VESTIBULAR DYSFUNCTION IN CHRONIC SUPPURATIVE OTITIS MEDIA PATIENTS WITH SENSORINEURAL HEARING LOSS

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I would like to dedicate my work to my parents, who have devoted their lives to ensure that we get the best of everything.

Last but not least, I thank my wife Dr Norhasimah Ismail; an Obstetrician and Gynecologist who has continuously inspiring and supporting me throughout my career, and our precious children; Yusuf, Maryam and our newborn Nuh.

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ABSTRAK

Objektif: Otitis media kronik (CSOM) atau jangkitan telinga tengah kronik pada amnya boleh menyebabkan kehilangan pendengaran sensorineural lantaran kesan terhadap koklea serta disfungsi keseimbangan disebabkan oleh kemasukan agen-agen keradangan serta toksin melalui jendela bulat. Kajian ini dijalankan untuk menentukan kewujudan disfungsi keseimbangan dikalangan pesakit CSOM yang mempunyai kehilangan pendengaran sensorineural; untuk menentukan kewujudan disfungsi keseimbangan dikalangan pesakit CSOM yang tidak mempunyai kehilangan pendengaran sensorineural; dan untuk menentukan hubungkait di antara disfungsi keseimbangan dengan pesakit CSOM yang kehilangan pendengaran sensorineural

Kaedah: Kajian ini dijalankan melibatkan 184 pesakit CSOM yang berumur diantara 15 hingga 55 tahun, di klinik ORL-HNS Universiti Sains Malaysia yang memenuhi kriteria pemasukan dan pengecualian. Pendengaran diuji menggunakan audiometri konvensional diikuti dengan ujian VHIT. Kajian ini telah diluluskan oleh Jawatankuasa Etika Penyelidikan Manusia USM (USM / JEPeM / 18020111). Kajian itu dilakukan mengikut Deklarasi Helsinki dan persetujuan bertulis diperolehi daripada pesakit.

Keputusan: Sejumlah 184 orang pseserta; 92 orang kehilangan pendengaran sensorineural dan 92 orang tanpa kehilangan pendengaran sensorineural, terlibat dalam kajian ini. Peratus pesakit CSOM yang mempunyai disfungsi keseimbangan serta kehilangan pendengaran sensorineural adalah 33.7%, dan peratusan pesakit CSOM yang mempunyai disfungsi keseimbangan tanpa kehilangan pendengaran sensorineural adalah 31.5%. Namun begitu, tiada kaitan signifikan

diantara disfungsi keseimbangan serta pesakit CSOM yang memiliki kehilangan pendengaran sensorineural ($p>0.05$)

Kesimpulan: Secara keseluruhan, jumlah pesakit yang mempunyai CSOM beserta dengan disfungsi keseimbangan adalah signifikan. Namun begitu, tiada kaitan yang signifikan diantara pesakit yang mempunyai disfungsi vestibular dan juga yang turut mempunyai CSOM dengan kehilangan pendengaran sensorineural.

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ABSTRACT

Objectives: Chronic suppurative otitis media (CSOM) may cause sensorineural hearing loss (SNHL) due to effect on cochlea, as well as vestibular dysfunction due to entrance of inflammatory agents and toxins through the round window. Our study was aimed to determine the prevalence of vestibular dysfunction in CSOM patients, with and without SNHL as well as the association between vestibular dysfunction and CSOM with SNHL.

Methods: This was a cross sectional study involving 184 patients with CSOM, aged from 15 till 55 years (92 CSOM patients with SNHL, and 92 CSOM patients without SNHL). Hearing test was done using conventional pure tone audiometry followed by video head impulse test (VHIT) for the balance assessment

***Results*:** A total of 184 participants; 92 CSOM with sensorineural hearing loss and 92 CSOM without sensorineural hearing loss, participated in the study. The prevalence of vestibular dysfunction in CSOM patients with SNHL was 33.7%, and prevalence of vestibular dysfunction in CSOM without SNHL was 31.5%. There was insignificant association between vestibular dysfunction and CSOM with SNHL ($p>0.05$).

Conclusions: Overall, there was a significant number of patients with CSOM having vestibular dysfunction, however there is no significant association between vestibular dysfunction and CSOM with SNHL.

Keywords: Chronic suppurative otitis media, Vestibular dysfunction, Video head impulse test, VHIT, Sensorineural hearing loss (SNHL)

CHAPTER 1:

INTRODUCTION

1.1 INTRODUCTION

Chronic suppurative otitis media (CSOM) is an infection of the middle ear for more than 12 weeks. It is characterized by various degrees of edema, submucosal fibrosis, hypervascularity and infiltration with lymphocyte, plasma and histiocyte. Generally, CSOM results in conductive hearing loss from the perforation of tympanic membrane, as well as the impairment in mechanical conduction of sound wave from pinna into the inner ear. The round window (RW) which is the only soft tissue barrier between middle and inner ear, is thought to be the likely portal entry for noxious substances from the middle ear into inner ear.[1] The RW is located at inferior part of medial wall of middle ear and lies in a niche where effusions can accumulate.

RW has three layers which are outer epithelial layer, middle connective tissue layer and inner epithelial layer. The structure of outer epithelium could allow the passage of substance from middle into inner ear by presence of microvilli which indicative of absorptive capabilities. Apart from that, it also has lots of organelles such as mitochondria, rough endoplasmic reticulum and Golgi complex which could carry out metabolic and transport activity.[2] The inner epithelial layer also lacks continuity of basement membrane and loose junctions; suggest an opening for substance to traverse the membrane.[2]

The toxins that can enter the inner ear through round window include biological and chemical toxin. Biological toxin includes inflammatory mediators and bacterial endotoxin,[3] while chemical toxin includes topical ototoxic agent such as aminoglycoside ear drop.[4,5] Due to the entrance of inflammatory agents[6] and toxins[7] through the round window, as well as by topical

ototoxic agents used in the treatment,[8] CSOM patients are at risk of getting sensorineural hearing loss due to effect on the cochlear.

Almost 84% of CSOM patient has conductive hearing loss while 12% have mixed type. [9,10] However, Brian et al states that there is a highly significant association between SNHL and chronic ear infection.[11] Functional and structural damage of the cochlea due to chronic otitis media has been reported.[12] Study has shown that inflammatory mediators and bacterial products can traverse through the round window membrane and into the labyrinth which then damage the organ of Corti, lateral wall and other structures of the cochlea.[1]

Apart from that, some patients who have chronic otitis media unfortunately experienced dizziness and vertigo which suggest that the inflammation can spread into the vestibular system due to its close anatomic proximity to cochlea.[13] As vertigo and instability can significantly affect patients' quality of life, assessment of vestibular function should be part of functional assessment of patients with CSOM. The association between dizziness and vestibular function testing was infrequently reported in the literature due to technical difficulty and anatomical asymmetry.

There are few techniques available to evaluate vestibular function such as caloric test, rotational chair test, vestibular evoked myogenic potential test (VEMP),[14] and video head impulse test (VHIT).[15] The caloric test and VEMP test were designed to assess the vestibular functions of superior vestibular nerve and inferior vestibular nerve.[16] Technically, it is not easy to do open loop water caloric test for patients with CSOM; moreover, it can also predispose to ear infection.

VHIT has been used in many dizzy clinics around the world for initial and final test for suspected vestibular disorders. It uses combination of high frame-rate camera and accelerometer to evaluate any reduction in vestibule-ocular reflex (VOR) gain or any evidence of saccades during rapid eye movements in the plane of canals that being tested. In normal condition, technically the VOR gain is in unity however if the semicircular canal function is affected, the gain will decrease leading to retinal slip, thus compensatory saccades will be generated. Head angular acceleration can be carried out in any of the three pair canal combinations (right lateral/left lateral, right anterior/left posterior, left anterior/right posterior). Thus, the information regarding all six semicircular canals can be measured.[17] VHIT systems are relatively cheaper compared to rotating device such as rotatory chairs. In contrast to caloric assessment, it is better tolerated by the patient even though all six canals are tested at the same time.[18]

In CSOM, we knew that the toxin can enter the labyrinthine system through the round window, then it is possible for the patient to get balance problem. Therefore, we conducted this study with the objectives of to determine the prevalence of vestibular dysfunction in CSOM patients with and without SNHL, as well as to determine the association between vestibular dysfunction and SNHL in CSOM patients. Thus, our ability to detect early manifestation of cochlear and vestibular dysfunction might help us to initiate early treatment and improve patient's quality of life.

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CHAPTER 2:

OBJECTIVES OF THE STUDY

2.0 OBJECTVES OF THE STUDY

2.1 General objective

To study prevalence of vestibular dysfunction in CSOM patients with sensorineural hearing loss (SNHL)

2.2 Specific objectives

1. To determine the prevalence of vestibular dysfunction in CSOM patients with sensorineural hearing loss (SNHL).
2. To determine the prevalence of vestibular dysfunction in CSOM patients without SNHL.
3. To determine the association between vestibular dysfunction and CSOM with SNHL.

CHAPTER 3:

MANUSCRIPT

3.1 TITLE PAGE

Vestibular Dysfunction in Chronic Suppurative Otitis Media Patients with Sensorineural Hearing Loss

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None

Conflict of interest

None

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3.2 ABSTRACT

Vestibular dysfunction in chronic suppurative otitis media patients with sensorineural hearing loss

Objectives: Chronic suppurative otitis media (CSOM) may cause sensorineural hearing loss (SNHL) due to effect on cochlea, as well as vestibular dysfunction due to entrance of inflammatory agents and toxins through the round window. Our study was aimed to determine the prevalence of vestibular dysfunction in CSOM patients, with and without SNHL as well as the association between vestibular dysfunction and CSOM with SNHL.

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***Results*:** Prevalence of vestibular dysfunction in CSOM patients with SNHL was 33.7%, and prevalence of vestibular dysfunction in CSOM without SNHL was 31.5%. There was insignificant association between vestibular dysfunction and CSOM with SNHL ($p>0.05$).

***Conclusion*:** Overall, a significant number of patients with CSOM having vestibular dysfunction, however there is no significant association between vestibular dysfunction and CSOM with SNHL

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3.3 INTRODUCTION

Chronic suppurative otitis media (CSOM) is an infection of the middle ear for more than 12 weeks. It is characterized by various degrees of edema, submucosal fibrosis, hypervascularity and infiltration with lymphocyte, plasma and histiocyte. Generally, CSOM results in conductive hearing loss from the perforation of tympanic membrane, as well as the impairment in mechanical conduction of sound wave from pinna into the inner ear. The round window (RW) which is the only soft tissue barrier between middle and inner ear, is thought to be the likely portal entry for noxious substances from the middle ear into inner ear.[1] The RW is located at inferior part of medial wall of middle ear and lies in a niche where effusions can accumulate.

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entrance of inflammatory agents[6] and toxins[7] through the round window, as well as by topical ototoxic agents used in the treatment,[8] CSOM patients are at risk of getting sensorineural hearing loss due to effect on the cochlear.

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VHIT has been used in many dizzy clinics around the world for initial and final test for suspected vestibular disorders. It uses combination of high frame-rate camera and accelerometer to evaluate any reduction in vestibule-ocular reflex (VOR) gain or any evidence of saccades during rapid eye movements in the plane of canals that being tested. In normal condition, technically the VOR gain is in unity however if the semicircular canal function is affected, the gain will decrease leading to retinal slip, thus compensatory saccades will be generated. Head angular acceleration can be carried out in any of the three pair canal combinations (right lateral/left lateral, right anterior/left posterior, left anterior/right posterior). Thus, the information regarding all six semicircular canals can be measured.[17] VHIT systems are relatively cheaper compared to rotating device such as rotatory chairs. In contrast to caloric assessment, it is better tolerated by the patient even though all six canals are tested at the same time.[18]

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3.4 METHODOLOGY

This is a cross sectional study conducted in a tertiary hospital from June 2018 till June 2019. This study was approved by the Human Research Ethic Committee with code number USM/JEPeM/18020111. The study was performed according to Helsinki Declaration and written consent was obtained from each subject.

Using the Power and Sample Size Software (PS), based on two proportion formula; with power 80%, confidence level at 95%, and significant level set at $p<0.05$, based on study by Mostafa et al 2013, the calculated sample size was 184 patients with CSOM, whereby 92 of them were CSOM with SNHL, and another 92 of them CSOM without SNHL. They were selected by random sampling method. The inclusion criteria include all CSOM patients aged were between 15 and 55 years old, while patients with cholesteatoma, familial history of young onset hearing loss, chronic exposure to noise, known history of receiving systemic ototoxic drugs, diabetes and presbycusis were excluded from the study.

Consented patient completed a proforma which include the participant's demographic data, past medical history, past surgical history, and medication history. Then, an otoscopic ear examination was performed to confirm the diagnosis of CSOM. Following that, the participant underwent pure tone audiometry (PTA) that measures hearing threshold at 125 till 8000 Hz. The test was done in a sound proof cabin in ORL clinic using Madsen Astera 2 clinical audiometer (Denmark). Both patients with and without SNHL underwent video head impulse test (VHIT); using Oto Suite Vestibular- ICS Impulse Otometrics (Denmark). In ICS impulse, normal range for

VOR gain for lateral impulse is 0.8-1.2 while for right anterior-lateral posterior (RALP) semicircular canals and lateral anterior-right posterior (LARP) semicircular canals gain is 0.7-1.2. On average 20 head trust tests were conducted for each canal pair and VOR gain values determined. The procedure took about 10 minutes.

The hearing levels of audiometry were categorized into mild, moderate, severe and profound hearing loss based on WHO grades of hearing impairment. The data was analyzed using IBM SPSS version 25.0 software. Categorical data was summarized with frequency and percentage. The prevalence of vestibular dysfunction in CSOM patients with and without sensorineural hearing loss (SNHL) respectively calculated at 95% confidence interval.

Pearson's chi-squared and independent t-test were applied to compare the association of two categorical data, specifically the association of vestibular dysfunction and CSOM with SNHL. The level of significance was set at 0.05 levels. All tests were done for two-sided.

3.5 RESULTS

During the study period as demonstrated by Table 1, there were 184 eligible participants included in the analysis. Table 1 summarized the demographic and clinical profiles of 184 study subjects. Most of them were female (71.2%), Malays (95.7%), and non-hypertensive (94.0%) as well as non-smokers (98.9%). In our study, out of 92 subjects with SNHL, 31 subjects had abnormal VHIT (33.7%), while 29 out of 92 subjects without SNHL (31.5%) had abnormal VHIT.

Table 1: Characteristic of study population (n=184).

	CSOM with SNHL N=92 N (%)	**CSOM without SNHL** N=92 N (%)
Gender		
Male	28(52.8)	25(47.2)
Female	64(48.9)	67(51.1)
Race		
Malay	85(48.3)	91(51.7)
Chinese	5(83.3)	1(16.7)
Indian	2(100.0)	0(0.0)
Site of CSOM		
Unilateral	23(46.9)	26(53.1)
Bilateral	8(72.7)	3(27.3)
Past Medical History		
Hypertension		
Yes	9(81.8)	2(18.2)
No	83(48.0)	90(52.0)
Video Head Impulse Test		
Abnormal	31(51.7)	29(48.3)
Normal	61(49.2)	63(50.8)
Smoking		
Yes	0(0.0)	2(100.0)
No	92(50.5)	90(49.5)

Table 2: Characteristic of study population

	CSOM with SNHL Mean (SD)	**CSOM without SNHL** Mean (SD)
Age	41.62(13.36)	26.97(12.89)

Table 2 shows the mean age of CSOM with SNHL (41.62) and mean age for CSOM without SNHL (26.97).

Table 3: Prevalence of vestibular dysfunction in CSOM patients with/without SNHL

Group	Prevalence of vestibular dysfunction (95% CI)
CSOM with SNHL	33.7 % (23.8, 43.5 %)
CSOM without SNHL	31.5 % (21.8, 41.2 %)

In our study, the prevalence of vestibular dysfunction among CSOM with SNHL is 33.7% (95% CI), while the prevalence of vestibular dysfunction among CSOM without SNHL is 31.5% (95% CI).

Table 4: VHIT abnormality in unilateral or bilateral type of CSOM

CSOM	**VHIT**	**CSOM with SNHL** N (%)	**CSOM without SNHL** N (%)
Unilateral	Normal	46(45.1)	56(54.9)
	Abnormal	23(46.9)	26(53.1)
Bilateral	Normal	15(68.2)	7(31.8)
	Abnormal	8(72.7)	3(27.3)

In our study, among the subjects who had abnormal VHIT in SNHL group, 23 of them had unilateral CSOM while 8 of the subjects had bilateral CSOM. Besides that, among the subjects with bilateral CSOM who had abnormal VHIT, 72.7% are from CSOM with SNHL group while only 27.3% of them from CSOM without SNHL group.

Table 5: Association between vestibular dysfunction and CSOM with SNHL; hypertension and smoking.

	Vestibular abnormalities		**P- value**
	Yes	No	
Variables	N (%)	N(%)	
CSOM			0.753
SNHL	61(66.3)	31(33.7)	
Non-SNHL	63(68.5)	29(31.5)	
Hypertension			0.751
Yes	7(63.6)	4(36.4)	
No	117(67.6)	56(32.4)	
Smoking			
Yes	2(100.0)	0(0.0)	
No	122(67.0)	60(33.0)	>0.950

Fisher Exact Test was applied.

Table 5 shows no association between vestibular dysfunction and CSOM patients with sensorineural hearing loss; hypertension; and smoking. (all p>0.050).

Table 6: Association between vestibular dysfunction with unilateral/bilateral CSOM, age and severity of hearing.

Variables	Normal VHIT n(%)	Abnormal VHIT n(%)	p-value
Type			
Unilateral	102(82.3)	49(81.7)	0.922[a]
Bilateral	22(17.7)	11(18.3)	
Age,mean	33.35(14.96)	36.25(15.04)	0.220[b]
Severity of hearing			
Normal	3(2.4)	0(0.0)	
Mild	56(45.2)	20(33.3)	
Moderate	55(44.4)	32(53.3)	0.227 [a]
Severe	9(7.3)	8(13.3)	
Profound	1(0.8)	0(0.0)	

[a] Pearson chi square test and [b] independent t-test were applied.

Table 6 shows the association between vestibular dysfunction with unilateral and bilateral CSOM, age as well as severity of hearing. However, there were no significant association between unilateral and bilateral CSOM, age, as well as severity of hearing with VHIT groups (all $p>0.05$).

3.6 DISCUSSION

To date, there are no studies have been done to assess vestibular dysfunction in CSOM patients with SNHL using VHIT, as well as the association between vestibular dysfunction among CSOM patients with SNHL. This study can be the basis of altering current standard of practice in management of CSOM patient by means of incorporating routine testing of vestibular assessment in all CSOM cases such as using VHIT during follow-up. CSOM most of the time, causing conductive hearing loss due to tympanic membrane perforation and ossicular changes.[19] Not only that, CSOM can cause dizziness and imbalance related with the entrance of inflammatory mediators and toxins through the round window causing vestibular as well as cochlear damage in the form of sensorineural hearing loss in conventional pure tone audiometry.[20,21]

In this study, we found that 31 out of 92 CSOM subjects with SNHL having abnormal VHIT, making the prevalence of 33.7 (95% CI). Mostafa et al also found a significant vestibular abnormality among their 14 CSOM patients with SNHL in which 92.8% of them had rotatory chair abnormalities, 57.1% of them had caloric test abnormalities and 21.4% of the subjects had vestibular evoked myogenic potential abnormalities.[22] In another study done by Gerard and James in 2018, they found 76% of their CSOM patients with or without cholesteatoma who were to undergo tympanomastoid surgery demonstrated either unilateral or bilateral caloric weakness.[23] However, in our study, we excluded patient who had cholesteatoma. Schaaf in 1988 who study the frequency of vestibular disorder in developmentally delayed preschoolers with otitis media reported that their patient had a significantly higher incidence of vestibular disorder.[24] Besides that, Rafael et al also noticed significant decrease in the density of type I and type II hair cells in

lateral semicircular canal, saccule and utricle with p value <0.05 among human temporal bone from patients with chronic otitis media, which suggest the decrease in number of vestibular sensory cells and dark cells that could be the cause of clinical symptom of imbalance in patient with chronic otitis media.[25]

The prevalence of vestibular dysfunction in CSOM without SNHL in our study was 31.5 (95% CI), which involved 29 out of 92 subjects. This finding was almost similar with the SNHL group, which could suggest that vestibular dysfunction can occur independently and may precede SNHL in CSOM patients. However, there were no other studies in the literature who studied specifically vestibular dysfunction among CSOM patient without SNHL. Besides that, we knew that in the pathogenicity of CSOM, inflammatory mediators and pore-forming toxins,[21] as well as the ototoxic elements from ear drops diffuse through round window, which can cause direct damage to basal turn of cochlea and causing subsequent vestibular damage.[6,20] Apart from that, gentamicin ear drops which have been proven for their vestibulotoxic rather than cochleotoxic,[26] frequently prescribed to patients with CSOM, as well as neomycin ear drop.[27] Moreover, Bath et al also noticed that patients with tympanic membrane defect who are using gentamicin ear drops for more than seven days developed ototoxicity and suggested the preparation to be discontinued shortly after the discharge has stopped.[26] Instead, the usage of ciprofloxacin ear drops which have been proven for its non-ototoxic capability to be used regularly.[28,29] However, in our study we did not make into account how long the duration of ear drops exposure and the duration of patients having diagnosed of CSOM.

In our study, we found that there were no associations between vestibular dysfunction and CSOM with SNHL, hypertension and smoking as well as unilateral/ bilateral CSOM and age; with all the p value > 0.05. Study done by Mostafa et al who evaluate the vestibular function in CSOM shows only the duration of disease (CSOM) show positive correlation with vestibular dysfunction; though the p-value just reaching statistically significant; 0.097.[22] However, the duration of disease (CSOM) is not evaluated in our study. Apart from that, our study shows no significant association between vestibular dysfunction with severity of hearing (p- value 0.227), in contrast to other study done by Pajor et al who studied the prognostic factors for vestibular impairment in SNHL noted that abnormal electroneurography was significantly correlated with the degree of hearing loss.[30]

There are few limitations of this study in which there is no previous study has been done for comparison with regards to prevalence of vestibular dysfunction specifically in CSOM with and without SNHL. Apart from that, we did not divide the patients either into active or inactive CSOM in the first place, as we included all CSOM patients in each group regardless of chronicity of illness itself as well as the duration of having diagnosed of CSOM. Besides that, we also did not exclude patients who just received ototoxic ear drops such as gentamicin or neomycin during the study, which could contribute to the non-significant results.

Therefore, in future research, CSOM patients who are on ototoxic ear drops should be excluded from the study and the duration of illness should be evaluated. If the usage of VHIT as the measuring tool for vestibular dysfunction we suggest that lesser impulse to assess the VOR gain should be applied as suggested by Wenzel et al.[31]

Conclusion:

Vestibular dysfunction can occur independantly and may precede SNHL in CSOM patients. The usage of ototoxic antibiotic ear drops must be used with precaution and in short term duration. CSOM without SNHL might warrant a more aggressive approach such as early surgical intervention, more frequent follow-up and audiological, as well as strict adherence to the usage and duration of topical antibiotics and all in all, can improve patient's quality of life.

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