A Dissertation on

"EFFECT OF DIABETES MELLITUS OF PATIENTS ON SENSORINEURAL HEARING LOSS IN A TERTIARY HEALTH CARE CENTER"

Dissertation submitted to

THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY, CHENNAI

With partial fulfillment of the regulations for the award of the degree of

M.S. OTORHINOLARYNGOLOGY

BRANCH-IV

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

KANYAKUMARI

2018

BONAFIDE CERTIFICATE

This is to certify that this dissertation is a bonafide record of work done by **Dr.GEOGIN GEORGE THOTTAN** on **"Effect Of Diabetes Mellitus Of Patients On Sensorineural Hearing Loss In A Tertiary Health Care Center",** during his M.S. ENT course from June 2016 to May 2019 Sree Mookambika Institute of Medical Sciences Hospital, Kanyakumari. He is appearing for his M.S. ENT (Branch-IV) Degree examination in May 2019 and his work has been done with partial fulfillment of the regulations of The Tamil Nadu Dr.M.G.R. Medical University, Chennai. I forward this to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, Tamil Nadu, India.

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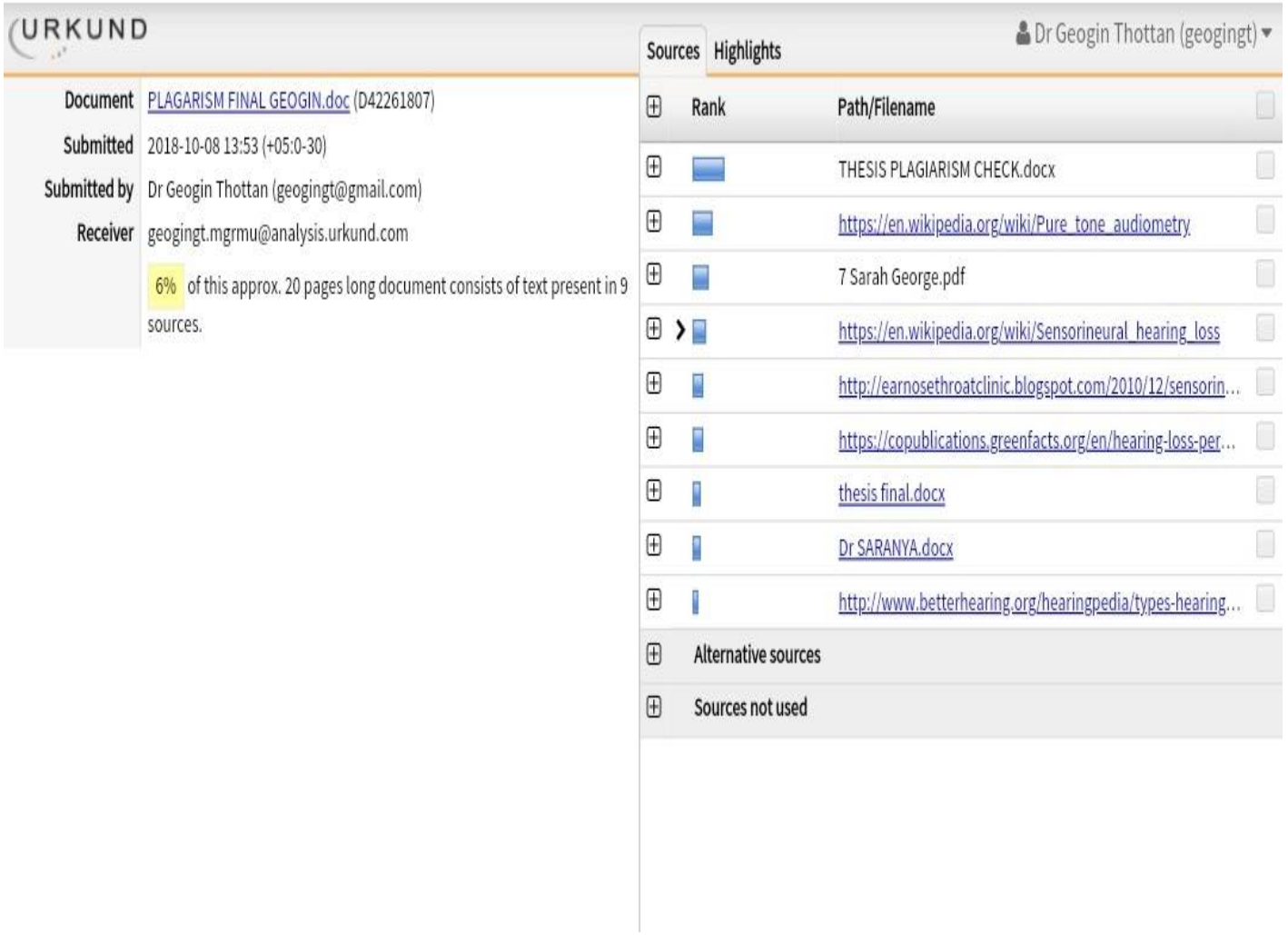

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DECLARATION

I solemnly declare that the dissertation entitled **"Effect of diabetes mellitus of patients on Sensorineural Hearing Loss in a tertiary health care center"** is done by me at Sree Mookambika Instiute of Medical Sciences, Kanyakumari during October 2016 to October 2018 under the guidance and supervision of **Prof.K.P.GOPAKUMAR M.S ENT,** to be submitted to The Tamil Nadu Dr. M.G.R Medical University towards the partial fulfillment of requirements for the award of M.S DEGREE IN **OTORHINOLARYNGOLOGY,** BRANCH-IV.

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Dr. GEOGIN GEORGE THOTTAN

ABSTRACT

INTRODUCTION

Diabetes Mellitus is the single most important metabolic disease which can affect nearly every organ system in the body. Almost all the macro and microvascular complications of diabetes have been studied extensively.

Sensorineural hearing loss (SNHL) is a type of hearing loss, or deafness, in which the root cause lies in the inner ear (cochlea and associated structures), vestibulocochlear nerve (cranial nerve VIII), or central auditory processing centers of the brain.

Hearing impairment is defined by the World Health Organization (WHO) as a hearing loss with thresholds higher than 25db in one or both ears. The degree of hearing loss is classified as mild, moderate, severe or profound.

Early detection of hearing loss is possible with the help of high frequency pure tone audiometry which may be undetected by a conventional audiometry.

RATIONALE

The link between diabetes and SNHL makes intuitive sense, given the documented neuropathic and microvascular complications of diabetes and the complex blood supply of the inner ear.

AIMS OF STUDY

- Early detection of Hearing loss in high risk individuals, with predilection to Diabetes Mellitus.
- To compare the efficacy of conventional hearing assessment (tuning fork test) against the high frequency audiometer in detection of hearing loss
- Early intervention and prevention of diabetes mellitus induced hearing loss
- Increase awareness among health care providers and laypersons.

METHODOLOGY

The study was a hospital based cross sectional study conducted in the department of ENT, Sree Mookambika Institute of Medical Sciences Hospital, Kanyakumari from December 2016 to October 2018 (Approximately 18 months). A total of 30 Human subjects were examined above the age 30years with Type 2 Diabetes Mellitus requiring assessment of hearing loss and willingness to participate in the study. All the cases were subjected to tuning fork test and pure tone audiometry.

Risks and Benefits of the Study:

- Benefits: Appropriate early diagnosis of causative factors for SNHL in diabetics to ensure prompt and effective management and to avoid or minimize the occurrence of complications.
- No risks so far have been detected following the study.

CONCLUSION

In patients with diabetes mellitus, by the time hearing loss is detected using conventional tuning fork tests, damage has already affected the sensorineural component, which will affect the hearing component of the patient and hence affect the quality of life. Therefore by using audiometry early detection of hearing loss in people affected with Type 2 Diabetes mellitus can be done. It will help us to take early steps to make the patients affected by diabetes aware of the deafness and to take early measures for prevention and further progression of deafness.

KEYWORDS

Pure tone audiometry, sensorineural hearing loss, conventional tuning fork test, microvascular, vestibulocochlear, neuropathic, type 2 diabetes mellitus.

ABBREVIATIONS

(S)SNHL	(SUDDEN) SENSORINEURAL HEARING LOSS
AC/BC	AIR CONDUCTION/ BONE CONDUCTION
AC/DC	ALTERNATING CURRENT/ DIRECT CURRENT
AVCN	ANTEROVENTRAL COCHLEAR NUCLEI
CN	COCHLEAR NUCLEI
dB	DECIBEL
DNA	DEOXYRIBONUCLEIC ACID
HL	HEARING LOSS
IHC	INNER HAIR CELL
NIDDM	NON-INSULIN DEPENDANT DIABETES MELLITUS
OAE	OTOACOUSTIC EMISSION
OHC	OUTER HAIR CELL
OHC	OUTER HAIR CELL
PAS	PERIODIC ACID- SCHIFF
PTA	PURE TONE AUDIOMETRY
PTS	PERMANENT THRESHOLD SHIFT

PVCN	POSTERO VENTRAL COCHLEAR NUCLEI
ROS	REACTIVE OXYGEN SPECIES
Rt/ Lt	RIGHT/LEFT
SOC	SUPERIOR OLIVARY COMPLEX
SPL	SOUND PRESSURE LEVEL
T2DM	TYPE 2 DIABETES MELLITUS
TTS	TEMPORARY THRESHOLD SHIFT
WHO	WORLD HEALTH ORGANIZATION

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INTRODUCTION

Diabetes Mellitus is the single most important metabolic disease which can affect nearly every organ system in the body. Almost all the macro and microvascular complications of diabetes have been studied extensively. [1, 2]

Sensorineural hearing loss (SNHL) is a type of hearing loss, or deafness, in which the root cause lies in the inner ear (cochlea and associated structures), vestibulocochlear nerve (cranial nerve VIII), or central auditory processing centers of the brain.[3]

Hearing impairment is defined by the World Health Organization (WHO) as a hearing loss with thresholds higher than 25db in one or both ears. The degree of hearing loss is classified as mild, moderate, severe or profound. [4]

Sudden sensorineural hearing loss (SSNHL) is defined as the sudden onset of unilateral sensorineural hearing loss of 30 dB over at least three contiguous audiometric frequencies [5]. Diabetes is a risk factor of SSNHL, possibly due to microangiopathy [6, 7]. Currently, the clinical studies of SSNHL rarely focus on diabetic patients. The correlations between biochemical data and hearing outcomes in SSNHL are seldom analyzed.

PTA is described as the gold standard for assessment of a hearing loss .Hearing impairment is defined by the World Health Organisation (WHO) as a hearing loss in one or both ears. The degree of hearing loss is classified as mild, moderate, severe or profound.[8] The results of PTA are a good indicator of hearing impairment. It can be used to differentiate between conductive hearing loss, sensorineural hearing loss, auditory and mixed hearing loss.

Considering the above, we notice that the results from the audiological evaluation of patients with diabetes mellitus are conflicting, making it necessary to broaden the studies in this line of research. Thus, the goal of the present study is to assess the auditory acuity of patients with diabetes and to assess the factors affecting hearing loss in patients with diabetes. With this study we aim to bring awareness to the clinicians and general public the need for evaluating sensorineural hearing loss in diabetic patients for prevention and early detection of hearing loss. We can give appropriate treatment to the patients and improve their quality of life.

HEARING LOSS

The degree of hearing loss can range from mild to profound as per WHO grade[9] (Table 1) and as per Biswas[10] (Table 2). The latter is widely used in India.

TABLE 1- WHO GRADES OF HEARING IMPAIRMENT [11]

	Grades Of Impairment	**Audiometric ISO Values (500,1000,2000,4000Hz)**	**Impairment Description**
0	No impairment	25Db HL	No or very slight hearing problems. Able to hear whispers
1	Slight impairment	26-40dB HL	Able to hear and repeat words spoken in normal voice at 1 metre
2	Moderate impairment	41-60Dbhl	Able to hear and repeat words using raised voice at 1 metre
3	Severe impairment	61-80dBHL	Able to hear some words when shouted into better ear
4	Profound impairment	81dBHL	Unable to hear and understand even shouted voice

TABLE 2 - WIDELY ACCEPTED GRADING [9]

Audiometric ISO (average of 500,1000,2000Hz)	Grade of Impairment
0 to 25 dB	Normal hearing level for all practical i.e. no deafness. The range between 16and 26dB is termed as very slight deafness by others
26 to 40Db	Mild deafness
41 to 55dB	Moderate deafness
56 to 70dB	Severe deafness
71 to 90 dB	Very severe deafness
Above 90dB	Profound deafness

AIMS AND OBJECTIVES

AIMS OF STUDY

- Early detection of Hearing loss in high risk individuals, with predilection to Diabetes Mellitus.
- To compare the efficacy of conventional hearing assessment (tuning fork test) against the high frequency audiometer in detection of hearing loss
- Early intervention and prevention of diabetes mellitus induced hearing loss
- Increase awareness among health care providers and laypersons about involvement of hearing loss in diabetes. [12]

OBJECTIVES

- To study the prevalence of sensorineural hearing loss in patients with type 2 Diabetes Mellitus of adult age group.
- To study the risk factors associated with sensorineural hearing loss among patients with Type 2 Diabetes Mellitus.

REVIEW OF LITERATURE

DESCRIPTIVE ANATOMY OF LABYRINTH

ANATOMY OF LABYRINTH[13,14]

Inner ear contains within the temporal bone's petrous part. Bony Labyrinth is comprised of cochlea, saccule, vestibule, and membranous labyrinth which lies within the labyrinth. The membranous labyrinth comprises of cochlear duct, saccule, utricle, and 3 semicircular canals. The inner periosteum space between the bony labyrinth and membranous labyrinth is filled with perilymph which is low in potassium and rich in sodium similar to extracellular fluid, while membranous labyrinth contains endolymph which is potassium high just as intracellular fluid. These ionic composition and potentials provide the driving force for mechano transduction, hence essential for the inner ear primary function. In mammalian cochlea, organ of corti is the receptor organ, which transduces the sound stimuli to electrical signals, transmitting them to higher auditory pathway.

ULTRA STRUCTURE OF COCHLEA[16]

The cochlea nomenclature is a Greek literature derivation meaning snail. It comprises the labyrinth's anterior part and lies anteriorly to vestibule. It makes 2 ¾ turns and has a height of 5mm. The cochlea's coil turns about a central core also known as modiolous.

The base of the modiolus faces the inferior portion of the internal acoustic meatus, while basal coil forms the bulge seen in the middle ear medial wall called promontory.

Bony spiral lamina arising from the modiolous' edge and membranous spiral lamina extends from the bony spiral lamina edge to the cochlea's outer wall, which divides each coil into upper scala vestibule (superiorly) and scala tympani (inferiorly). At the apex of the cochlea, both the scala communicate through the helicotrema.

The middle ear and inner ear communication is through the oval window of the vestibule and stapes foot plate which sits on the oval window membrane respectively.

Perilymphatic fluid and subarachanoid space located in the posterior fossa, communicates through a bony channel called a cochlear aqueduct which is in the base of osseous spiral lamina.

Rosenthal canal accommodates the bipolar ganglion cells of the spiral ganglion. From the Rosenthal canal many tiny canals habernula perforating in a radial fashion through the osseous spiral lamina to its rim and carry fascicles of the cochlear nerve to the organ of corti.

BONY AND MEMBRANOUS LABYRINTH[17]

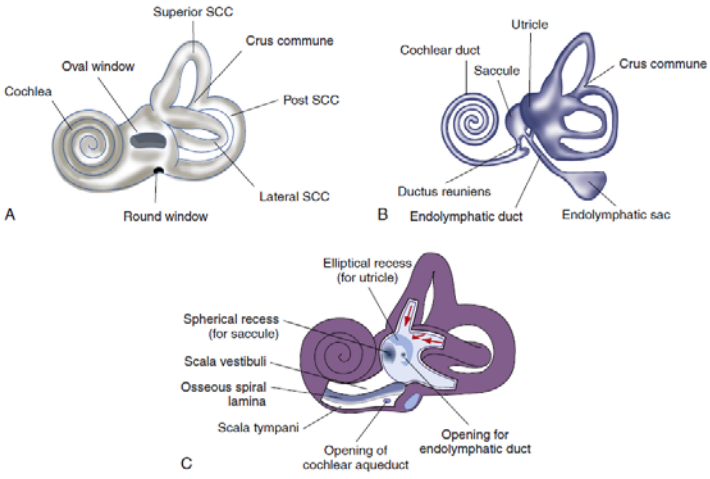


FIG 1- (A) Left Bony Labyrinth. (B) Left Membranous Labyrinth. (C) Cut section of Bony Labyrinth.

MEMBRANOUS LABYRINTH[16]

Scala Media: It is a spirally arranged tube lying on the upper surface of spiral lamina and its length varies between 29-40mm and it is triangular in cross section.

The floor of cochlear duct is formed by bony spiral lamina which separates into two ridges, upper ridge in the spiral limbus from which tectorial membrane originates; lower ridge gives rise to basilar membrane.

The sensory organ of hearing, Organ of Corti resides in the membranous labyrinth. Underneath the basilar membrane a layer of spindle shaped cells, tympanic cells, spiral vessels are present.

The length of the basilar membrane is 35mm and width increases from base to apex. It separates scala media and scala tympani. Spiral limbus seated on the top of spiral lamina serves as a point of attachment of Reissners membrane and gives rise to tectorial membrane. It is composed of type II collagen fibers. Tectorial membrane lies over the inner and outer hair cells. The border cells of Held lines the inner spiral sulcus.

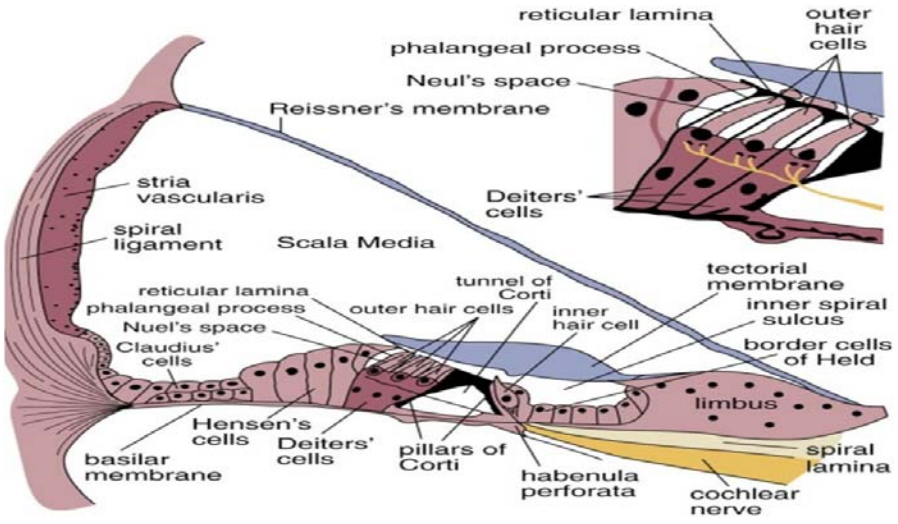


FIG 2 - Cross section of the Organ of Corti with major structures [17]

Organ of Corti pillars are between inner and outer hair cells, originating from spiral lamina and basilar membrane, finally converging at the top to form the tunnel of Corti.

Three rows of outer hairs cells lie lateral to the tunnel of Corti and is supported inferiorly by supporting Deiters cells. These cells have phalangeal process which make them project apically. Nuels space is a fluid filled space between outer hair cells and phalangeal process of deiters cells.

Cells that lie lateral to outer hair cells are: Hensen and Claudius cells. The Reticular lamina is also formed by phalangeal cells, phalangeal process of deiter's cells and the outer hair cell's superior surface.

Scala media is separated from the scala vestibule by the Reissner's membrane, which stretches from the bony spiral lamina up to the upper part of the lateral wall of cochlear duct.

2 layers of cells comprising the Reissner's membrane are: Mesothelial layer facing the scala tympani and the endothelial layer facing the scala media. Tight Junctions within each cellular layer are impermeable to small molecules and ions.

HAIR CELLS[15]

They transduce mechanical sound stimulus into the electrical stimuli to stimulate auditory nerve.

INNER HAIR CELLS [16]

There are 3500 inner hair cells forms a single row, running along the inner side of sensory organ. Inner hair cells have flattened or concave apical surface and flask shaped cell body.

The actin containing stereocilia are arranged according to their height which are on the inner hair cells. The inner hair cells comprises of two to three rows of stereocilia. They have dense rootlets therefore penetrating into the apical cuticular plate. They are connected together by lateral links and binded to the rows, across and sideways.

As the synaptic pole is at the basal end, hence afferent fibers make synaptic contact at the basal end. This region contains uncoated and coated membranous tubules vesicle.

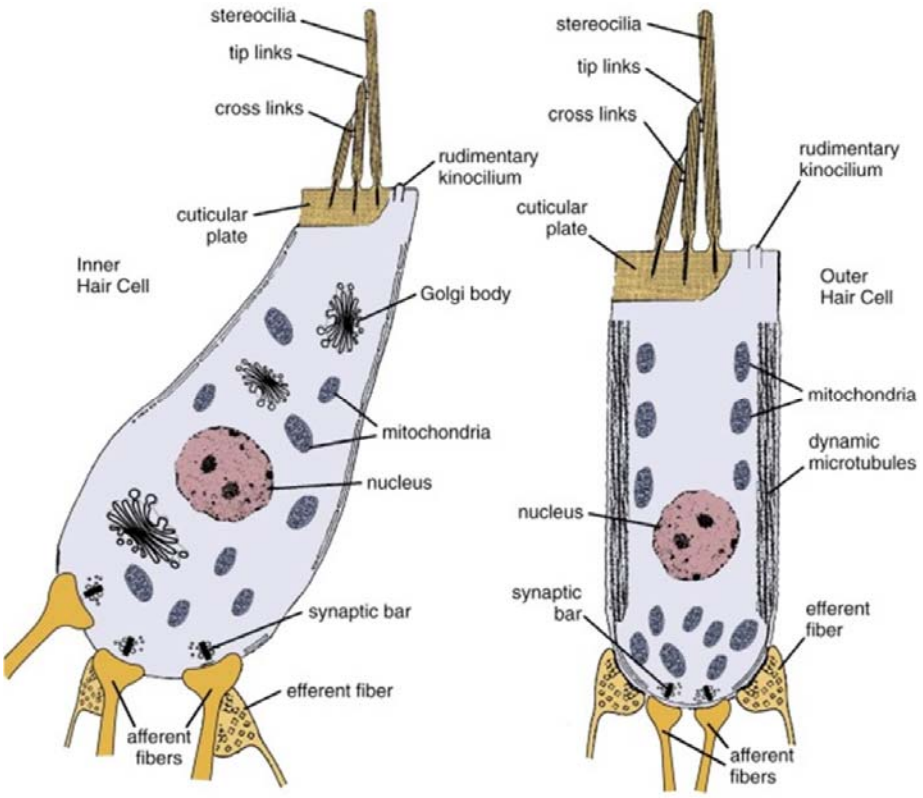


FIG 3 - Schematic diagram of inner (*left*) and outer (*right*) hair cells[14]

OUTER HAIR CELLS: The outer hair is of 3 to 5 rows, 12000 in numbers, and has a long cylindrical shaped body. Several rows of stereocilia are present at the Apex, whose surface is flattened and the stereocilia is arranged in patterns of 'V' or 'W' shaped with beveled tips. They contain actin filamentous core, with cross linking with plastin and espin proteins. The top of the stereocilia is in contact which may be in a floating manner with tectorial membrane. The OHC Base comprises of synaptic pole where afferent nerve fibers connect. The tectorial membrane arising from spiral limbus, extends over the organ of corti and attaches in proximity to Hensen cell.

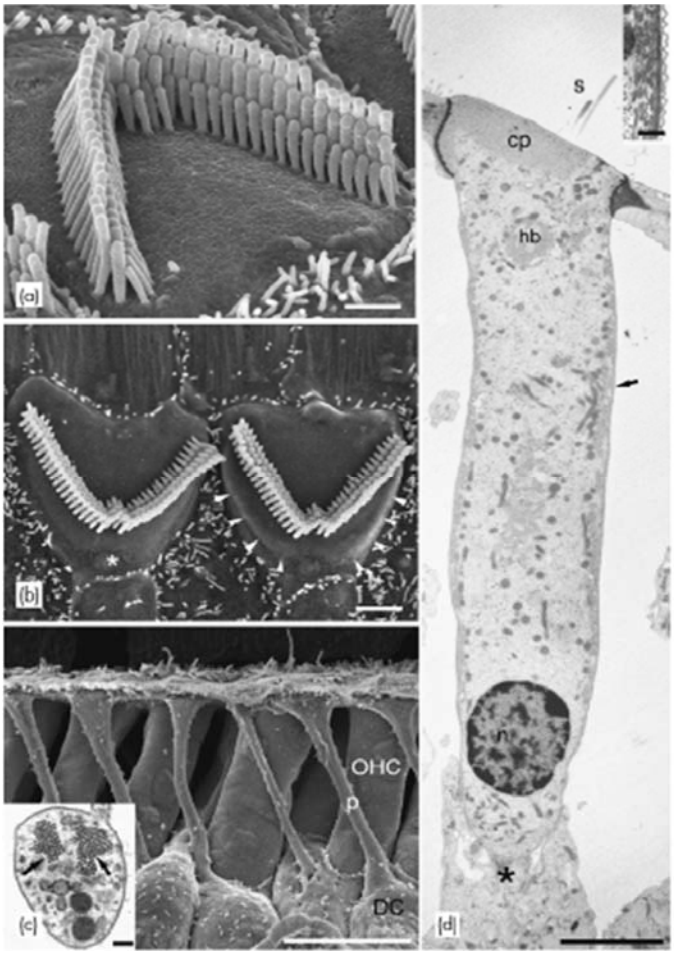


FIG 4 - OUTER HAIR CELLS UNDER ELECTRON MICROSCOPE[16]

THE LATERAL WALL OF COCHLEAR DUCT

Consists of three zones, superiorly stria vascularis, inferiorly spiral prominence and transitional zone intermediately and the spiral ligament. The three layers of stria vascularis have cells, they are as follows: Marginal, intermediate and basal cells. Marginal cells face scala media and connect with highly convoluted membranes of intermediate cells with tight junctions, which help in maintaining ionic composition of the fluids within the scala media. It also contains various enzymes and ion pumps.[18]

Inner and outer hair cells both are overlaid by the tectorial membrane which attaches to the spiral limbus and loosely connected to supporting cells. The OHC's stereocilia embeded in the tectorial membrane enhances the cochlear frequency sensitivity and also contributes to the tonotopic cochlear organization by helping create microphonics and mechanical amplification.

Two fluid systems in the cochlea are: Perilymph present between membranous and osseous labyrinth. It has high sodium and low potassium ion concentration which makes it similar to cerebrospinal fluid. On the contrary, Endolymphatic fluid is present within the membranous labyrinth, has high potassium and low sodium ion concentration maintained by stria vascularis. The Endolymphatic sac has communication with membranous labyrinth through endolymphatic duct and vestibular aqueduct. [15]

SPIRAL GANGLION [14]

The spiral ganglion located in the Rosenthal Canal contains afferent neuron cells bodies. The organ of corti release neurotransmitters that excite the dendrites.

Ganglionic neurons are of namely two types: type I and II. Type I neurons act on inner hair cell by innervating through a converging pattern while type II neuron acts on OHCs in a diverging pattern of innervation, these neuronal axons project to the brain stem, maintaining the tonotopic organization of organ of corti in the afferent system also.

INNERVATIONS OF COCHLEA:

Cochlear innervations are carried out by 3 types of fibers: autonomic, afferent and efferent fibers. Autonomic fibers supply the cochlear blood vessels. [19] Approximately 30000 auditory nerve fibers provide ascending information to central auditory pathway.

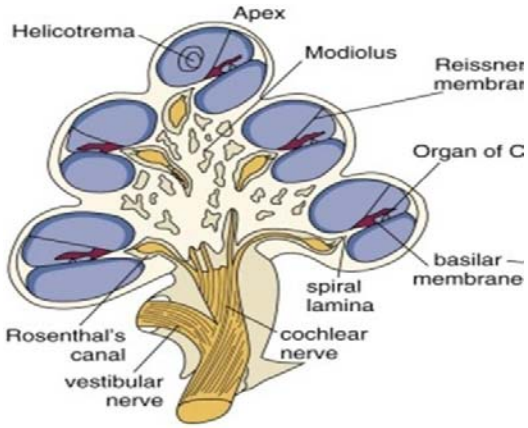


FIG 5 – Cochlear Nerve Passage seen in Cochlear cross section through the modiolus leading in to the organ of Corti

The auditory information transmitted through the cochlear nerve goes from inner and outer hair cells up to brain stem. Afferent fiber cell bodies forming spiral ganglion are located in the Rosenthal's canal within the modiolus. The hair cell is reached by passing through the habenulae perforatae. Majority fibers are large myelinated and project from the inner hair cells, while those unmyelinated 5-10%

communicate with OHCs. They reach spiral canal through modiolous and project to cochlear nucleus. The maximum diameter of the cochlear nerve reaches at the spiral canal base. As per the occupancy of the fibers, the low frequency are at the centre while the high frequency at the periphery of the nerve.

The initial auditory processing occurs when cochlear nerve's central process reaches the cochlear nucleus, which divides into ventral and dorsal nuclei.

The ventral nuclei are further subdivided into anteroventral cochlear nuclei (AVCN) and posteroventral cochlear nuclei (PVCN). The localization of frequency fibers are based on: low are ventrolaterally and high dorsomedially.

The auditory nerve afferents in the AVCN terminate in the principal projection neurons of the cochlear nucleoar complex and expands into very large terminal called bulb of Held. The very low frequency fibers branch to form two end bulbs. These end bulbs contain large number of neurotransmitter vesicles and helps in rapid transmission of signal AVCN, responsible for the original frequency selectivity and sensitivity or cochlear response. The cells in these nuclei analyze the pattern of sound and determine the intensity.

PVCN receives wide frequency range input and is responsible for the precise sound arrival time. The signal is then sent to the brain stem and midbrain motor nucleus and takes part in acoustic startle response. Dorsal Cochlear Nuclei's complex response determines sound type.

The cochlear nuclear complex auditory pathway gets divided into dorsal and ventral pathways. The dorsal pathway is a direct projection in to inferior colliculus while ventral projects to ipsilateral and contra lateral superior olivary complex, making binaural sound comparison possible.

Superior olivary complex consists of the following nuclei: 'S' shaped lateral olivary, medial olivary, medial nucleus of the trapezoid body with smaller periolivary. Medial olivary nucleus detects interaural difference in time. The 'S' shaped nuclei gets signals for excitation from the ipsilateral cochlear nuclei and inhibition from contralateral cochlear nuclei which helps detecting sound intensity difference. Superior Olivary complex helps in sound localization.

Through the lateral lemniscus the input from the brain stem auditory nuclei is projected to inferior colliculi. The two pathways emerge from the cochlear nuclear complex and join in the inferior colliculus and further analysis is made.

The inferior colliculi contain a central nucleus and outer region composed of dorsal cortex and external lateral cortex. The external portion receives information from cerebral cortex. A tonotopic map is made in the inferior colliculi, by arranging high frequency bands towards the midline of the brain and low frequency bands towards outside.

This map is the basis for recognizing patterns in sound and sound localizations. Inferior colliculus also involved in motor response like controlling middle ear muscle, turning head or moving eye in response to sound.

The thalamus receives information from the inferior colliculi. Thalamus has medial geniculate body, posterior nucleus and reticular nucleus, which are involved in auditory function. The ventral division is organized tonotopically into low frequency layers and receives input from the central nucleus of inferior colliculus. The dorsal division is not tonotopically organized and medial division receives multimodal inputs.

From the ventral division of the medial geniculate nucleus, fibers project to Brodmann area 41 within the lateral fissure of the temporal lobe and dorsal division project to non-primary areas around A1.

Auditory area also organized into ISO frequency layers, arranged tonotopically, the low frequency sound in the rostral end and high frequency in the caudal end. Most cells in A1 respond to binaural stimulation. The main function of primary auditory cortex is sound localization. Areas around A1 have complex response and it detects specific delays and simultaneous occurrence of harmonically related frequencies.

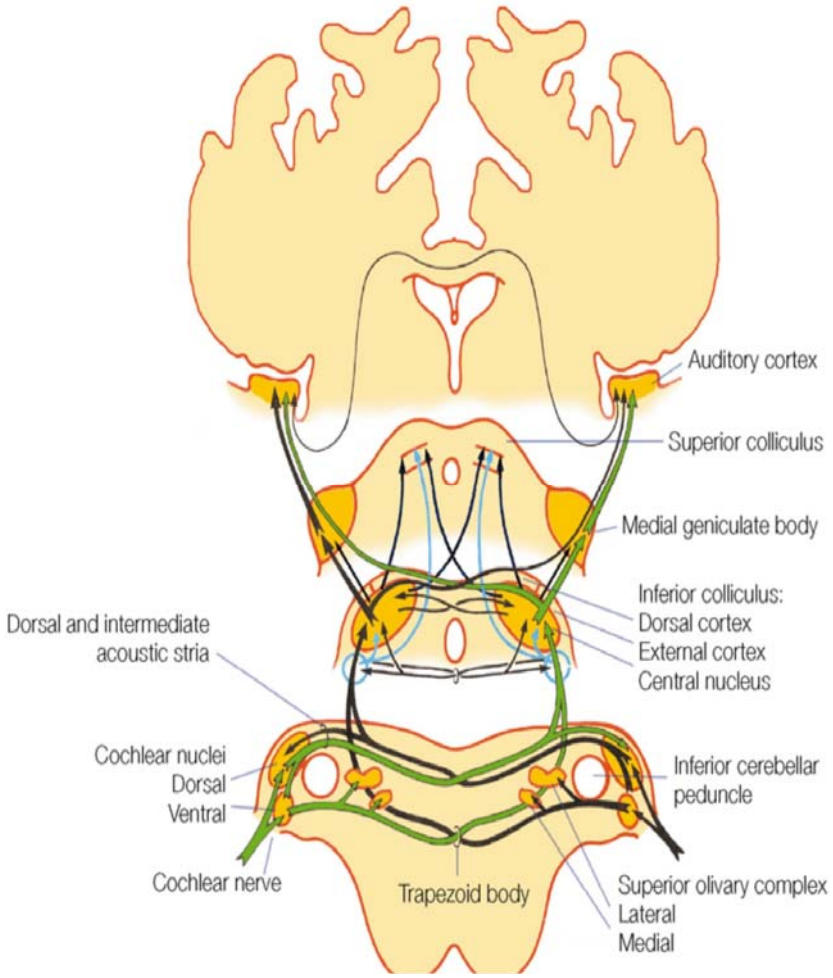


FIG 6 - ASCENDING AUDITORY PATHWAYS [16]

DESCENDING PATHWAYS

The descending pathway may participate in attention level and anticipation of signals. The major one is olivocochlear feedback loop which originate in SOC and projects back to cochlea. It projects to outer hair cells and is called medial efferent system. It helps in suppression of outer hair cell mobility to make the cell less sensitive and provides protection from loud sounds. The lateral efferent system from lateral superior olivary complex supply inner hair cells which helps in sound localization and binaural comparison.

VASCULAR SUPPLY [15] [17]

Arterial Supply:

Two arteries branch from common cochlear artery. They are:

1. Main cochlear which supplies the modiolus particularly at upper basal, middle and apical coils.

2. Cochlear ramus of the vestibulocochlear artery, which supplies one-fourth of the basilar coil and modiolus. Once within the modiolus the arteries branch to form an external and an internal radiating arteriole each. The external one travels within the inter-scalar septum to the lateral wall of the coil. The internal radiating arteriole supplies the medial wall of the coil and organ of Corti.

Venous Supply:

The venous drainage of inner ear is through the veins of vestibular and cochlear aqueducts. The primary drainage of cochlea is by anterior and posterior spiral veins. The posterior vein drains the infero-medial aspect of cochlea mainly

spiral ganglion, scala media and scala tympani. The anterior spiral vein drains the supero-lateral aspect mainly scala vestibuli and osseous spiral lamina. These veins enter the common modiolar vein which enters the vein of cochlear aqueduct, tributary of inferior petrosal sinus.

PHYSIOLOGY OF SOUND TRANSMISSION [16]

Sound is transmitted to the inner ear through the middle ear ossicles, When the sound waves strike the tympanic membrane, it increases tympanic membrane pressure in a frequency sensitive way. An efficient middle ear impedance transformer will change the low pressure high displacement vibration of the sound waves into low displacement and high pressure vibrations.

A compression wave is developed in the inner ear fluid due to the vibration of the stapes footplate, which travels across the scala vestibuli, around the helicotrema, and out across the scala tympani toward the round window. An inward motion of the stapes causes an outward motion of the round window. This compression wave travels across the scala vestibule. The pressure in the scala vestibuli is higher than the pressure in the scala tympani. This set up a pressure gradient, which causes the cochlear partition to vibrate. A travelling wave is set up in the basilar membrane. This movement is from base to apex.

A shearing motion is developed between reticular lamina and tectorial membrane. This shearing force causes a deflection of the hair cell stereocilia. This reaches maximum at a particular place of the basilar membrane and decays.

Molecular structure at that location of the basilar membrane determines the characteristic frequency. The cochlea is tuned for higher frequency upto 20kHz. This tonotopic gradient is manifested in hair cell height also.

TRANSDUCTION BY HAIR CELLS [20]

The stereocilia on the hair cells are rigid and braced together with cross links, so they move as a stiff bundle. When stereocilia is deflected in the direction of tallest stereocilia, the tip links are stretched and result in the opening of ion channels.

Ca^{2+} ions play an important role in the opening of ion channels. The relative motion between tectorial membrane and recticular lamina produce a stimulus which is coupled to stereocilia. This results in opening of ionic channels of stereocilia, Na+, K^+ and $Ca2^+$ will enter the cell.

The apical surface which faces the endolymph has high positive potential of +80mv and high K^+ ion concentrations. Inside the cell, negative intracellular potentials, - 45mv and - 70mv for inner and outer hair cells respectively is maintained, which combine to give a total of 125mv and 150mv for inner and outer hair cells of potential drop across the channels.

The K+ ions from the endolymph enters the cell and makes the cell more positive inside and when channels shut cells become more negative during opposite phase of sound wave. K+ is the main ion involved in transducer mechanism. The main energy comes from the stria vascularis by ion pumping. All these mechanism produce a receptor potential and neurotransmitters are released from the basolateral membrane of inner hair cell.

INNER HAIR CELLS (IHC) - ELECTRICAL TRANSDUCTION

The inner hair cells convert mechanical stimulation into electric signals which is transported to brain. This transduction occurs near the tips of steriocilia. Because of shearing motion between adjacent stereocilia, it is transmitted to all hair cells. This leads to opening of the channel protein upon stimulation and leads to depolarization of the cell. This is followed by hyper polarization of the cell where stereocilia are deflected to shorter stereocilia. In these two processes, rapid channel closure and slow adaptation occurs. IHC detects movement of basilar membrane and responds to velocity changes. The basolateral wall of IHC acts as a capacitor.

ELECTRICAL RESPONSE OF OUTER HAIR CELL (OHC) [16]

OHCs are mainly for amplification and sharp tuning of basilar membrane at a low pressure level and act by changing its length. The contraction of OHC due to stimulation leads to depolarization pulling the basilar membrane. OHC length elongation causes hyperpolarisation. Prestin is the OHCs' motor protein, responsible for its actions. Anions are dissociated on depolarization, decreasing the surface area causing contraction. On the contrary, surface area increases at hyperpolarisation.

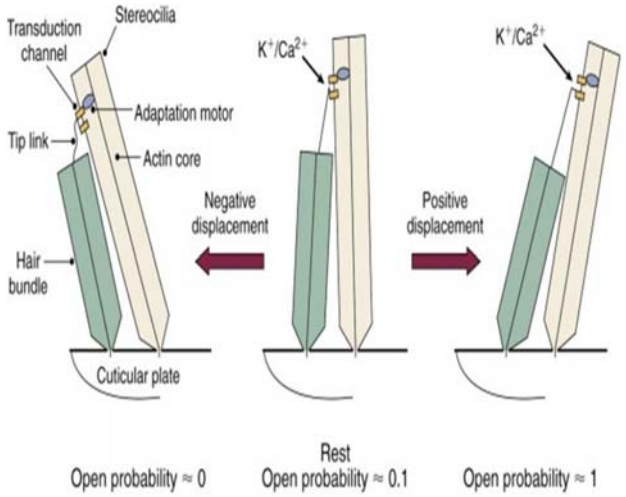


FIG 7 - HAIR CELL SIGNAL TRANSDUCTION SHOWING ROLE OF TIP LINKS [15]

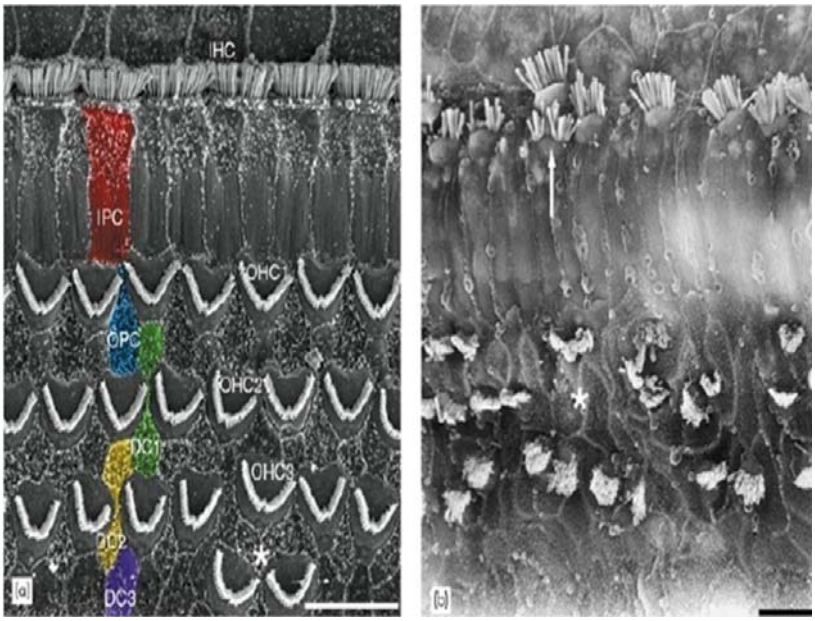


FIG 8 - UPPER SURFACE OF ORGAN OF CORTI SHOWING HAIR CELL ON ELECTRON MICROSCOPIC PICTURE: Single row of inner hair cells (RED, IHC). Four rows of inner and outer pillar cells (OPC), outer hair cells (OHC), and deiters cells (DC3) [16].

ELECTRICAL RESPONSE OF THE COCHLEA [17]

Four types of potentials are: 3 from the cochlea and 1 from CN VIII fibres, which are:

1. Endocochlear potential: It is a direct current (DC) potential recorded from scala media. It is +80 mV and is generated from the stria vascularis by Na+/K+-ATPase pump and provides source of energy for cochlear transduction (Figure 9). It is present at rest and does not require sound stimulus. This potential provides a sort of "battery" to drive the current through hair cells when they move in response to a sound stimulus.

The resting potential in scala media is +80mv known as endolymphatic potential and hair cell has –80mv, So that there is potential difference of 160mv between scala media and interior of hair cells.

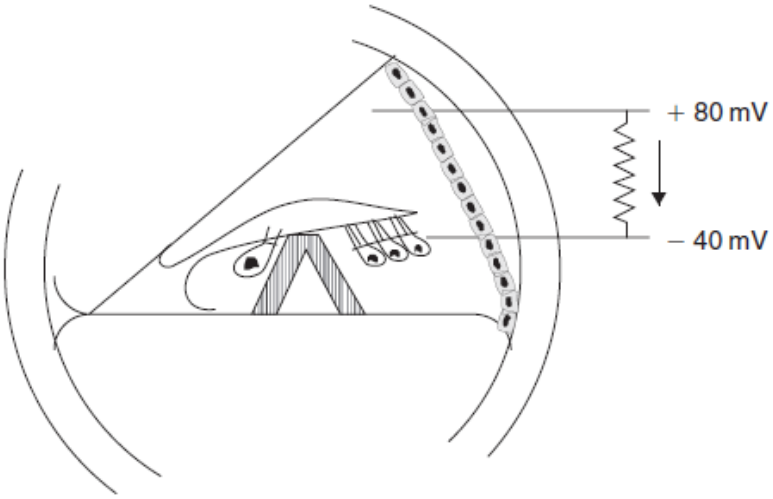


FIG 9 - Davis' battery model of cochlear transduction.

Scala media has a DC potential of 180 mV. Stimulation of hair cells produces intracellular potential of 240 mV. This provides flow of current of 120 mV through the top of hair cells

2. Cochlear microphonic (CM): When basilar membrane moves in response to sound stimulus, electrical resistance at the tips of hair cells changes allowing flow of K+ through hair cells and produces voltage fluctuations called cochlear microphonic. It is an alternating current (AC) potential.

The cochlear microphonics is the main component and confers upon the cochlear potentials. It has two elements cochlear microphonics I, which is oxygen dependent and cochlear microphonics II, which is oxygen independent. Cochlear microphonics is generated at the hair cell tectorial membrane area by piezoelectric effect due to deformation by sound vibration of the hair or hair cell bodies.

3. Summating Potential (SP): It is a DC potential and follows "envelope" of stimulating sound. It is produced by hair cells. It may be negative or positive, depends on the stimulus. It is the distortion component of the outer hair cell response and small contribution from inner hair cells also. It reaches maximum amplitude after the onset of stimulus.SP has been used in diagnosis of Ménière's disease. It is superimposed on VIII nerve action potential.

Both CM and SP are receptor potentials as seen in other sensory end-organs. They differ from action potentials as follows: (i) Graded instead of all or none phenomenon, (ii) No latency, (iii) Non-propagated and (iv) No post response refractory period.

4. Compound Action Potential or Neural Potential:

It is produced at the onset of stimulus from the massed action potential of auditory nerve.

RESPONSE OF AUDITORY NERVE FIBERS

Action potentials are generated in the auditory nerve fibers, when neurotransmitters are released at the base of inner hair cells. The auditory stimulus is excitatory. The transmitter release and action potential generation is in synchrony with the each cycles of stimulus.

When the sound stimulus intensity increases, the basilar membrane vibration's mainly amplitude also increases. This results in activation of inner hair cells and the auditory nerve firing rate increases. There is also non linear mechanical response present in cochlea.

Physiology of hearing

Humans can perceive sound in a range of 16 and 20000 Hertz. The signal is conducted and amplified by the outer and middle ear and finally reaches the inner ear. Here, as a function of the hair cells, the mechanical stimulus is translated to an electrical signal, which runs across the hearing pathway.

THEORIES OF HEARING

Telephonic Theory (Rutherford):

Entire cochlea responds as a whole to all frequencies instead of being activated in a plate by lace basis. Here sounds of all frequencies are transmitted as in a telephone cable & frequency analysis is performed at a higher level.

Place Theory (Helmholtz):

Basilar membrane has different segments that resonate to different frequencies.

Place-Volley Theory (Lawrence):

Combining both place and volley theory attempts to explain sound perception and transmission.

Volley Theory (Wever):

Several neurons acting as a group can fire in respond to high frequency sound even though none of them individually could do it.

Travelling Wave Theory (Georg Von Bekesy):

Sound stimulus produces a wave-like vibration of basilar membrane starting from basal turn towards apex of cochlea. It increases in amplitude as it moves until it reaches a maximum and dies off. Sound frequency is determined by point of maximum amplitude. High frequency sound causes wave with maximum amplitude near to basal turn of cochlea. Low frequency sounds have their maximum amplitude near cochlear apex.

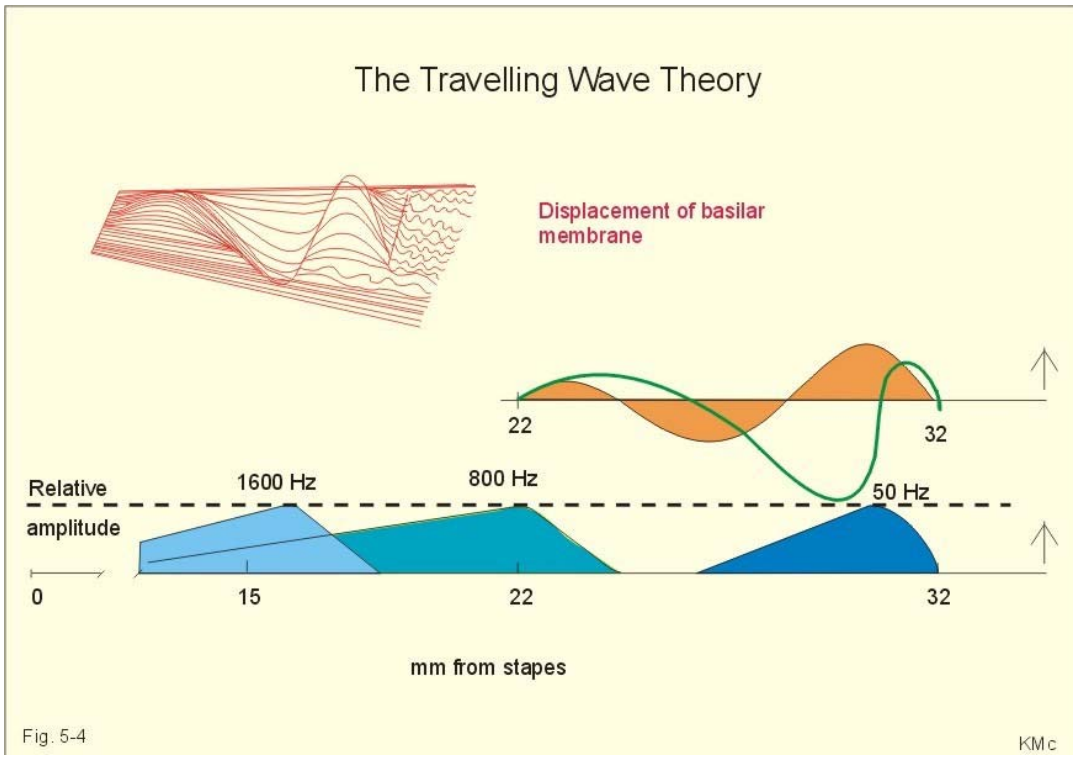


Figure 10: Travelling Wave Theory

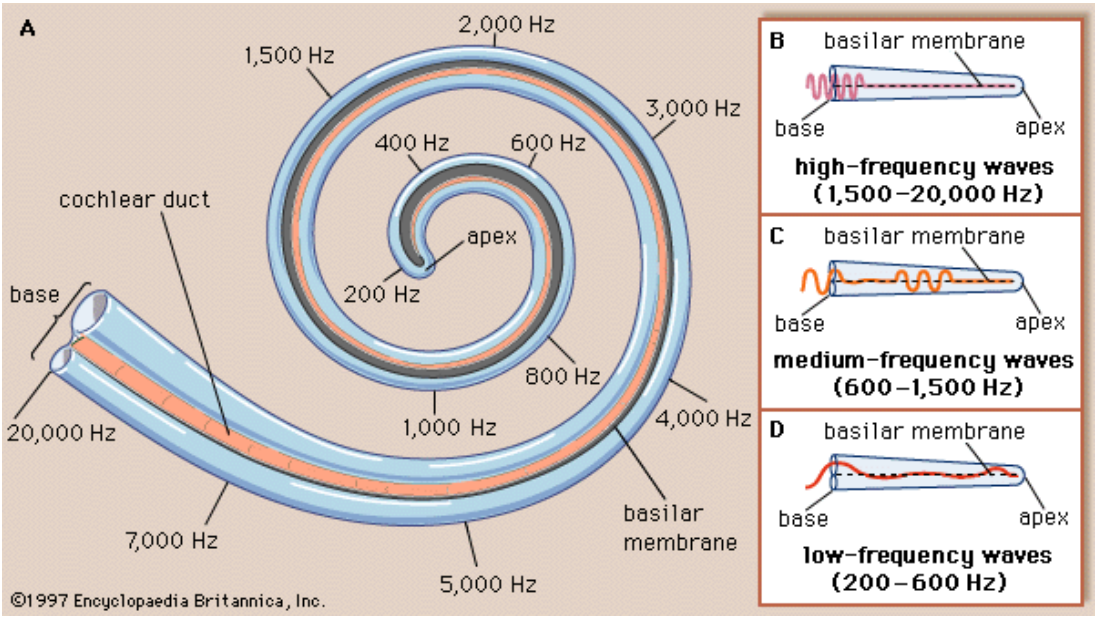
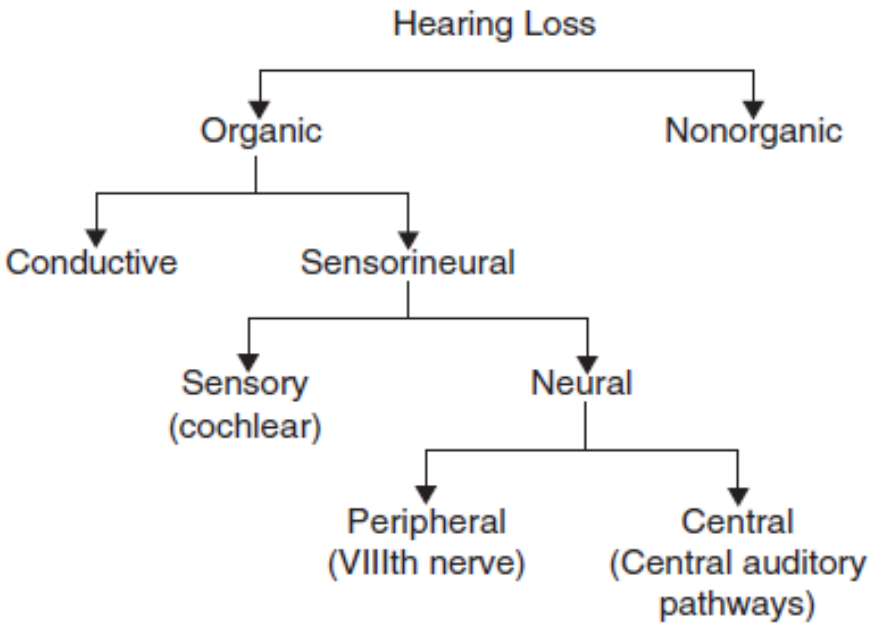


Figure 11: Representation of different frequencies in cochlea

HEARING LOSS [17]



Types of hearing loss

Based on the hearing measurements, hearing loss can be conductive, sensorineural and mixed. In the conductive type, damage of the conducting system can be located anywhere from the pinna until the stimulus reaches the hair cells.

SENSORINEURAL HEARING LOSS

In the sensorineural form, either lesion of the inner ear (cochlear) or VIIIth nerve or central auditory pathways (retrocochlear), may be present at birth (congenital) or start later in life (acquired).

CONGENITAL: It is present at birth and is the result of anomalies of the inner ear or damage to the hearing apparatus by prenatal or perinatal factors.

ACQUIRED: Appears later in life. Genetic hearing loss may manifest late (delayed onset) and may affect only the hearing, or present as a syndrome with multi-system involvement (syndromal).

Sensorineural Hearing Loss Characteristics are:

1. Positive Rinne test, i.e. AC > BC.
2. Weber lateralized to better ear.
3. Bone conduction reduced on ABC test.
4. More often involving high frequencies.
5. No gap between air and bone conduction curve on audiometry (Figure 12).

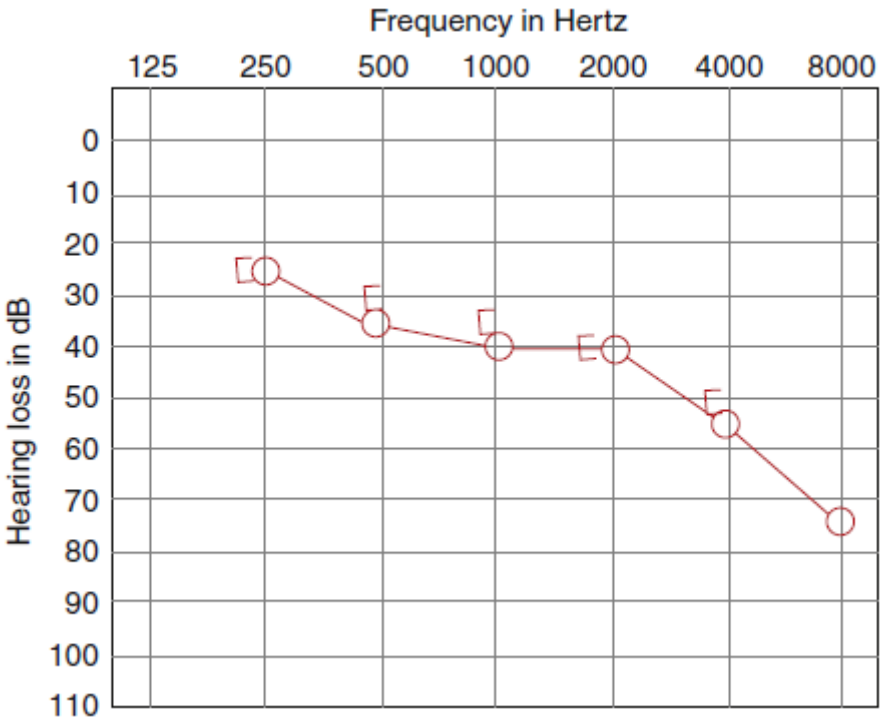


FIG 12 – RT EAR AUDIOGRAM showing sensorineural loss with no A–B gap[17]

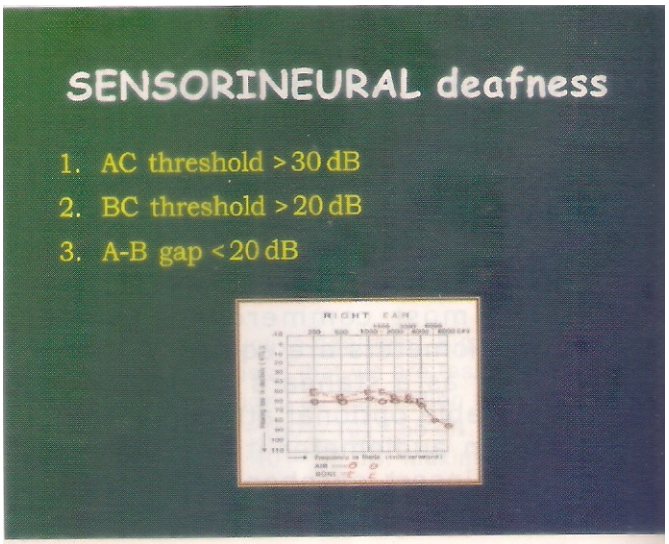


FIG 13 - SENSORINEURAL DEAFNESS[10]

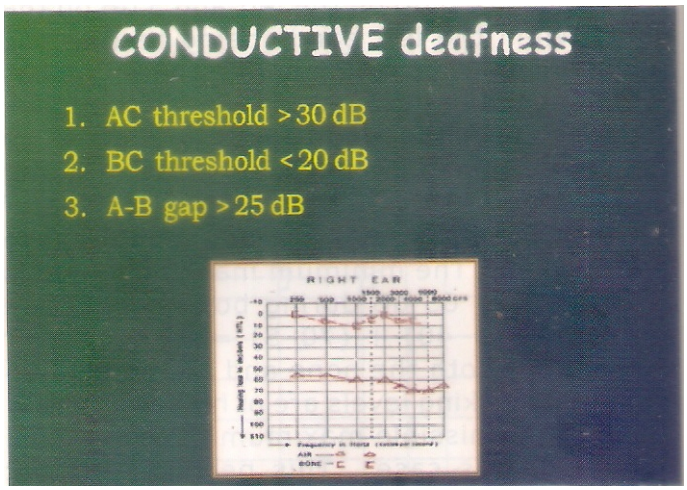


FIG 14 - CONDUCTIVE DEAFNESS[10]

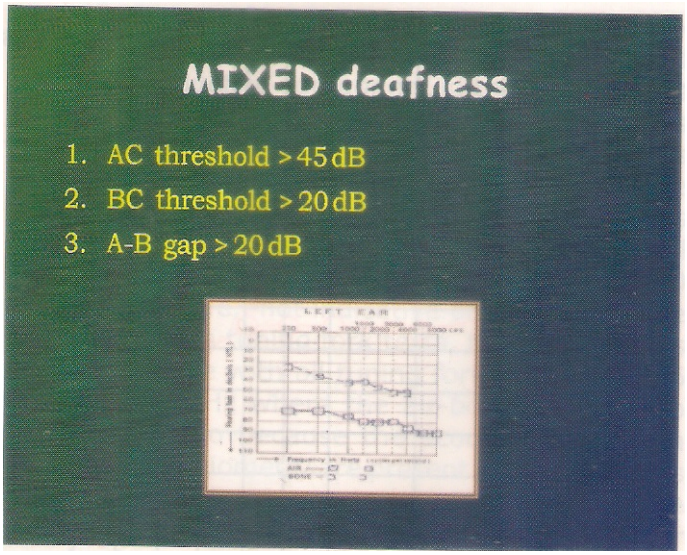


FIG 15 - MIXED DEAFNESS[10]

Etiology of sensorineural hearing loss [17]

Sensorineural hearing loss can be present even at birth or may develop during later stages of life. The cause of congenital sensorineural hearing loss remains unclear in 57 %, with 18% of acquired origin and 25% with genetic background. Usually, functional failure of the hair cells can be found in these patients, but in 20% of the cases, bony malformation of the cochlea can be detected as well.

Hearing loss due to environmental factors can develop in any stage of life. Among these factors, usage of drugs with ototoxic side effects like aminoglycoside antibiotics (kanamycin, gentamicin) or diuretics (furosemide, ethacrynic acid) is very common.

Degree of hearing loss

Hearing loss can also be classified according to its severity: Mild, moderate, severe and profound hearing loss as well as complete deafness can be distinguished. The type of rehabilitation is determined by the degree of hearing loss.

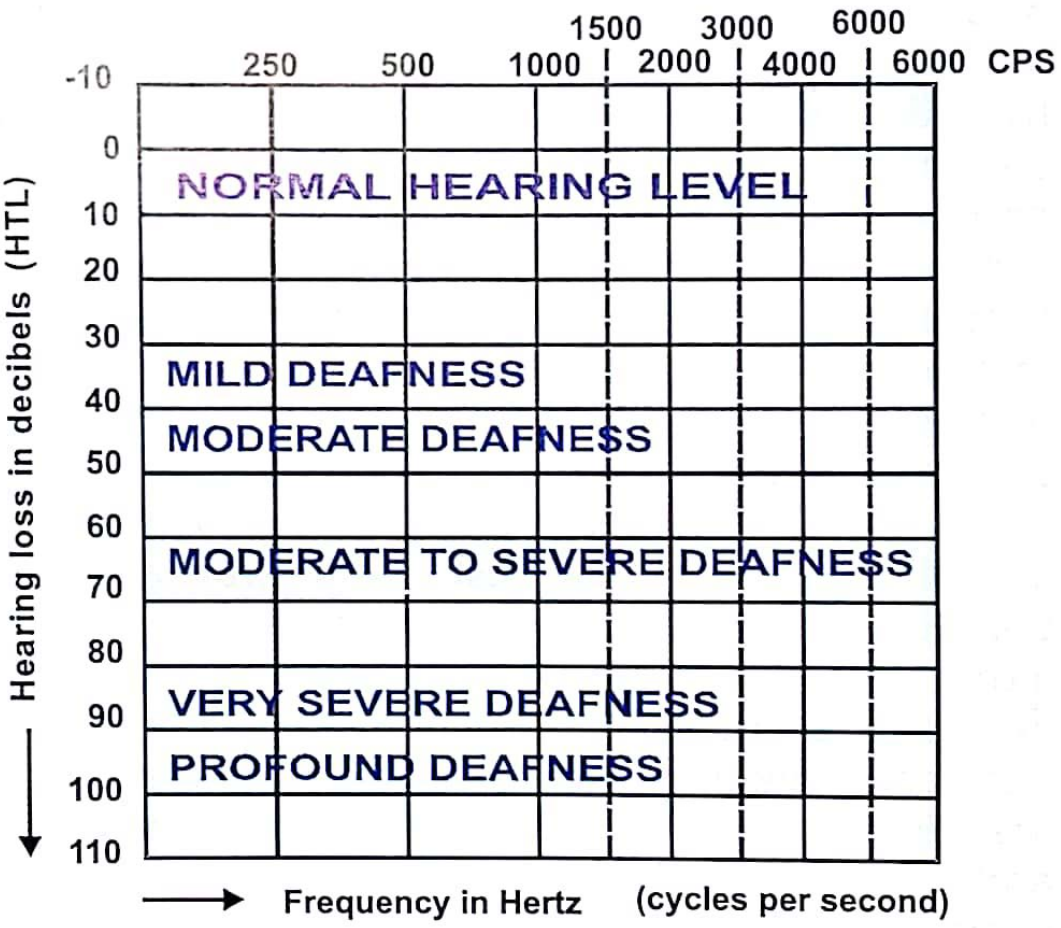


FIG 16 – GRADING OF DEAFNESS[17]

Pathogenesis of Sensorineural Hearing Loss in Diabetics[14]

The three main theories in the pathogenesis of sensorineural hearing loss in diabetic patients are microangiopathy of cochlear vessels, neuropathy of auditory nerve and alteration in inner ear glucose levels. The angiopathy of the inner ear leads to deafness either by diminution of transport of nutrients through thickened capillary walls or by diminution of blood flow through narrowed vasculature. The primary diabetic neuropathy may be due to accumulation of

Sorbitol within the nervous tissue, the secondary neuropathy is due to decrease in the blood flow of vasa nervosum causing secondary degeneration of eighth cranial nerve. The inner ear utilizes glucose to produce energy and changes in the glucose concentration in the inner ear may alter hearing. Recently it is been recognized that diabetics with mitochondrial DNA abnormalities are associated with sensorineural hearing loss. The pathogenesis being disruption of energy production which thus compromises tissues with high metabolic energy requirements like labyrinth of the ear.

Histopathological changes seen in inner ear in diabetes mellitus: [15]

Microangiopathic changes with PAS positive precipitates in stria vascularis, internal auditory artery, modiolus, vasa nervosum of eighth nerve and spiral ligament.

There was also demonstration of hemorrhage in endolymph and perilymph along with loss of hair cells, atrophy of spiral ganglion demyelination of eighth nerve and degenerative changes in brain stem and cerebellum.

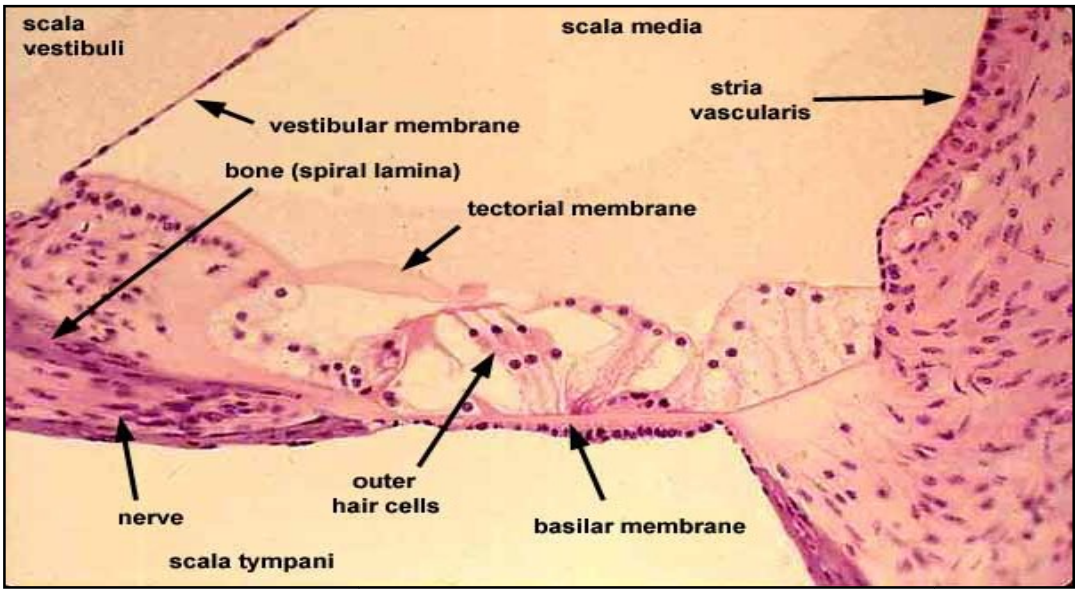


Figure 17: Normal Organ of Corti

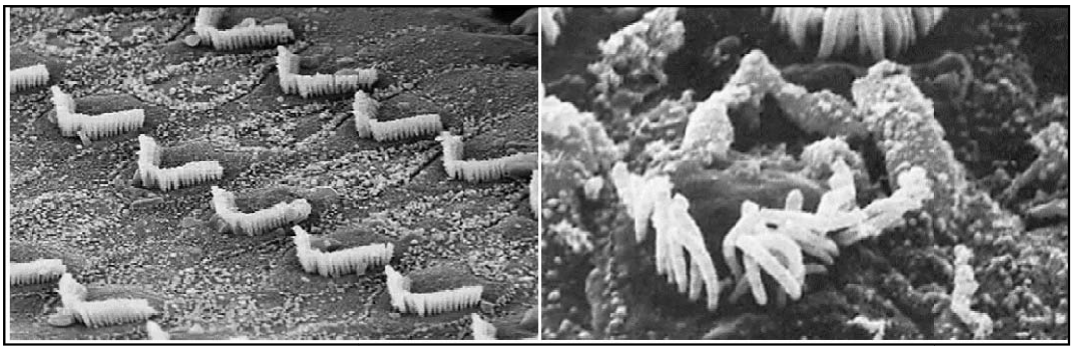


Figure 18: Electron Microscopy Showing Presence of Healthy & Damaged Hair Cells

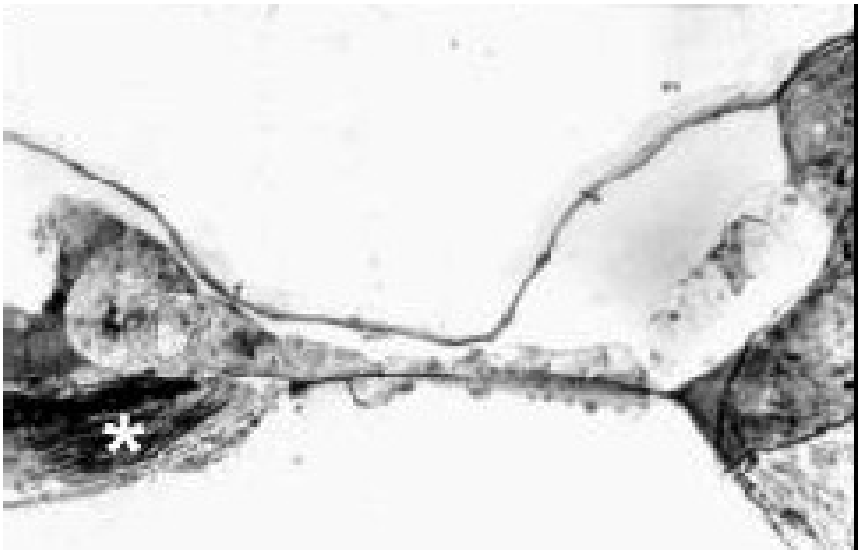


Figure 19: Organ of Corti affected by Diabetes Mellitus

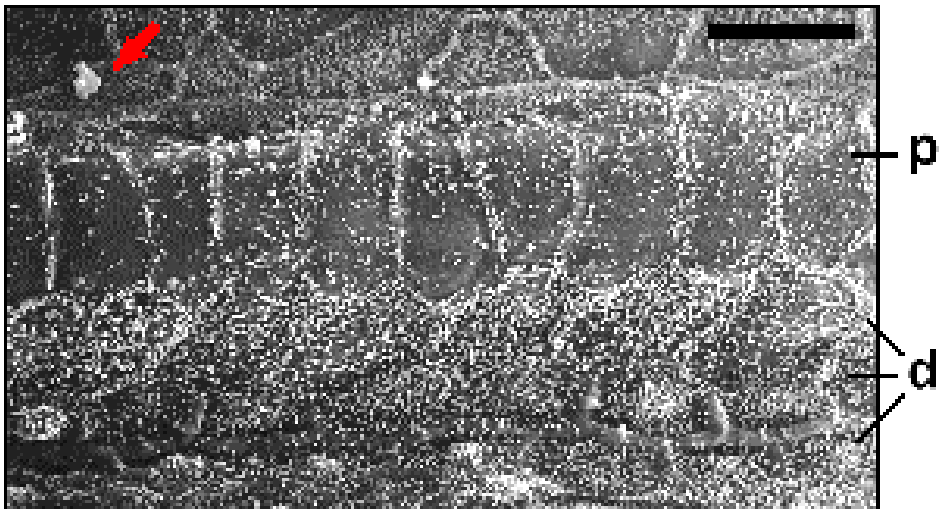


Figure 20: Loss of Hair Cells Under Electron Microscope

NEUROPATHY IN DIABETES MELLITUS

Neuropathy affects around 50% of diabetics during their lifetime exhibiting as polyneuropathy, mononeuropathy or autonomic neuropathy. The development and severity of neuropathy is determined by the duration of diabetes and degree of metabolic control [21]. Diabetes mellitus affects both myelinated and non-myelinated nerve fibers. In diabetics of short duration institution of insulin therapy improves the impaired motor conduction velocity [22].

Loss of myelin, corresponding to segments of nerve underlying individual Schwann cells has been found in diabetes. There is also a possibility that diabetic neuropathy affects primarily either the cell body or axon and that segmental demyelination is a secondary event.

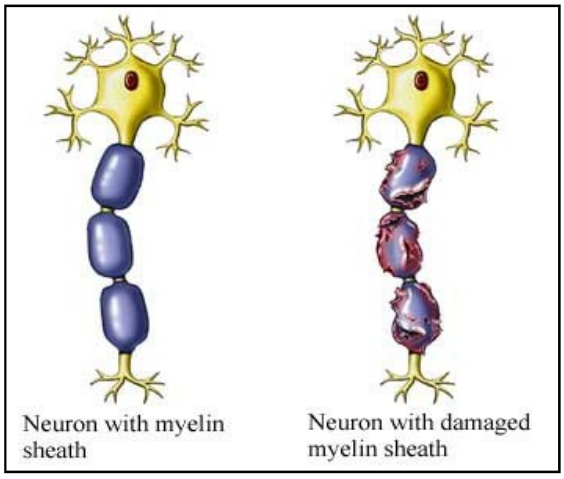


Figure 21: Normal (Left) and Diabetic (Right) Neuron Comparison

The structural changes in the neurons of peripheral nervous system due to age related pathologies show loss of cells and axons, decreases in size of neurons and axons and pre-degenerative changes [23].

There is threefold increase in prevalence of parasympathetic and sympathetic neuropathy in patients with diabetic neuropathy, ten years after the initial diagnosis of the same [21].

The proposed abnormalities implicated in the pathogenesis of diabetes neuropathy are:

Vascular Etiology of Neuropathy in Diabetes Mellitus:

1. Basement membrane thickening and reduplication.
2. The endothelial cell swelling and pericyte degeneration
3. Occlusive platelet thrombi
4. Closed capillaries
5. Multifocal ischemic proximal nerve lesions
6. Epineural vessel atherosclerosis
7. Increased oxygen and free radical activity
8. Reduced endothelial nitric oxide activity
9. Nerve hypoxia
10. Advanced glycation of vessel wall

INVESTIGATIONS [24]

Audiometric testing is the primary most diagnostic tool of Diabetes Induced Hearing Loss.

Diagnostics of hearing loss/ hearing measurements:

Subjective measurements: Pure tone and speech audiometries are the most common subjective hearing measurements. For proper result, active attention of the person is required. Measurement for children or non-cooperating subjects cannot be achieved.

Objective measurements: No active attention of the patient is needed in objective measurements. Brainstem evoked response audiometry (BERA) or electrocochleography (ECoG) are mainly used for children or in animal studies. With these methods, objective hearing threshold or place of damage along the pathway can be defined.

PURE TONE AUDIOMETRY [10]

In pure tone audiometry, we test the hearing sensitivity of a subject only for pure tone sounds. But the sounds that we hear in nature are complex sounds and not pure tone sounds. A complex sound is composed of sounds of various frequencies and intensities. However, all complex sounds are nothing but a mixture of different pure tone sounds and can be mathematically broken into their waves of different frequencies by a process known as Fourier's Analysis. Hence, by estimating the pure tone hearing threshold in a number of frequencies as we do in PTA, we can have a fairly accurate idea of the hearing sensitivity of a subject for complex sounds.

It is often felt by some clinicians that since the clinical voice tests and a perfectly done serial tuning fork test can give us a fairly accurate assessment of hearing loss, both qualitatively and quantitatively in a faster and much simpler way, the rigors of a pure tone audiometry test are a waste of time and energy and do not give us much additional benefit. This however is not true. The pure tone audiometry

test, in addition to providing a quantitative measurement of the subject's hearing, also gives a scientific credibility to the results of the clinical tests. Moreover, the audiometry test establishes a baseline for any changes which may occur as a result of treatment or due to the natural progression of the disorder.

The aims of performing the PTA test are to ascertain:

a) Whether the subject has any definite hearing loss,

b) Whether the hearing loss is conductive/ sensorineural/mixed,

c) If sensorineural, then whether it is cochlear or retrocochlear

d) The degree of hearing dysfunction.

Though the PTA test does not determine the exact pathology of the disorder, nevertheless, by broadly classifying the deafness into three categories, i.e., conductive/sensorineural/mixed, it does help to limit the number of possibilities in the diagnostic work-up.

PTA is a science as well as an art for ascertaining the hearing acuity of a subject for pure tone sounds of various frequencies. The result, when plotted graphically, is called a pure tone audiogram. The instrument used for this is an electronic device called pure tone audiometer.

Pure tone audiometer consists of an audio-oscillator which generates pure tone sounds of various frequencies usually at regular steps of 125, 250, 500, 1000, 1500, 2000, 3000, 4000, 6000 and 8000 Hz. The tones are attenuated by an attenuator dial which is marked in decibels and graduated in 5dB steps from -10 to 110dB.

Most modern sophisticated audiometers however have graduations in steps of 2 dB and 1 dB also in addition to the 5 dB steps, which is sufficient for clinical audiometry tests.

The audiometer is connected to standard and specified earphones or to a bone conduction vibrator through which the sound is presented to the subject's ears. The ear phones which are placed over the ears or may be intra-aural insert ear-phones which are deep inside the external auditory meatus. The audiometer is operated by means of a noiseless switch called interrupter which can introduce or interrupt a tone.

PROCEDURE OF PTA [10]

Conduction Tests Requisites

- **Calibration of Instrument**
- **Reasonably Noiseless Test Environment**
- **Patient Cooperation:** As PTA is a subjective test, patient response is essential for obtaining proper results.
- **Position of Headphones (for Air Conduction Tests):** Diaphragm of headphone must be placed exactly over the opening of the external auditory meatus. Ensuring the canal is void of any foreign object or wax. Avoidance of ear canal collapse is necessary.

Placement of Bone Conduction Vibrator (for Bone Conduction Tests):

Mastoid Placement: Most sensitive area over the mastoid bone is examined over which the vibrator is placed particularly. The examining ear is left open, while the

other is masked with the help of the earphone. This helps in creating an osseotympanic bone conduction sound, called occlusion effect, which is absent is conductive pathologies, but present in normal and sensorineural pathologies.

Frontal Placement: Vibrator is placed over the forehead. More specific and less sensitive compared to mastoid placement. Both cochlea are stimulated equally, while masking the ear which is not tested.

PTA Test Technique (for Air and Bone Conduction)

- Detailed clinical history obtained
- Frequency testing of better ear performed to obtain adequate octaves.
- The threshold is ascertained in each frequency by 5-up-10-down method after the patient has been introduced to the tone at suprathreshold level.

MASKING [10]

Preventing the contra lateral ear from being stimulates when testing the ear to be examined, separately and individually, is known as masking. If masking is not done, a false threshold of the tested ear due to stimulation of the non-test ear will be obtained, which is termed as shadow curve. Contralateral Masking means presenting a noise into the non-test ear so that the non-test ear is acoustically blocked and does not participate in the hearing test.

FLOW CHART FOR MASKING

STEP I

MASKING NECESSITY DETERMINATION

BC Test: Always mask C/L ear

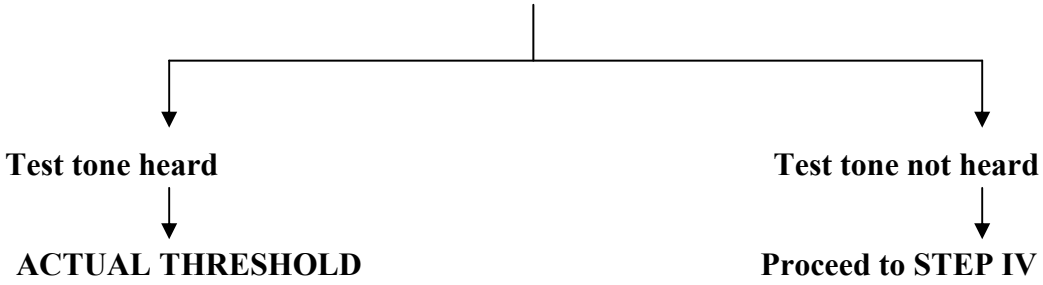
AC Test: Always mask C/L ear if test ear is the comparatively poorer ear and ≥45db sounds are used

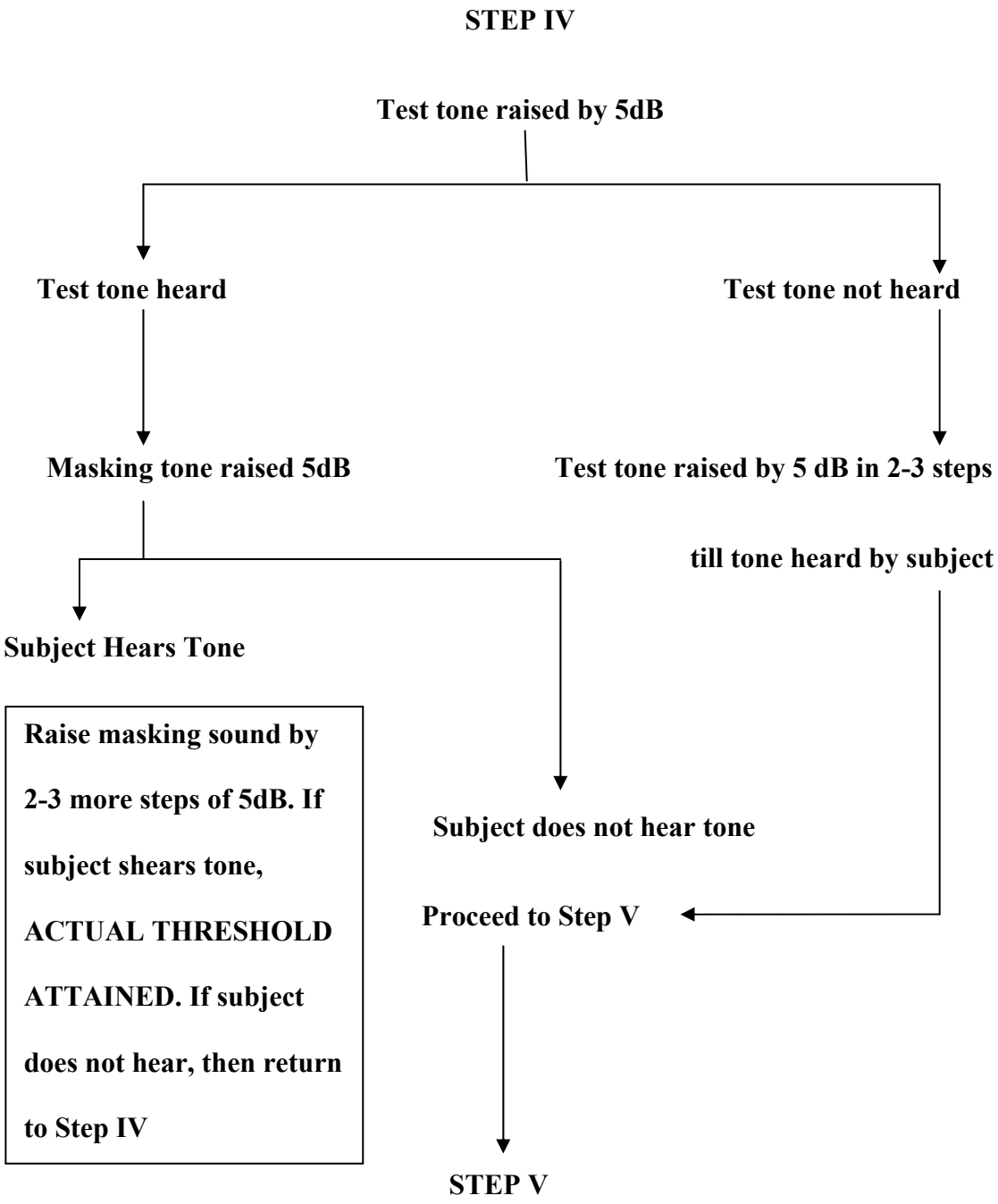
STEP II

Obtaining AC threshold (unmasked) in both ears

STEP III

Non test ear presented with masking sound at 15dB above non-test ear AC threshold and test tone presented at unmasked threshold in test.





Raise test-tone and masking alternatively in 5dB steps till subject continues to hear the test tone in spite of 2-3 increments of 5dB masking noise.

OBTAINING ACTUAL THRESHOLD

LIMITATIONS AND SHORTCOMINGS OF PTA

1. Audiograms are often inaccurate due to improper technique, test condition, test instrument, examiner.
2. Subjective and time consuming test.
3. Does not assess other salient features of hearing as it assesses hearing at threshold only.
4. Only pathology nature is identified as it gives basic qualitative and quantitative analysis.
5. Bone conduction test has challenges in giving out the true sensorineural reserve.

DIAGNOSIS

- History of preexisting diabetes mellitus for a long term and no history of other otological problems.
- Pure tone audiogram shows sensorineural hearing loss.

MANAGEMENT: No well recognized and validated treatment is specifically available.

Rehabilitation of hearing loss [25]

The way of hearing rehabilitation is determined by the type or degree of the hearing loss. Hearing aid is the most frequently used method in sensorineural hearing

loss, amplifying the signal to replace the non-functional outer hair cells. Furthermore, implantable hearing devices are also available on the market.

PREVENTION: Early detection of hearing loss and periodical audiological check up to rule out associated conditions of hearing loss and its timely management.

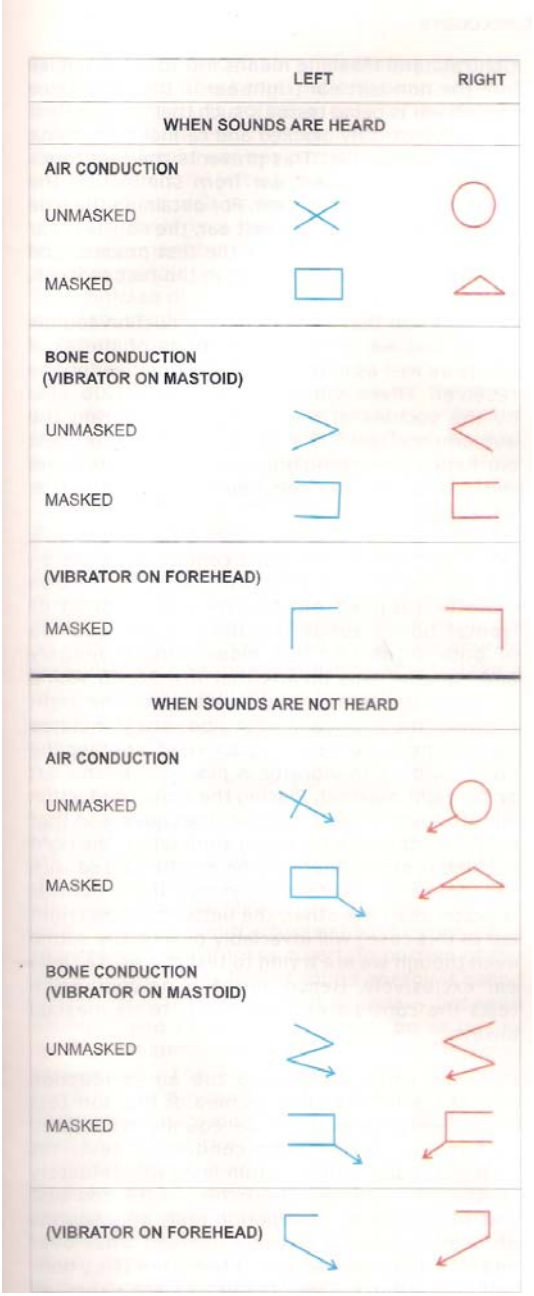


FIG 22 – BASIC SYMBOLS FOR PLOTTING PURE TONE AUDIOGRAM [10]

PUBLISHED ARTICLES

1. Dayna S. Dalton, Karen J. Cruickshanks, Ronald Klein et al. evaluated the association of NIDDM with hearing loss in a large population-based study of 3,571 study participants during the period of September 1987 upto May 1988, 344 were classified as having NIDDM out of which hearing loss percentage among NIDDM against Non-diabetics was 59 vs. 44%. Age had no significant statistical difference. No association observed between diabetes duration or glycemic control and hearing loss [26].

2. Venkata Kakarlapudi, Robert Sawyer, and Hinrich Staecker reviewed electronic medical record from 1989 to present to identify The Effect of Diabetes on Sensorineural Hearing Loss at Maryland, U.S.A. of 53,461 nondiabetic age-matched patients and 12,575 diabetic patients. Observing, SNHL was more common in patients with diabetes than in the control nondiabetic patients, and severity of hearing loss seemed to correlate with progression of disease. The prevalence of diabetes in the group of patients with SNHL was 23%, compared with 19% in the group without hearing loss. The prevalence of SNHL in the diabetic group was 13.1%, compared with 10.3% in the group without diabetes, which was statistically significant [27].

3. Kathleen E. Bainbridge, Howard J. Hoffman, and Catherine C. Cowie concluded from their study on Diabetes and Hearing Impairment in the United States: Audiometric Evidence from the National Health and Nutrition Examination Survey 1999 to 2004, that age-adjusted prevalence of low- or mid-frequency hearing impairment of mild or greater severity was 21.3% among 399 adults with diabetes as compared to 9.4% among 4741 non-diabetic adults.

The association between diabetes and hearing impairment was independent of known risk factors for hearing impairment, such as noise exposure, ototoxic medication use, and smoking [28].

4. Abdulbari Bener, Ahmad H. A. Salahaldin, Sara M. Darwish et al inferred from their study on association between hearing loss and Type 2 Diabetes Mellitus in elderly people in a newly developed society done from the month of January 2003 upto November 2006 , that the prevalence of hearing loss was higher in men than in women and higher in Qataris than in non-Qataris along with additional evidence that diabetic mellitus type 2 has association with hearing impairments and have significant negative impact on quality of life older persons [29].

5. Jianmin Ren, Peng Zhao, Li Chen et al. studied Hearing Loss in Middle-aged Subjects with Type 2 Diabetes Mellitus at Department of Otolaryngology, Qilu Hospital, Shandong University, Jinan, P.R. China in 2008 and obtained that middle-aged subjects with T2DM have subclinical hearing loss, impaired auditory brainstem response and diminished otoacoustic emissions, and the peripheral right ear advantage is being lost. [30]

6. Afaf H. Bamanie and Khaled I. Al-Noury studied prevalence of hearing loss among Saudi type 2 diabetic patients among 196 patients who attended the Otolaryngology Department at King Abdulaziz Universtiy Hospital from January 2005 to December 2009 among which Control was 87 and T2DM was 87 and identified strong relationship between T2DM and hearing loss (low and mid frequencies) than matched controls [31].

7. B. Viswanatha, V. Priyadarshini, M.S. Vijayashree et al. conducted a comparative study over a period of 5 years from 2008- 2013 on Effect of Type II Diabetes Mellitus on 8th Cranial Nerve: Prospective Study, among 2 Groups 100 cases each: diagnosed diabetes mellitus type II in group1 and non-diabetic controls in group 2 and concluded that there is significantly higher prevalence of hearing loss among diabetics [2].

8. Deepti Pandey, Abha Pandit, Abhay Kumar Pandey did a cross sectional study over the period of January 2011 to September 2012 in patients under outdoor care of Ashadeep Trust Hospital Indore, Central India for audio vestibular dysfunction in type2 diabetes mellitus and found hearing loss was fairly common even in mild early disease. Therefore, findings imply, more complex relation of audio vestibular complications to diabetes than, to glycemic status or duration of disease. Monitoring of such complications from the earliest, may alone, bring understanding of their pathogenesis and proper prevention and management [32].

9. Louise Ziani de David, Marcele Machado Finamor, and Ceres Buss completed a study in 2012 on possible hearing implications of diabetes mellitus: a literature review, as the association between hearing loss and diabetes mellitus (type I and type II) has been debated since it was first mentioned by Jordan in 1857 and realized Diabetes mellitus is the affection most commonly related with auditory disorders, and the incidence of neurosensory hearing loss in patients with diabetes mellitus varies from 0% to 80% [33].

10. OiSaeng Hong, Julia Buss, and Elizabeth Thomas reviewed previous studies of Type 2 diabetes and hearing loss leading to insight on research conducted over

the past several decades upto 2013 has brought attention to sensorineural hearing loss among individuals with diabetes. They have hence moved their inference of hearing loss associated with diabetes mellitus from being controversial to being accepted [34].

11. Karnire Nitesh Bhaskar, Sajid Chalihadan, Ravi Vaswani et al. conducted a study from October 2011 to May 2013 which included 57 cases who were diagnosed to have diabetes mellitus and 50 controls without diabetes mellitus in Yenepoya Medical College Hospital, Deralakatte, on "Clinical and Audiometric Assessment of Hearing Loss in Diabetes Mellitus" and came to a conclusion that association of SNHL with diabetes with an incidence of 78.2% as compared to 38% among non-diabetics.10 patients reported gradual hearing loss rest did not realize the gradual progression of hearing loss. As age and duration of diabetes increases the incidence of SNHL increases [1].

12. Ramlakhan Meena, Divij Sonkhya, and Nishi Sonkhya evaluated hearing loss in patients with type 2 diabetes mellitus of fifty patients as a part of hospital based observational cross sectional study carried out from February 2013 to January 2014. Study confirms the presence of SNHL in relatively young type 2 diabetes mellitus. The use of audiological tests to monitor hearing in diabetic patients should be considered as a routine procedure [35].

13. Fazıl Emre Ozkurt, Mehmet Akdag, Mazhar Muslum Tuna et al. conducted a study for Hearing impairment in middle-aged patients with diabetes from January through June 2014 which comprised of 40 patients with T2DM and 40 age and sex similar non-diabetic controls. Forty subjects with T2DM (19 males, 21 females) between 40 and 50 years of age and 40 normal controls (20 males,

20 females) between 40 and 50 years of age (45.8 ± 3.6 years) were compared. At all frequencies, the thresholds of the T2DM group were higher than the control group for both right and left ears and also significant. The T2DM group's thresholds were higher than 20 dB HL and considered to be a higher degree of hearing loss [36].

14. Stephen Semen Yikawe, Kufre Robert Iseh, Anas Ahmad Sabir et al. did a cross‑sectional descriptive study on Effect of Duration of Diabetes Mellitus on Hearing Threshold among Type 2 Diabetics conducted between October 2015 and May 2016 in Usmanu Danfodiyo University demonstrated a relationship between duration of diabetes and hearing threshold of 170 type 2 diabetics out of which 98 (57.6%) were females and 72 (42.4%) were males where in mean pure tone average increased with increase in duration of diabetes ($P < 0.001$) with hearing threshold ($P < 0.0001$) [37].

15. Dr Raj Tajamul Hussain, Dr Kiran Bala, Dr Roopakshi Pathania et al underwent a study on frequency of sensory neural hearing loss in type 2 diabetic patients: an experience from a tertiary level hospital in Kashmir, 136 patients attending Government Medical College, Srinagar, J&K, comprising a duration of six month from July 2017 to December 2017 and concluded the hearing threshold is increased in type 2 diabetics mainly in the higher frequencies. This study emphasized to do audiometry test for all diabetics in order to recognize this complication. A prevalence of sensorineural hearing loss was found in 63.23% of type 2 diabetic patients. Duration of diabetes and long term glycaemic control had a telling effect on the hearing threshold of the subjects [38].

MATERIALS AND METHODS

AIMS AND OBJECTIVES:

- Early detection of Hearing loss in high risk individuals, with predilection to Diabetes Mellitus.
- To compare the efficacy of conventional hearing assessment (tuning fork test) against the high frequency audiometer in detection of hearing loss
- Early intervention and prevention of diabetes mellitus induced hearing loss
- Increase awareness among health care providers and laypersons [12].

Secondary Objectives

- To study type of hearing loss in diabetes mellitus.
- To study audiometric pattern of hearing loss in diabetes mellitus.

METHODOLOGY

Study Design: Hospital based cross sectional study.

Study Participants: Human

Inclusion Criteria: Any patient male or female with Type II Diabetes Mellitus above the age 30 years, with complaints of hearing loss and requiring assessment of hearing loss and willingness to participate in the study.

Exclusion Criteria:

- Any person not willing to be included in the study
- Patients with history of middle ear diseases or surgeries
- Patients with conductive hearing loss.
- Patients with history of any chronic illness or any known neurological diseases other than diabetes mellitus.
- Patients on any ototoxic medications.
- Patients with occupational noise exposure.

No. of Groups to be Studied, Identify groups with definition: Patients with Diabetes Mellitus above the age 30 years in single group of 30 patients belonging to any gender coming to ENT OP department with complaints of Hearing Loss.

SAMPLING

Sampling Population: Patients with Diabetes Mellitus above the age 30 years.

Sample Size Calculation: It is calculated by the formula $4pq/d^2$

p = available local prevalence rate in the target population (obtained from comparable studies)

q = 100 – p, d = relative precision i.e. 20% of previous prevalence

In this study,

p = 78.2[1] , q = 21.8, d = 15.6

Substituting these values in the formula,

$4pq/d^2 = (4 \times 78.2 \times 21.8) / (15.6)^2 = 28.02$, approximately 30 cases.

Sampling Technique: Convenient Sampling

Randomization details (for interventional details) – Interventional details with standardization techniques (Drugs/ Devices/ Invasive Procedures/ Non-Invasive Procedures/ Others): **Pure Tone Audiometer**

INVESTIGATIONS

- History Taking
- Otoscopic Examination
- Pure tone audiometry

STUDY PROCEDURE:

All the patients with Hearing Loss with Type II Diabetes Mellitus who have come to the ENT OPD and an informed consent will be obtained from those willing for the study. Data including age, sex, occupation, weight, history of smoking, alcoholism, diabetes, hypertension, and hypothyroidism history are noted. Investigations such as level of Hemoglobin, FBS/ppBS and HbA1c are done as routine investigations. Results regarding these investigations will be noted from the IP/OP chart of the patient.

Assessment of hearing loss in these patients is done using PTA. In this method, they are exposed to pure tones, the intensity of which can be increased or decreased in 5 dB steps. Air conduction thresholds are measured for tones of 125,

250, 500, 1000, 2000 and 4000 and 8000 Hz and bone conduction thresholds for 250, 500, 1000 and 2000 and 4000 Hz. The amount of intensity that has to be raised above the normal level is a measure of the degree of hearing impairment at that frequency. It is charted in the form of a graph called audiogram. The threshold of bone conduction is a measure of cochlear function. The difference in the thresholds of air and bone conduction (A-B gap) is a measure of the degree of conductive deafness.

The audiometer is so calibrated that the hearing of a normal person, both for air and bone conduction, is at zero dB and there is no A-B gap.

Data Collection Methods:

Periodicity: December 2016 to October 2018 (Approximately 18 months)

Setting: Sree Mookambika Institute of Medical Sciences (SMIMS), Kulasekharam

- Department of ENT
- Department of Speech and Audiology

List of Variables and their measurement methods with standardization techniques

Age, sex, occupation, weight, history of smoking, alcoholism, diabetes, hypertension, and hypothyroidism history are noted. Investigations such as Hemoglobin level, FBS/ppBS, HbA1c and conduction thresholds using PTA are taken into account [39].

Independent Variables: Duration of illness, Etiological factors.

Outcome Variables: Sensorineural hearing loss.

Confounding and Interacting Variables: Age, Sex.

List Variable Wise Statistical Test to be used for Data Analysis:

Study parameters entered in Microsoft Excel Worksheet Version 2013

Data analysis: Statistical Package of Social Sciences (SPSS) Trial Version 20.0

Significant level decided before starting of study: $p \leq 0.05$

Statistical tests to be used for data analysis: Chi square test

Benefits and Risks of the Study: Appropriate early diagnosis of causative factors for SNHL in diabetics and to ensure prompt and effective management to avoid or minimize the occurrence of complications.

No risks so far have been reported in prior studies.

RESULTS AND ANALYSIS

FREQUENCY BASED ON AGE GROUP:

Mean = 55.53 Yrs; Standard Deviation = 10.71

AGE GROUP	FREQUENCY	PERCENT
35-50	11	36.7
51-65	12	40.0
66-80	7	23.3
Total	30	100.0

TABLE 1

FREQUENCY BASED ON GENDER:

GENDER	FREQUENCY	PERCENT
MALE	17	56.7
FEMALE	13	43.3
TOTAL	30	100

TABLE 2

Among 30 subjects, as age and gender frequencies had comparability, following inferences were: Patients' ages were tallied to obtain mean of 55.53 with standard deviation of 10.71. Furthermore, ages was grouped in 3 parts 35-50, 51-65, 66-80years, among them maximum participants were in 51-65 years group with a frequency of 12(40%). [TABLE 1, CHART 1]

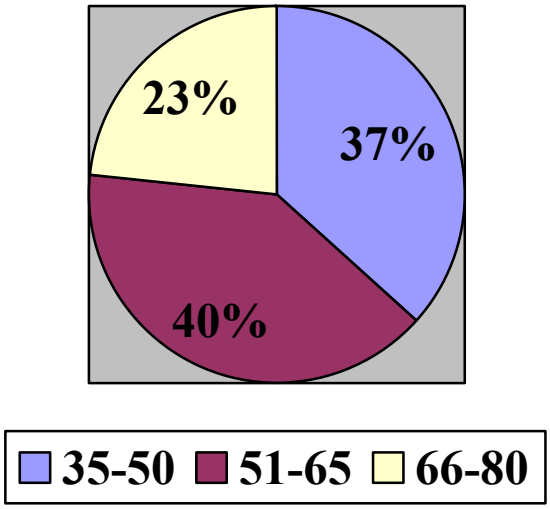


CHART 1 - AGE GROUP BASED FREQUENCY IN PERCENTAGE

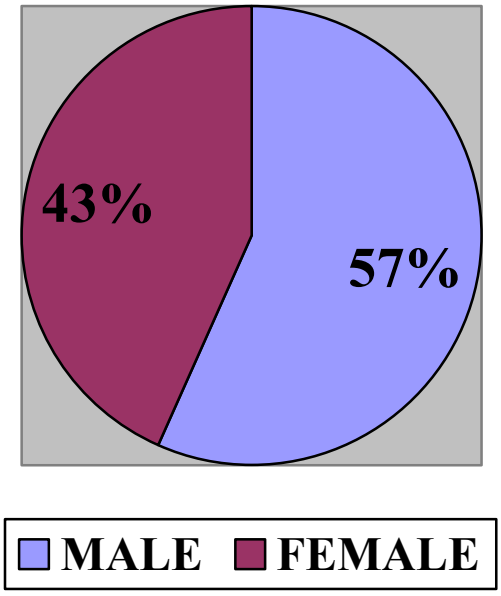


CHART 2 - GENDER BASED FREQUENCY IN PERCENTAGE

Gender frequency distribution was slightly higher in males, 17(56.7%) as compared to females, 13(43.3%). [CHART 2, TABLE 2]

FREQUENCY BASED ON DURATION OF DIABETES MELLITUS

DM Duration (in years)	Frequency	Percent
≤15	22	73.3
>15	8	26.7
Total	30	100
Mean = 11.53; Standard Deviation = 8.17		
Mean of Weight= 67.4kgs ± 11.72		

TABLE 3

Duration of Diabetes Mellitus was grouped after obtaining mean of 11.53 with a standard deviation of 8.17years. The grouping was approximated with respect to 15 year mark for better understanding of short and long term affliction of diabetes mellitus.

The distribution among the study sample showed majority among ≤15years duration of DM. at 73% (22 out of 30). [TABLE 3]

An average of weight distribution was taken to assess the mean which was recorded at 67.4±11.72Kgs, for to compare with other parameters if it may matter.

FREQUENCY BASED ON HEARING LOSS TYPE:

HEARING LOSS TYPE	FREQUENCY	PERCENT
NORMAL	10	33.3
SNHL	17	56.7
MIXED	3	10.0
TOTAL	30	100.0

TABLE 4

FREQUENCY BASED ON HEARING LOSS DEGREE:

HEARING LOSS DEGREE	Frequency	Percent
Normal	10	33.3
Mild	1	3.3
Mild- Moderate	5	16.7
Moderate	6	20
Moderate- Moderately Severe	3	10
Moderately Severe	1	3.3
Moderately Severe- Severe	1	3.3
Severe	3	10
TOTAL	30	100

TABLE 5

The frequency pattern for patients with hearing loss with diabetes was significant in the SNHL group with at 56.7% (17 out of 30) while normal and mixed hearing were 10 and 3(33.3% and 10%) respectively.[TABLE 4, CHART 3]

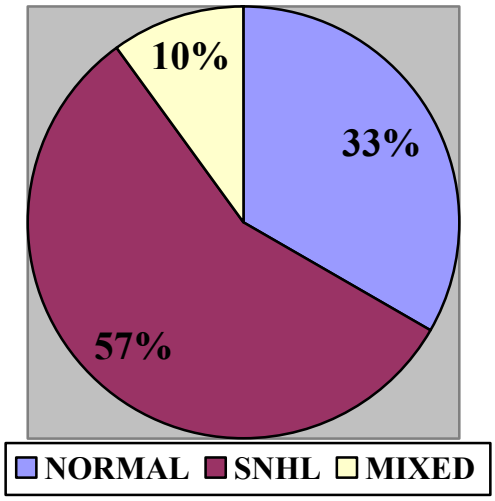


CHART 3- HEARING LOSS TYPE BASED FREQUENCY IN PERCENTAGE

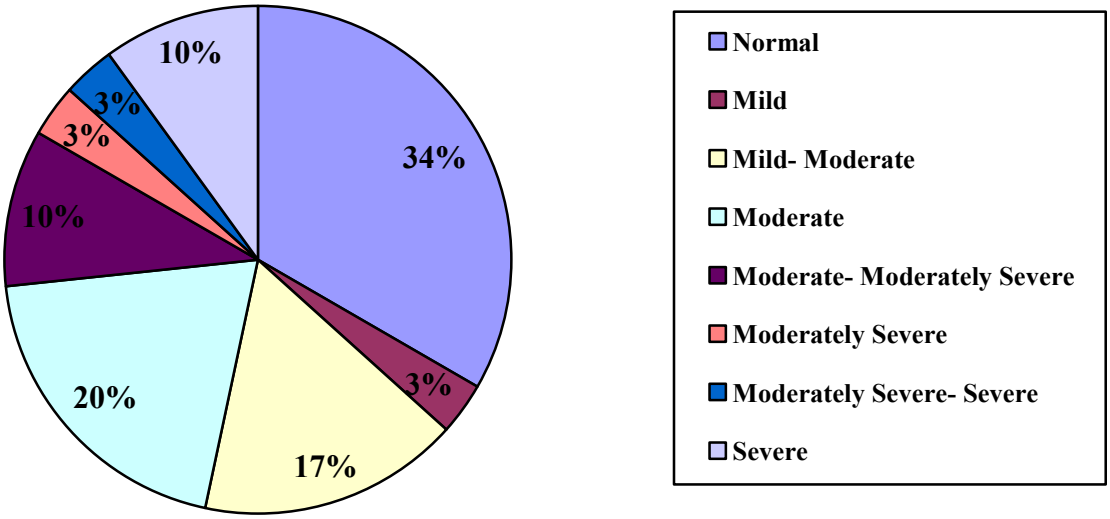


CHART 4- HEARING LOSS SEVERITY BASED FREQUENCY IN PERCENTAGE

The maximum distribution was from mild to moderate degrees of hearing loss which were further redistributed according to WHO Grading of hearing loss in to mild-moderate (17%), moderate(20%) and moderate-moderately severe(10%). [TABLE 5, CHART4].

FREQUENCY BASED ON PURE TONE AUDIOMETRY:

HEARING LOSS (Db)	Rt PTA		Lt PTA	
	Frequency	Percent	Frequency	Percent
NORMAL (≤25)	10	33.3	10	33.3
MILD (26-40)	8	26.7	6	20
MODERATE (41-60)	7	23.3	9	30
SEVERE (61-80)	4	13.3	5	16.7
PROFOUND (>80Db)	1	3.3	-	-
Total	30	100	30	100

TABLE 6

Audio logical frequencies of hearing loss degree tested by PTA showed comparative variance with in right and left sides, such that right PTA had 8 out of 30 (26.7%) in mild degree (26-40dB) and moderate (41-60dB) 7(23%), while left was inverse with 9 in moderate degree (30%) and mild at 20%(6 out of 30 cases).Rest groups showed no prevalence among significant frequencies. [TABLE 6, CHART 5, 6].

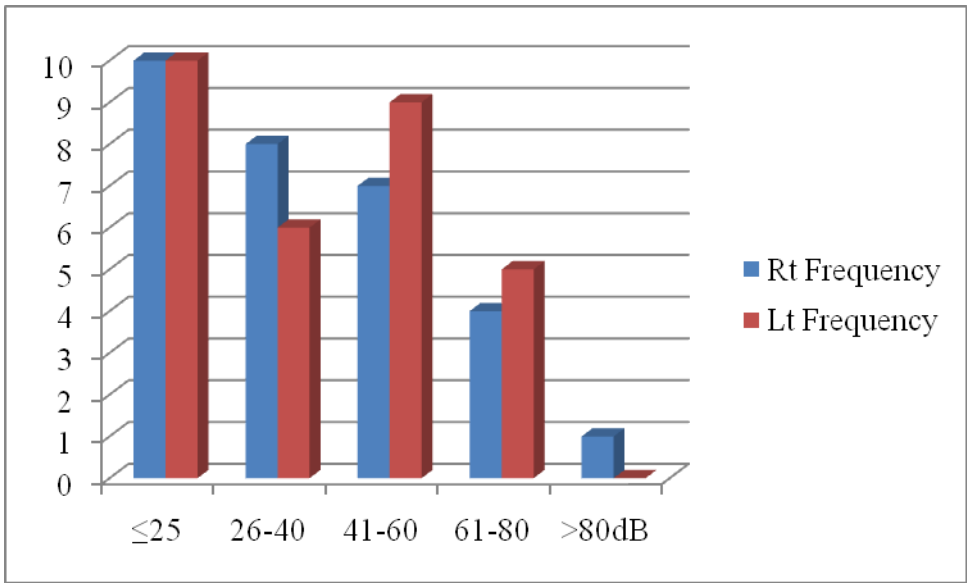


CHART 5- PTA FREQUENCY

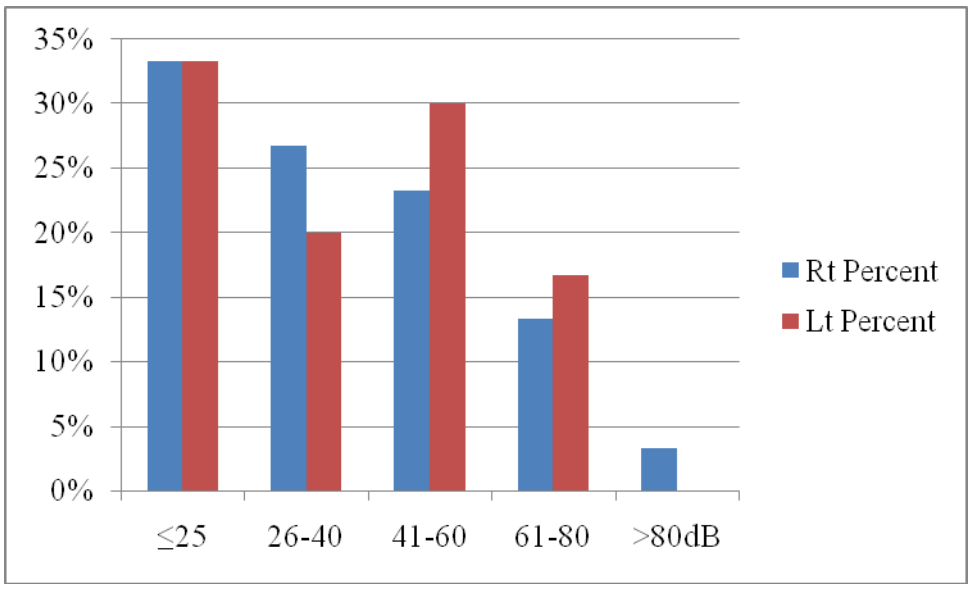


CHART 6- PTA FREQUENCY IN PERCENTAGE

COMPARISON BETWEEN AGE GROUP Vs. HEARING LOSS TYPE

HEARING LOSS TYPE	Age Group						Total	Total Percentage
	35-50	Percent	51-65	Percent	66-80	Percent		
Normal	4	13.30%	5	16.70%	1	3.30%	10	33.30%
SNHL	6	20.00%	5	16.70%	6	20.00%	17	56.70%
Mixed	1	3.30%	2	6.70%	0	0.00%	3	10%
Total	11	36.70%	12	40.00%	7	23.30%	30	100.00%

TABLE 7

COMPARISON BETWEEN GENDER vs. HEARING LOSS TYPE:

Hearing Loss Type	Gender				Total	Total PERCENT
	MALE	Percent	FEMALE	Percent		
Normal	5	16.70%	5	16.70%	10	33.30%
SNHL	10	33.30%	7	23.30%	17	56.79%
Mixed	2	6.7%	1	3.30%	3	10.00%
Total	17	56.70%	13	43.30%	30	100%

TABLE 8

Since P-value is significant at 0.05, age and gender are statistically insignificant as shown below.

Chi-Square Test	Value	P- VALUE
AGE	3.812	**0.432**
GENDER	.335	**0.846**

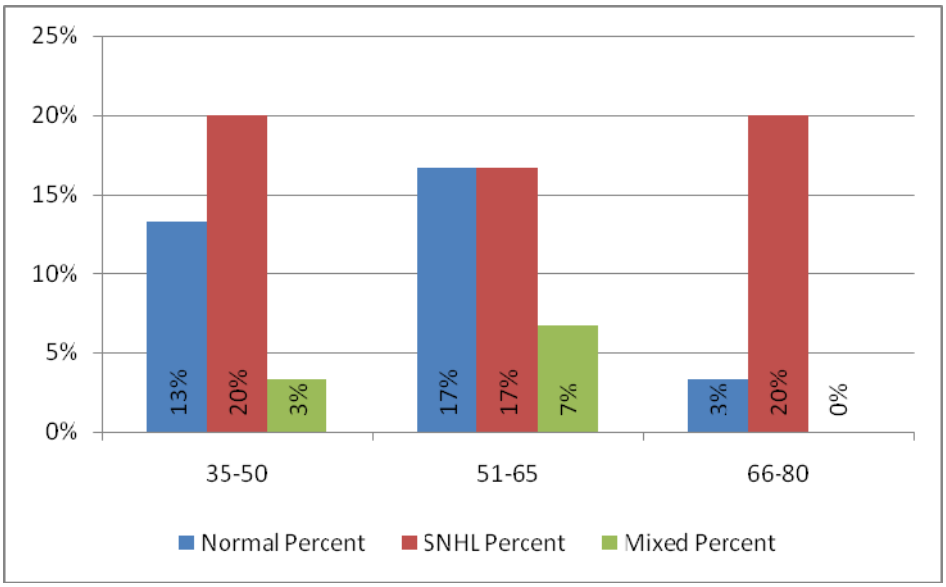


CHART 7– COMPARISON OF HEARING TYPE IN AGE (%)

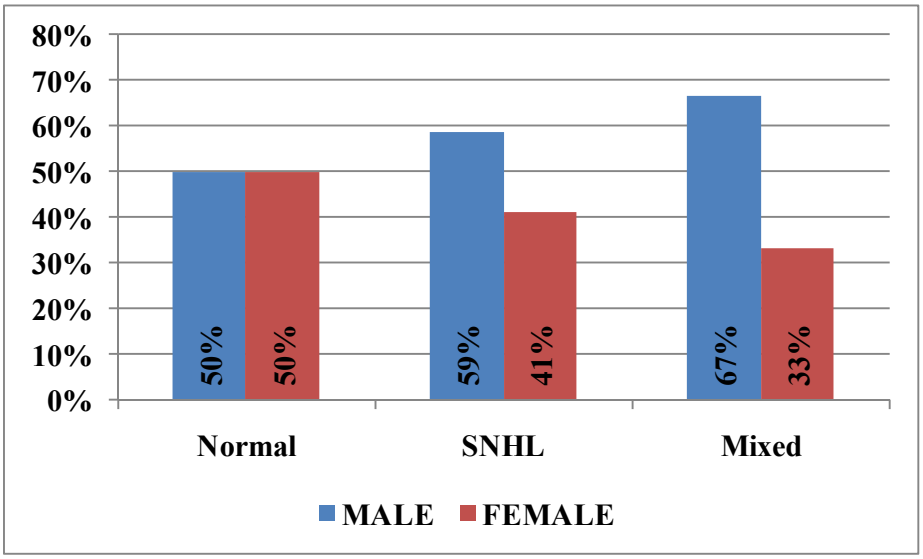


CHART 8– COMPARISON OF HEARING TYPE IN SEX(%)

DURATION OF DIABETES MELLITUS Vs. HEARING LOSS TYPE

HEARING LOSS TYPE	DM DURATION (Years)				Total	TOTAL PERCENT
	<15years	PERCENT	>15years	PERCENT		
Normal	10	33.30%	0	0.00%	10	33.30%
SNHL	9	30.00%	8	26.70%	17	56.70%
Mixed	3	10.00%	0	0.00%	3	10.00%
Total	22	73.30%	17	56.70%	30	100%

TABLE 9

Pearson Chi-Square Value= 8.342 **P- VALUE=0.015 (<0.05)**

In this study, type of hearing is adequate correlation to duration of diabetes mellitus as p-value is statistically significant at 0.015. Hence making SNHL prevalent in diabetics at 56.7% having a distribution of 9 (30%) subjects and 8 (26.7%) among 30 study participants diagnosed with DM.

DEGREE OF HEARING LOSS- DEGREE Vs TYPE. (Rt EAR)

Hearing Loss Degree	Hearing Loss Type Hearing Loss Type Seen in Rt PTA						Total	TOTAL PERCENT
	NORMAL	PERCENT	SNHL	PERCENT	MIXED	PERCENT		
≤25	10	33.3%	0	0%	0	0%	10	33.3%
26-40	0	0%	7	23.3%	1	3.3%	8	26.7%
41-60	0	0%	6	20%	1	3.3%	7	23.3%
61-80	0	0%	4	13.3%	0	0%	4	13.3%
>80	0	0%	0	0%	1	3.3%	1	3.3%
Total	10	33.3%	17	56.7%	3	3.3%	30	100%

TABLE 10

Pearson Chi-Square Value	39.622
P- VALUE	**0.000**

To understand SNHL degree better, hearing loss was assessed with the help of PTA testing obtaining results shown in tables 10 and 11. They have been graphically presented in frequency bar charts in charts 9 and 10.

DEGREE OF HEARING LOSS DEGREE Vs TYPE (Lt EAR)

Hearing Loss Degree (dB)	Hearing Loss Type Seen in Lt PTA							TOTAL PERCENT
	NORMAL	PERCENT	SNHL	PERCENT	MIXED	PERCENT	Total	
≤25	10	33.3%	0	0%	0	0%	10	33.3%
26-40	0	0%	5	16.7%	1	3.3%	6	20%
41-60	0	0%	8	26.7%	1	3.3%	9	30%
61-80	0	0%	4	13.3%	1	3.3%	5	16.7%
Total	10	33.3%	17	56.7%	3	3.3%	30	100%

TABLE 11

Pearson Chi-Square Value	30.327
P- VALUE	**0.000**

PTA tested degree of hearing loss against hearing loss type is statistically significant at 0.001 with SNHL having highest prevalence at 56.7% (17/30 subjects). Additionally, Rt side shows slightly more significance as the Chi-square value is 39 while Lt is 30. [TABLE 10 AND 11]

FREQUENCY GRAPHS BETWEEN HEARING LOSS- DEGREE AND TYPE IN PTA

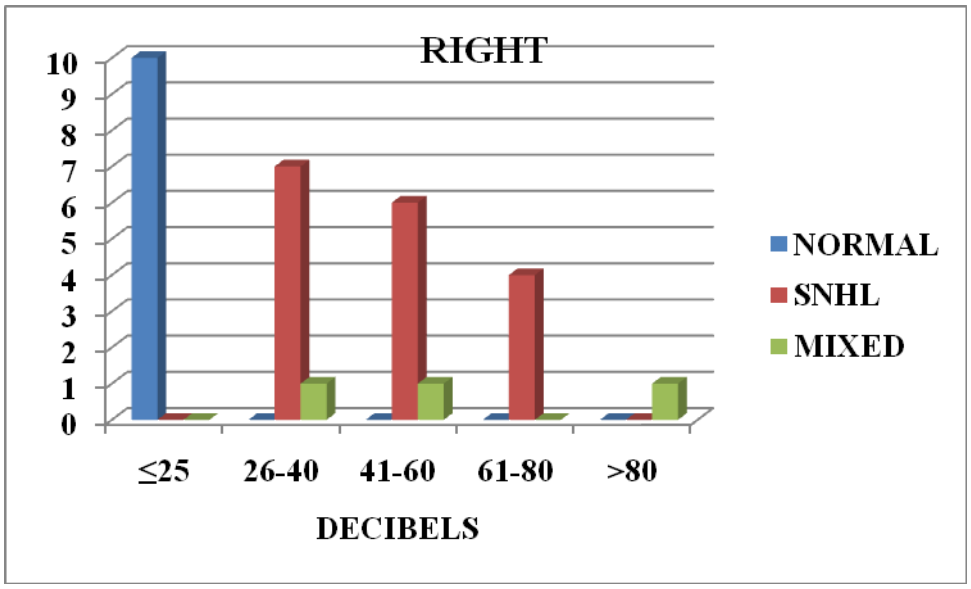


CHART 9- RIGHT SIDE

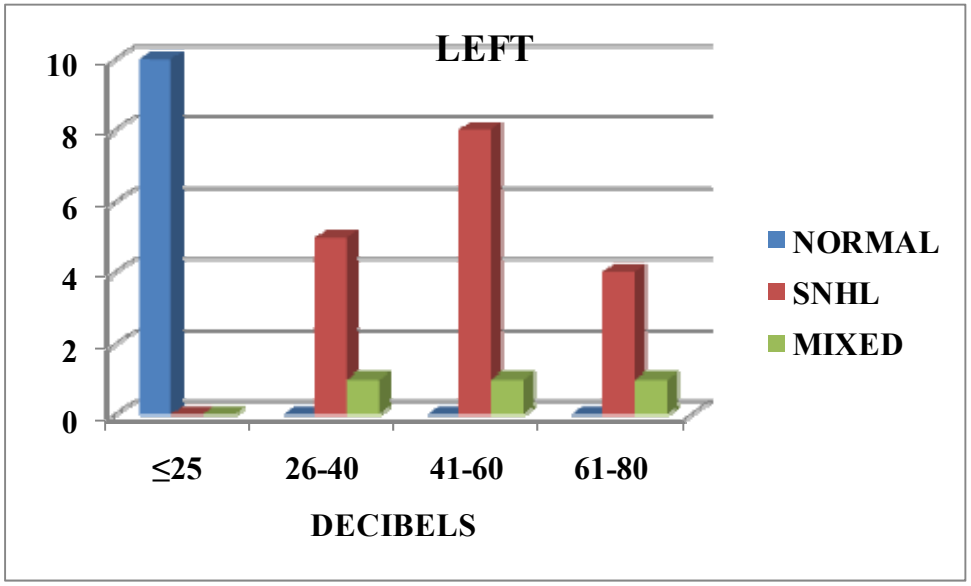


CHART 10- LEFT SIDE

DEGREE OF HEARING LOSS DEGREE In Rt and Lt PTA Vs. DM DURATION

Rt PTA (dB)	DURATION OF DIABETES MELLITUS (in years)				Total	Total PERCENT
	≤15	PERCENT	>15	PERCENT		
≤25	10	33.3%	0	0%	10	33.3%
26-40	6	20%	2	6.7%	8	26.7%
41-60	5	16.7%	2	6.7%	7	23.3%
61-80	0	0%	4	13.3%	4	13.3%
>80	1	3.3%	0	0%	1	3.3%
Total	22	73.3%	8	26.7%	30	100%

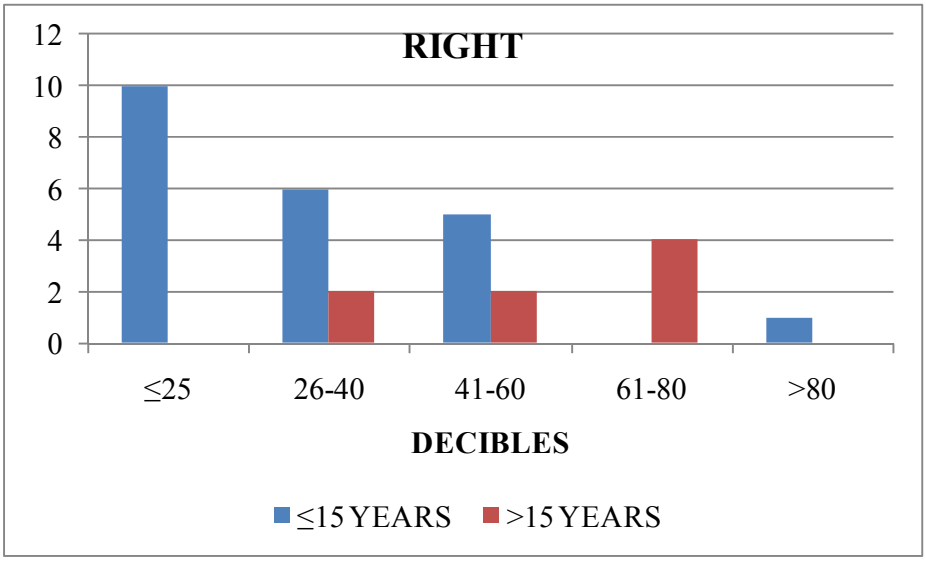
TABLE 12

Lt PTA (dB)	DURATION OF DIABETES MELLITUS (in years)				Total	Total PERCENT
	≤15	PERCENT	>15	PERCENT		
≤25	10	33.3%	0	0%	10	33.3%
26-40	5	16.7%	1	3.3%	6	20%
41-60	6	20%	3	10%	9	30%
61-80	1	3.3%	4	13.3%	5	16.7%
Total	22	73.3%	8	26.7%	30	100%

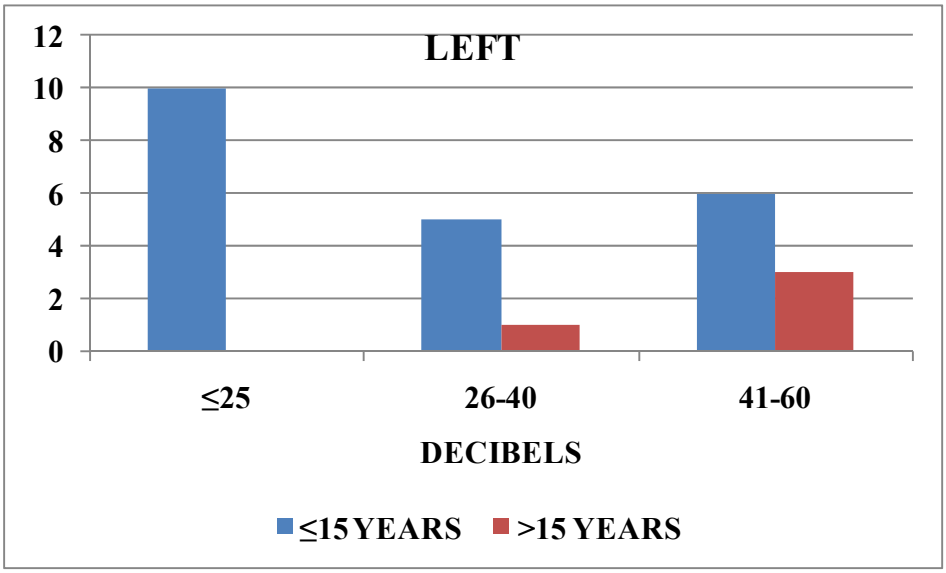
TABLE 13

Duration of DM shows significance among PTA results of hearing loss degree with P-value <0.01. This helps to make relation with degree of hearing loss and diabetes duration.

Chi-Square Test	Value	**P- VALUE**
Rt PTA	15.024	**0.005**
Lt PTA	11.420	**0.01**



CHARTS 11&12 – DIABETES DURATION AGAINST PTA DEGREE OF HL



ABC TEST DEGREE Vs. DM DURATION

ABC TEST	DURATION OF DIABETES MELLITUS (in years)				Total	Total PERCENT
	≤15	PERCENT	>15	PERCENT		
NORMAL	12	40%	2	6.7%	14	46.7%
MILD	6	20%	0	0%	6	20%
REDUCED	4	13.3%	6	20%	10	33.3%
Total	22	73.3%	8	26.7%	30	100%

TABLE 14

DEGREE OF HEARING LOSS -PTA Vs. ABC TEST

Hearing Loss Rt PTA Degree	Hearing Loss Degree in ABC						Total	TOTAL PERCENT
	NORMAL	PERCENT	MILD	PERCENT	REDUCED	PERCENT		
≤25	10	33.3%	0	0%	0	0%	10	33.3%
26-40	1	3.3%	5	16.7%	2	6.7%	8	26.7%
41-60	3	10%	1	3.3%	3	10%	7	23.3%
61-80	0	0%	0	0%	4	13.3%	4	13.3%
>80	0	0%	0	0%	1	3.3%	1	3.3%
Total	14	46.7%	6	20%	10	33.3%	30	100%

TABLES 15– HEARING LOSS DEGREE IN Rt SIDE

Hearing Loss Lt PTA Degree	Hearing Loss Degree in ABC						Total	
	NORMAL	PERCENT	MILD	PERCENT	REDUCED	PERCENT		
≤25	10	33.3%	0	0%	0	0%	10	33.3%
26-40	1	3.3%	4	13.3%	1	3.3%	6	20%
41-60	3	10%	2	6.7%	4	13.3%	9	30%
61-80	0	0%	0	0%	5	3.3%	5	16.7%
Total	14	46.7%	6	20%	10	33.3%	30	100%

TABLES 16 –HEARING LOSS DEGREE IN Lt SIDE

Chi-Square Test In ABC TEST	Value	**P- VALUE**
DM DURATION	8.961	**0.011**
RIGHT	31.148	**0.000**
LEFT	30.317	**0.000**

In my study to collect samples before performing PTA test on necessary study group, ABC test was conducted to confirm hearing loss, which lead to the results obtained the above findings, they were in coherence with the findings of PTA and also showed relation to diabetic duration.

DISCUSSION

Study shows the effect of diabetes mellitus on SNHL with relation to age, gender, duration of disease that is associated to hearing loss.

The sample population consisted of 30 diabetic patients above the age of 30 years, among the majority 40% were from age group 51-65 and 43% male subjects.

Audiological investigation, PTA was performed by the department audiologist in sound treated room after necessary clinical examination for hearing loss was undertaken. Clinical examination that aided to maintain inclusion criteria were local examination of ear, nose, throat and systemic examination for other co-morbidities and tuning fork test which helped attaining the focused group.

PTA test was measured with instrument ALPs Advanced digital audiometer AD 2100, Telephonics Headphone, Bone vibrator Radio ear B-71, at varied frequencies of 250Hz, 500 Hz, 1 KHz, 4 KHz, 8 KHz.

After assessing and confirming the type and degree of hearing loss by PTA, confirmation and classification of degree of hearing loss was done with the help of WHO grades of hearing impairment [11].

In this study, SNHL comprised of majority at 56.7% [Table 4]. While comparing degrees of hearing loss, from bilateral mild to moderate comprised of 40% [Table 5]. In the past, studies gave outcomes ranging from 40% onwards. Friedman et al [40] incurred an average of 55% hearing loss in diabetic patients.

Ren et al [41] and Kakarlaupadi et al [27] found that hearing loss in diabetics coincided with higher frequencies yielding to moderate degree of hearing loss. Celik o et al [42] compared age groups and gender similar to this study. Similarly, they also compared age groups with duration of diabetes and other diabetic related conditions, hence establishing relation of duration of diabetes with hearing loss.

Affection of bilateral SNHL was seen in study conducted by Meena R et al [35] which showed near equal distribution in various frequency thresholds. Even though SNHL was in majority, diabetics included in this study also showed sudden onset SNHL before 15 years having dominance at 30% participants showing hearing loss.

SSNHL in diabetes may be a result of microangiopathy showed a study by Shikowitz MJ et al [6], while Friedman [40] and Cullen A. showed SNHL onset in younger individuals.

Li et al [43] and Abdulbari Bener et al [29] found significant hearing loss with advancement of age and disease in diabetics. Therefore, to avoid large discrepancies in age related changes in hearing status, conducted study in DM patients were focused from 35-80 years age group in comparison to their DM illness duration which was a maximum of 30 years and was included in DM duration of >15 years which comprised of 57% of study subjects.

In this study, even though DM duration had comparative significance P-value = 0.011, ABC test showed better significance at P value = 0.001 which was further confirmed by PTA in relation to SNHL where 56.7% SNHL cases with 50% mild-moderate level of hearing loss were present.

Degree of bilateral type hearing loss in correlation to DM duration at 37% in early diabetics and majority comprised of mild-20%, moderate-7% degrees which was similarly observed in the study where Tay HL et al [44] and Morales LV et al [45] described.

SUMMARY

In summary, Hearing loss in type II diabetics showed no significant relation to age and gender. But early diabetics were prevalent as age groups were taken with consideration to their Type 2 DM duration.

Furthermore hearing loss degree has significant correlation with ABC test which PTA confirms according to WHO grading of hearing loss. [11]

Lastly, all associations lead to confirming significant traits of SNHL even though normal and mixed hearing loss components are insignificantly present among confirmed diabetic subjects.

CONCLUSION

Keeping in mind the limitations of time and sample size, the study gives significant insight into clinical outcome of undertaken subject that is effect of diabetes on SNHL.

Hearing loss observed in diabetics is mostly bilaterally symmetrical, progressive, ranging from mild to severe.

Factors such as age, gender, family history, weight, occupation had no role in etiology of hearing loss. In addition to above factors, non communicable conditions or diseases, such as smoking, drinking, hypertension and thyroid disorders which may affect hearing loss in different manners were considered and excluded, so as to show direct effect of diabetes on hearing loss.

Even though clinical tests may help finding and proving hearing loss type and to a certain extent the degree as well, health care providers must take into account, the condition progression and refer to audiology for proper screening and evaluation for all diabetes mellitus cases, to have a better insight as well as preparedness for the outcome.

In future, there is a lot of scope to understand other aspects of SNHL with timely assessment of hearing threshold and diabetic management to improve auditory status.

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ANNEXURE-I

INSTITUTIONAL HUMAN ETHICS COMMITTEE

INSTITUTIONAL HUMAN ETHICS COMMITTEE

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES,
KULASEKHARAM, TAMILNADU

Communication of Decision of the Institutional Human Ethics Committee(IHEC)

SMIMS/IHEC No:1 /Protocol no: 35 / 2016

Protocol title: EFFECT OF DIABETES MELLITUS ON SENSORINEURAL HEARING LOSS IN A TERTIARY HEALTH CARE CENTRE
Principal Investigator: Dr.Geogin George Thottan
Name& Address of Institution: Department of ENT Sree Mookambika Institute of Medical Sciences, Kulasekharam ☑ New review ☐ Revised review ☐ Expedited review
Date of review (D/M/Y): 15.12.2016 Date of previous review , if revised application:
Decision of the IHEC: ☑ Recommended ☐ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions/ Reasons/ Remarks:
Recommended for a period of : eighteen months

Please note*

- Inform IHEC immediately in case of any Adverse events and Serious adverse events.
- Inform IHEC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above. Annual report to be submitted to IHEC.
- Members of IHEC have right to monitor the trial with prior intimation.

Reneegalgangadhar

Signature of Member Secretary IHEC

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES * KULASEKHARAM *
IHEC
Date 21/12/16

ANNEXURE-II

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

KULASEKHARAM

RESEARCH COMMITTEE

CERTIFICATE

This is to certify that The Research Protocol Submitted by DR. GEOGIN GEORGE THOTTAN

~~*Faculty*~~ */ Post Graduate from Department of* OTORHINOLARYNG-OLOGY (ENT) *Titled* STUDY OF EFFECT OF DIABETES MELLITUS ON SENSORINEURAL HEARING LOSS IN A TERTIARY HEALTH CARE CENTER

is approved by the Research Committee.

Chair Person

Prof. & H.O.D.
Dept. of Bio-Chemistry
Sree Mookambika Institute of Medical Sciences
Kulasekharam 629 161

Convenor

Prof. & H.O.D.
Dept. of Physiology
Sree Mookambika Institute of Medical Sciences
Kulasekharam 629 161

Date : 16/11/2016

ANNEXURE- III

CONSENT FORM

INFORMED CONSENT DOCUMENT (ICD)

PATIENT/PARTICIPANT INFORMATION SHEET

INFORMATION FOR PARTICIPANTS OF THE STUDY

1. **Title of the Study:-** Effect of diabetes mellitus of patients on Sensorineural Hearing Loss in a tertiary health care center

2. **Name of the investigator :** Dr. Geogin George Thottan

   MS ENT Post Graduate

   Department of ENT,

   Sree Mookambika Institute of Medical Sciences

Name of the Guide : Dr. K.P Gopakumar

Professor and Head of department

Department of ENT

Sree Mookambika Institute of Medical Sciences

Institute : Sree Mookambika Institute of Medical Sciences,

Kulasekharam, Kanyakumari district – 629161, Tamil Nadu

3. **Purpose of this project/study:** Hearing loss in diabetes has not received as much attention and more research needs to be done in this area, so as to determine the magnitude of the problem, establish a cause and effect and increase awareness among health care providers and laypersons.

- To assess hearing loss in subjects with diabetes mellitus by clinical and audiometric examination.

- To study type of hearing loss in diabetes mellitus.

- To study audiometric pattern of hearing loss in diabetes mellitus.

4. Scientific Justification of Study:

Hearing loss in diabetes has not received as much attention and more research needs to be done in this area, so as to determine the magnitude of the problem, establish a cause and effect and increase awareness among health care providers and laypersons.

Hence In this dissertation, we are doing a hospital based study to find out the effect of diabetes mellitus on Sensorineural Hearing Loss in a tertiary health care center. This knowledge is very important for the clinicians for the appropriate early diagnosis of causative factors to ensure prompt and effective management and to avoid or minimize the occurrence of complications. Moreover, a study on this topic has not been done yet in the Kanyakumari district of Tamil Nadu, India.

5. Procedure of study:

The present study will be carried out in Sree Mookambika Institute Of Medical Sciences. Relevant clinical and demographic data including history will be obtained from the patient.

- HISTORY TAKING:

Proforma is used for documenting age/sex/address/clinical information/symptoms/

Predisposing factors and any previous history of treatment.

- Collection of Samples:

All the patients with Hearing Loss with predisposition to Type II Diabetes Mellitus who have come to the ENT OPD and an informed consent will be obtained

from them. Data including name, age, sex, occupation, weight, history of smoking, alcoholism, diabetes, hypertension history are noted. Investigations such as level of Hemoglobin, FBS/ppBS and HbA1c are done as routine investigations. Results regarding these investigations will be noted from the IP/OP chart of the patient.

- Grouping of Samples :

Assessment of hearing loss in these patients is done using pure tone audiometry. In this method they are exposed to pure tones, the intensity of which can be increased or decreased in 5 dB steps. Air conduction thresholds are measured for tones of 125, 250, 500, 1000, 2000 and 4000 and 8000 Hz and bone conduction thresholds for 250, 500, 1000 and 2000 and 4000 Hz. The amount of intensity that has to be raised above the normal level is a measure of the degree of hearing impairment at that frequency. It is charted in the form of a graph called audiogram. The threshold of bone conduction is a measure of cochlear function. The difference in the thresholds of air and bone conduction (A-B gap) is a measure of the degree of conductive deafness. The audiometer is so calibrated that the hearing of a normal person, both for air and bone conduction, is at zero dB and there is no A-B gap.

5. Expected risks for the patients: No risk

6. Expected benefits of research for the participants: Appropriate early diagnosis of causative factors to ensure prompt and effective management and to avoid or minimize the occurrence of complications.

7. Maintenance of Confidentiality : All data collected for the study will be kept confidentially and would reflect on general statistical evaluation only, would not reveal any personal details.

8. Why have I been chosen to be in the study?

- You have been found to be diagnosed with Hearing loss and fulfil the criteria of selection

- You are ready to give consent

9. How many people will be there in the study: 30

10. Agreement of compensation to the participant: In case of study related injury, the participant will be provided standard medical care and treatment as per the institutional guidelines.

11. Anticipated prorated payment, if any, to the participant(s) of the study: Nil

12. Can I withdraw from the study at any time during the study period: Yes

13. If there is any new findings/information, would I be informed: Yes

14. Expected duration of Participant's participation in the study: Single visit

15. Whom do I contact for further information: Dr. Geogin George Thottan

For any study related queries, you are free to contact
Dr.Geogin George Thottan
MS ENT Post Graduate
Department of ENT
Sree Mookambika Institute of Medical Science, Kulasekharam
Mobile No: 9047588354/9567357296
Email ID: drgeogingt@gmail.com

Place: Kulasekharam

Date: Signature of Principal Investigator

Place: Kulasekharam

Date: Signature of Participant

CONSENT FORM

PART 2 0F 2

PARTICIPANTS CONSENT FORM

The principal investigator has explained to me in writing the details of the study of "Effect of diabetes mellitus of patients on Sensorineural Hearing Loss in a tertiary health care center", to be conducted in the department of ENT, Sree Mookambika Institute of Medical Sciences, Kulasekharam. He has also explained to me that by being a part of this study no new medication will be tried out on me. I confirm that I have understood the study and had the opportunity to ask questions. I am aware of my right to opt out of this study at any stage without any hindrance to my ongoing treatment. No additional financial burden will be placed on me by being part of this study. Data collected for the study will be kept under strict confidentiality and would reflect on general statistical evaluation only and would not reveal any personal details. Keeping the above facts in mind I, Whole heartedly, without any compulsion agree to participate in this study.

Signature of the Participant: Date:

Signature of Witness: Date:

Name and Address of Witness:

Signature of the Investigator: Date:

ANNEXURE- IV

CASE RECORD FORM

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

Department of E.N.T

Kulasekharam, Kanyakumari District, Tamil Nadu, India

CASE RECORD FORM

Name: Age: Gender:

Occupation: Education:

MR number: Study number:

Address with contact number:

Date of examination:

Chief complaints:

History of presenting illness:

Other diseases (if any):

EAR	RIGHT	LEFT
EAR DISCHARGE		
FULLNESS OF THE EAR.		
DEAFNESS.		
ITCHING IN THE EAR		
EAR ACHE		

LOCAL EXAMINATION

EAR	RIGHT	LEFT
PREAURICULAR		
POST AURICULAR		
EXTERNALAUDITORY CANAL		
TYMPANIC MEMBRANE		

TUNING FORK TEST:-

A. Questionnaires

a. Assessment of hearing loss in subjects with diabetes mellitus by clinical and audiometric examination.

b. Evaluation of type of hearing loss in diabetes mellitus.

c. Analysis of audiometric pattern of hearing loss in diabetes mellitus.

B. Tools: Pure Tone Audiometer

IMPRESSION:

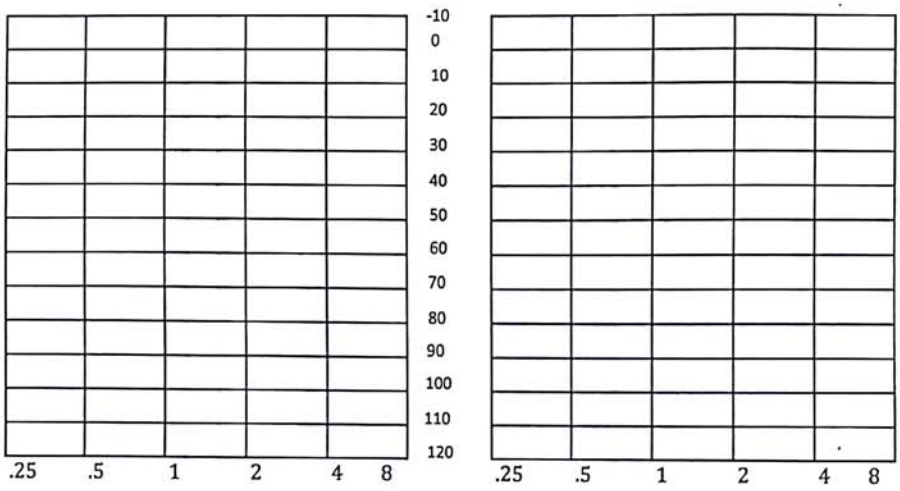
SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

Velayuthan Pillai Memorial Hospital Complex, Padanilam Kulasekharam - 629 161

DEPARTMENT OF ENT-AUDIOLOGY

Name: **Age:** **Op No :**

Date : **Audiometer :**



Right: **Left:**

AIR CONDUCTION	RIGHT	LEFT
Unmasked	○	X
Masked	△	□
No response	↷	↘
BONE CONDUCTION		
Unmasked	<	>
Masked	⊏	⊐
No response	≤	≥

Provisional Diagnosis:

Recommentation :

AUDIOLOGIST.

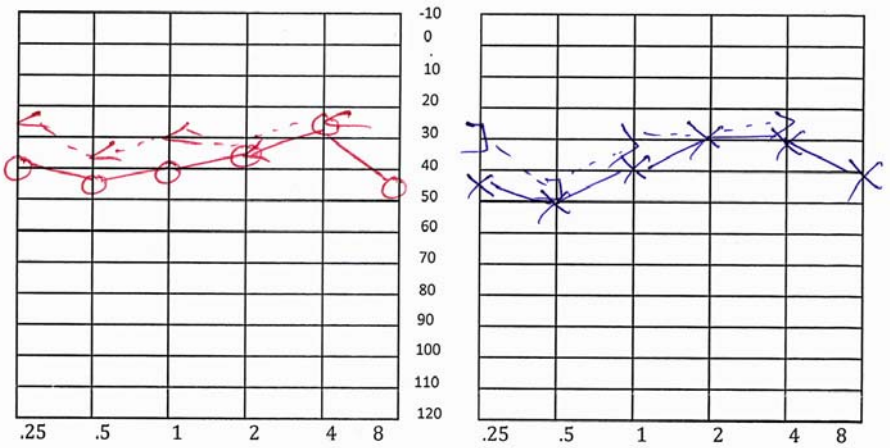
SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

Velayuthan Pillai Memorial Hospital Complex, Padanilam Kulasekharam - 629 161

DEPARTMENT OF ENT-AUDIOLOGY

Name: Sahul Hamud **Age:** 63y/m **Op No :** 17075959

Date : 10/5/17 **Audiometer :** AL13



Right: Mod13 **Left:** Mod13

AIR CONDUCTION	RIGHT	LEFT
Unmasked	○	X
Masked	△	□
No response	↷	↘
BONE CONDUCTION		
Unmasked	<	>
Masked	⊏	⊐
No response	≤	≥

Provisional Diagnosis:

Bl Mild- Moderate SNHL except 2kHz.

Recommentation :

→ENT review
→follow up

AUDIOLOGIST.

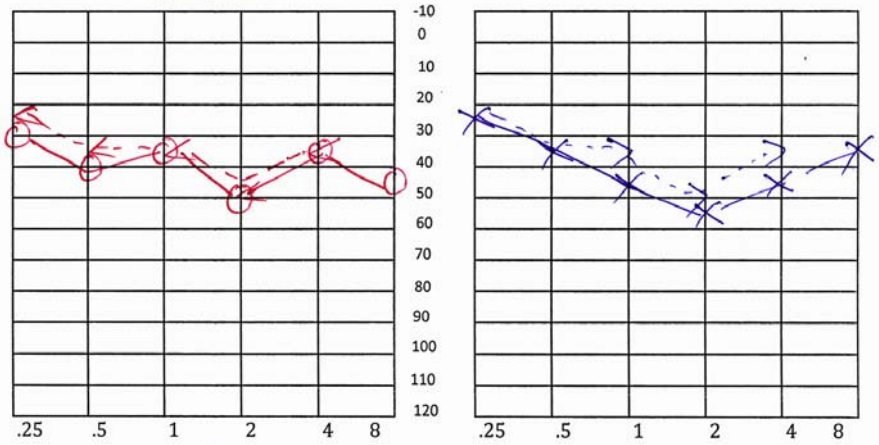
SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

Velayuthan Pillai Memorial Hospital Complex, Padanilam Kulasekharam - 629 161

DEPARTMENT OF ENT-AUDIOLOGY

Name: Antony Venu **Age:** 38y/M **Op No :** 16060233

Date : 5/12/2016 **Audiometer :** ALPS



Right: 41.6dB **Left:** 45dB

AIR CONDUCTION	RIGHT	LEFT
Unmasked	○	X
Masked	△	□
No response	↷	↘
BONE CONDUCTION		
Unmasked	<	>
Masked	⊏	⊐
No response	≤	≥

Provisional Diagnosis:

B/L Mild- Moderate sensorineural hearing loss.

Recommentation :

→ ENT review
→ follow up

AUDIOLOGIST.

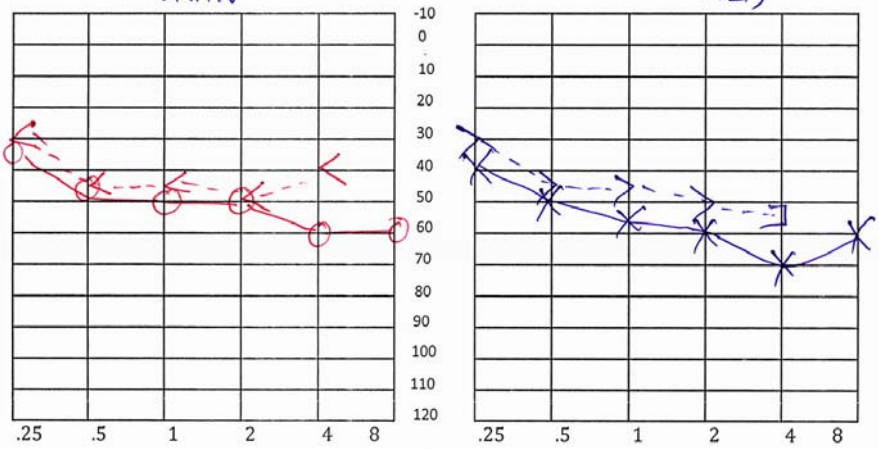
SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

Velayuthan Pillai Memorial Hospital Complex, Padanilam Kulasekharam - 629 161

DEPARTMENT OF ENT-AUDIOLOGY

Name: Prathakaran Nair **Age:** 74y/M **Op No :** 18014935

Date : 19/1/18 **Audiometer :** AD3



Right: 48.3dB **Left:** 55dB

AIR CONDUCTION	RIGHT	LEFT
Unmasked	○	X
Masked	△	□
No response	↷	↘
BONE CONDUCTION		
Unmasked	<	>
Masked	⊏	⊐
No response	≤	≥

Provisional Diagnosis:

B/L Moderate - Moderately severe SNHL except 4KHz.

Recommentation :

→ HAI
→ ENT review
→ Follow up

AUDIOLOGIST.

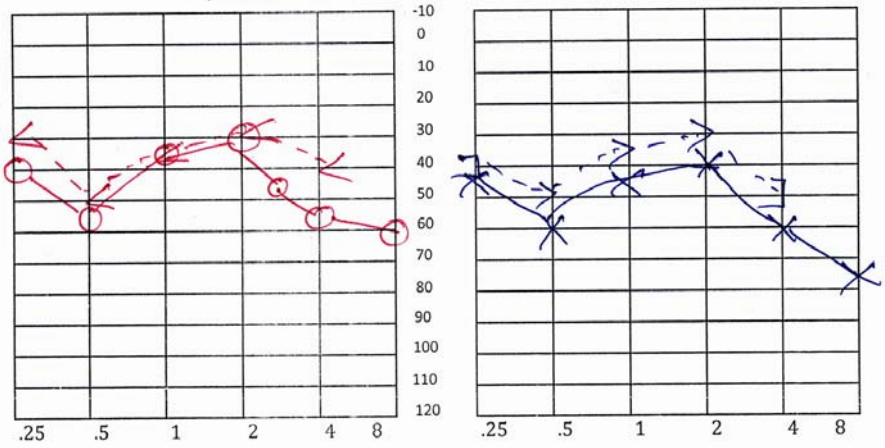
SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

Velayuthan Pillai Memorial Hospital Complex, Padanilam Kulasekharam - 629 161

DEPARTMENT OF ENT-AUDIOLOGY

Name: Bhagyalakshmi **Age:** 59y/F **Op No :** 18073802

Date : 16/4/18 **Audiometer :** ALPs



Right: 60dB **Left:** 48.3dB

AIR CONDUCTION	RIGHT	LEFT
Unmasked	○	X
Masked	△	□
No response	↷	↷
BONE CONDUCTION		
Unmasked	<	>
Masked	⊏	⊐
No response	≮	≯

Provisional Diagnosis:

B/L Moderate SNHL

Recommentation :

→ENT review
→follow up

AUDIOLOGIST.

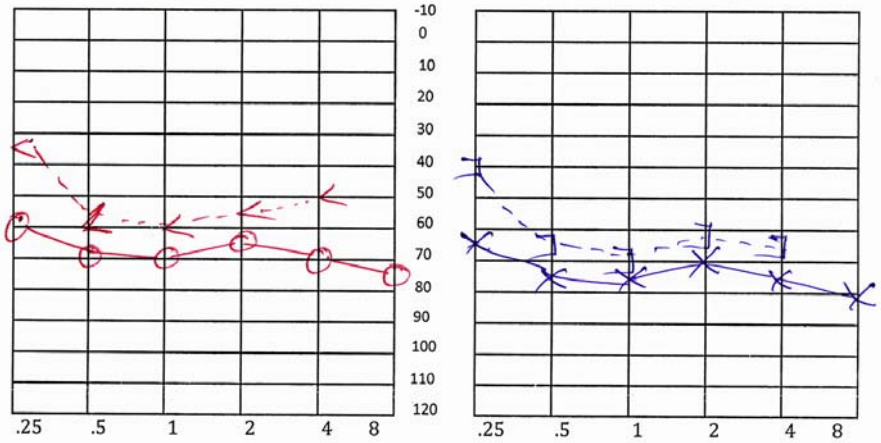
SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES

Velayuthan Pillai Memorial Hospital Complex, Padanilam Kulasekharam - 629 161

DEPARTMENT OF ENT-AUDIOLOGY

Name: Rejeena **Age:** 62yrs/F **Op No :** 17133326

Date : 4/08/2017 **Audiometer :** AJLB



Right: 68.3dB **Left:** 73.3dB

AIR CONDUCTION	RIGHT	LEFT
Unmasked	○	X
Masked	△	□
No response	↷	↘
BONE CONDUCTION		
Unmasked	<	>
Masked	⊏	⊐
No response	≤	≥

Provisional Diagnosis:

B/L Moderately severe - severe sensorineural hearing loss.

Recommentation :

→ ENT review
→ follow up

AUDIOLOGIST.

ANNEXURE – V

MASTER CHART KEY

GENDER	MALE – 1 FEMALE- 2
SMOKING/DRINKING/HTN/DM/THYROID Dx	YES-1 NO-2
DURATION	≤10YEARS- 0 >10YEARS-1
RINNE TEST	POSITIVE-1 NEGATIVE-2
WEBER TEST	CENTRAL-0 RIGHT-1 LEFT-2
ABC	NORMAL-0 MILDLY REDUCED-1 REDUCED-2
PTA	≤25 dB -0 26-40dB -1 41-60 dB -2 61-80dB -3 >80dB -4
TYPE OF HEARING LOSS	NORMAL-0 SNHL-1 MIXED-2

S_No	Date	OP_No	Age	Gender	Occuptaion	Smoking	Drinking	Weight	Hypertension	DM	DM_Duration	Thyroid_Disorder	Rinne_Test	Weber_Test	ABC_Test	Rt_PTA	Lt_PTA	Hearing_Loss_Type	Hearing_Loss_Degree
1	12/05/16	16060233	38	1	Bus Driver	0	0	65	0	1	7	0	1	0	0	2	2	1	Mild- Moderate
2	22/02/2017	17068584	67	1	Retired Office Worker	0	0	73	0	1	23	0	1	0	2	3	3	1	Severe
3	04/11/17	18067771	60	2	House Wife	0	0	57	0	1	12	0	1	0	0	2	2	1	Moderate
4	10/09/17	633680	66	2	Home Maker	0	0	63	0	1	16	0	1	0	2	3	3	1	Moderately Severe
5	25/06/2018	15192202	68	2	Retired Bank Employee	0	0	48	0	1	22	0	1	0	2	3	3	1	Severe
6	05/10/17	17075989	63	1	Business	0	0	82	0	1	25	0	1	0	0	1	1	1	Mild- Moderate
7	08/04/17	17133326	62	2	Teacher	0	0	63	0	1	19	0	1	0	2	3	3	1	Moderately Severe- Severe
8	19/01/2018	18014935	71	1	Retired Farmer	0	0	59	0	1	28	0	1	0	0	2	2	1	Moderate- Moderately Severe
9	16/04/2018	18073802	59	1	Lecturer	0	0	52	0	1	14	0	1	2	1	1	2	1	Moderate
10	04/05/17	17067101	72	1	Business	0	0	84	0	1	30	0	1	0	2	2	2	1	Moderate
11	20/03/2017	17003935	70	1	MilkMan	0	0	68	0	1	20	0	1	0	2	1	2	1	Moderate- Moderately Severe
12	10/11/16	15033611	53	2	Shopkeeper	0	0	59	0	1	12	0	1	0	0	0	0	0	Normal
13	15/1/2017	17191404	51	2	Principal	0	0	63	0	1	13	0	1	0	0	0	0	0	Normal
14	02/12/17	14185872	48	1	Musician	0	0	74	0	1	5	0	1	0	0	0	0	0	Normal
15	30/11/2017	16237722	64	1	Watchman	0	0	79	0	1	3	0	1	0	0	0	0	0	Normal
16	31/10/2016	16219653	65	1	Retiree	0	0	87	0	1	7	0	1	0	0	0	0	0	Normal
17	11/06/16	17259249	53	2	Typist	0	0	48	0	1	14	0	1	0	2	1	1	2	Mild- Moderate
18	12/09/16	16262051	49	1	Technician	0	0	63	0	1	4	0	1	0	1	2	2	2	Moderate
19	17/7/2017	15003366	52	1	Manager	0	0	86	0	1	12	0	1	2	2	4	3	2	Severe
20	18/4/2018	18084691	42	2	Home Maker	0	0	57	0	1	4	0	1	0	0	0	0	0	Normal
21	04/10/18	18078437	46	1	Business	0	0	66	0	1	7	0	1	0	0	0	0	0	Normal
22	16/7/2018	18152806	49	1	Office Staff	0	0	75	0	1	13	0	1	0	1	1	1	1	Moderate
23	26/2/2017	16002484	45	2	Singer	0	0	50	0	1	7	0	1	0	1	1	1	1	Mild- Moderate
24	14/1/2017	17134234	37	1	Receptionist	0	0	62	0	1	3	0	1	0	1	1	1	1	Mild
25	09/07/18	18192239	60	2	Pensioner	0	0	73	0	1	8	0	1	0	2	2	2	1	Moderate
26	13/10/2016	16200884	60	2	Home Maker	0	0	68	0	1	2	0	1	0	0	0	0	0	Normal
27	30/1/2017	17179512	47	2	Teacher	0	0	71	0	1	2	0	1	0	0	0	0	0	Normal
28	20/12/2016	16256123	66	1	Office Staff	0	0	87	0	1	8	0	1	0	0	0	0	0	Normal
29	12/03/16	16243596	48	1	Car Mechanic	0	0	82	0	1	4	0	1	0	1	1	1	1	Mild- Moderate
30	27/3/2017	16002484	35	2	Singer	0	0	58	0	1	2	0	1	1	2	2	2	1	Moderate- Moderately Severe