing of TMP preoperatively was recorded.

Visual estimation was chosen to assess size of perforation in percentage. Preoperatively, The size of TMP was divided into 3 groups; small (<50%), medium (50-75%) and large (>75%) that was based on estimation as percentage of the tympanic membrane surface.

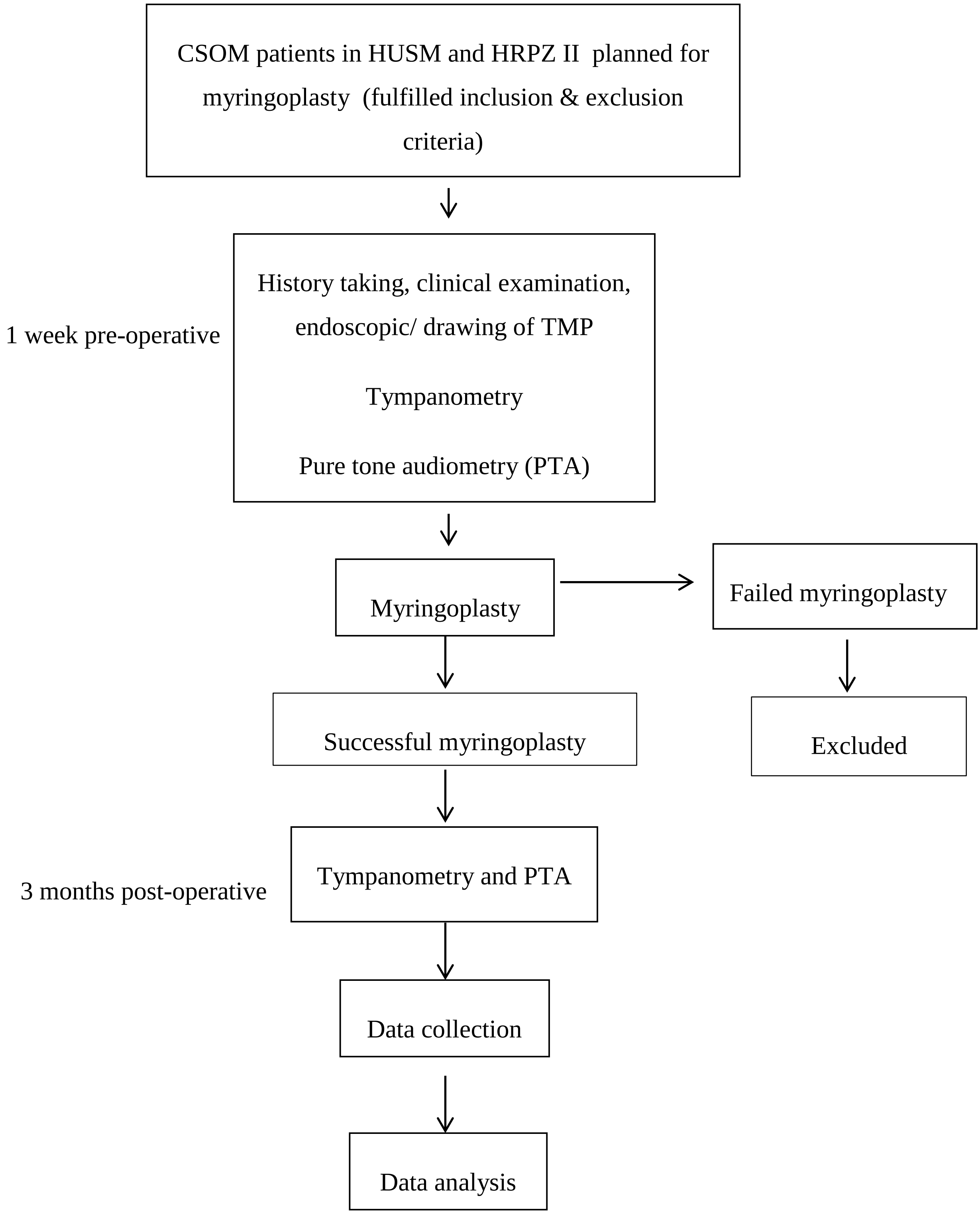
Patients who underwent myringoplasty were assessed for graft-take rate and hearing level post operatively. Only complete closure of tympanic membrane post operatively were included in this study. Audiological assessment such as and tympanometry were done at 3 months post myringoplasty.

MEV was obtained by difference between ear canal volume (ECV) from tympanogram pre and post myringoplasty. It was divided into two subgroups by the mean MEV of 2.8 ml. The small MEV less than or equal to 2.8 ml and large MEV is greater than 2.8 ml. Hearing improvement was measured by difference mean of ABG pre and post-operatively. We also analysed the hearing outcome in each 5 frequencies (250 Hz, 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz). While, hearing improvement is referred to improvement by difference ABG at least 10 dB post operatively.

3.7 DATA ENTRY AND ANALYSIS

The data from PTA and tympanometry that was collected, were recorded into computer and then analysed. Data was entered and analyzed using Statistical Package for Social Science (SPSS) version 22 software. Descriptive analysis was used to calculate demographic data including mean of MEV. The hearing improvement was analysed by comparing the pre and post-operative mean ABG using paired-t test. The effect size of TMP on hearing improvement was analysed using one-way ANOVA. While the effect of MEV on hearing improvement post myringoplasty was analysed using paired-t test. Correlation of MEV and size perforation pre-operatively on hearing improvement post myringoplasty was analysed using two-way ANOVA.

3.8 STUDY FLOW CHART



CHAPTER 4 : RESULTS

4.1 DESCRIPTIVE ANALYSIS

The descriptive analysis showed age of 15 to 60 with mean age of 30.7 years among subjects. From 72 subjects, female are (52.8%) more than male subjects (47.2%). All subjects are from the Malay population group. TMP showed that majority of patients has smaller size (41.7%) of perforation. Followed by medium size group (30.6%) and larger group (27.8%). This study showed 59.7% has small MEV while 40.3% has larger MEV. Mean pre ABG in our study was 27.58 dB and post ABG was 14.33 dB. The mean hearing improvement in this study was 13.25 dB.

Table 4.1 : Descriptive analysis of variables of 72 subjects

Variables	**mean (SD)**
Age	30.67 (15.61)

Variables	**n (%)**
Gender	
Male	34 (47.2)
Female	38 (52.8)
Race	
Malay	72 (100.0)

Chinese	0 (0.0)
Indian	0 (0.0)
Others	0 (0.0)
Size (%)	
< 50 (small)	30 (41.7)
50 -75 (medium)	22 (30.6)
> 75 (large)	20 (27.8)
Middle ear volume	
Small (≤ 2.8 ml)	43 (59.7)
Large (> 2.8 ml)	29 (40.3)
Mean ABG and Hearing improvement	**mean (SD)**
Pre ABG[a]	27.58 (9.48)
Post ABG[a]	14.33 (7.49)
Difference improvement[a]	13.25 (7.91)

4.2 HEARING IMPROVEMENT POST MYRINGOPLASTY

Hearing outcome showed significant improvement in all 5 frequencies. Greatest hearing improvement was found in low frequency from 250 Hz followed by 500 Hz, 1000 Hz and 4000 Hz. The least different ABG pre and post operatively noted in 2000 Hz (8.33 dB).

Table 4.2 : Hearing improvement for each frequencies (250Hz, 500Hz, 1kHz, 2kHz, 4kHz)

Frequency (Hz)	**Air bone gap (ABG) Mean (SD)**		**Mean difference (95% CI)**	**t-statistics (df)**	**p-value**
	Pre	**Post**			
250	39.17 (10.68)	20.28 (11.00)	18.89 (16.47, 21.31)	15.58 (71)	< 0.001
500	29.31 (13.49)	13.13 (10.89)	16.18 (13.31, 19.06)	11.22 (71)	< 0.001
1000	26.46 (14.05)	13.75 (9.52)	12.71 (9.79, 15.63)	8.68 (71)	< 0.001
2000	18.13 (9.55)	9.79 (8.86)	8.33 (5.93, 10.74)	6.90 (71)	< 0.001
4000	24.86 (13.16)	14.72 (10.03)	10.14 (7.11, 13.17)	6.674 (71)	< 0.001

4.3 OBJECTIVE 1

Mean of MEV

From descriptive analysis , mean of MEV in patient with inactive CSOM was 2.83 with SD = 2.01.

4.4 OBJECTIVE 2

The association size of TMP on hearing improvement post myringoplasty

Result of one-way ANOVA test showed there was no significant different of mean of hearing improvement among the three groups of TMP size for 250 Hz, 500 Hz, 1000 Hz 2000 Hz and 4000 Hz (*p*-value > 0.05).

Table 4.3: Mean of hearing improvement between different sizes of TMP for each frequency.

Frequency (Hz)	**Size of TMP**	**n**	**Hearing improvement Mean (SD)**	**F-statistics (df)**	***p*-value**
250	< 50	30	19.67 (9.28)	0.16 (2)	0.850
	50 – 75	22	18.64 (11.04)		
	> 75	20	18.00 (11.29)		

500	< 50	30	17.00 (9.79)	0.85 (2)	0.432
	50 – 75	22	13.41 (12.85)		
	> 75	20	18.00 (14.73)		
1000	< 50	30	11.17 (11.65)	1.14 (2)	0.326
	50 – 75	22	11.59 (12.85)		
	> 75	20	16.25 (12.97)		
2000	< 50	30	7.50 (8.78)	0.54 (2)	0.588
	50 – 75	22	10.23 (10.41)		
	> 75	20	7.50 (12.19)		
4000	< 50	30	8.33 (11.84)	0.93 (2)	0.399
	50 – 75	22	13.18 (13.14)		
	> 75	20	9.50 (14.13)		

4.5 OBJECTIVE 3

The association of MEV on hearing improvement post myringoplasty

From the result of independent t-test, there was no significant difference of mean of hearing improvement between small and large middle ear volume for 250 Hz, 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz (*p*-value > 0.05).

Table 4.4 : Mean of hearing improvement between different MEV for each frequency

Frequency (Hz)	**MEV**	**Mean (SD) of ABG closure dB**	**Mean difference (95% CI)**	**t-statistics (df)**	***p*-value**
250	Small (n = 43)	20.47 (10.57)	3.91 (-0.96, 8.79)	1.60 (70)	0.114
	Large (n = 29)	16.55 (9.55)			
500	Small (n = 43)	17.91 (12.40)	4.29 (-1.53, 10.10)	1.47 (70)	0.146
	Large (n = 29)	13.62 (11.72)			
1000	Small (n = 43)	14.53 (12.24)	4.54 (-1.36, 10.43)	1.53 (70)	0.129
	Large (n = 29)	10.00 (12.39)			
2000	Small (n = 43)	8.49 (10.50)	0.39 (-4.56, 5.33)	0.16 (70)	0.877
	Large (n = 29)	8.10 (10.04)			
4000	Small (n = 43)	11.05 (14.00)	2.25 (-3.95, 8.45)	0.73 (70)	0.471
	Large (n = 29)	8.79 (11.15)			

4.6 OBJECTIVE 4

The correlation of MEV and size of TMP on hearing improvement post myringoplasty

Two-way ANOVA showed there is no significant different in mean of hearing improvement among different group of MEV (*p*-value > 0.05) and size of TMP for 250 Hz, 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz frequencies (*p*-value > 0.05).

Table 4.5 : Comparison of mean hearing improvement among study factors for 250 Hz (n = 72)

Factors	n	Mean (SD)	t-stat (df)/ F-stat (df)	*p*-value
MEV				
Small	43	20.47 (10.57)	1.60 (70)[a]	0.114
Large	29	16.55 (9.55)		
Size of TMP (%)				
< 50	30	19.67 (9.28)	0.16 (2)[b]	0.850
50 – 75	22	18.64 (11.04)		
> 75	20	18.00 (11.29)		

[a]Independent t-test was applied

[b]One-way ANOVA test was applied