SOUTH BAYLO UNIVERSITY

# Objective Diagnosis of Tinnitus through MTM (Modulated Tinnitus Masking) Protocol and Acupuncture Treatment Effect: Case Series

# MTM protocol 을 통한 이명의 객관적인 진단과 그에 대한 침치료의 효과 분석

by

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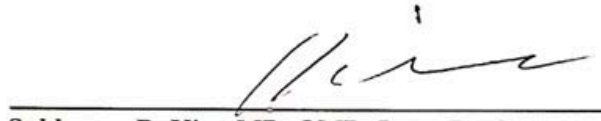

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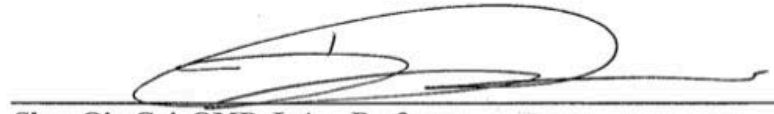

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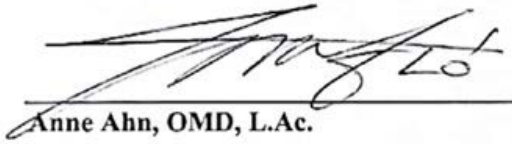

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이런 경험들이 앞으로 저는 어떤 모습의 한의사가 되어야 하는지 그려볼 수 있는 계기가 되었고 더 경험하고 공부하고 싶은 분야들이 생겨서 좀더 즐겁고 재미있는 한의사의 길을 갈수 있을 것 같은 희망과 기대감이 생겼습니다.
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# Objective Diagnosis of Tinnitus through MTM (Modulated Tinnitus Masking) Protocol and Acupuncture Treatment Effect: Case Series

# MTM protocol 을 통한 이명의 객관적인 진단과 그에 대한 침치료의 효과 분석

**Sairomi Choi**

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ABSTRACT

Objective: To obtain an objective diagnosis of tinnitus using the Modulate Tinnitus Making (MTM) protocol and evaluation of acupuncture treatment on improvement of tinnitus after using MTM diagnosis.

Method: The study involves patients who are suffering from tinnitus. The patients were tested using the RCPTA test and later given the THI survey questionnaires at their first visit. RCPTA test was done every other week. After an RCPTA test, and prescribed customized Threshold Sound conditioning therapy with REVE 134, the participants were then given a Visual Analog

Scale test. The participants were given a 4-10 weeks' acupuncture treatment once or twice a week. All needles were used once and properly disposed of in a sharp's container, following the CCAOM CNT 7th edition manual of regulations. Participants also do the Three questionnaires for severity for Tinnitus at their first and last sessions.

Result: One of the cases, 60-year-old man, the left side showed an improvement of about 11.88% of HLI and the right side showed an improvement of 2.09%. A total of 5.88% of HLI change was shown. The VAS ranged from 8 to 5, which indicated an improvement of about 37.5%. Three simple question survey showed a decrease of 15.4% from 13 in the first month to 11 after one month. THI showed a 50% improvement from 68 (grade 4) to 34 (grade 2).

There is a 44-year-old man, his left side showed an improvement of about 23.7% of HLI and the right side showed an improvement of 28.11%. a total of 26.1% of HLI change.

The VAS ranged from 8 to 3, indicating an improvement of about 62.5%. Three simple question survey showed a decrease of 35.7% from 14 in the first month to 9 after treatment. THI showed a 71.8% improvement from 78 (grade 5) to 22 (grade 2).

Conclusion: Acupuncture is effective in reducing the loudness and severity of tinnitus. MTM protocol can be a valuable diagnostic tool since it is objective and can visualize Tinnitus. These two methods are effective in improving the quality of life of patients who suffer from tinnitus.

TABLE OF CONTENTS

LIST OF FIGURES

# I. INTRODUCTION

Tinnitus, the perception of sound in the ears or head without the presence of audible external source, is a symptom, rather than a disease entity, that originates internally without an external auditory input.[1] [2] The noise may be constant or come in bouts and may vary in intensity and character. It may sound like a high-pitched whistle, like bells, like an engine running, rushing water or cicada's crying sound.[3]

It is relatively common in the elderly, but the actual reported prevalence varies according to the surveyed region and definition of tinnitus.[4] About 12 million people in the United States suffer from tinnitus.[5] According to the National Center for Health Statistics of the United States, about 32% of all US adults report having tinnitus at one-time point in their lives and about 6.4% of them characterizes tinnitus as severe.[6] According to the national statistics in Iran, at least 5.2million people in Iran suffer from bothersome tinnitus.[7] Also, British study reported that 10% of adults have prolonged spontaneous tinnitus, 15% experience severe annoyance caused by tinnitus, and 0.5% of adult experience tinnitus that severely reduced their ability to lead a normal life[8] and a large scale Swedish study found that 14% of adults reported experiencing tinnitus "often "or "always". And 2.4% reported that "Tinnitus plagues me all day".[9] Five Italian cities were recently investigated, and 14.5% of the population reported prolonged spontaneous tinnitus.[10]

Tinnitus is often associated with sudden, temporary hearing loss, and it can have a powerful detrimental impact on a patient's quality of life. In some studies, the most common disorders related to tinnitus were sleep disturbance, persistent discomfort, communication and

concentration problems, instability, hopelessness, and drug dependence.[11] Therefore, it is said that tinnitus causes disability in the overall range of daily life, such as leisure use, exercise, social life, family relationships, and the creation of friendships rather than physical discomfort. Severe tinnitus may also lead to serious mental illness and suicidal tendencies[12]

Recently, the number of patients with tinnitus is increasing due to cause such as the aging of the population and the noise by the development of industrial society and stress related to the complex social environment. until now, the causes of tinnitus include sympathetic nervous system dysfunction, autonomic nervous system dysfunction, endocrine dysfunction, bacterial infection, allergy, metabolic disorder, water and salt metabolism disorder, and vitamin deficiency theory, etc. However, the exact cause of tinnitus is not yet known, and it is difficult to objectify the severity of subjective symptoms at present, and a clear diagnosis method has not been presented.[13]

A various of therapies are used to treat tinnitus, including drugs, surgery, cognitive behavioral therapy and acupuncture. However, while these treatments work well for some patients, they may not be good for others. Among these therapies, cognitive behavioral therapy is the most effective treatment for improving the quality of life of tinnitus patients.[14]

Tinnitus can be multifaceted phenomenon that causes physical disability, including personal hearing impairment, as well as impairment in all aspects of daily life such as emotional and life style. As a result, it can be seen that the majority of tinnitus patients are experiencing personal and social discomfort and that the symptoms of tinnitus are affecting their quality of life.[15]

No effective drug therapy is available to reduce or eliminate tinnitus. Although a combination of counseling and behavioral approaches has been recommended, there is little rigorous evidence of

the effectiveness of this combined therapy. Also, several studies have demonstrated the positive effects of acupuncture on tinnitus.[16]

Acupuncture has been used to treat tinnitus for a long time in Far Eastern countries such as Korea and China. Its use is primarily based on anecdotal data. Kiyoshita has developed a hypothetical rationale for the use of acupuncture on the grounds that it may influence the function of the olivocochlear nucleus.[17] Anderson and Lyttkens have reviewed the trial of acupuncture for tinnitus, but their narrative review is open to criticism because the literature was not searched systematically and uncontrolled studies were not excluded. [18]

Although tinnitus has various forms and characteristics, it is not clearly recognized by others, and even an objective diagnostic method for the diagnosis of tinnitus has not been developed. Therefore, it is possible to find out what type of tinnitus the patient complains and what condition it is in by listening to the symptoms that most patients complain of. History is important in all medical domains, but it is particularly meaningful in tinnitus, which is assessed primarily as a subjective symptom. Therefore, all patients with tinnitus require a detailed history and acoustic and scientific evaluation to obtain information on treatment options.

Subjective tinnitus is evaluated using various questionnaires before and after treatment. This is because it is difficult to objectively measure the intensity and frequency of tinnitus. The questionnaires used are largely divided into qualitative questionnaires and quantitative questionnaires. Tinnitus Handicap Inventory (THI) is the most widely used quantitative questionnaire and its reliability and validity have already been verified. THI is useful for grading tinnitus as a quantitative test, clinical treatment, and research, but it has limitations in understanding the characteristics of each patient's tinnitus in detail. Therefore, there is a need for a qualitative approach that can compensate for these shortcomings.[19]

This study aims to making the diagnosis of tinnitus more objective through the MTM protocol, the types of tinnitus were identified, and the evaluating the effect of acupuncture diagnosis and treatment of tinnitus patients. And evaluate the scale of, this treatment how the effect to tinnitus patient's quality of life.

## OBJECTIVES

The purpose of this study is to diagnosis of tinnitus more objective using Modulated Tinnitus Masking(MTM) protocol and evaluate the effect of acupuncture treatment follow by this MTM diagnosis of tinnitus. Also, evaluate the scale of quality of patient's life before and after treatments which use acupuncture and MTM Customized Sound conditioning therapy.

The detailed goals for this study are as follows:

1. To find accurately dB and Hz where tinnitus appears using the MTM test and compare and analyze objective MTM result with acupuncture diagnosis.
2. To evaluate the effect of acupuncture treatment based on the results of the MTM test using Visual Analog Scale (VAS) before and after the treatments.
3. This study will analyze the objective and subjective result of acupuncture treatment for tinnitus using MTM protocol system and Visual Analog Scale.
4. This study will evaluate the subjective improvement of tinnitus patients through THI questionnaires before and after tinnitus treatment.

## LITERATURE REVIEW

Sound waves travel through the ear canal to the middle and inner ear, where hair cell in part of the cochlea help transform sound waves into electrical signals that then travel to the brain's auditory cortex via the auditory nerve. When hair cells are damaged by loud noise or ototoxic drugs, the circuits in the brain do not receive the signals they're expecting. This stimulates abnormal activity in the neurons, which results in the illusion of sound, or tinnitus.[20]

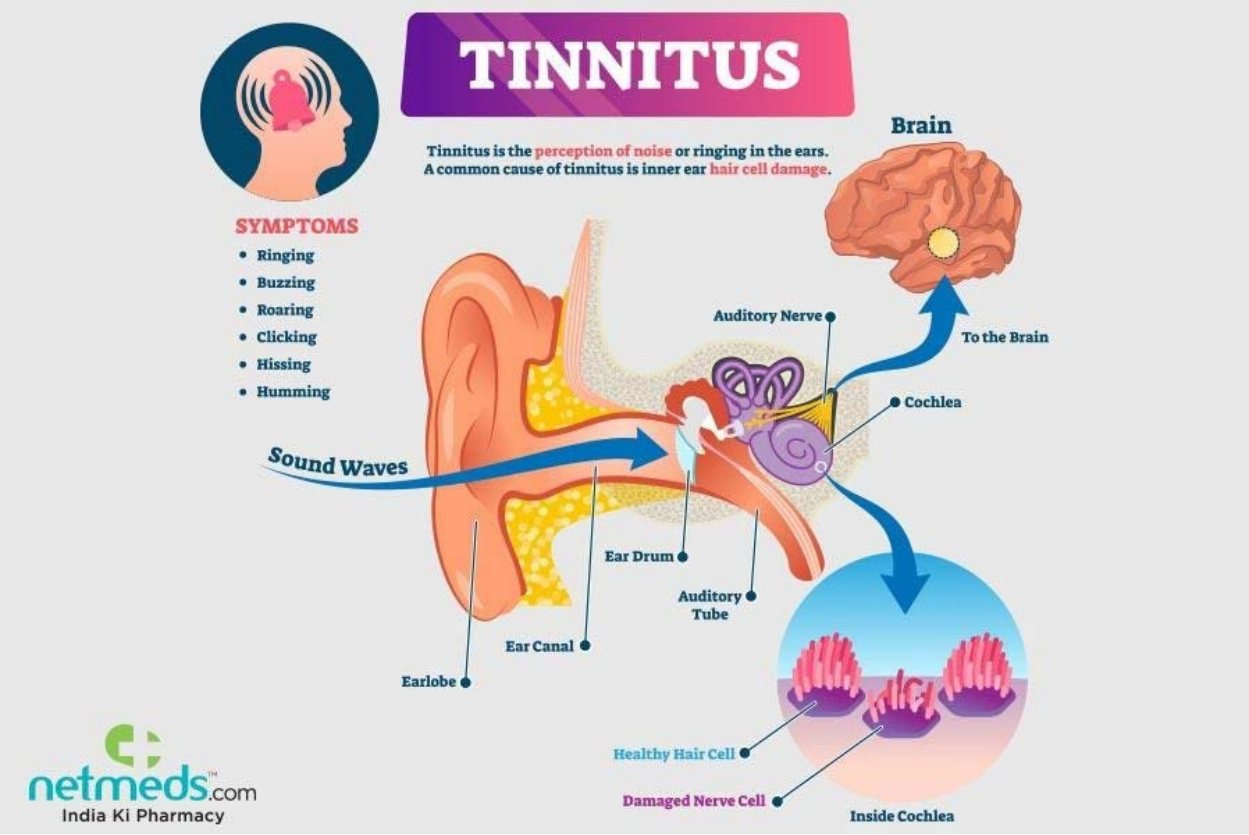



*Figure 1. The pathogenesis of Tinnitus*

Tinnitus can occur anywhere along the auditory pathway from the outer ear through the middle and inner ear to the auditory cortex of the brain. One of the most common causes of tinnitus is hair cell damage in the cochlea.

There are about 15000 auditory cells in the cochlea, and various frequencies ranging from 20-20000Hz are being processed. These cells help convert sound waves into nerve signals. Pulsatile tinnitus is often suggestive of a vascular origin and can be subjective or objective. Non-pulsatile tinnitus is almost always subjective and is the most common form of tinnitus. In most patients, tinnitus is associated with hearing loss, but it can also occur in people with normal haring[21]. Sometimes, there is a structural lesion as like acoustic neuroma or pathological condition such as Meniere's disease and multiple sclerosis as the cause of tinnitus and hearing loss,[22] but often, tinnitus and hearing loss occur together without structural lesions or other conditions.[23] In such cases, the symptoms are attributed to ear damages caused by noise or ototoxic materials or other agents.[24]

Non-pulsatile tinnitus can be differentiated into mild to severe forms. Mild tinnitus is the noise that people hear occasionally or only in quite places, and is not usually annoying however sever tinnitus is extremely annoying and often disturbs the patients' quality of life and sometimes in very severe cases, it can lead to suicide[25]

In acoustics, a branch of physics, the characteristics of sound are largely divided into tone and noise. The tone is further divided into two types: a pure tone with only one frequency component and a complex tone composed of two or more pure tones. Since tinnitus is a sound perceived by the brain, it can be divided into tone tinnitus and noise tinnitus according to the acoustic characteristics of tinnitus. Tone tinnitus is further divided into pure tone tinnitus and complex tone tinnitus.[26]

Tinnitus can also be classified according to the number of frequency components. Tinnitus consisting of only one frequency component is called simple tinnitus. When two or more simple tinnitus occurs at the same time, it is called complex tinnitus. There may be tinnitus simple or

complex tinnitus that occurs only in one ear, and tinnitus simple or complex tinnitus that occurs in both ears at the same time. So, tinnitus is divided into pure tone tinnitus, complex tone tinnitus, and noise tone tinnitus according to whether the component frequency characteristic is tone or noise, and is divided into simple tinnitus and complex tinnitus according to the number of component frequencies.

MTM is a treatment protocol for diagnosing and treating tinnitus by inducing fundamental hearing changes in tinnitus patients with TSC (Threshold Sound Conditioning) and quantitatively observing and analyzing the changes using the 67band-based RCPTA algorithm.

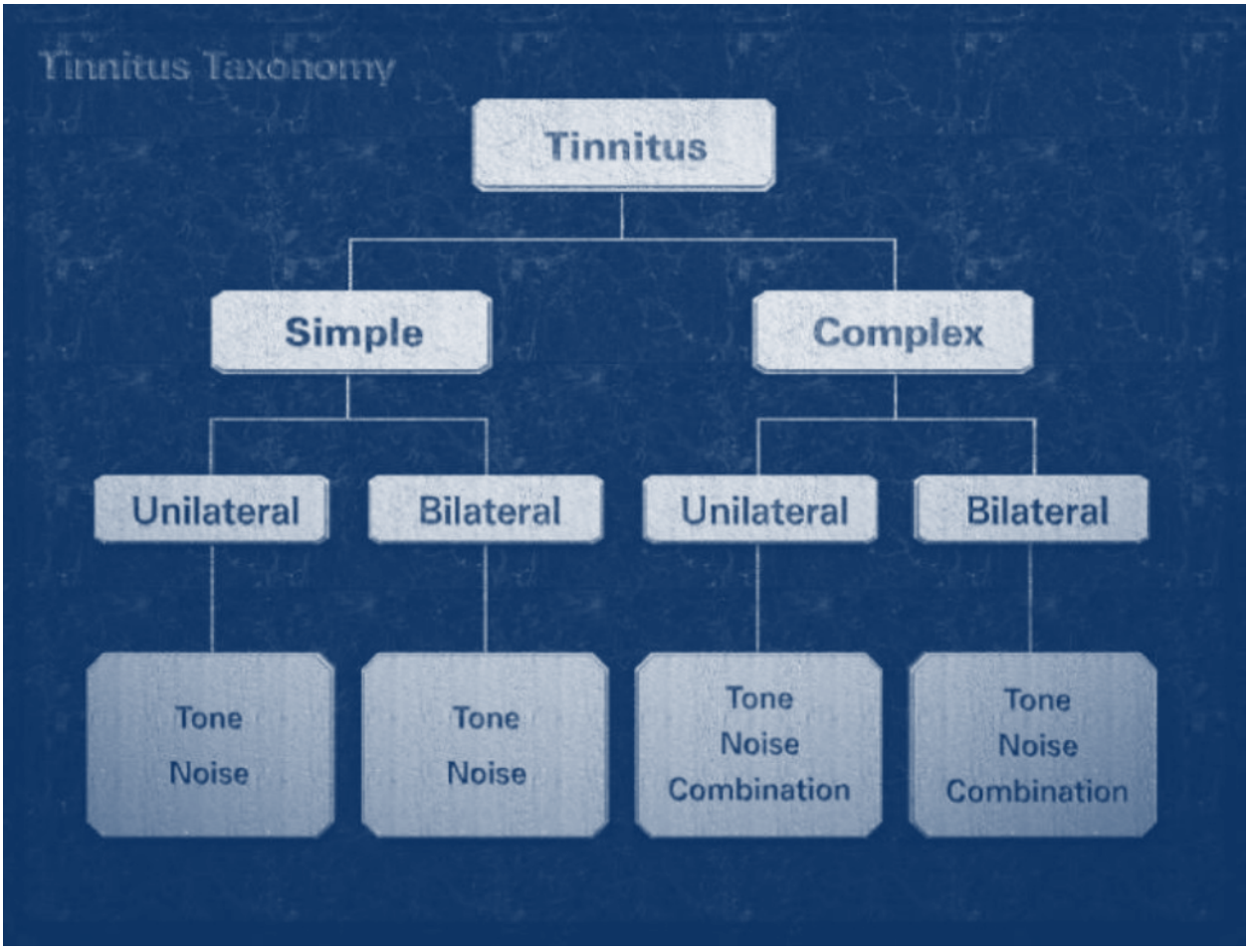



*Figure 2 Tinnitus Taxonomy*

MTM has two meanings that Modulated Tinnitus Masking and Masked Threshold Management. Modulated Tinnitus Masking is literally a modulated tinnitus masking technique. The general unmodulated masking technique refers to the existing traditional tinnitus masking treatment.[27] Masking is a basic treatment method for tinnitus, and it is a method to reduce tinnitus by giving sound from the outside. Patients feel symptom relief because masking sounds are easier to hear than tinnitus sounds. Determining the masking sound is not easy because the masking sound must be louder to mask the tinnitus, but also not to be noisy to the patient. 90% of patients who visit the tinnitus clinic usually have hearing impairment at the same pitch as the tinnitus.[28] Modulated Tinnitus Masking: MTM, is the addition of a modulated method to this traditional tinnitus masking method. In MTM, modulation is divided into frequency modulation and amplitude modulation. Modulated signal designed to adequately mask tinnitus symptoms occurring within the audible frequency band must be an acoustic signal within the audible frequency band. A frequency modulated signal pithing an audible frequency band induces an effective biological response when combined with an amplitude modulation method. This is because three-dimensional auditory information combining not only the frequency information of the acoustic signal but also the intensity information can be simultaneously transmitted to the auditory center.

When masking tinnitus symptoms within the audible frequency band, the masking strength must be the descending threshold. The descending threshold is when the volume of the modulated sound signal is gradually reduced from the point where it is heard to the point where it is not heard. This is the point at which the signal becomes inaudible for the first time.

If there is a difference between traditional tinnitus masking and MTM, there is also a difference in the auditory characteristics of the masking signal, but the intensity point itself at which the

masking is made is different. In the case of traditional tinnitus masking, the volume of the masking stimulus is set to sufficiently mask the tinnitus or to an intensity equivalent to the tinnitus. Existing traditional tinnitus therapy using white noise is mostly based on tinnitus masking, and the intensity of the masking stimulus is higher or equal than to the tinnitus volume. On the other hand, in MTM, the intensity of the modulated sound signal is adjusted not to the point where the tinnitus is shielded, but to the downward threshold point where the modulated sound signal itself is completely blocked by the tinnitus. The reason for masking the modulated sound signal located at the lower threshold with tinnitus is to prevent additional hearing loss while attempting to alleviate or eliminate the symptoms of tinnitus. Through this MTM system, subjective tinnitus can be diagnosed more objectively.

In Acupuncture, it is believed that the ear has the closest relationship with the kidney. Although the kidneys are open to the ears, many other organs influence the ears and may be involved in causing tinnitus. Apart from the internal organs, many channels influence the ears: Gall bladder, Triple burner, small intestine, bladder, stomach and large intestine connecting channel.[29]

The ears are also influenced by the heart, as it is one of the functions of the mind to control the sense orifices and senses, and by the lungs, as they house the corporeal soul, which influences all senses.[30] The lungs also influence the ears because they house the Corporeal Soul, which is a physical soul that activates all senses and sense orifices. Phlegm is the main pathogenic factor that affect the ears, because this pathogenic factor is particularly “obstructive” and,[31] when in the head, it obstructs the sense orifices. In the ears, it may cause tinnitus or deafness. Some types of

tinnitus are due to the failure of the clear yang to rise to the head, others to the failure of turbid yin to descend.[32]

Acupuncture is a traditional Chinese medical treatment which has been used for thousands of years to treat a variety of diseases as well as to relive pain [33]

In 1979, the World Health Organization (WHO)approved the use of acupuncture for the treatment 41diseases including ear,[34] nose and throat and various type of pain.[35]

The pathophysiology of tinnitus is unclear. Its treatment is poorly effective and remains a challenge[36]. For most patients, tinnitus is a chronic disease, and its treatment aims to improve its associated symptoms and relieve its effects on the quality of life, rather than achieve an absolute cure. [37]

Various therapies are recognized to treat tinnitus, including drugs, surgery, cognitive behavioral therapy, and acupuncture. However, these therapies may have a good effect on some patients but poor on others. Most patients with tinnitus accept simple therapies, such as taking medicine or wearing hearing aids.[38] Some researchers have pointed out that tinnitus, similar to pain, is generally a symptom for many diseases. Different tinnitus may be related to various conditions and therefore required different treatment schemes. [39]

In East Asian countries, acupuncture is a usual and convenient treatment. It has been used to treat numerous disease and symptoms, including various physiological and psychological discomforts and pain. Acupuncture therapy for tinnitus has been used for centuries, and the effect has been recommended in Chinese medical science. Acupuncture provided by well-trained physicians is relatively safe and has few side effects. Most adverse events are minor, such as bleeding, local hematoma, pain, or vegetative symptoms [40]

Several studies have demonstrated some of the positive effects of acupuncture on tinnitus. Tinnitus may be functional disorder related to the complex network of the body involving the central auditory and non-auditory systems [41]

It may be caused by many systemic disorders, such as autonomic nervous system disorder or endocrine disorders.[42] [43] Several studies show that acupuncture can regulate the autonomic nervous system [44] relieve the pain and regulate the endocrine system.[45]

Acupuncture regulates neurochemicals and promotes neurogenesis and cell proliferation in the central nervous system.[46]

Many patients with tinnitus suffer from a sleep disorder, and acupuncture treatment is effective in increasing the sleep quality of patients with insomnia and in improving their psychological health. Therefore, the use of acupuncture therapy to treat patients with tinnitus could be promising.[47]

## II. MATERIALS AND METHODS

2.1Materials

2.1.1 Acupuncture needle

They will get 6-10weeks acupuncture treatment once or twice a week. Acupuncture treatment lasts 6 to 10 weeks, and treatment is performed once or twice a week. The needle will use in this study that manufactured by Haeng Lim Seo Won Medical Co. and all needles were sterilized, and stainless steel. All needles are disposable and used once. Every needle after treatment to the biohazard sharp container immediately followed by recommended and regulated by CCAOM CNT 7$^{TH}$ manual.

**Model** YS-001

**Name** Hand Needles

**Thickness** 0.16mm

**Length** 7~8mm

**Package** 50pcs/Package

**Etc.** Disposable Needles

*Figure 3. Characteristics of Needle used in study*

2.1.2 RCPTA Test[48]

RCPTA is meaning for Random Controlled Pure Tone Audiometry hearing test to measure pure tone hearing. The MTM protocol uses the RCPTA algorithm to find the tinnitus frequency of a tinnitus patient. Since the frequency and intensity of tinnitus and the tone of the tinnitus are very diverse, it is the core of MTM tinnitus treatment to derive the most objective result through an

automated algorithm test. RCPTA stands for Randomized Controlled Pure Tone Audiometry. RCPTA is a fine audiometry algorithm based on random presentation of 67 frequency test sounds, and is and optimized version of AMA-PTA for tinnitus diagnosis.

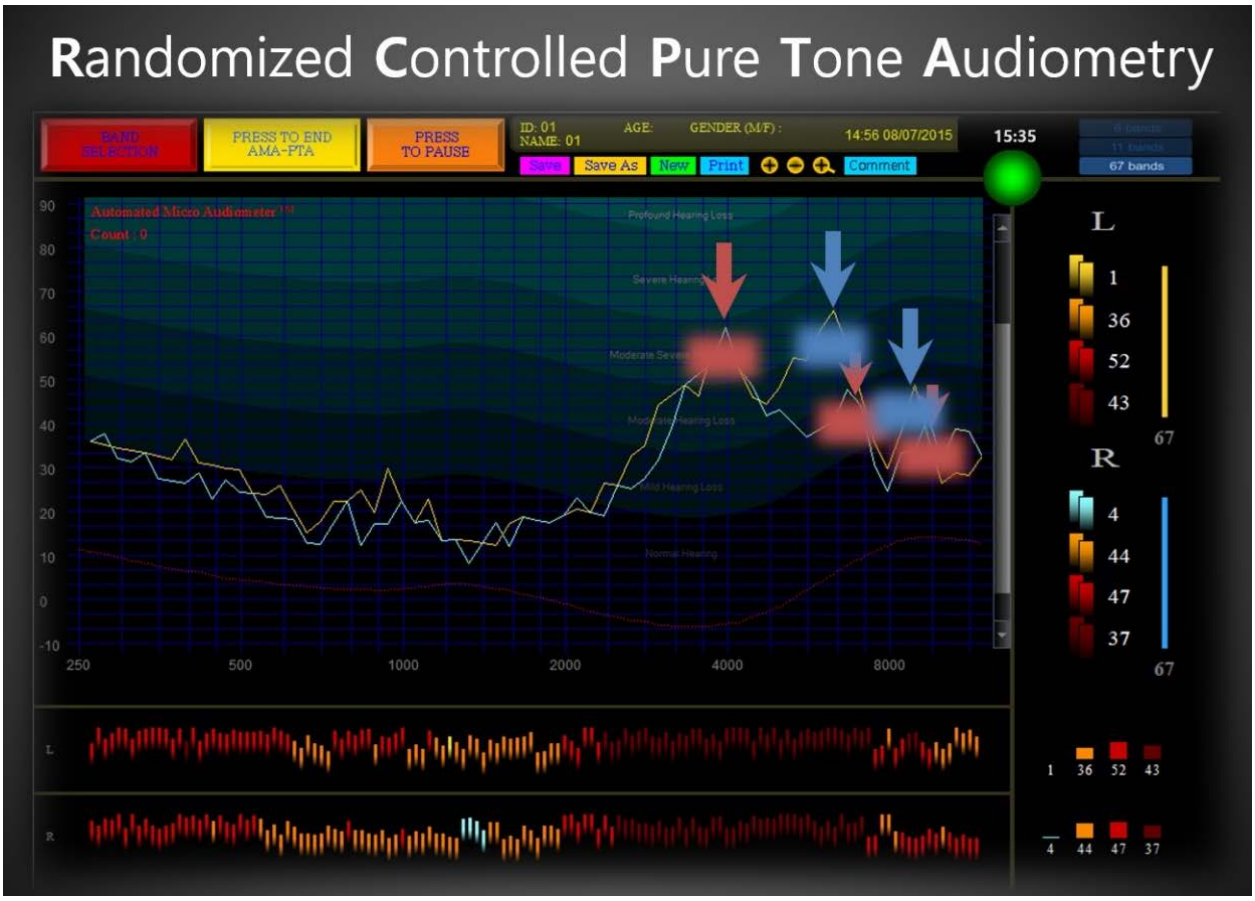



*Figure 4. RCPTA test*

The RCPTA algorithm tracks the approximate primary thresholds for representative frequencies of about 17 critical bands in the main audible frequency band, 250-12000Hz, and based on the primary hearing threshold values determined by tracking, total 67 frequency bands it consists of

the step of determining the final threshold by tracing the secondary hearing threshold again. 67 frequency test tones are randomly presented to both ears according to the RCPTA algorithm.

During the RCPTA hearing test, the examinee presses the response button at every moment when the auditory sense of the black false sound randomly presented by the algorithm presents the next test sound by recognizing the moment when the subject's finger is removed from the response button. The algorithm is designed to unconditionally present the next test sound if the subject does not press the response button within 2.5 seconds from the time of presentation of the test sound.  2.5 seconds is enough time for human hearing to determine whether a sound is present or not. If you fail to press the answer button because you cannot make a decision about whether or not for 2.5 seconds, it is the same as not recognize the sound. The reason for presenting test sounds in random order is to control auditory cues that can unnecessarily manipulate the auditory nervous system of the examiner. Control of cues is very important in behavioral response tests.

### 2.1.3 Visual Analog Scale (VAS)

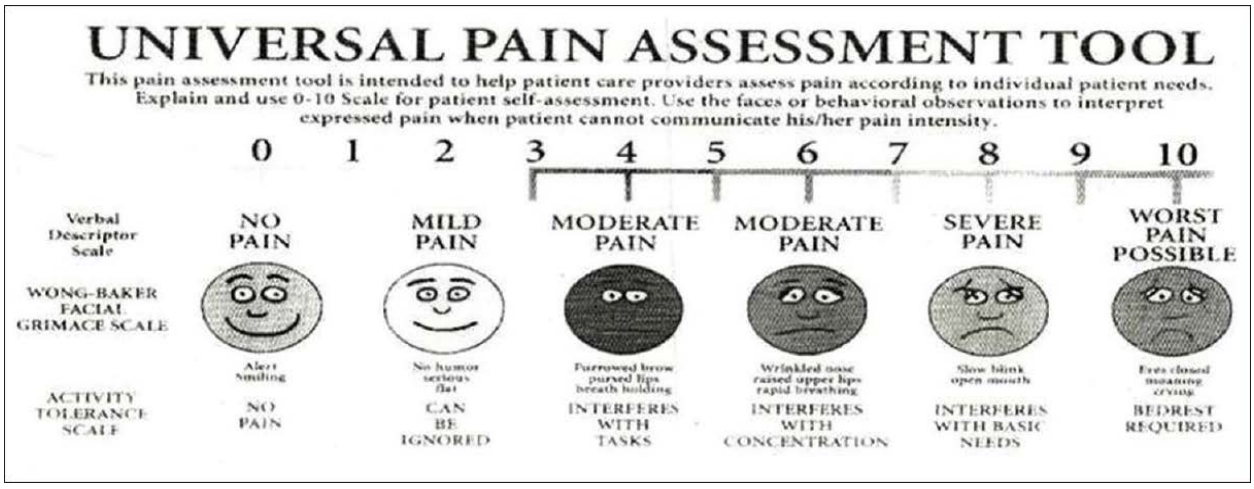



*Figure 5. Visual Analog Scale by Annals of Maxillofacial Surgery*

A tool used to help a person rate the intensity of certain sensations and feelings, such as pain. The visual analog scale for pain is a straight line with left end (0) meaning no pain and the other right end (10) meaning the worst pain imaginable. A patient marks a point on the line that matches the amount of pain patient feels. Although this method cannot compare one patient to another, it can give fairly accurate judgements about how pain changes in the same patient.

### 2.1.4. Tinnitus Handicap Inventory Questionnaires

The Tinnitus Handicap Inventory is a self-administered test that ear, nose and Throat physicians(otolaryngologists), audiologists and other clinicians use to help determine the degree of distress suffered by the tinnitus patient. It is widely used in medical offices and in clinical trials to determine the effectiveness of a given therapy. The Tinnitus Handicap Inventory is the most recent, most reliable, and most widely used of several questionnaires developed over the last 20years. Craig W. Newman, PhD, with two other researchers developed the Tinnitus Handicap Inventory in 1996 and it is the default questionnaire used to this day.[49] It consists of 25 questions divided into 3groups in functional, emotional, and catastrophic.[50] Eleven items are included in the functional scale, 0 in the emotional scale and 5 in the catastrophic scale. Prefixes in the numbered questions are used to indicate to which subgroup the question belongs.[51]

It is important to note that question 24, relating to the effect for stress on tinnitus, has the highest correlation to the total score. Stress is a fundamental element in determining the degree of distress.[52]

## Tinnitus Handicap Inventory (THI)

*This form is for informational purposes only and should not take the place of consultation and evaluation by a healthcare professional.*

Your Name: _____ Date: _____

**Instructions:** The purpose of this questionnaire is to identify, quantify, and evaluate the difficulties that you may be experiencing because of tinnitus. Please do not skip any questions. When you have answer all the questions, add up your total score, based on the values for each response.

| | | | | |
|---|---|---|---|---|
| 1. | Because of your tinnitus, is it difficult for you to concentrate? | Yes (4) | Sometimes (2) | No (0) |
| 2. | Does the loudness of your tinnitus make it difficult for you to hear people? | Yes (4) | Sometimes (2) | No (0) |
| 3. | Does your tinnitus make you angry? | Yes (4) | Sometimes (2) | No (0) |
| 4. | Does your tinnitus make you feel confused? | Yes (4) | Sometimes (2) | No (0) |
| 5. | Because of your tinnitus, do you feel desperate? | Yes (4) | Sometimes (2) | No (0) |
| 6. | Do you complain a great deal about your tinnitus? | Yes (4) | Sometimes (2) | No (0) |
| 7. | Because of your tinnitus, do you have trouble falling to sleep at night? | Yes (4) | Sometimes (2) | No (0) |
| 8. | Do you feel as though you cannot escape your tinnitus? | Yes (4) | Sometimes (2) | No (0) |
| 9. | Does your tinnitus interfere with your ability to enjoy your social activities (such as going out to dinner, to the movies)? | Yes (4) | Sometimes (2) | No (0) |
| 10. | Because of your tinnitus, do you feel frustrated? | Yes (4) | Sometimes (2) | No (0) |
| 11. | Because of your tinnitus, do you feel that you have a terrible disease? | Yes (4) | Sometimes (2) | No (0) |
| 12. | Does your tinnitus make it difficult for you to enjoy life? | Yes (4) | Sometimes (2) | No (0) |
| 13. | Does your tinnitus interfere with your job or household responsibilities? | Yes (4) | Sometimes (2) | No (0) |
| 14. | Because of your tinnitus, do you find that you are often irritable? | Yes (4) | Sometimes (2) | No (0) |
| 15. | Because of your tinnitus, is it difficult for you to read? | Yes (4) | Sometimes (2) | No (0) |
| 16. | Does your tinnitus make you upset? | Yes (4) | Sometimes (2) | No (0) |
| 17. | Do you feel that your tinnitus problem has placed stress on your relationships with members of your family and friends? | Yes (4) | Sometimes (2) | No (0) |
| 18. | Do you find it difficult to focus your attention away from your tinnitus and on other things? | Yes (4) | Sometimes (2) | No (0) |
| 19. | Do you feel that you have no control over your tinnitus? | Yes (4) | Sometimes (2) | No (0) |
| 20. | Because of your tinnitus, do you often feel tired? | Yes (4) | Sometimes (2) | No (0) |
| 21. | Because of your tinnitus, do you feel depressed? | Yes (4) | Sometimes (2) | No (0) |
| 22. | Does your tinnitus make you feel anxious? | Yes (4) | Sometimes (2) | No (0) |
| 23. | Do you feel that you can no longer cope with your tinnitus? | Yes (4) | Sometimes (2) | No (0) |
| 24. | Does your tinnitus get worse when you are under stress? | Yes (4) | Sometimes (2) | No (0) |
| 25. | Does your tinnitus make you feel insecure? | Yes (4) | Sometimes (2) | No (0) |

**The sum of all responses is your THI Score >>>**

*Figure 6. Tinnitus Handicap Inventory questionnaires*

### 2.1.5. Three Question Survey

A three-item tinnitus questionnaire was used to diagnosis the current status of tinnitus and to analyze the results of tinnitus treatment. All three questions were about the intensity of tinnitus and the frequency of tinnitus. The questionnaire was completed on the first and last day of the clinical trial. The questionnaire can be scored from 3 to 15points, with 3 indicating the minimum tinnitus status and 15 indicating the highest tinnitus status.

### 2.1.6. Threshold sound conditioning therapy (TSC therapy)

Sound Conditioning technique is a non-invasive and non-drug treatment that uses a specified sound that has a very small volume and therefore is very safe. The technique and effectiveness has also been verified through scientific and systematical clinical trial of the internationally recognized clinical authority. In this study, after the hearing test, TSC acoustic signals to stimulate single or multiple tinnitus frequency bands are prescribed to the patient. For this purpose, a sound signal is produced using REVE 134

REVE 134 is an abbreviation for Restoration and Elevation of Viscoelasticity and Electro motility. It is a new technology to improve hearing ability through the restoration of visco-elasticity, electro motility and neuroplasticity of auditory system. 134 means it separates and analyses the cochlea's 12000 auditory cell into 134 groups. REVE 134 is an auditory stimulation where the treatment stimulation is in between the range 250-12000Hz. The REVE134 stimulation rehabilitating treatment proceeds by making the patient listen to the mid-frequency stimulation that can stimulate a particular auditory cell that has been chosen for a period of time. The restoration efficiency can vary according to the seriousness of the illness and the type of hearing loss but the hearing restoration effect reaches to about 10-50dB.


*Figure 7. REVE 134*

## 2.2 Methods

### 2.2.1 Participants

The participants who visited South Baylo University, Specialty and Research Clinic at Los Angeles campus, from July 2022 to December 2022. The patients who is suffered from the sensorineural tinnitus or diagnosis of subjective tinnitus. Also, selected patients who was not to receive another treatment during the clinical trial period. The patients informed about the

purpose of the study, and also only patient who is voluntary selected. All age, race, ethnic, gender was not affecting the selecting the participation.

### 2.2.2 Excluded participants.

Patients excluded who has objective tinnitus. Objective Tinnitus is audible to the examining/auscultating physician, whereas subjective tinnitus can only be perceived by the patient.

Also, patients who underlying disease or history of cochlea implant, ear drum transplant surgery, cerebral vascular events, neurodegenerative disorder, Otitis media, Acoustic tumor, prior brain surgery, inner ear malformation, head trauma, Ototoxic drug medication, Women in pregnancy and lactation or without contraception and who are currently using hearing aids.

### 2.2.3 Study Design

This study designed to evaluate the effect of acupuncture treatment with using MTM protocol of tinnitus patient. Participant fill out the THI, VAS, and Three simple questionnaire at the first visit and conduct the MTM test. First acupuncture treatment performed follow the MTM test. Acupuncture treatment performed once or twice a week on defends the patient's condition and circumstances. Two weeks later from the first visit, MTM test repeated again. MTM tests are performed once every other week from the first visited. When patients in this study, the patients undergo at least 4 acupuncture treatment, and 3 MTM test. The VAS and Three simple questionnaire must be completed by the patient at the beginning and end of treatment session. maximum of 10 acupuncture treatment and 6 MTM tests performed. When all treatment is finished, the patients took the last MTM test, VAS, Three Simple Questionnaire and THI

questionnaires. Based on this, analyze both the subjective part and the objective part of how much improvement shown in tinnitus during the total treatment period.

### 2.2.4 Acupuncture protocol

Tinnitus may also be caused by anatomic abnormalities, but sometimes no etiological structural defect can be found.[53] The prevalence of tinnitus in people with normal hearing is 26.6%, which increases to 35.1% in people with hearing impairment.[54] Its incidence is not related to age or gender.[55] Tinnitus may be classified in: para-auditory(perceptible) with vascular or muscular origin, and subjective tinnitus of neurosensory origin.[56] Its treatment is a major challenge and there are several therapeutic modalities to eliminate or, ,in most cases, attenuate tinnitus, such as Tinnitus Retraining Therapy, auditory prostheses, electrical stimulation with cochlear implants, biofeedback  and psychotherapy.[57] Acupuncture is one of the pillars of the Traditional Chinese Medicine(TCM), developed as form the observation of nature phenomena, a system presenting human body as a whole and s part of nature, based on the stimulation with needles of specific points defined in the human anatomy.[58] Acupuncture for treatment of tinnitus is similar to its use to relieve pain, because both conditions produce unpleasant emotional and sensory experiences.[59]

Pathology of the extra meridian often shows in the orifices, among which the mind(神), the orifice of the Heart, is included. The Yin Link Vessel nourishes Blood and the Heart thus has a strong influence on the Mind. The Governor Vessel stems from the Kidneys, flows through the Heart and enters the brain, so it also strongly influences the Mind.[60] The Yang Link Vessel influences the ears which connected to Lesser Yang: San Jiao and Gall Bladder meridians.[61] San Jiao(SJ) meridian points, one considers its external and inter pathway, traveling through the auricular region of the inner and outer ear, and joining through its internal pathway the

circulation pericardial meridian(PC), with the stomach meridian(ST) and the gall bladder meridian(GB). The stomach meridian crosses the face in its internal pathway and the GB meridian in its external pathway crosses the region of the ear and face.[62] It is also considered that the external SJ median pathway, when climbing through the posterior shoulder, crosses points of the small intestine meridian (SI). In case of the auditory system, it is located in the petrous portion of the temporal bone (crossed by GB meridian), which is related to the tensor and elevator muscle of velum and of the auditory tube which is related to SI and SJ meridian. When these structures are in permanent contraction due to emotional stress, they induce constant vasoconstriction of such muscles, interfering with the entrance of air, thus unbalancing internal atmospheric pressure, which would cause tinnitus. Emotionally, the indication of the presence of the emotional factor may be observed by the intense red color of the tip of the tongue, area corresponding to the heart meridian according to the tongue microsystem.[63]

Therefore, in this study, the five acupuncture points of Gall Bladder meridian and San Jiao meridian which passing through the ear were set as basic acupuncture points for the treatment of tinnitus. When locating the five finger points, use the hand opposite the patient's problem ear. That is, when threating the patient's left ear, the operator's right hand is used to find the acupuncture point, and when treating the patient's right ear, the operator's left hand is used to find the acupuncture point. Place the operator's thumb on the SI19 Tinggong (청궁) , and place the index finger on the conspicuous point of the GB8 Shuaigu (솔곡), or GB9 Tianchog (천충)site. And when baby finger is located in GB12 Wangu (완골), there is a place where the middle and ring fingers are naturally found that SJ19Luxi(노식) and SJ18 Qimai(계맥) In this

way, acupuncture needles in the 5 areas where the fingertips touches. Tinnitus can be divided into several meridian problems, but it can be applied by divided the meridians that pass in front of the tragus of ear, which are Hand Shao Yang San Jiao, Hand Tai Yang Small Intestine, and Foot Shao yang Gall Bladder.[64]

As a result of the MTM test, if tinnitus appears mainly appears in a place higher than 6000Hz, it can be considered as a problem on Hand Shao Yang San Jiao meridian. The bias of cold energy occurs due to the bias of Sanghwa. Also, neurological disease may appear along with the body fluid. If it is suspected that it is a lesion of the San Jiao meridian, it can be confirmed that there is tenderness in the Ren5 Shimen(석문), Ren17 Tanzhong(전중) at the same time. With this case, acupuncture in order to JS8 Sanynaglou(삼양락), GB8 Shuaigu (솔곡), GB12 Wangu (완골) that SJ19Luxi(노식), SJ18 Qimai(계맥) and SJ21Ermen(이문).

Hand Tai Yang Small intestine meridian always has symptoms of flaring up of the deficient fire due to the lack of the taiyang cold(태양한수). Because it is Yang Meridian, there is not enough energy to descend with Yang, and patient can always complain of a cold symptom. Therefore, if the patient has symptoms of cold stomach and up flaring of the asthenic toward to face, it should consider a lesion of the Small Intestine Meridian. If it is considered that can be confirmed as a tender point of the 천종(SI11, Tianzong). Acupuncture in order on SI3 Houxi (후계), LI11 Quchi9(곡지), GB8 Shuaigu (솔곡), GB12 Wangu (완골) that SJ19Luxi(노식), SJ18

Qimai(계맥) and SI19 Tinggong(청궁). In this case, the MTM test shows tinnitus between 300Hzand 6000-7000Hz.

Due to the lack of calming power, a feeling of shaking of the branches of a tree appears, resulting in stiffness of muscles and a state of mental excitement. If it is considered that it is a gallbladder disease, it can be confirmed by tenderness in the GB21 Jianling (견정). MTM test shows this type of tinnitus in ranges of under the 3000Hz. Acupuncture in the order of ST36 Zusanli (족삼리), GB41 Zulinqi(족임읍), KD2 Rangu (연곡), GB8 Shuaigu (솔곡), GB12 Wangu (완골) that SJ19Luxi(노식), SJ18 Qimai(계맥) – GB2Tinghui (청회)

The patients will get the acupuncture treatment with the face down position if they have point on back side and will get the face up posture after finish the back side treatment. Back side acupuncture treatment doing 10minutes and front side which has face up position going 15 minutes acupuncture treatments.

### 2.4.5 Threshold Sound Conditioning (TSC)

The MTM protocol uses the 67 band RCPTA algorithm to find the tinnitus frequency of a tinnitus patient. Since the frequency and intensity of tinnitus and the tone of tinnitus are as diverse as much as of tinnitus patients, it is the core of MTM tinnitus treatment to derive the most objective result through an automated algorithm test. When the tinnitus frequency at the relevant point is identified through at least two tests every two weeks, a TSC sound signal to stimulate the auditory cells at the corresponding location is produced.

Tinnitus patient who has been prescribe TSC listen to the conditioning sound for 30 minutes each morning and afternoon every day, but depending on the situation, it may be divided into 4sessions of 15 minutes each.

The patient should adjust the volume of the TSC before starting each listening session. The volume should be adjusted to the downward threshold, which is the point at which the treatment sound begins to become inaudible. Do not change the volume in the middle of listening. It is recommended to listen to the conditioning sound in a quiet room as much as possible.

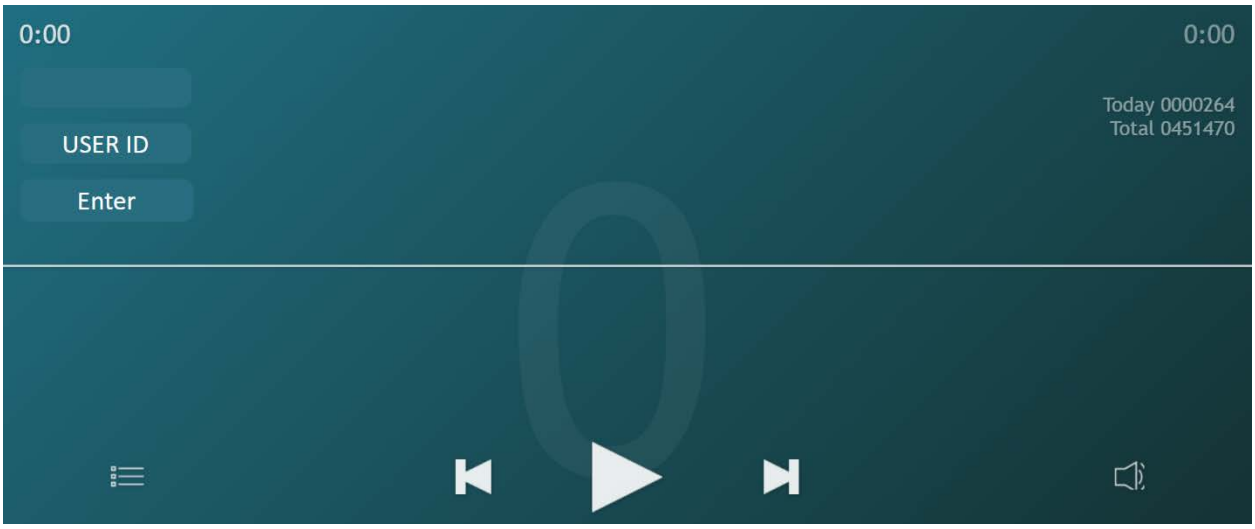



*Figure 8 Threshold Sound conditioning Therapy*

## III. RESULT

Case 1.

1. Male (60)
2. Treatment period
    a. 11/01/ 2021 – 12/01/2021
3. chief complaint
    a. – Tinnitus
        i. Wing –wing sound, constantly hearing the sound, happen in right side of ear.
        ii. Onset over 1year. Hearing loss happen too.
        iii. It getting worst when he smoking and drinking.
        iv. Hearing sound louder when covered hand on ear.
        v. No pain. But hearing got worst
        vi. Severity 8/10
4. Present Illness
    a. High Blood Pressure
    b. Chronic Rhinitis from 30s, - stuffy nose
    c. Migraine – feeling of heaviness
    d. Often sweating at night, feels hot on head area several times.
    e. Insomnia – waking up 3-5 times during night time sleep.
    f. Alcohol intake almost of everyday, smoking

5. Past Medical history: Unremarkable
6. Family Hx : Unremarkable
7. Tongue: little white coat, wet body, wide, tooth marks on the side.
8. Pulse: excess, wiry

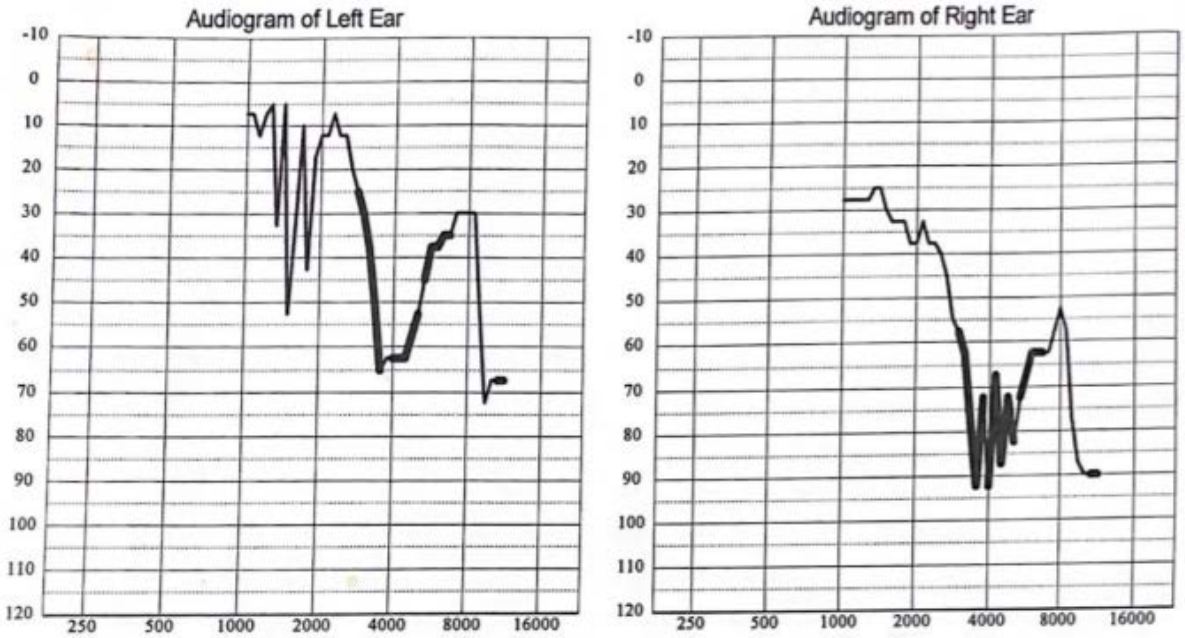
The patient was seen for the first time November, 1st, 2021 and complained of tinnitus. His first episode of tinnitus was a year ago, but he complained that it had gotten worst in the last few months. The patient also reported hearing loss along with tinnitus. He said that if he covers his ears with hands, the tinnitus become a little less, and on days when he smokes or drink, tinnitus gets louder. He said he drinks a little bit of alcohol almost every night due to help with his insomnia. He was not sure what causes his tinnitus. He complained that he wakes up 3-5times during the night and difficulty getting a good night's sleep. He said that he often sweats while sleeping and often feels heat on his face. He currently works as an Uber driver and a YouTuber.

On the first visit, VAS and THI questions were asked, and a questionnaire about the status of tinnitus was completed. Initially, the VAS measured was at 8. THI was 68 and the result was Grade 4, as severe handicap. 13 points were obtained on the tinnitus status questionnaire. This patient visited the clinic once a week, and a total of 4 MTM tests were performed on November, 1st. November 15th, November 29th, and December 1st.

Test results showed that tinnitus appeared between 3000Hz and 8000Hz. There was a slight difference between right and left hearing. This is result showed a correlation with the patient complaining of tinnitus and hearing loss on right side. His TSA result, showed that his tinnitus was related to the Heart

# TSA RESULT SHEET

| ID | Name | Sex | Age | Time / DD / MM / Year | Reliabilty |
|---|---|---|---|---|---|
| X95897 | | M | 60 | 10:37 01/11/2021 | Fair/Unfair |




HLI: 3910.0

Gross Hearing in L 43 Bands: 1515.0

Targeted Frequency (Hz)

GroupA3@L: T1 = 11840 / T1-1 = 5920 / T2 = 4435 / T3 = 3136

Targeted Threshold (dBzHL)

GroupA3@L: T1 = 82.5 / T1-1 = 41.5 / T2 = 67.5 / T3 = 30.5

Gross Hearing in R 43 Bands: 2395.0

Targeted Frequency (Hz)

GroupA3@R: T1 = 11840 / T1-1 = 5920 / T2 = 4435 / T3 = 3322

Targeted Threshold (dBzHL)

GroupA3@R: T1 = 89.2 / T1-1 = 69.5 / T2 = 84.5 / T3 = 68.0

*Figure 9. 1st MTM test result for Case 1*

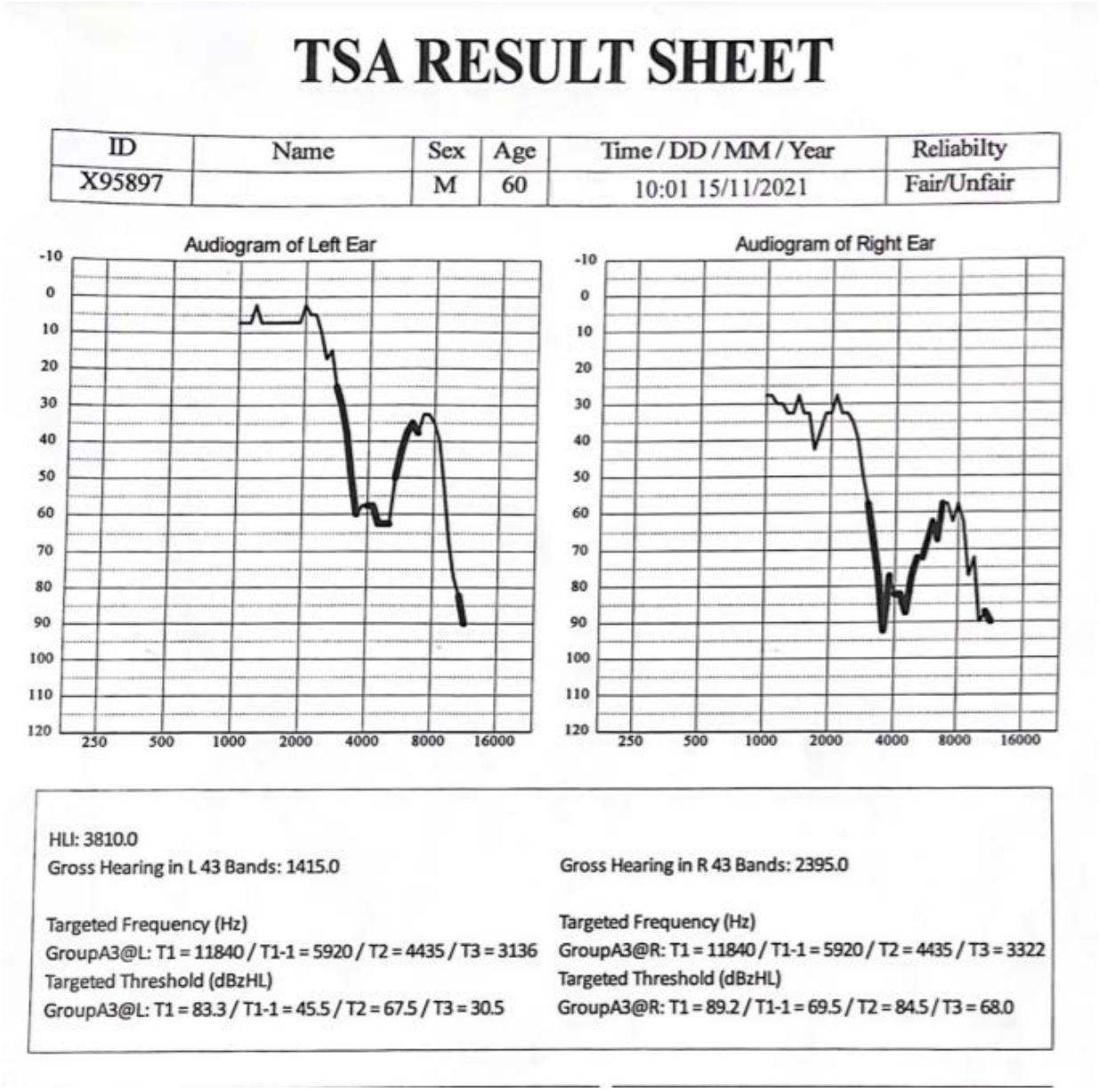



*Figure 10. 2nd MTM test result for Case 1*

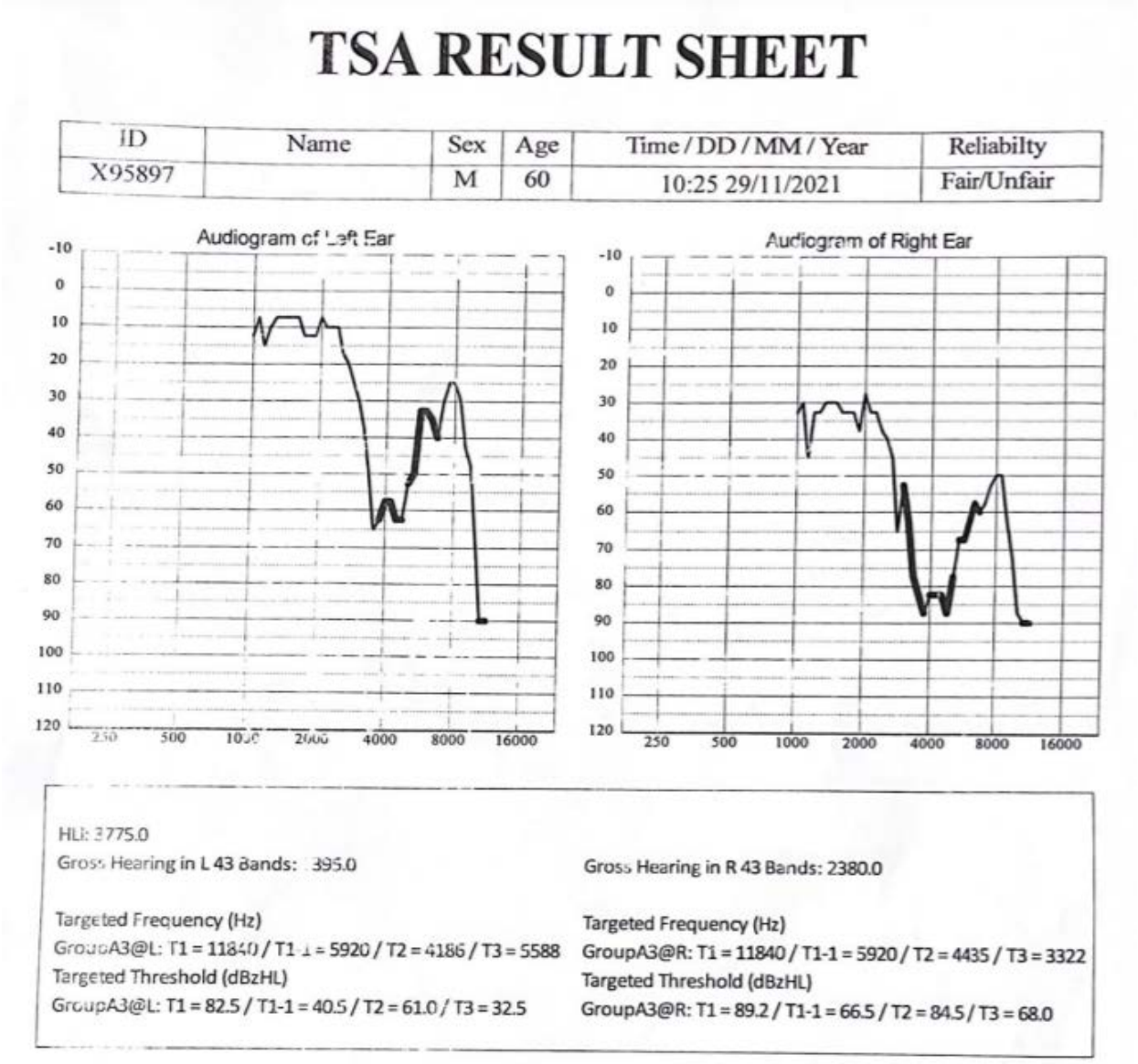



*Figure 11. 3rd MTM test result for Case 1*

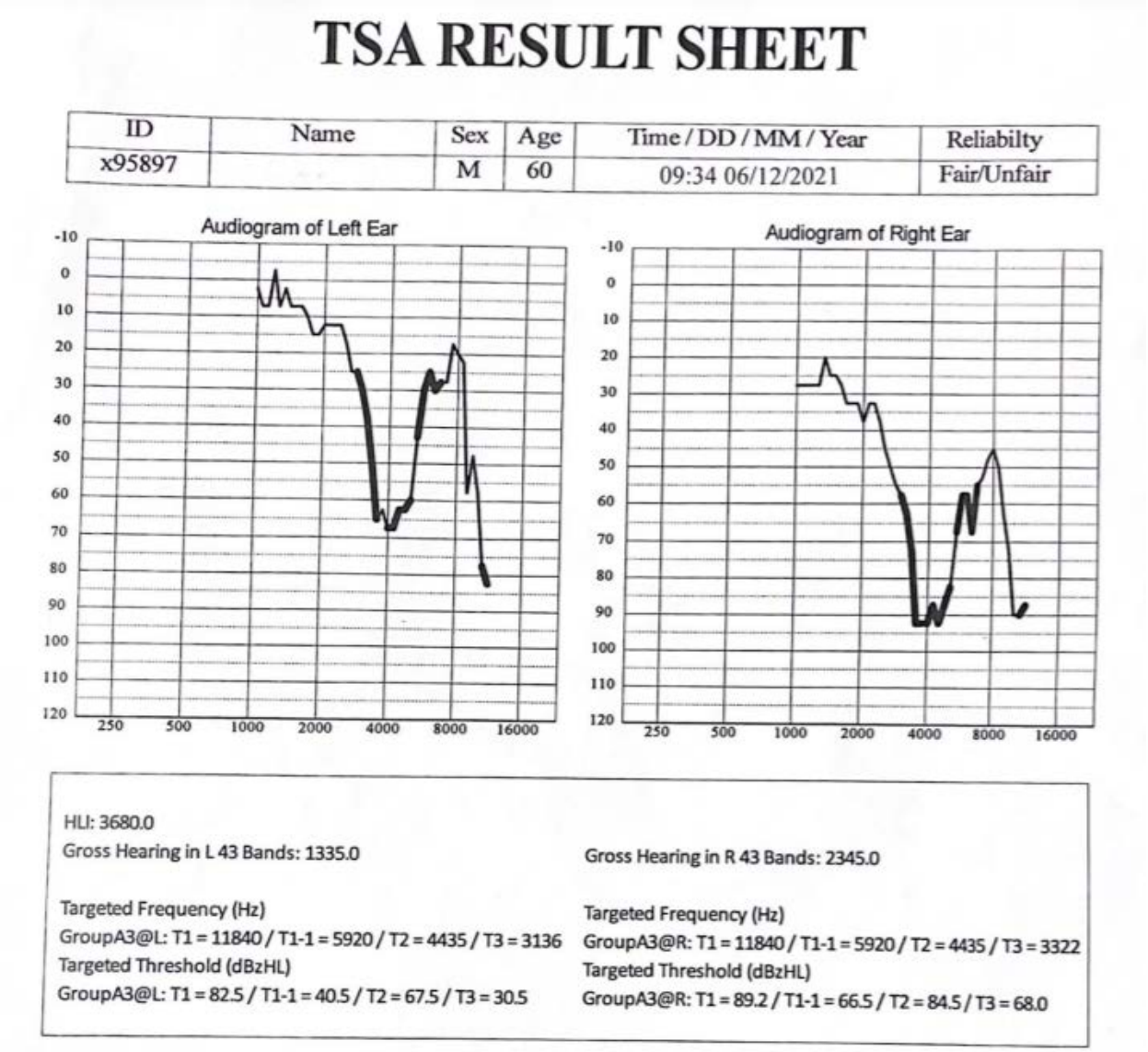



*Figure 12. 4th MTM test result for Case 1*

On November 1st, the left HLI was 1515 and the right HLI was 2395 with total of HLI was 3910. On November, 15th, the left HLI was 1415 and the right HLI was 2395, with total of HLI was 3810. Two weeks later, on November 29th, the left of HLI was 1395, the right of HLI was 2380 and total of HLI was 3775. And from the last MTM test which has on December 1st, the left of HLI was 1335, the right of HLI was 2345 and total of HLI was 3680 came out.

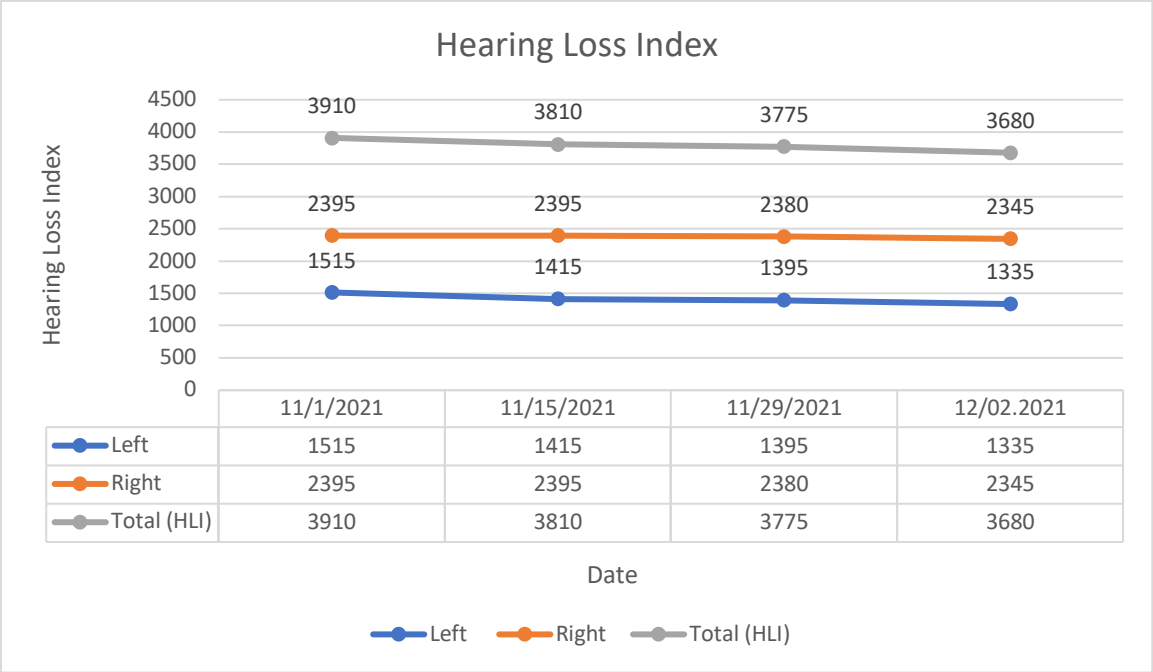



*Figure 13. Hearing Loss Index for Case 1*

During the treatment period, the left side showed an improvement of about 11.88% of HLI and the right side showed an improvement of 2.09%. a total of 5.88% of HLI change was shown. On the last day, December 1st. the VAS, THI and Three Simple Questionnaire were complete again. The results are shown in the table below.

The VAS ranged from 8 to 5, indicating an improvement of about 37.5%. Three simple question survey showed a decrease of 15.4% from 13 in the first month to 11 after one month. THI showed a 50% improvement from 68(grade 4) to 34(grade 2).

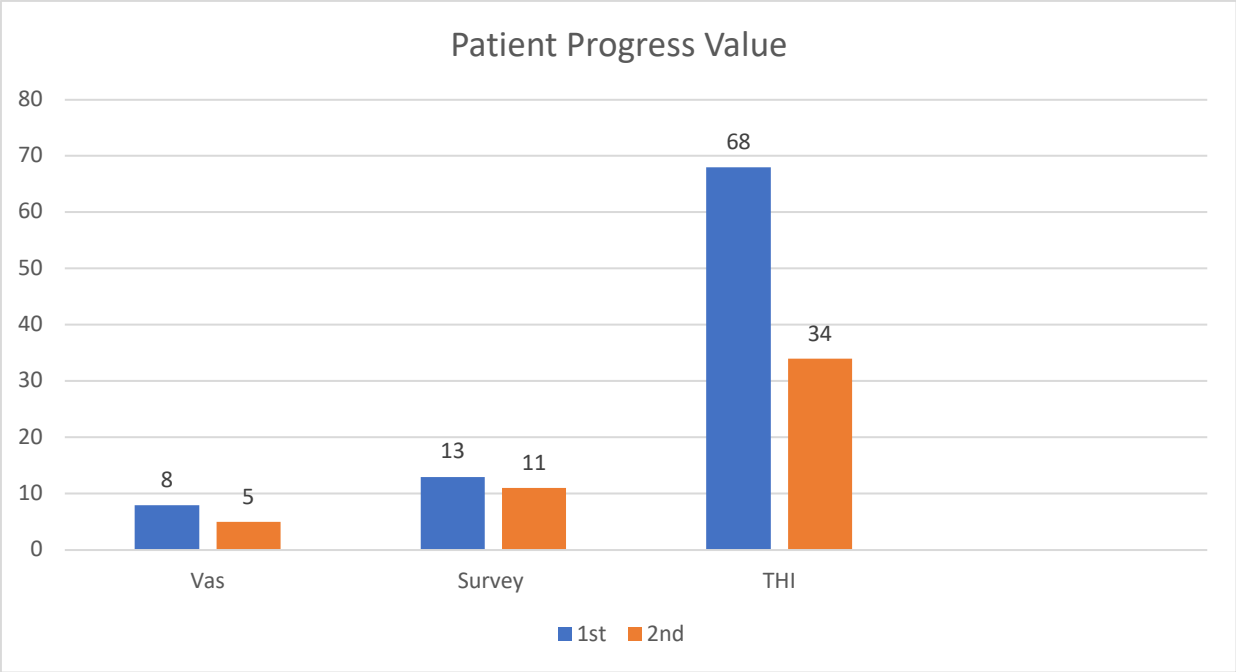



*Figure 14. VAS, Survey, THI progress Value for Case 1.*

Case 2.

1. Male (44)
2. Treatment period
    a. 08/27/2021 – 10/22/2021
3. Chief complaint
    a. Tinnitus
        i. On the right side 1month before
        ii. Tinnitus started in left side 1year ago.
        iii. It gets worst right before sleep or quiet environment.
        iv. Noise sounds have begun to change, now to high pitch sound.
        v. Severity 8/10 more severe at night time
4. Presence Illness
    a. Suffering from neck pain and headache (behind the eyes)
    b. Sleep disorder, insomnia causing the tinnitus
5. Past medical history
    a. Vocal cord polyp

6. Family Hx : Unremarkable
7. Tongue: pale to purple, tooth marks on the sides, wet, wide shape, little white coat
8. Pulse :
    a. Right: wiry, weak
    b. Left: weak

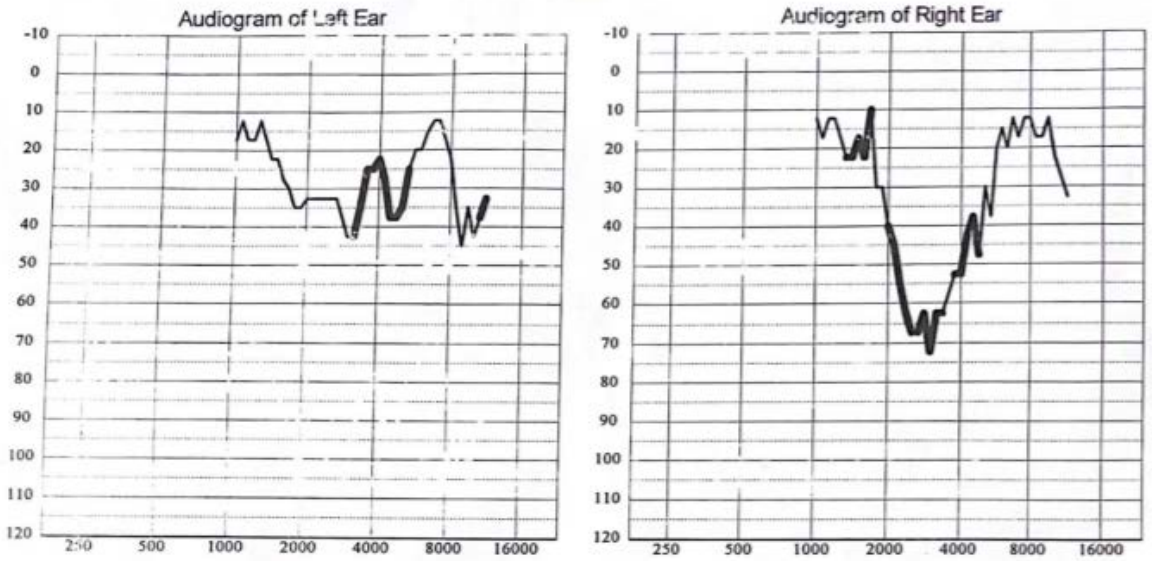
The patient visited for the first time August 27th, 2021 and complained of tinnitus. He firsts had tinnitus about a month ago. He complains that it had gotten worst at night right before sleeping or when it is quiet. He said that the tinnitus is louder in a quiet place and becomes faint during activity. So, he suffers from insomnia at night due to his tinnitus. He said he had a hearing test at the otolaryngology and tried music therapy. However, it did not work well. He said he was currently working for a trading company, where he is exposed to loud noise coming from a large running conveyor belt. He majored in classical vocal music and is currently attending school to become a music teacher. Before the pandemic he worked as a conductor at the church every Sunday, but after the pandemic started, he could not go to church, so he could not work as a conductor. He complained of a headache from behind his eyes as well as neck pain.

On the first visit, VAS and THI questions were asked, and a questionnaire about the status of tinnitus was completed. Initially, the VAS was measured as 8. THI was 78 and the result was Grade 5 as Catastrophic handicap. 14 points were obtained on the tinnitus status questionnaire. He visited the clinic every two or three weeks depending on his schedule. He performed 4 MTM tests on August 27th, September 3rd, September 24th, and October 22nd.

The results are shown in the table below.

# TSA RESULT SHEET

| ID | Name | Sex | Age | Time / DD / MM / Year | Reliabilty |
|---|---|---|---|---|---|
| X96540 | | | 44 | 15:29 27/08/2021 | Fair/Unfair |







HLI: 2625.0

Gross Hearing in L 43 Bands: 202.5

Targeted Frequency (Hz)
GroupA1@L: T1 = 11840 / T2 = 3520 / T3 = 4699
Targeted Threshold (dBzHL)
GroupA1@L: T1 = 47.5 / T2 = 41.0 / T3 = 37.5

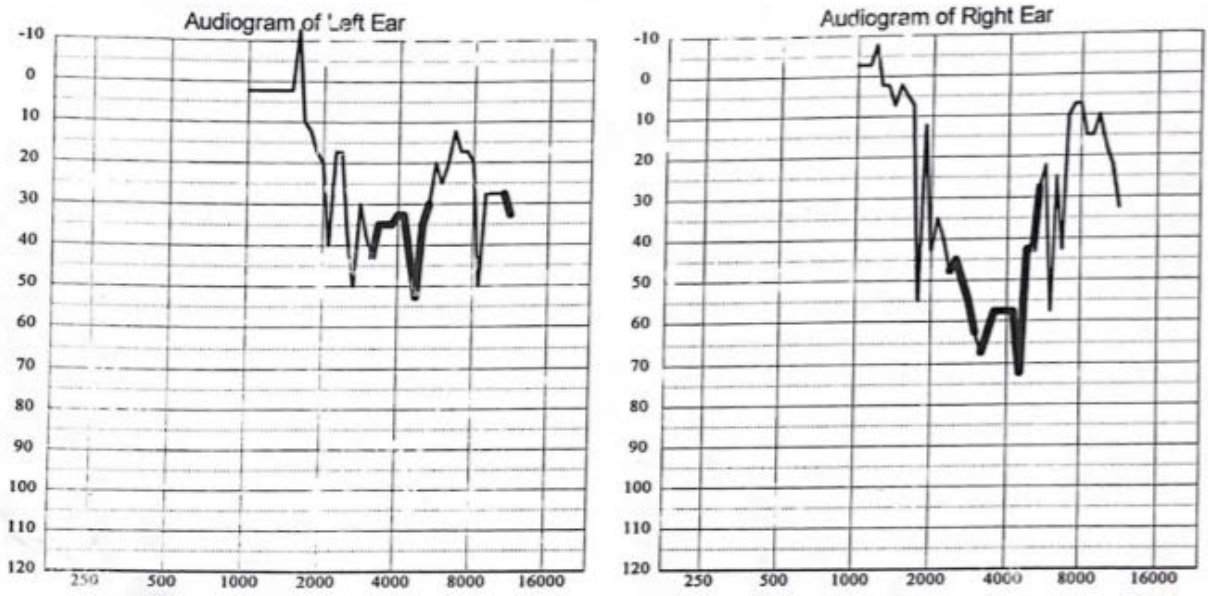
Gross Hearing in R 43 Bands: 1422.5

Targeted Frequency (Hz)
GroupA3@R: T1 = 2960 / T1-1 = 1480 / T2 = 4186 / T3 = 2217
Targeted Threshold (dBzHL)
GroupA3@R: T1 = 66.5 / T1-1 = 20.5 / T2 = 60.5 / T3 = 46.5

*Figure 15. 1st MTM test for Case 2*

# TSA RESULT SHEET

| ID | Name | Sex | Age | Time / DD / MM / Year | Reliabilty |
|---|---|---|---|---|---|
| X96540 | | M | 43 | 17:08 03/09/2021 | Fair/Unfair |




HLI: 2282.5

Gross Hearing in L 43 Bands: 1295.0

Targeted Frequency (Hz)
GroupA1@L: T1 = 11840 / T2 = 3520 / T3 = 4699
Targeted Threshold (dBzHL)
GroupA1@L: T1 = 47.5 / T2 = 41.0 / T3 = 37.5

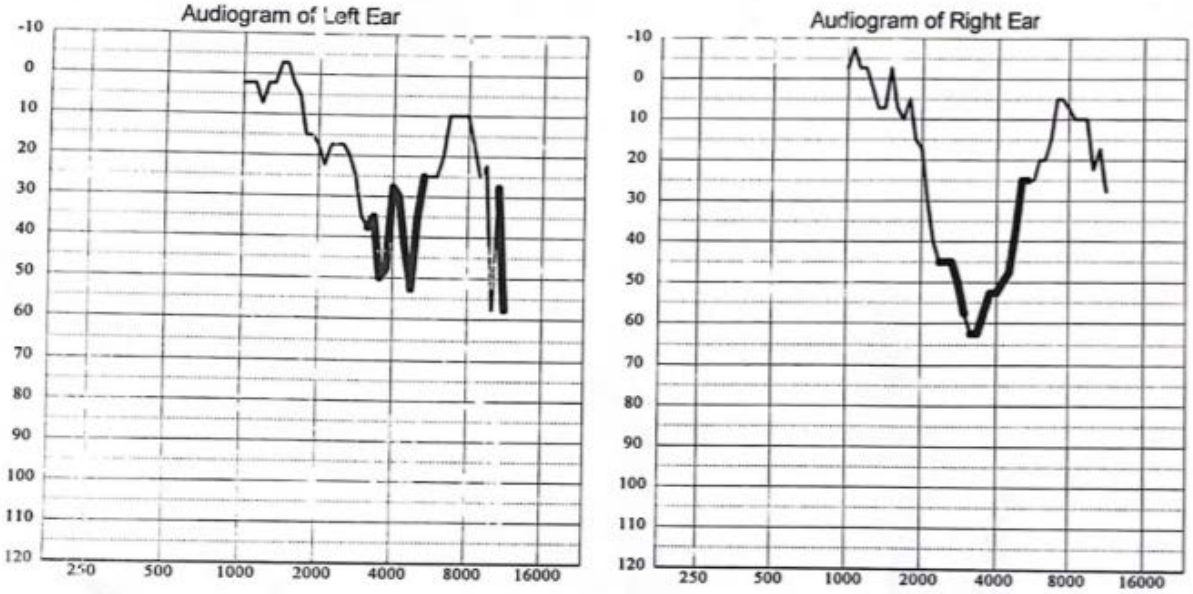
Gross Hearing in R 43 Bands: 1287.5

Targeted Frequency (Hz)
GroupA2@R: T1 = 3520 / T2 = 4699 / T3 = 2637
Targeted Threshold (dBzHL)
GroupA2@R: T1 = 61.5 / T2 = 54.5 / T3 = 45.0

*Figure 16 2nd MTM test for Case 2*

# TSA RESULT SHEET

| ID | Name | Sex | Age | Time / DD / MM / Year | Reliabilty |
|---|---|---|---|---|---|
| X96540 | | M | 44 | 17:05 24/09/2021 | Fair/Unfair |




HLI: 1960.0

Gross Hearing in L 43 Bands: 925.0

Targeted Frequency (Hz)
GroupA1@L: T1 = 11840 / T2 = 3520 / T3 = 4699
Targeted Threshold (dBzHL)
GroupA1@L: T1 = 47.5 / T2 = 41.0 / T3 = 37.5

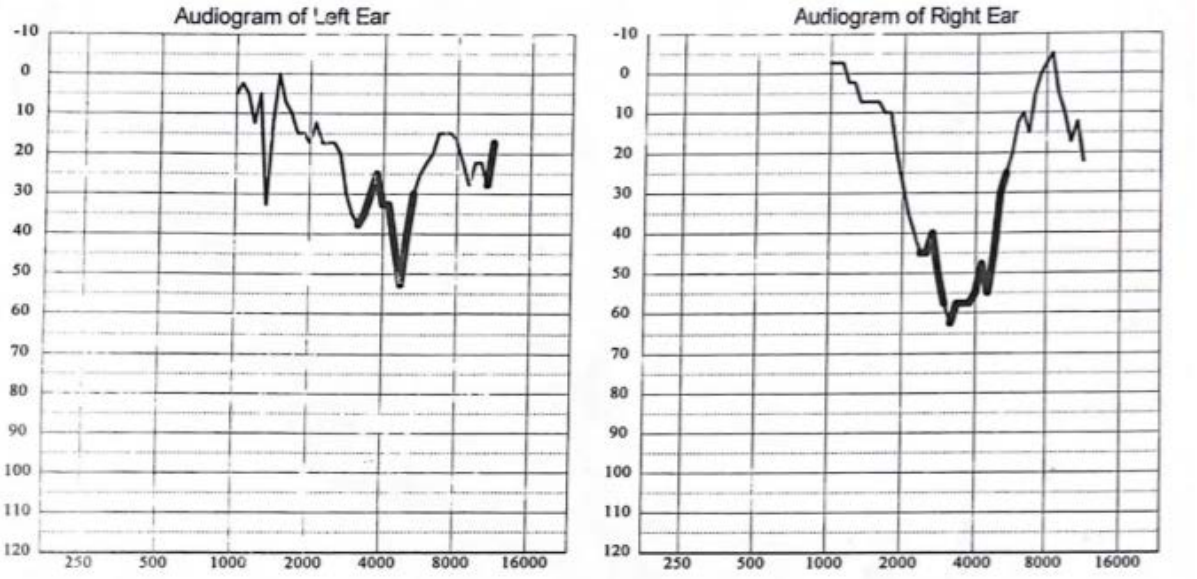
Gross Hearing in R 43 Bands: 1035.0

Targeted Frequency (Hz)
GroupA2@R: T1 = 3520 / T2 = 2637 / T3 = 4699
Targeted Threshold (dBzHL)
GroupA2@R: T1 = 58.5 / T2 = 45.0 / T3 = 42.5

*Figure 17. 3rd MTM test for Case 2*

# TSA RESULT SHEET

| ID | Name | Sex | Age | Time / DD / MM / Year | Reliabilty |
|---|---|---|---|---|---|
| X96540 | | M | 44 | 17:12 22/10/2021 | Fair/Unfair |




HLI: 1940.0

Gross Hearing in L 43 Bands: 917.5

Gross Hearing in R 43 Bands: 1022.5

Targeted Frequency (Hz)
GroupA1@L: T1 = 11840 / T2 = 3520 / T3 = 4699
Targeted Threshold (dBzHL)
GroupA1@L: T1 = 47.5 / T2 = 41.0 / T3 = 37.5

Targeted Frequency (Hz)
GroupA2@R: T1 = 3520 / T2 = 2637 / T3 = 4699
Targeted Threshold (dBzHL)
GroupA2@R: T1 = 58.5 / T2 = 45.0 / T3 = 42.5

*Figure 18. 4th MTM test for Case 2*

On August 27th, the left HLI was 1202.5 and the right HLI was 1422.5 with total of HLI was 2625.

On September 3rd, the left HLI was 995 and the right HLI was 1287.5, with total of HLI was 2282.5. On September 24th, the left of HLI was 925, the right of HLI was 1035 and total of HLI was 1960. And from the last MTM test which has on October 22nd, the left of HLI was 917, the right of HLI was 1022.5 and total of HLI was 1940 came out.

During the treatment period, the left side showed an improvement of about 23.7% of HLI and the right side showed an improvement of 28.11%. a total of 26.1% of HLI change was shown.

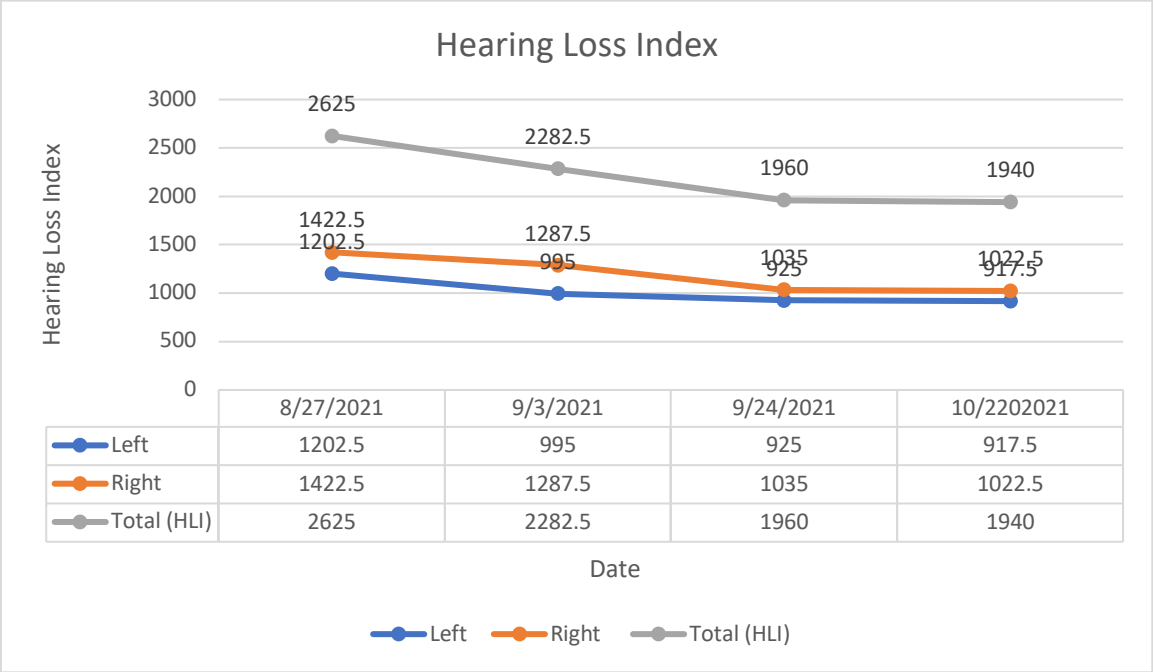



*Figure 19. Hearing Loss Index for Case 2*

On the last day, October 22nd. the VAS, THI and Three Simple Questionnaire were completed again. The results are shown in the table below.

The VAS ranged from 8 to 3, indicating an improvement of about 62.5%. Three simple question survey showed a decrease of 35.7% from 14 in the first month to 9 after treatment. THI showed a 71.8% improvement from 78(grade 5) to 22(grade 2).

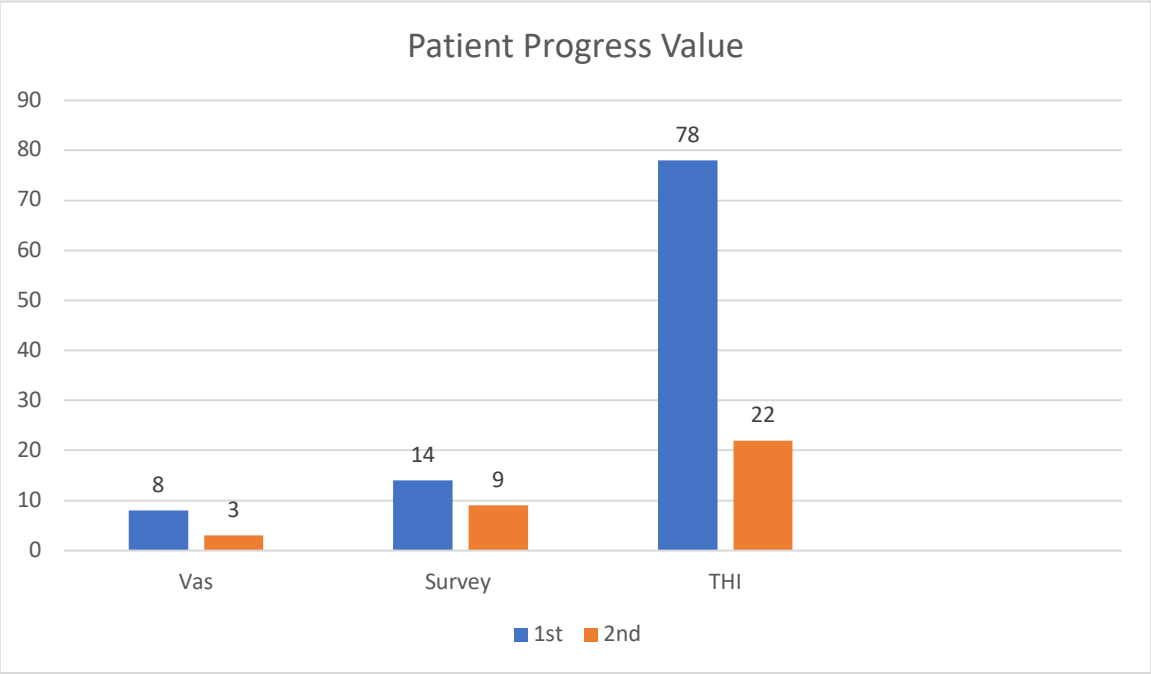



*Figure 20. VAS, Survey, THI progress Value for Case 2*

# IV. DISCUSSION

Tinnitus the perception of sound in the ears or head without the presence of audible external source, is a symptom, rather than a disease entity, that originates internally without an external auditory input. The noise may be constant or come in bouts and may vary in intensity and character. If so, how many people live with tinnitus?

It is relatively common in the elderly, but the actual reported prevalence varies according to the surveyed region and definition of tinnitus.[65] About 12 million people in the United States suffer from tinnitus.[66] According to the National Center for Health Statistics of the United States, about 32% of all US adults report having tinnitus at one-time point in their lives and about 6.4% of them characterizes tinnitus as severe.[67] According to the national statistics in Iran, at least 5.2million people in Iran suffer from bothersome tinnitus.[68] Also, British study reported that 10% of adults have prolonged spontaneous tinnitus, 15% experience severe annoyance caused by tinnitus, and 0.5% of adult experience tinnitus that severely reduced their ability to lead a normal life[69] and a large scale Swedish study found that 14% of adults reported experiencing tinnitus "often "or "always". And 2.4% reported that "Tinnitus plagues me all day".[70] Five Italian cities were recently investigated, and 14.5% of the population reported prolonged spontaneous tinnitus.[71] Tinnitus is often associated with sudden, temporary hearing loss, and it can have a powerful detrimental impact on a patient's quality of life. In some studies, the most common disorders related to tinnitus were sleep disturbance, persistent discomfort, communication and concentration problems, instability, hopelessness, and drug dependence.[72] Therefore, it is said that tinnitus causes disability in the overall range of daily life, such as leisure use, exercise,

social life, family relationships, and the creation of friendships rather than physical discomfort. Severe tinnitus may also lead to serious mental illness and suicidal tendencies[73]

Recently, the number of patients with tinnitus is increasing due to several causes, such as the aging of the population and the noise generated by the industrial society and stress related to the complex social environment. Until now, the causes of tinnitus include sympathetic nervous system dysfunction, autonomic nervous system dysfunction, endocrine dysfunction, bacterial infection, allergy, metabolic disorder, water and salt metabolism disorder, and vitamin deficiency theory, etc.[74] However, the exact cause of tinnitus is not yet known, and it is difficult to objectify the severity of subjective symptoms at present, and a clear diagnosis method has not been presented. So, in this study, the diagnosis of tinnitus was done more objectively to help patient understand their tinnitus and evaluate the effect of acupuncture treatment to better quality of life whose suffering from tinnitus.

In this study, a new program called Modulated Tinnitus Masking (MTM) protocol was used. MTM is new protocol to diagnose and treat sensorineural tinnitus and hearing loss. This program diagnoses tinnitus and shows it visually to tell the patients exactly where the tinnitus is occurring. As a result of these tests, the cause of tinnitus was diagnosed, how much the tinnitus changed during acupuncture treatment, and evaluate the effect of this change in quality of life of tinnitus patients. The TSC test result can be divided into three parts, which are under ranges of 3000Hz, between 3000Hz and 6000-7000Hz, and upper ranges of 6000hz. As a result of the MTM test, if tinnitus appears mainly appears in a place higher than 6000Hz, it can be considered as a problem on Hand Shao Yang San Jiao meridian. The bias of cold energy occurs due to the bias of Sanghwa(相火). Certain neurological diseases may appear along with the body fluid

disorders. If it is suspected that it is a lesion of the San Jiao meridian, With this case, acupuncture can be done on points JS8 Sanynaglou(삼양락), GB8 Shuaigu (솔곡), GB12 Wangu (완골) that SJ19Luxi(노식), SJ18 Qimai(계맥), and SJ21Ermen(이문).

Hand Tai Yang Small intestine meridian always has symptoms of flaring up of the deficient fire due to the lack of the Tai yang cold(태양한수). Because it is Yang Meridian, there is not enough energy to descend with Yang, and patient can always complain of a cold symptom. Therefore, if the patient has symptoms of cold stomach and up flaring of the asthenic toward to face, it should consider a lesion of the Small Intestine Meridian. Acupuncture can be done on SI3 Houxi (후계), LI11 Quchi9(곡지), GB8 Shuaigu (솔곡), GB12 Wangu (완골) that SJ19Luxi(노식), SJ18 Qimai(계맥), and SI19 Tinggong(청궁). In this case, the MTM test shows tinnitus between 300Hzand 6000-7000Hz.

Due to the lack of calming power, a feeling of shaking of the branches of a tree appears, resulting in stiffness of muscles and a state of mental excitement. If it is considered that it is a gallbladder disease, it can be confirmed as tenderness in the GB21 Jianling (견정). MTM test shows this type of tinnitus in ranges of under the 3000Hz. Acupuncture can be done on ST36 Zusanli (족삼리), GB41 Zulinqi(족임읍), KD2 Rangu (연곡), GB8 Shuaigu (솔곡), GB12 Wangu (완골) that SJ19Luxi(노식), SJ18 Qimai(계맥) and GB2Tinghui (청회).

For this treatment, reference was made from Juheng Acupuncture (주행침구학) studies conducted by Jung Yun goo (정연구).

In the first case of the 60-year-old man, tinnitus appeared between 3000Hz and 6000Hz in the MTM test results. And cause of tinnitus was identified as deeply related to the heart, and acupuncture and sound therapy was performed simultaneously. From November1st to December 6$^{th}$ he visited the clinic once a week. Immediately after the first treatment, the patient said that the tinnitus was barely audible for 3days, he has said that the tinnitus, which had been heard all day, could not be heard unless he focuses his attention on it. From the 4$^{th}$ day, the tinnitus increased slightly, but the sound became lesser than before treatment. The same acupuncture treatment was applied at the second visit, and the number of waking up at night decreased by one or two after the second treatment. After the third treatment, the frequency of tinnitus decreased, but the intensity when tinnitus appeared was similar. The same treatment was performed in the fourth treatment. At the end of the last treatment, the patient's insomnia improved the most. Objectively numerical Tinnitus Handicap Index (THI) was improved by about 50%. With this treatment, both side's Hearing Loss Index (HLI) improved by about 11.8% on the left and 2.09% on the right. However, this patient complained of tinnitus and hearing loss in the right ear, but with this treatment, the hearing in the right ear was still weaker than the hearing in the left ear. Although this patient still has some tinnitus, it did not bother or inconvenience him. The headache also disappeared as insomnia improved. He said that the feeling of being heavy and stuffy disappeared and his overall body felt better condition. After the last treatment, the intensity or discomfort of his tinnitus was reduced to about 37.5%. Tinnitus Handicap Inventory decreased by 50%, it is changing from Grade 4(68points) to Grade 2(34points).

| GRADE | SCORE | DESCRIPTION |
|---|---|---|
| 1 | 0-16 | Slight: Only heard in quiet environment, very easily masked. No interference with sleep or daily activities. |
| 2 | 18-36 | Mild: Easily masked by environmental sounds and easily forgotten with activities. May occasionally interfere with sleep but not daily activities. |
| 3 | 38-56 | Moderate: May be noticed, even in the presence of background or environmental noise, although daily activities may still be performed. |
| 4 | 58-76 | Severe: Almost always heard, rarely, if ever, masked. Leads to disturbed sleep pattern and can interfere with ability to carry out normal daily activities. Quiet activities affected adversely. |
| 5 | 78-100 | Catastrophic: Always heard, disturbed sleep patterns, difficulty with any activity. |

*Figure 21. Tinnitus Handicap Inventory Severity Scale*

In the second case of the 44-year-old male, he visited the clinic for the first time on August 27th and performed VAS, MTM test, Tinnitus Handicap Inventory (THI) and Three questionnaire for the scale and discomfort of tinnitus on the same day. He said that tinnitus first started about a month ago, and he complained that tinnitus got worse when he was in a quiet place and he felt it was worst when he was about to go to sleep at night. In his MTM test, the left side showed tinnitus between 3000hz -6000Hz and the right side showed that the tinnitus was distributed between 1300Hz-5000Hz. According to these results, Threshold Sound conditioning(TSC) therapy and acupuncture were performed on the first visit. Acupuncture was mixed with points of 3000Hz or less part and points are in the middle part which is between 3000Hz and 6000Hz. On the day of the first treatment, the patient felt that the intensity of tinnitus became lower, and as a result, he was able to sleep deeply at night. The next day, the tinnitus increased again at night, but did not significantly interfere with sleep. At the second visit, the patient again complained of an increase in the intensity of the tinnitus, and the MTM test was performed again to provide a new TSC therapy sound source. And the same acupuncture as the first treatment was performed. He said the after the second treatment, the sound of tinnitus became smaller for about

4 days, and there were times when he felt that he could not hear the tinnitus unless he deliberately thought about it. The headache no longer occurred. The neck pain was still there. At the 3rd visit, a new MTM test was conducted, and the numerical results showed a similar trend as at the 2nd visit. However, it was found that the patient's tinnitus became softer due to the change in the graph. The patient stated that the tinnitus was thought to have decreased in intensity overall. In the actual graph, it was confirmed that a more stable and smoother curve appeared in the third test compared to the previous curve. The 4th visit was conducted approximately 4 weeks after the 3rd visit. In the meantime, the Threshold Conditioning Sound was updated remotely so that is could be heard continuously. When he actually visited the clinic for the last time, he filled out the MTM test, VAS for intensity about the tinnitus, Tinnitus Handicap Inventory (THI) and Three simple questionnaire.

With this treatment, the patient's Hearing Loss Index improved by 23.7% on the left and 28.11 % on the right side. The intensity and frequency of tinnitus decreased by 35.7% and the Tinnitus Handicap Inventory decreased by 71.8%, it is changing from Grade 5 to Grade 2.

The purpose of this study was to find out how the new tinnitus diagnosis and treatment system called MTM protocol was utilized in oriental medicine treatment and its effects were shown. In my opinion more cases and related studies are still needed. However, through this study, it was found that the MTM test results have a positive effect on the diagnosis of tinnitus in oriental medicine. Using the results of the MTM test, it was possible to determine which meridians should be diagnosed and treated, and objective results of how effective the treatment was for the patient could be known through VAS, THI and MTM test. In addition to acupuncture, there was also additional benefit using specially designed MTM Threshold Sound conditioning. Both patients received 4 acupuncture treatments, but the first patient received sound therapy for only 4

weeks and the second patient received sound therapy for approximately 8 weeks. Among these two patients, the second patient showed a greater change in the objective values of the VAS, THI, and MTM tests.

# V. CONCLUSION

As a result of comparative analysis of two patients complaining of tinnitus among patients who visited clinic from June, 2021 to December 2021, following conclusions were drawn on the effect of tinnitus diagnosis and treatment using the MTM protocol on the patient.

One of the cases, 60-year-old man, the left side showed an improvement of about 11.88% of HLI and the right side showed an improvement of 2.09%. A total of 5.88% of HLI change was shown. The VAS ranged from 8 to 5, which indicated an improvement of about 37.5%. Three simple question survey showed a decrease of 15.4% from 13 in the first month to 11 after one month. THI showed a 50% improvement from 68 (grade 4) to 34 (grade 2).

There is a 44-year-old man, his left side showed an improvement of about 23.7% of HLI and the right side showed an improvement of 28.11%. a total of 26.1% of HLI change.

The VAS ranged from 8 to 3, indicating an improvement of about 62.5%. Three simple question survey showed a decrease of 35.7% from 14 in the first month to 9 after treatment. THI showed a 71.8% improvement from 78 (grade 5) to 22 (grade 2).

It was found that the cause of tinnitus can be diagnosed using the results of the MTM test rather than only through oriental medical questionnaires, and the treatment results are effective. Also, found that the use of the MTM protocol can objectively and visually show the intensity and location of tinnitus, which has a positive effect on treatment of Tinnitus and quality of their life.

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# APPENDICES

## Informed Consent Form

**You are invited to participate in a research study** about the "Objective Diagnosis of Tinnitus through MTM (Modulated Tinnitus Masking) protocol and Acupuncture Treatment Effect: case series."

**Total goal of this research study** is obtaining an objective diagnosis of tinnitus using the Modulate Tinnitus Making (MTM) protocol and evaluation of acupuncture treatment on improvement of tinnitus after using MTM diagnosis.

**The study design** is that the patients were tested using the RCPTA test and later given the THI survey questionnaires at their first visit. RCPTA test was done every other week. After an RCPTA test, and prescribed customized Threshold Sound conditioning therapy with REVE 134, the participants were then given a Visual Analog Scale test. The participants were given a 4-10 weeks acupuncture treatment once or twice a week. All needles were used once and properly disposed of in a sharps container, following the CCAOM CNT 7$^{th}$ edition manual of regulations. Participants also do the Three questionnaires for severity for Tinnitus at their first and last sessions.

**This study is being conducted by Sairomi Choi, L.Ac.**

**Your participation in this research is entirely voluntary**. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research

project, you will be offered the treatment that is routinely offered in this clinic. You may change your mind later and stop participating even if you agreed earlier.

Participating in this study may not benefit you directly, but it will help to enrich the knowledge on Acupuncture and Asian Medicine.

**By participating in this research, it is possible that you will be at greater risk** than you would otherwise be. There is, for example, a risk that your condition will not get better and that the new medicine or treatment doesn't work even as well as the old one. If, however, the medicine or treatment is not working, we will give the medication or treatment routinely offered to make you more comfortable. While the possibility of this happening is very low, you should still be aware of the possibility.

**The information you will share with us if you participate in this study will be kept completely confidential to the full extent of the law**. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researcher will be able to see it. Any information about you will have a number on it instead of your name. only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except Sairomi Choi, L.Ac.

**If you have any questions about this study, please contact Sairomi Choi, L.Ac**. at 213-675-4409 and semichoi@southbaylo.edu. If you have any questions or concerns regarding your rights as a subject in this study, you may contact Dr Alfredo Briones, MD, L.Ac. supervisor of South Baylo University Los Angeles Clinic or Dr Joseph Suh, Ph.D, L.Ac. Research Coordinator and

Faculty Doctor Program Director of the South Baylo University. Institutional Review Board(IRB) at 213-738-0712.

YOU WILL BE GIVEN A COPY OF THIS FORM WHETHER OR NOT YOU AGREE TO PARTICIPATE.

## Certificate of Consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

| | |
|---|---|
| _____ | _____ |
| Name of Participant (Print) | Name of Witness (Print) |
| _____ | _____ |
| Signature of Participant | Signature of Witness |
| _____ | _____ |
| Date: Day/Month/Year | Date: Day/Month/Year |

## Statement by the researcher/person taking consent:

I have accurately explained the information sheet to the potential patient. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant

_____

Print Name Researcher (Print)

_____

Signature of Researcher

_____

Date: Day/Month/Year

1. Tinnitus Handicap Inventory

## Tinnitus Handicap Inventory (THI)

*This form is for informational purposes only and should not take the place of consultation and evaluation by a healthcare professional.*

Your Name: _____ Date: _____

**Instructions:** The purpose of this questionnaire is to identify, quantify, and evaluate the difficulties that you may be experiencing because of tinnitus. Please do not skip any questions. When you have answer all the questions, add up your total score, based on the values for each response.

| | | | | |
|---|---|---|---|---|
| 1. | Because of your tinnitus, is it difficult for you to concentrate? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 2. | Does the loudness of your tinnitus make it difficult for you to hear people? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 3. | Does your tinnitus make you angry? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 4. | Does your tinnitus make you feel confused? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 5. | Because of your tinnitus, do you feel desperate? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 6. | Do you complain a great deal about your tinnitus? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 7. | Because of your tinnitus, do you have trouble falling to sleep at night? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 8. | Do you feel as though you cannot escape your tinnitus? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 9. | Does your tinnitus interfere with your ability to enjoy your social activities (such as going out to dinner, to the movies)? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 10. | Because of your tinnitus, do you feel frustrated? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 11. | Because of your tinnitus, do you feel that you have a terrible disease? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 12. | Does your tinnitus make it difficult for you to enjoy life? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 13. | Does your tinnitus interfere with your job or household responsibilities? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 14. | Because of your tinnitus, do you find that you are often irritable? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 15. | Because of your tinnitus, is it difficult for you to read? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 16. | Does your tinnitus make you upset? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 17. | Do you feel that your tinnitus problem has placed stress on your relationships with members of your family and friends? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 18. | Do you find it difficult to focus your attention away from your tinnitus and on other things? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 19. | Do you feel that you have no control over your tinnitus? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 20. | Because of your tinnitus, do you often feel tired? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 21. | Because of your tinnitus, do you feel depressed? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 22. | Does your tinnitus make you feel anxious? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 23. | Do you feel that you can no longer cope with your tinnitus? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 24. | Does your tinnitus get worse when you are under stress? | ● Yes (4) | ● Sometimes (2) | ● No (0) |
| 25. | Does your tinnitus make you feel insecure? | ● Yes (4) | ● Sometimes (2) | ● No (0) |

**The sum of all responses is your THI Score >>>** 0

0-16: Slight or no handicap (Grade 1)
18-36: Mild handicap (Grade 2)
38-56: Moderate handicap (Grade 3)
58-76: Severe handicap (Grade 4)
78-100: Catastrophic handicap (Grade 5)



Newman CW, Jacobson GP, Spitzer JB. (1996) "Development of the Tinnitus Handicap Inventory." Archives of Otolaryngology - Head and Neck Surgery. 122(2):143-8.
McCombe, A., Baguley, D., Coles, R., McKenna, L., McKinney, C. & Windle-Taylor, P. (2001). "Guidelines for the Grading of Tinnitus Severity: the Results of a Working Group Commissioned by the British Association of Otolaryngologists, Head and Neck Surgeons." Clinical Otolaryngology. 26, 388-393.

2. Three Questionnaire

20 . . . AM PM H M

# Three Questionnaire (설문지)

NAME (성명) :

Read the questions below and answer O to the appropriate number

아래 질문을 읽고 해당 번호에 O 로 답하세요

1. **What is my tinnitus for the last 3days?**
   **최근 3 일간 나의 이명은 ?**
   ① Always heard 언제나 들렸다
   ② Heard often 자주 들렸다
   ③ Sometimes heard 가끔 들렸다
   ④ Barely heard 거의 들리지 않았다
   ⑤ Did not hear it at all 전혀 들리지 않았다.

2. **At this moment, my tinnitus volume is**
   **지금 이순간 나의 이명 볼륨은?**
   ① Loud Sound 크게 들린다.
   ② Sounds decent 적당히 들린다.
   ③ Small sound 작게 들린다.
   ④ Barely audible 거의 들리지 않는다.
   ⑤ Cannot hear it at all 전혀 들리지 않는다

3. **What is my tinnitus today?**
   **오늘 나의 이명은?**
   ① Audible continuously 꾸준히 지속적으로 들린다.
   ③ Sometimes I heard but sometimes don't 들렸다 안들렸다 한다.
   ⑤ Cannot hear at all 들리지 않는다

- Questionnaire score evaluation method (maximum score 15points, minimum score 3points)
- Simple sum of answer numbers for 3 questions.

3. Visual Analog Scale