ASSESMENT OF HEARING STATUS IN PATIENTS WITH RHEUMATOID ARTHRITIS - A ONE YEAR OBSERVATIONAL STUDY IN KLES Dr PRABHAKAR KORE HOSPITAL

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ABBREVATIONDS USED

RA	:	Rheumatoid Arthritis
HI	:	Hearing Impairment
SNHL	:	Sensory Neural Hearing Loss
CHL	:	Conductive Hearing Loss
CRP	:	C-Reactive Protein
ESR	:	Erythrocyte Sedimentation Rate
DMARDs	:	Disease Modifying Anti-Rheumatoid Drugs
PTA	:	Pure Tone Audiometry
EAC	:	External Auditory Canal
dB	:	Decibel, Unit of sound intensity
et al	:	et alii (Latin; ‘and others’)

ABSTRACT

Objectives: To assess the hearing status in Rheumatoid Arthritis Patients

Methods: it was a one-year observational study. A total of 52 patients participated in the study in that 26 patients belonged to the Rheumatoid Arthritis group and other 26 patients belonged to control group. Rheumatoid Arthritis group was selected according to the ACR-EULAR criteria. In this study PTA was done to assess the hearing status and compared with the normal group.

Results: In this present study evaluated the hearing status in Rheumatoid arthritis patients with a pure tone audiometry, ESR, RA factor. The Male: Female ratio in this series is 1:3 The serum level of ESR and RA factor was measured in patients and was found to have no influence on the hearing loss Audiological evaluation was done and found to have hearing impairment in $1/3^{rd}$ the population but it was statistically insignificant.

Conclusion: From the observations in the study, we can conclude that there is a need for continual assessment of hearing status in patients with Rheumatoid Arthritis

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INTRODUCTION

Rheumatoid Arthritis is an Auto-immune connective tissue disease which presents with various systemic manifestations. Prevalence of hearing loss among rheumatoid arthritis patients is debated over years and studies are done to verify that.

Rheumatoid arthritis has an auto-immune origin that can cause articular, extraarticular and systemic effects. The hearing apparatus can be involved by the different methods through the involvement of joints of middle ear ossicles, inflammation of vascular and nerve supply of ear, and the damage which can occur through the usage of drugs that are used in the treatment of the disease but none of the theories have been proved.[1]

Rheumatoid arthritis can present with either conductive, sensory neural hearing loss or mixed. The ossicles of the middle ear are real diarthrodial type of joint that can be affected in the event of systemic arthritis which can lead to conductive type of hearing loss. Sensory neural hearing loss can be because of involvement of vasa vasorum in the form of inflammation of the vessel , inflammation of the nerve, drugs that cause damage to hair cells in the inner ear which are given in treatment of RA and autoimmune effect on the hair cells or can be due to immune complex deposition.[2]

In a study conducted by Lasso de la Vega M, et al.[3] stated that sensory neural type of hearing loss in Rheumatoid patients occurs on both ear with most of the time having same severity in hearing loss .On comparing the gender they have concluded that male above the age of 40 are in high risk of having hearing loss compared to Females.

The goal of this study is to evaluate the hearing loss in Rheumatoid patients by analysing through the help of pure tone audiometry and serum parameters such as erythrocyte sedimentation rate, RA factor.

OBJECTIVE: To assess the hearing in Rheumatoid Arthritis patients.

REVIEW OF LITERATURE:

In a study done by Hyemin Jeong, Young-soo chang in 2016 they have analysed the audiological results to evaluate the hearing in patients with Rheumatoid arthritis according to this study they evaluated the relationship of hearing status and Rheumatoid Arthritis in Korean community. In this study analysis between hearing loss in high frequency and RA did not have any relationship but it might be related with hearing loss of low/mid-frequency after adjusting the risk factors.[4]

According to a study conducted by Adem Yildirim, Gulseren Suruku in 2016 – in this study they compared hearing impairment linking Rheumatoid patients and the normal population and also the relationship of active and re-mission phase of Rheumatoid using audiometry evaluating all the frequency. This study had 88 Rheumatoid patients and 50 normal population were involved. In this study they have concluded that patients with RA have increased risk of hearing impairment, and the active phase of disease increases this risk, especially in higher frequencies.[5]

A study conducted by Louisa Murdin, Sanjeev Patel in 2008 the goal of their study is to compare the hearing impairment in younger patients (55 patients) with Rheumatoid with normal population using PTA and transient evoked otoacoustic emission (TEOAEs) to correlate the disease activity by duration and DAS28 disease activity score. They concluded that 1.9% patients had conductive hearing loss particularly at the mid and low frequencies and there is no significant connection between the disease and the ability to hear.[6]

Amir Emamifar, Kristine Bjoerndal conducted a study in 2016 in that they evaluated the clinical reports published which are related to HI in RA patients and to discuss the pathology behind it and they concluded that Rheumatoid patients are at high risk of HI compared to normal population and that mechanism of injury and the risk factor are not completely clear.[7]

According to study conducted by Chung-Ming Huang, Hsuan-Ju Chen in the year 2018 which was a retrospective study was conducted to find the correlation between hearing impairment and RA and they have concluded that Rheumatoid population is at higher risk of hearing loss then they stressed the need for scheduled auditory examination in Rheumatoid patients for early diagnosis and to prevent hearing loss.[8]

A study by Ioannis Kastanioudakis, Antonios Skevas the goal of the study is to establish the connection of SNHL and RA. They have taken 45 RA patients and subjected them to completed physical and audiological evaluation and, in the end, they stated that mild involving both ear which was equal in both side and is of sensorineural type of hearing loss - cochlear type in 35.5 per cent of patients; and prolongation of acoustic-reflex latency which appeared in a 10% of patients[9]

Wolfe F in his study to weigh the efficacy of C- reactive protein and Erythrocyte Sedimentation Rate in investigating about Rheumatoid Arthritis, CRP is a good acute phase reactant but ESR is effective in identifying the immunoglobulin in his comparison he has concluded that combining CRP and ESR is effective.[20]

In a study conducted by Matteson EL et al they have mentioned the use of Methotrexate in autoimmune disease which can benefit in preserving the hearing in autoimmune disease. [22]

In a study conducted by Polanski JF, Tanaka EA et al they have done hearing test in patients with SLE who were on treatment with anti-malarial drug and they have concluded that hearing loss and drug have no relationship.[23]

According to a study conducted by Nair TS, Raphael Y et al they have discovered that hearing loss is present in patients with monoclonal antibodies.[24]

RHEUMATOID ARTHRITIS

Rheumatoid arthritis is a common connective tissue disorder that leads to inflammatory arthritis, it has a prolonged course and intermittent exacerbations and remissions.

Genetic and environmental factors play an important role in rheumatoid arthritis. The risk genes involved are the major histocompatibility complex (MHC) immune system, immune system and CTLA4, class II, PTPN2. The, HLA-DR4, MHC class II gene, is the major gene haplotype- this HLA-DR4 will have severe disease and decreased response to treatment; DR1 is more commonly affected in India. Risk factors are cigarette smoking (strong risk factor) and in some cases infections are considered – periodontal infections, viruses such as Epstein– Barr & cytomegalovirus, Increased risk in post-partum period this indicated that immune and hormone interaction may play a role.[25]

The beginning of rheumatoid is by infiltration of synovial joint by plasma cells, lymphocytes, macrophages and dendritic cells. Multiple inflammatory factors interact with the synovium. Lymphoid follicles in the synovium intern act on B cells producing cytokines, including Rheumatoid Factor and Anti-citrullinated peptide antibody. Synovial macrophages are activated by deposition of immune bodies and regional damage-occurs leading to tissue damage and remodelling of bone. The joint now becomes deprived of oxygen and this leads to new vessel growth – leading to formation of granulation.

The granulation -pannus produced spreads in the cartilage covering the articulating surface, it leads to erosion which in turn destroys it in the long run. Similar granulations can for in the extra articular areas such as sclera, pleura, etc,

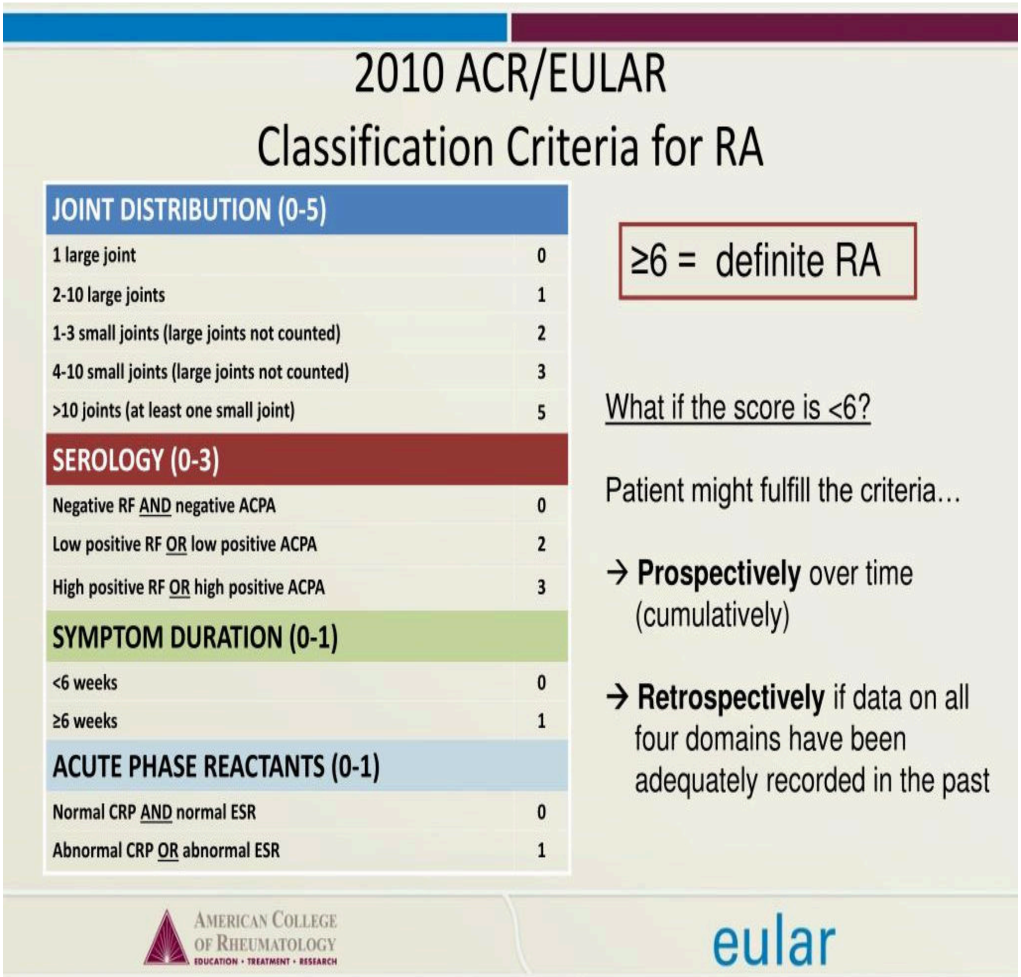
RA not only produces clinical features related to joints it has ability to affect extra articular organs also. RA patients usually present with joint disorders such as morning stiffness, joint pain particularly involving small joints such as PIP, MCP.

The extra articular involvement is mainly because of the immune mediated complex deposition leading to granulation formation and this leads to multiple system involvement including vascular, cardiac and even neurological lesions. So, in our study we wanted to assess the involvement of hearing in Rheumatoid patients. Over the years multiple pathologies have been proposed on how hearing involvement is present in RA.

Fig 1. Swan neck deformity of hand in Rheumatoid Arthritis patients

The Patients included in the study was based on ACR EULAR criteria which was proposed on 2010.

Fig 2. ACR/EULAR criteria



Inflammatory blood tests:

ESR and CRP levels indicate the inflammatory levels in blood are routinely done tests to identify the serum protein levels which indicates the inflammatory levels.

ESR (Erythrocyte Sedimentation Rate)

Once blood is withdrawn it is stored in a vial coated with anticoagulant and left to stand vertically. The red cells of the blood that is the erythrocytes settled down in the base of the tube and plasma in the upper part. "The Erythrocyte Sedimentation Rate is nothing but the speed at which the red cells of the blood settle down at the bottom and it is measure in millimetres / hour". [27]

In inflammatory conditions the inflammatory proteins enclose the red blood cells and this will make the red cells stick to each other which leads to rapid fall of erythrocytes. In conclusion high ESR is directly proportional to the inflammation in the body. [27]

The ESR level is normally higher in females compared to males and with increasing age the ESR levels will also increases. [27]

Normal ESR range is: [27]

Table 1: Normal ESR range

Gender	ESR range
Men below 50 years	Less than15 mm/hr
Men above 50 years	Under 20 mm/hr
Women below 50 years	Under 20 mm/hr
Women above 50 years	Under 30 mm/hr
Newborns and children	2-13 mm/hr

<u>CRP (C-Reactive Protein)</u>

C-Reactive Protein - acute phase reactant and their levels in serum increases if there is a inflammatory condition in our body.

It Is measured by collecting blood in a vial and processing it this test indicates the one specific protein which in turn indicates the inflammation of the body.

“Normal value - 0.0-0.8 mg/dl”. [27]

<u>Disease Modifying Anti-Rheumatic Drugs (DMARD):</u>

Disease-Modifying Antirheumatic Drugs (DMARDs) are a group of medications used to treat inflammatory arthritis like psoriatic arthritis, rheumatoid arthritis and spondylitis. DMARDs are also used to treat other conditions like connective tissue disorders like SLE (systemic lupus erythematous), SSc (systemic sclerosis) and SS (Sjogren’s syndrome) and also in treatment of inflammatory conditions involving the vessels, muscle, uvea, bowel and some type of cancers.[21]

DMARDs causes immunosuppression and immunomodulation and are classified as conventional or biologic.

Conventional type of DMARDs – Example: Methotrexate, Leflunomide

Biological type of DMARDs – Example: Rituximab, Infliximab, Etanercept. [21]

DMARDs used in treatment of Rheumatoid Arthritis

Lot of newer drugs are used to treat Rheumatoid Arthritis out of these drugs methotrexate is one of the frequently used drugs to treat Rheumatoid. Before beginning the treatment of Rheumatoid arthritis several factors to be considered like the severity of the disease, phase of disease, comorbidities in the patient and patient factor to be considered like cost of the drug, route of administration.

Rheumatoid treatment can be a single drug therapy or it can be by combination of drugs, several studies showed that combination therapy if very effective compared to single drug therapy.

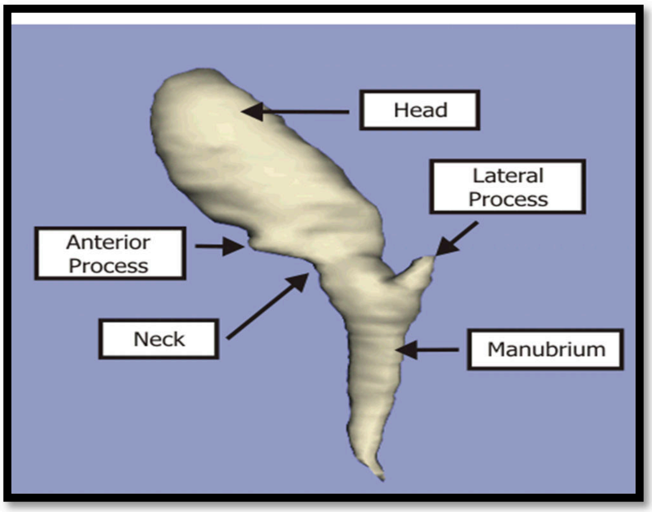
The aim of treatment in Rheumatoid is to control the disease activity, to reduce the remission rate and reduce the progression. The treatment should be started as early as possible so the progression of the disease can be reduced which is found by radiological evaluation and the progression is very evident in first few months of disease. [21]

Middle Ear – ossicles

The Middle Ear contains 3 movable ossicles – that is the Malleus, Incus and Stapes.

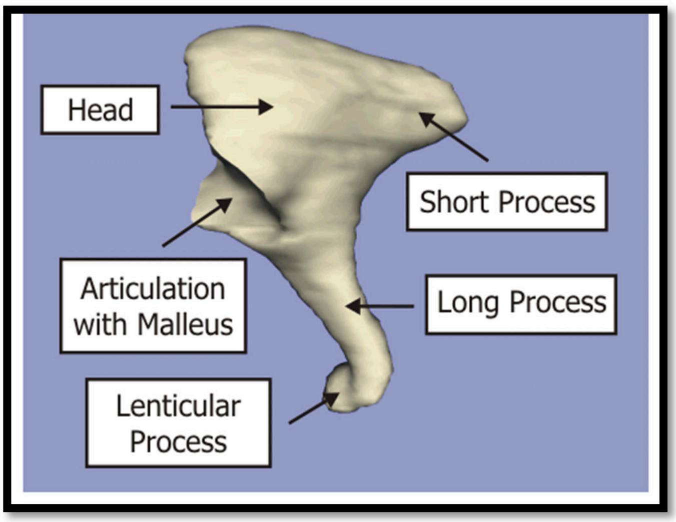
The Malleus – biggest bone of the middle ear , which has a Head, Neck and three process arising below the neck – *anterior* which anchors the anterior ligament which inserts into the petrotympanic fissure, *lateral* which gives attachment to the anterior and posterior malleolar fold and “the *handle of malleus*- this handle of malleus runs downwards and is secured in between the outer and inner layer of tympanic membrane”. Tensor tympani muscle gets attached in the medial side of the handle of malleus and it has additional support from superior ligament to stay in the position. On the medial surface there is a facet to articulate with the incus bone. The facet represents the cartilage of the synovial joint that articulates with the incus.

Fig 3. Malleus bone



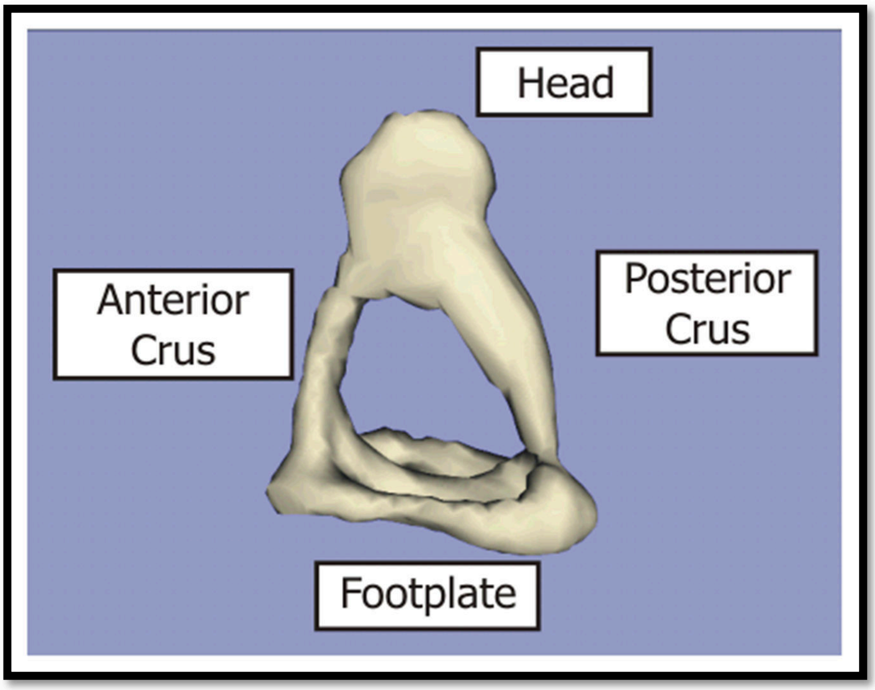
Incus bone – it forms the incudomalleolar joint with the malleus ; parts of Incus- Body which is present in the epitympanum and 2 process – *the short process* which is present in the fossa incudis and is attached to short ligament, *the long process* which projects downwards and in the tip which projects medially called as Lenticular process which forms connects the incus and stapes bone.

Fig 4. Incus bone



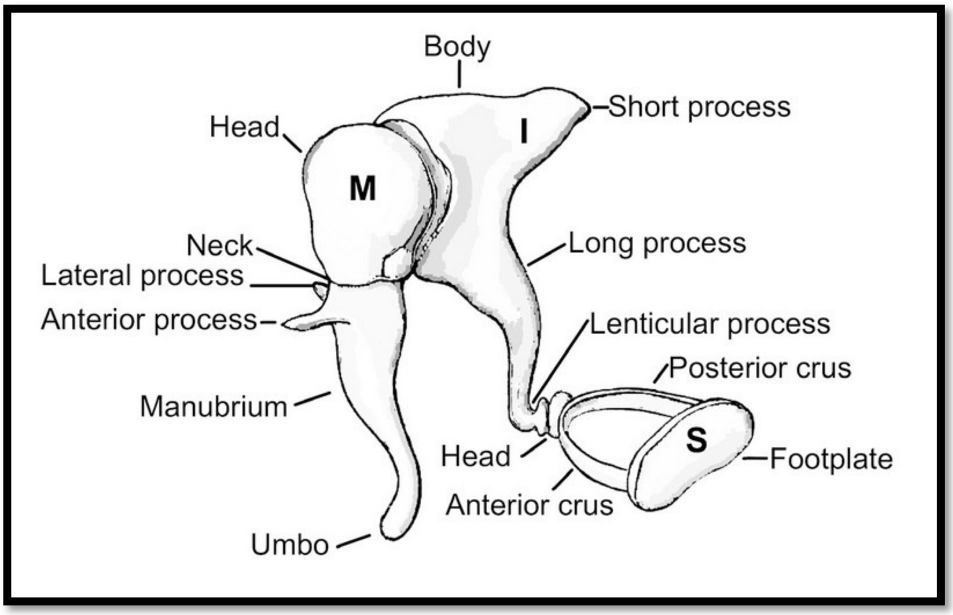
The stapes – parts of stapes are head, neck, 2 crura ,a base also called as foot end of plate . Head of stapes which projects outside have cartilage lined articular region for lenticular process, it is synovial covered joint. The stapedial tendon gets inserted in the neck region. The two cruras joins at the foot plate and the footplate lies over the fenestra vestibuli and is fixed by annular ligament. This foot plate separates Middle part of ear from the inner part of ear by oval window.

Fig 5. Stapes bone



The ossicular joint – " the *incudomalleolar joint* and the *incudostapedial joint*" are little synovial joints. The function of these ossicles is to transfer the sound from the external to the inner part of ear which are transferred as vibrations – on contrary to other synovial joints the movement of the joints are limited and precise.

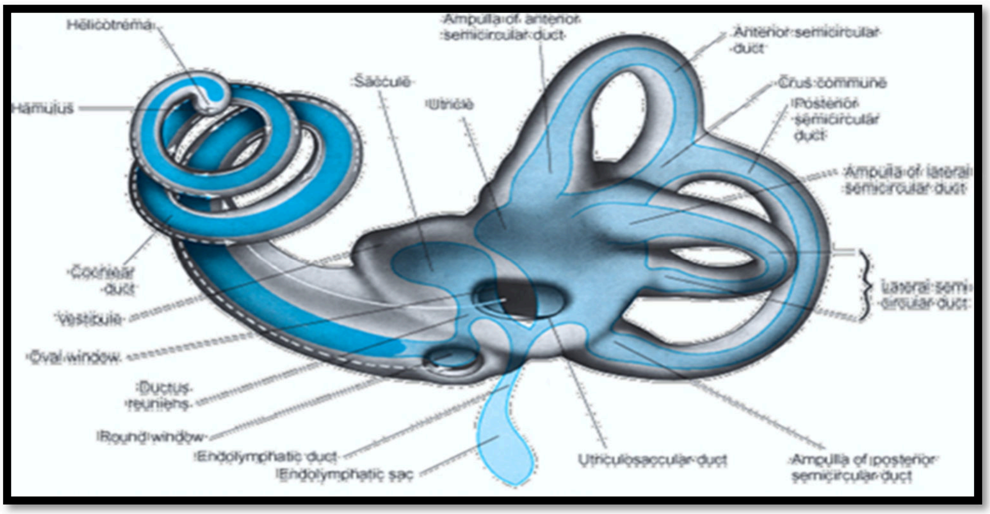
Fig 6. Ossicular joint of the middle ear



Inner ear

Inner part of ear/ labyrinth has "bony & membranous part". The bony part of inner ear consists of 3 parts – the vestibule, cochlea and semi-circular canals. The membranous labyrinth contains macula of utricle and saccule, semi-circular duct, cochlear duct and endolymphatic sac.

Fig 7. Bony labyrinth and Membranous Labyrinth

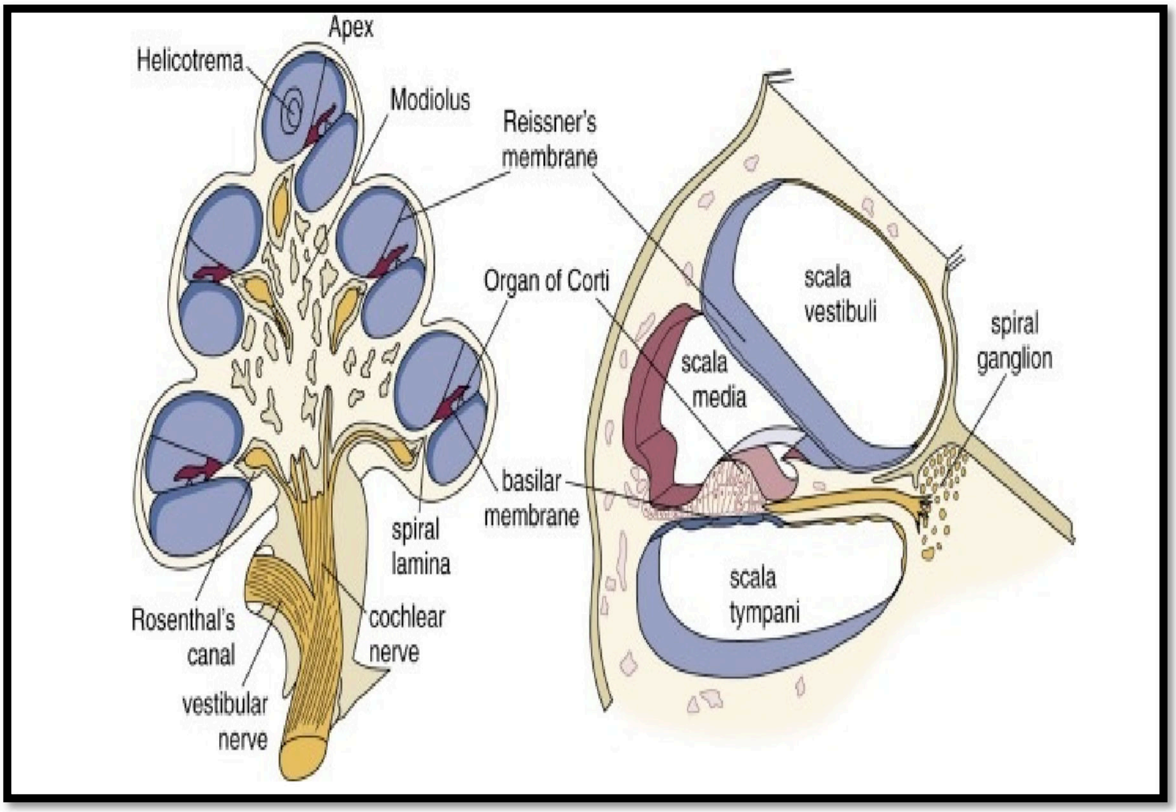


Membranous labyrinth houses sensory epithelium and cochlear duct. Semi-circular canals and the ventricle which houses the macula of utricle and saccule are responsible for equilibrium – they sense the angular and linear acceleration.

The cochlea on the other hand is responsible for hearing. The cochlear duct is a spiral duct running inside the bony cochlea. The bony cochlea has approximately two and half turns. The cochlea turns around the modiolus. It tapers from a broad base to slender apex.

The membranous part that is the cochlear duct is divided into three portions by two membranes. The membranes are Reissner's membrane and basilar membrane. The three portions are scala vestibuli, scala media and scala tympani.

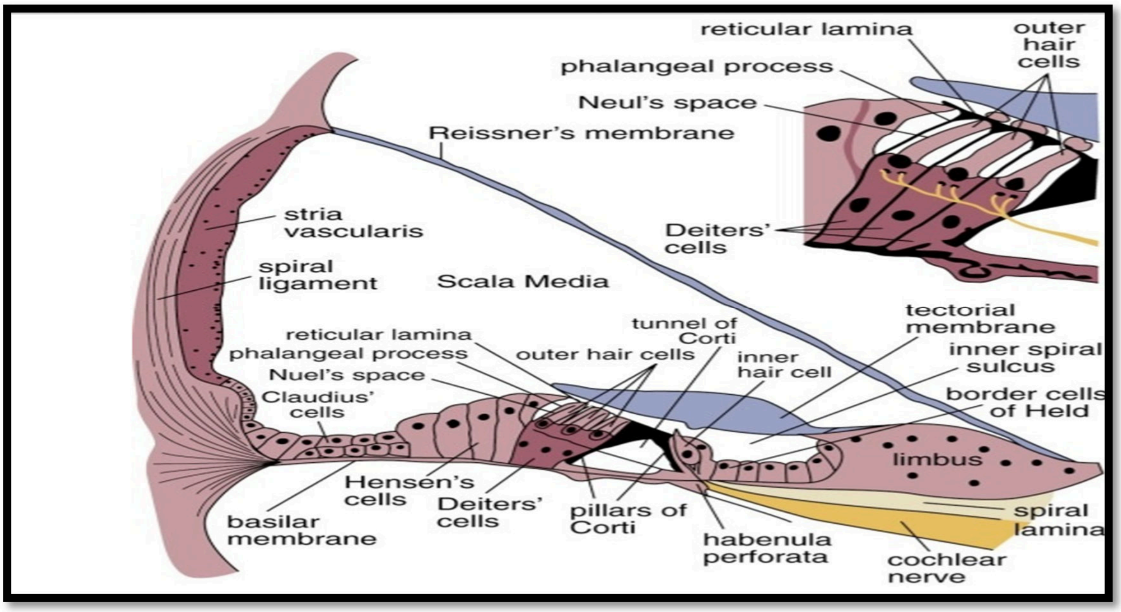
Fig 8. Cross section of labyrinth



In this scala-vestibuli comes in touch with stapes foot plate and scala tympani comes in contact with the round - window and scala -media houses "The organ of corti".

“The organ of corti” is a sensory epithelium lying on on zona arcuata of basilar membrane. Towards inside, on the superior portion of spiral lamina is the limbus, which gives attachment to “Reissner's membrane and tectorial membrane”. The “tectorial membrane” is a gelatinous structure overlying the hair cells it moves up and down over the hair cells on vibration. Hair cells have inner and outer cells – inner cells have one row and are surrounded by s.upporting c.ells. Both inne'r & oute'r hair cells lie inside the “The organ of corti”. The supporting cells are ' Deiters’ cell, Hensen's cells and Claudius’ cells'. The neul's space and the tunnel of corti are filled with perilymph and remining space is filled with endolymph.

Fig 9. Cross section of scala media



“The organ of corti” has outer and inner hair cells. Outer hair cells - cylindrical in shape and are more in number (approx. 12000) afferent fibres are carried by the auditory part of the VIII cranial nerve and efferent is by Medial superior olivary complex. The outer hair cells prone to damage. Inner hair cells on the other hand are flash shaped and few in numbers compared to that of outer hair cells (approx. 3500) afferent is similar to that of outer hair cells and efferent is by lateral superior olivary complex and they are more resistant to injury compared to outer hair cells.

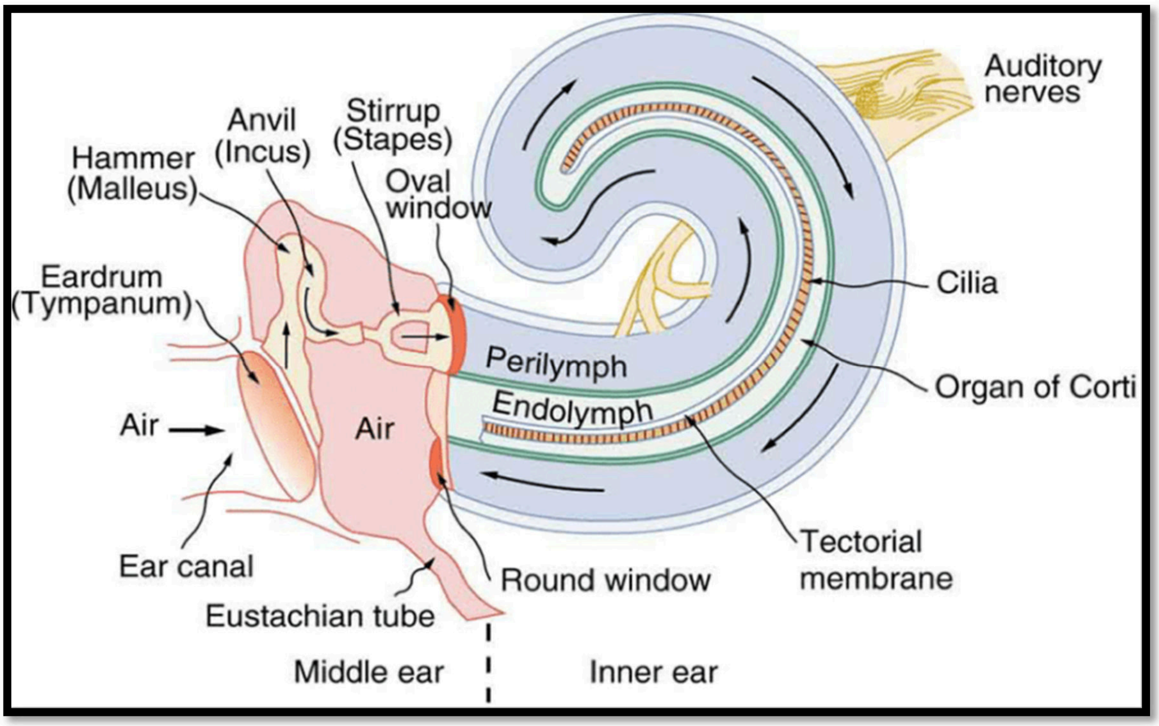
Physiology of hearing

Mechanism of hearing:

- Mechanical conduction of the sound
- Conversion of mechanical energy into electrical impulse (sensory system)
- Electrical impulse into the cerebral cortex (neural pathway).

Signals from the ear are converted to electrical impulse as it travels through air to fluid – filled inner part of ear. Transmission of sound power from air–fluid medium leads to loss of intensity to match this external and middle ear increase sound pressure by certain mechanisms.

Fig 10. Sound Transmission from External to Inner Part of Ear



Loss of sound energy is compensated by the impedance matching, that is accomplished by:

- Ossicular- lever chain ratio. (1.3:1).
- Ratio of area of tympanic membrane and oval window (effective ratio is 14:1)
- Phase difference between oval and round window

Reception of sound

Oval window is pushed by the sound transmission which in turn causes movement of fluids in the inner part of ear. This wave travel through the perilymph and causes changes in elastic tension of the basement membrane travelling wave sets in Hair cell deflection & impulse generation on organ of corti –**mechanoelectrical transduction.**

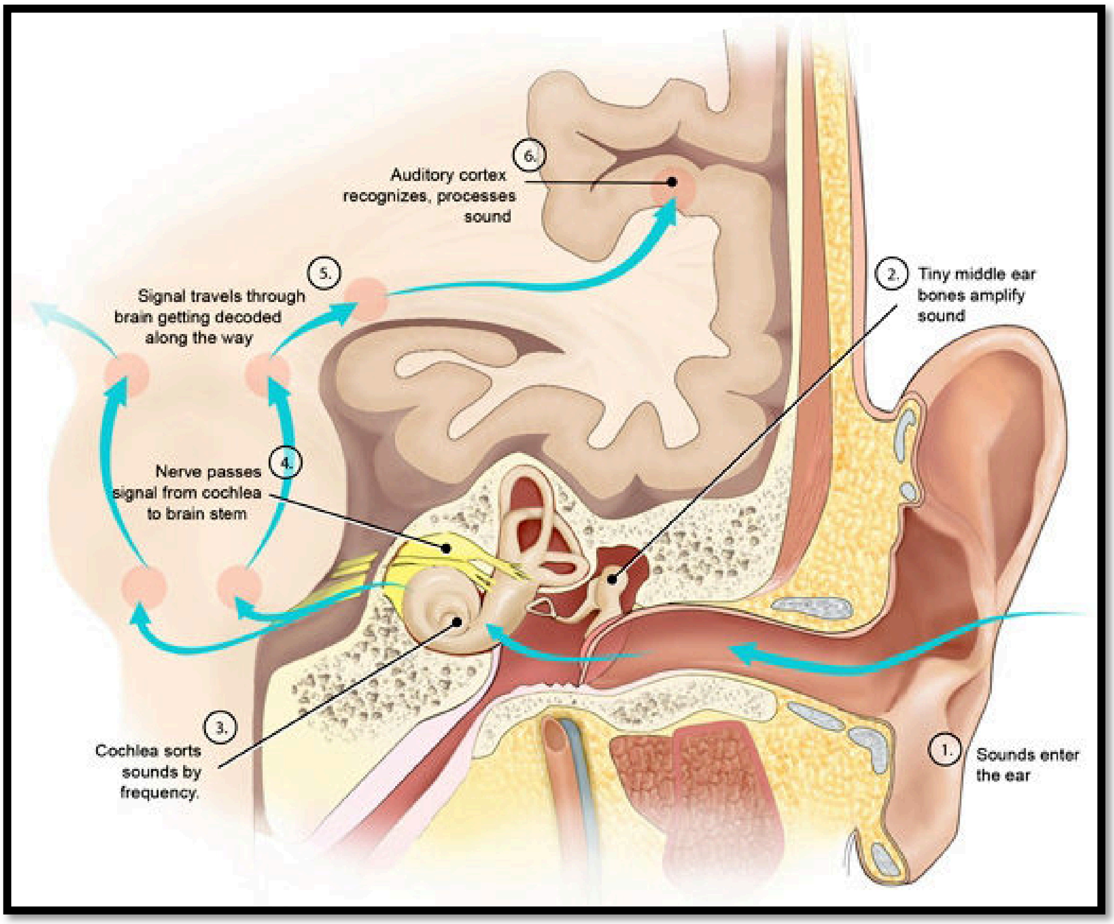
This is further explained by understanding the function of hair cells in the conversion of mechanical energy into electrical energy. The compressional wave causes a rub of the tip of hair cell and tectorial membrane leads to change of direction of the hair cell tip. This opening up of the hair cell leads to discharge or gain of electrical charge in the hair cell. By this mechanism the mechanical energy gets converted to electrochemical signal.

The Hot spots which are voltage gated calcium channels present in the floor of the inner hair cells which contains nerve synapse comes in contact with ascending auditory nerve fibers. Once inner hair cells are discharge voltage-gated calcium channels open this triggers release of neurotransmitter across synapse and activates auditory nerve fibres.

Auditory pathway

Nerve impulses that have generated at the sensory hairs of spiral organ, transmitted through Cochlear nerve. This nerve combines with vestibular nerve and together they form ‘vestibulocochlear nerve or cranial nerve VIII '. Pathway of the neurons here ends up in AUDITORY CORTEX where the sounds are interpreted.

Fig 11. Auditory Pathway



Pure Tone Audiometry:

Pure-tone audiometry - "gold standard test of audiologic examination". Role of this test is to evaluate the hearing. The hearing by air conduction is measured by thresholds and are measured by stimulation through tones that range from 0.125kHz - 8 kHz using a headphone. Bone conduction also measured similarly in this the probe is placed in bone in mastoid region tonal stimulation of frequencies form 0.25 – 4 kHz. Then graph is plotted by connecting the threshold of hearing in various frequency, is called "audiogram," "pure-tone audiogram," "tonal audiogram."

Pure-tone audiometry – frequently done test to evaluate hearing. Pure-tonal signal were delivered to the external ear through air conduction and bone conduction in different frequencies, patient replies to the sound by signalling examiner with button or raising a hand.[28]

Theories of hearing

"Helmholtz's place theory (1883) :In this theory it is postulated that basilar membrane acts as a series of tuned resonators similar to piano strings high frequency excites basal region low frequency excites apical region

Rutherford's frequency/ telephone theory (1886):In this theory it is postulated that all frequencies activate the entire length of the basilar membrane along with the hair cells.

He believed that all vibrations are portrayed by the nerve impulses to the brain without complex vibrations in the cochlea

Wever's volley resonance theory (1949): This theory combines both the place and telephone theories. According to this theory high frequency are perceived in basal turn and low frequency – stimulates nerve action potential equal to frequency stimulation.

Von Bekesy's travelling wave theory (1960): In this theory it is stated that wave begins from the base and move towards the apex. High frequency produces short wave that does not travel beyond the basal turn where as Low frequency produces maximum displacement near the apex."

Proposed changes in hearing by rheumatoid arthritis

"1. Synovial destruction of incudostapedial (IS) and incudomalleolar (IM) joints by an inflammatory process. As IM and IS joints are true diarthroses, they may consequently be involved in RA, like any other joints in the body. This may cause no clinical symptoms since these two joints are functionally fixed during sound transmission[7].

2. Rheumatoid nodules are the most prevalent extra-articular manifestation in RA patients that may present in different locations, however commonly found subcutaneously at points of pressure.

Various ear nose throat sites including pharynx, larynx and nose as well as the ears may be affected. Treatment with methotrexate and possibly tumour necrosis factor (TNF) inhibitors may cause rheumatoid nodules or aggravate the tendency to development[7].

3. Auditory neuropathy due to a probable vasculitis as a part of mononeuritis multiplex[7].

4. Destruction of the cochlear hair cells, or the inner ear due to immune complex deposition[7].

5. Drug-induced ototoxicity: Certain kind of drugs including salicylates, non-steroidal anti- inflammatory drugs (NSAIDS), antimalarial and some other disease-modifying antirheumatic drugs (DMARDS) can affect the auditory system[7].

• Tinnitus, loss of absolute acoustic sensitivity and alterations of perceived sounds are the most frequent side effects of large doses of salicylates. Symptoms develop shortly after treatment initiation, fluctuating during the treatment, and are generally reversible[7].

• Hydroxychloroquine and chloroquine are associated with variable injuries to the cochlear sensory hair cells and a decrease in neuronal population and supporting structures as well as atrophy of stria vascularis resulting in SNHL. This might be reversible if appropriate treatment with corticosteroids in addition to cessation of the drugs is initiated[7]."

METHODOLOGY

Study Design– An observational study.

Study Period–1st January 2020 to 31st December 2020 over a period of one year.

Source of Data– Patients diagnosed with Rheumatoid Arthritis and control containing healthy population with in age of 18 - 60 years presenting to Medicine & ENT OPD at "the KLES Dr. Prabhakar Kore Hospital and Medical Research Centre and Charitable Hospital, Belagavi"

Sample Size– 52cases.

"Ethical Clearance– Obtained from the Institutional Ethical Committee

Inclusion Criteria –

1.All patients in the age group of 18 to 60 years

2.Diagnosed case of Rheumatoid Arthritis based on ACR/EULAR 2010 criteria who are willing to undergo PTA and blood investigations

3.The control group will consist of patients with a normal state of health, free from all signs or symptoms of ear disease and from obstructing wax in the ear canal, and with no history of exposure to noise, potentially ototoxic drugs other than drugs used for rheumatoid arthritis , or familial hearing loss those will attend our ENT department".

Exclusion Criteria –

1.Patients who suffered from other immune-mediated disease

2.Patients suffering from external, middle and inner ear disorders

3.Traumatic head injury,

4.Metabolic diseases Metabolic disorders such as diabetes mellitus, hyperlipidaemias, thyroid dysfunction and renal disorders

5. Hypertension

6.Noise exposure

7.Ototoxic drugs other than RA medication

Methodology:

- "After taking informed consent from the patient, their details and a through clinical history will be obtained for duration of hearing loss, duration of rheumatoid arthritis and drugs taken for it will be assessed.
- All patients will be clinically examined including general physical examination, careful examination of the ear, nose and throat, tender and swollen joints. Patients visual analogue scale will be recorded
- Otoscopic examination and tuning fork tests will be performed.
- Hearing assessment will be done with MAICO MA53 audiometer.
- The hearing threshold for Pure Tone audiometer will be determined in a sound treating room at frequencies ranging from 125-8000 Hz for air conduction and 250-4000 Hz for bone conduction.
- ACR EULAR and ESR will be used as a measure of disease activity for

RA"

Pure Tone Audiometry

The assessment of hearing was done on an outpatient basis with the help of pure tone audiometry. This test was performed by using the MAICO MA-53 apparatus (as shown in Pic). Here, the subject is made to sit in a soundproofed room, and wear headphones such that the designated cup falls over the designated ear. Testing is done separately for each ear.

Pure tones (sounds of a single frequency) are presented to each ear in order of increasing frequency and the lowest perceived intensity for each tested frequency is recorded. This lowest perceived intensity is called the threshold for that frequency. The average increase in the thresholds of speech frequencies gives the magnitude of hearing loss in decibels (dB). Air conduction is tested by microphones in EAC and bone conduction tested with help through placing specialized microphone over the mastoid process in the post auricular region. The rationale is that impairment in hearing will reduce the perception of low intensity sounds (i.e., sounds of less loudness).

A graphic representation of thresholds for increasing frequencies of pure tones is made, and the resulting plot gives an indication of the type of hearing loss. The audiogram shows absent or negligible air-bone difference for sensorineural hearing loss and air conduction as well as the bone conduction curves show elevated hearing thresholds.

Interpretation of Audiogram

In this study the hearing loss is classified based on WHO classification

It is classified as:

Table 2: WHO classification of hearing loss

Degree of Hearing Loss	Hearing Threshold (PTA)
Mild	26-40dB
Moderate	41-55dB
Moderate – Severe	56-70dB
Severe	71-90dB
Profound	> 91dB

STATISTICAL METHODS USED:

"Data was analysed using following statistical methods

1. Diagrammatic representation.
2. Mean ± Standard deviation.
3. Chi square test.
4. Kolmogorov Smirnov test for normalcy of the parameters.
5. Karl Pearson's correlation coefficient method to check the correlation"

RESULTS

In all, 52 Patients diagnosed with Rheumatoid Arthritis & control group of healthy individuals with age group between 18 - 60 years presenting to Medicine & ENT OPD at "the KLES Dr. Prabhakar Kore Hospital and Medical Research Centre and Charitable Hospital, Belagavi"

1. Sex distribution

In 52 patients who were involved in this study ;26 individuals are included in case group and 26 individuals in control group. There was a female predominance in the study.

Fig 12: Gender Distribution of the sample

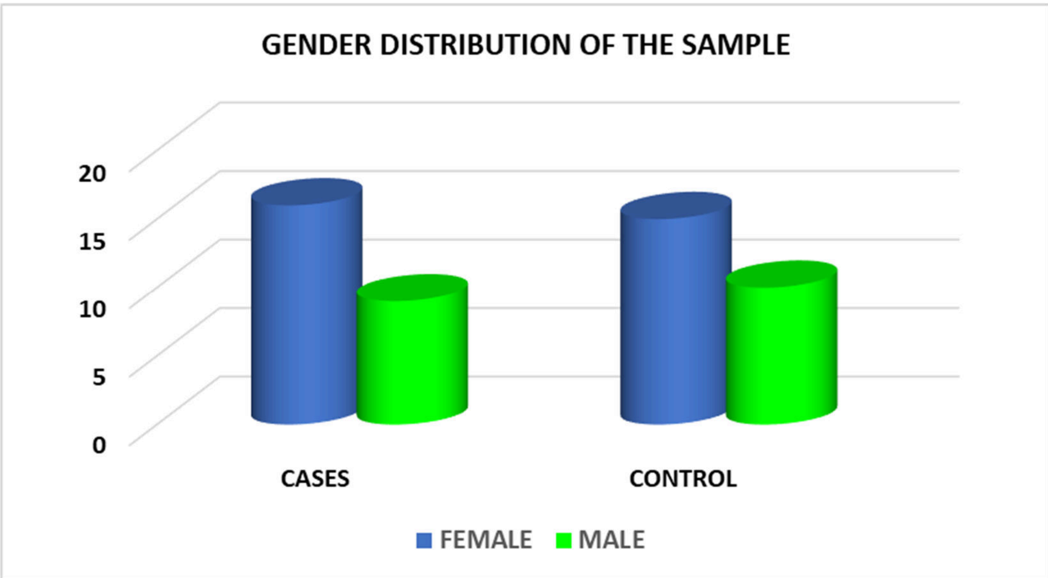


Table 3: Gender Distribution of the sample

Gender	Cases	Control
Male	10	11
Female	16	15
Total	26	26

2.Age wise distribution of patients.

Figure 13: Age Distribution of the sample

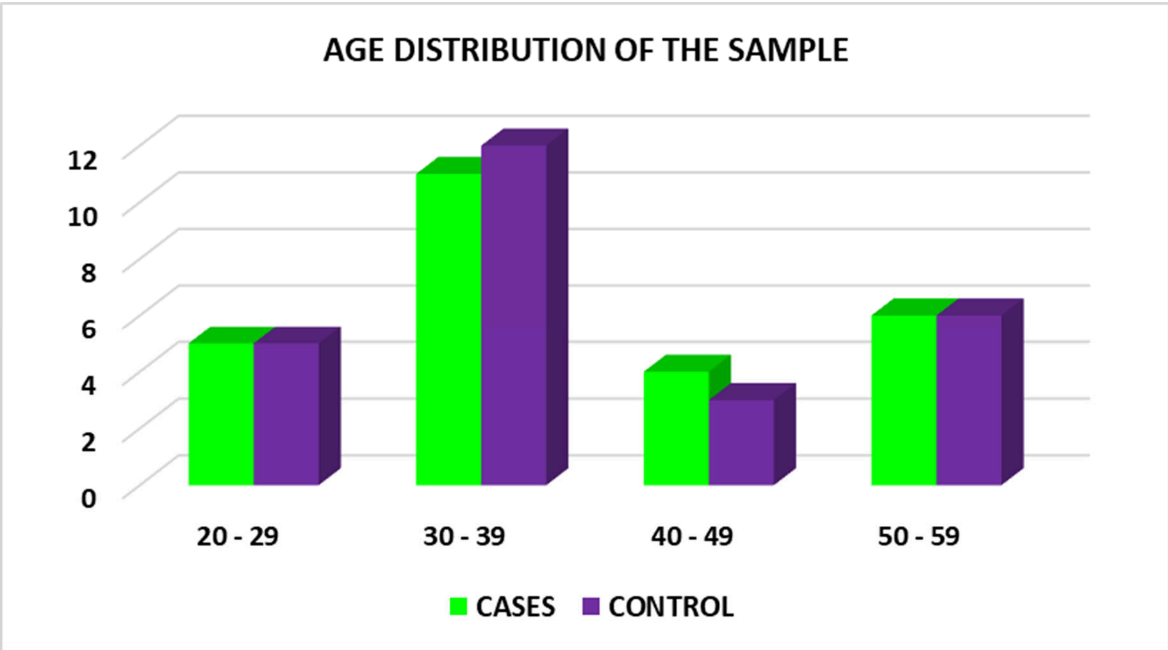


Table 4: Age Distribution of the sample

AGE	CASES	CONTROL
20 - 29	5	5
30 - 39	11	12
40 - 49	4	3
50 - 59	6	6
TOTAL	26	26

In the total of 52 patients in this study a age between 18-60 years are included in the study and there was a peak seen in the age around 30-39 years and 50-59 years

It is due to the bimodal distribution seen in the rheumatoid arthritis disease

3. Type of Hearing loss seen in this study

Figure 14: Distribution of type of hearing loss

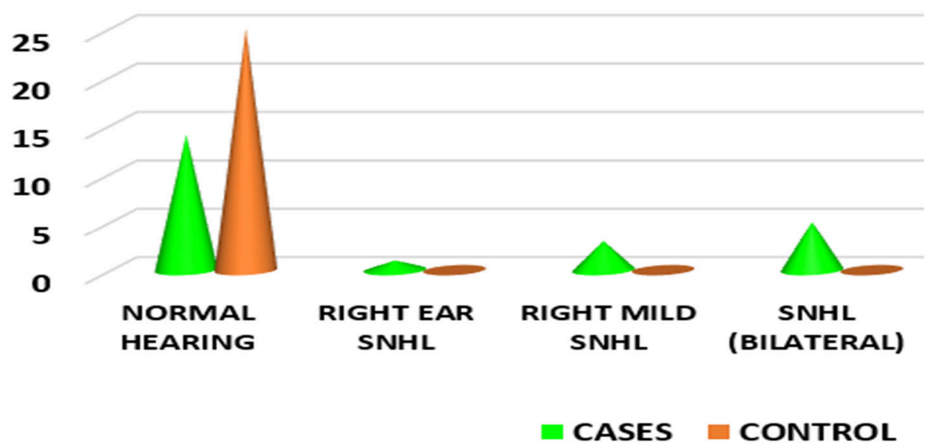


Table 5: Type of hearing loss in the sample

Types of Hearing Loss	Cases	Control
Normal Hearing	13	26
SNHL (Bilateral)	6	0
SNHL(Unilateral)	6	0
Mild CHL	1	0
Total	26	26

In this study 26 cases were included and around 13 patients had normal hearing and the hearing loss was divided into sensory neural and conductive hearing loss in this case group around bilateral SNHL was seen around 6 patients and 'unilateral SNHL was seen in 6 patient's and a mild CHL was seen in 1 patient in case group and control group all 26 patients had normal hearing'

4.Frequency of hearing loss

Table 6: frequency of hearing loss in the sample

Frequency of hearing loss	Number	%
2000Hz	6	26.00
2500Hz	2	6.00
3000Hz	2	6.00
Below 2000Hz	2	6.00
Normal hearing	14	56.00
Total	26	100.00

In the case group of 26 patients 14 patients had normal hearing and 6 patients had SNHL in 2000 HZ and 2 patients have SNHL in 2500 HZ; 3 patients have SNHL in 3000 HZ and in low frequency in 2 patients

5. Correlation Between Hearing loss and Rheumatoid Arthritis

Figure 15: Correlation Between Hearing loss and Rheumatoid Arthritis

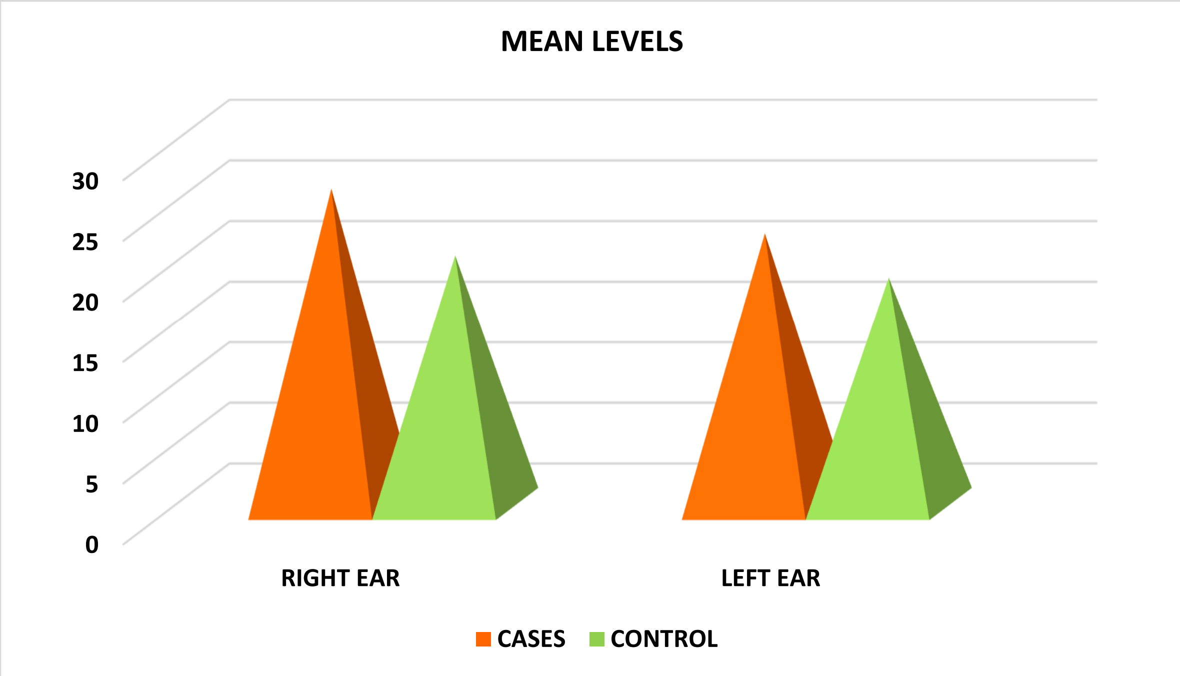


Table 7: correlation between Rheumatoid Arthritis and hearing loss

	CASES				CONTROL					
	MEAN	**S.D.**	**MIN**	**MAX**	**MEAN**	**S.D.**	**MIN**	**MAX**	**p VALUE**	**INFERENCE**
RIGHT EAR	25.98	10.42	11.6	45	20.47	5.64	11.6	35	0.0243	S
LEFT EAR	22.30	8.90	11.6	45	18.64	4.21	11.6	29	0.0690	NS

The Relevance of hearing loss and Rheumatoid Arthritis was calculated and compared to controls the case group has more prevalence of hearing loss and comparison was carried between right and left ear which showed statistically significant hearing loss in right ear in case group and in left ear it was not statistically significant

6.ESR level and Rheumatoid arthritis

Table 8: ESR level in sample

ESR Levels	Mean	S.D.	Min	Max
Cases	37.24	21.30	8	96

In a total of 26 Rheumatoid Arthritis patient ESR levels were evaluated to look for any correlation between acute phase reactants (active stage of Rheumatoid Arthritis) and hearing loss and a mean value was calculated and there was nil correlation statically between hearing loss & ESR values.

7.Duration of RA and DMARDs relationship with Hearing

Table 9: Duration of RA and DMARDs relationship with hearing

Cases	Mean	S.D.	Min	Max
Duration of RA	4.67	4.80	0.25	22
DMRDAs	3.64	4.43	0.04	20

The duration of RA was noted in patients having Rheumatoid Arthritis to look for any relevance with hearing loss and a mean value was created there was no positive relationship between duration in RA and hearing impairment.

The disease duration in patients taking DMRDAs was also correlated with duration as patients are almost always started with DMRDAs after conformation of the disease and the use of DMRDAs also does not have any positive correlation with hearing loss.

DISCUSSION:

Results of the study showed that there is no statistically significant hearing loss associated with Rheumatoid arthritis.

"All continuous variables are presented as the mean ± SD and compared using independent t test. Categorical data are shown as percentages and compared using the Chi square test".

Sex distribution: comparison with present study:

Table 10: Sex distribution: comparison with present study

STUDIES	MALE	FEMALE
Muhammed et al[1]	10	36
Ahmadzadeh et al[2]	7	75
Present study	21	31

The sex distribution between various groups are discussed in the above tabulation in one study conducted by Muhammed et.al total of about 46 patients in that number of male are 10 and female are 36 ; in an another study conducted by Ahmadzadeh et al total number of patients were 82 in that number of male is 7 and female is 75.

Age distribution and hearing loss:

According to Scott Brown 8th edition[17], the prevalence of age associated hearing loss in a population is tabulated:

Table 11: Age distribution and hearing loss prevalence

Age group (years)	Prevalence (%)
18–30	2
31–40	5
41–50	10
51–60	17
61–70	30
71–80	53

In this present study, it is found that a positive correlation exists between advancing age and hearing loss, with the p values of 0.99 and 0.06 for each ear.

Total ESR levels:

Table 12: Total ESR levels

]Studies	RA group (average value)	Non – RA group (average value)
Muhammed et al[1]	15	6
Ahmadzadeh et al[2]	35.1	7.1
Present study	37.24	10

ESR signifies the inflammation associated with conditions like infection, cancer and inflammatory disease. The ESR level signifies the inflammatory process associated with this disease.

Normal ESR level is 0-22mm/hr - men; 0-29mm/hr - women. In a study conducted by Muhammed et al in-RA group the average value of ESR was 15 and in Non – RA group it was 6 and, in another study, conducted by Ahmadzadeh et al the mean ESR level in RA group was 35.1 and in Non- RA group it was 7.1. In our study there was a statistically significant ESR value in RA group that was 37.24.

DMARDs and their association with hearing loss:

Table 13: DMARDs and their association with hearing loss

Studies	Drugs	No of years DMRDs used in average
Takatsu M et al[10]	NSAIDs	20
	Steroids	27
	Other DMARDs	31
Present study	NSAIDs	19
	Steroids	20
	Other DMARDs	25

Disease modifying Anti-rheumatoid drugs in literature was told to be ototoxic and cochleotoxic and in a study by Takatsu et.al they found that there is no positive relationship between DMARDs usage and hearing impairment, the results were not significant.

Similarly, in our study the duration of consumption of DMARDs and the hearing loss were not significant.

Duration of the disease and hearing loss:

Table 14: Duration of RA and hearing loss

Study	Disease duration	P value
Takatsu M et al[10]	8.1 years	Not significant
Present study	11 years	Not significant

In a study conducted by Takatsu M et al[10] stated that the disease duration doesn't have any significance in hearing loss and in the present study the duration of the study didn't have any significant changes in hearing loss.

Hearing loss in Rheumatoid Arthritis:

Table 15: Hearing loss in Rheumatoid arthritis in comparison with a study

Study	RA group	Non- RA group	Significance
Muhammed et al[1]	In 19 patients – 15 had hearing loss	In 19 patient no hearing loss	0.001
Present study	In 26 patients – 13 had hearing loss	In 26 patients – no hearing loss	0.1863

"In a study conducted by Muhammed et al[1] there was a significant hearing loss but in our current study there was no clinical significance in hearing loss and rheumatoid arthritis.

In a study conducted by Elwany SA et al they have concluded that in a total of 48 patients 20 patients had hearing loss they have concluded that in some cases cochlear pathology was present but there is no significant relationship between hearing loss and the activity of the disease or drugs used in its treatment.[11]

Salvinelli F et al they have concluded that high prevalence of hearing loss is present in autoimmune disease like rheumatoid arthritis.[12]

In another study conducted by Kiakojuri K et al they have found that there is a positive correlation between hearing loss in Rheumatoid arthritis particularly in high frequency around 4000 to 8000 Hz.[13]

Rahne T et al in their study concluded that there is a significant correlation found between hearing loss in cumulative dose of steroids and in other autoimmune disorders like Systemic Lupus Erythematosis, wegners granulomatosis, in the above autoimmune disorders there were a moderate to high risk of conductive hearing loss but in contrast low risk in Rheumatoid Arthritis patients. [14]

According to a study conducted by Dikici O, Muluk NB et al in 20 patients they have done transient evoked otoacoustic emission in early period of Rheumatoid Arthritis, they have concluded that due to inflammation and fibrosis in active stage of the disease causes conductive hearing loss but in their study majority of the patient had sensorineural hearing loss. [15]

Lasso de la Vega M, Villarreal IM et in their study found that sensorineural hearing loss must be considered and they have demonstrated that an an extended-high-frequency audiometry is a useful audiological test that must be performed within the diagnostic and follow-up testing of patients with rheumatoid arthritis, providing further insight into a disease-modifying treatment or a hearing loss preventive treatment.[16]

According to a study conducted by Rosenberg JN, Moffat DA they have compared pure tone audiometry results in case and control there were no subjects in either group showed hearing loss on pure tone audiometry. [17]

Pascual-Ramos V et al in their study in Mexican population with rheumatoid arthritis had previously undiagnosed Hearing Impairment, mainly of sensorineural type, of mild severity, and bilateral.[18]

Emamifar A et al reviewed literature in that they have found there is a link between hearing impairment and they have suggested that to test hearing in all newly diagnosed RA patients at diagnosed as well as regularly during the course of disease”.[19]

According to a study conducted by Chen R, Schwander M, et al using muraine model and studying the hearing loss in this study by taking a micro – CT of the ossicles and in age matched muraine model they have compared the diseased ones concluding that there was narrowing in space between the incudo-stapedial joint (diarthrosis) and it was worth to check hearing in human subjects suffering from Rheumatoid Arthritis for their wellbeing.[29]

Gamal NM, El-Oseily AM, et al conducted a study in which they have included 85 female and 10 male Rheumatoid patients and conducted a high frequency extended audiometry in these patients and found to have hearing loss in 68.4%and 64.2%. they have concluded that hearing loss was sensory neural in most of the patients.[30]

CONCLUSION

Rheumatoid Arthritis is an autoimmune inflammatory disorder that can affect more than just joints. In some patients this condition can damage various organs, like the skin, lungs, blood vessels and heart. In this present study we are evaluating the hearing status in Rheumatoid arthritis patients with a pure tone audiometry, ESR, RA factor

In review of literature with auditory evaluation shows there is a positive correlation between hearing loss and Rheumatoid Arthritis

I. The Male: Female ratio in this series is 1:3

II. The serum level of ESR and RA factor was measured in patients and was found to have no influence on the hearing loss

III. Audiological evaluation was done and found to have hearing impairment in $1/3^{rd}$ the population but it was statistically insignificant

"From the observations in the study, we can conclude that there is a need for continual assessment of hearing status in patients with Rheumatoid Arthritis".

SUMMARY

This study was conducted in “KLES Dr Prabhakar Kore Hospital, Belagavi during a study period of one year on patients aged between 18 and 60 years with Rheumatoid Arthritis attending ENT & HNS outpatient department”.

All patients’ through history taking and examination was done. These patients were subjected to Pure Tone Audiometry for assessment of hearing threshold and fasting ESR estimation. The following results were noted. 1)Male: Female ratio was 1:3 2) There was no statistically significant hearing impairment in Rheumatoid patients in case group who are proven case by RA factor and according to ACR- EULAR criteria. 3)There was no statistically significant hearing loss in patients taking DMARDs and there is no significance between duration of the disease of Rheumatoid Arthritis.

But, according to literature it is suggested that all newly diagnosed with Rheumatoid Arthritis and in regular intervals is suggested to undergo hearing test as sensory neural hearing loss was prevalent in this population.

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ETHICAL CLEARANCE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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Ref: MDC/DOME/ 305 **Date: 24/12/2019**

To,
BE0119007
PG student in Otorhinolaryngology and Head & Neck Surgery,
J. N. Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ASSESSMENT OF HEARING STATUS IN PATIENTS WITH RHEUMATOID ARTHRITIS – A ONE YEAR OBSERVATIONAL STUDY IN KLES DR. PRABHAKAR KORE HOSPITAL"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Anita Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

INFORMED CONSENT

"ASSESMENT OF HEARING STATUS IN PATIENTS WITH RHEUMATOID ARTHRITIS A ONE YEAR OBSERVATIONAL STUDY IN KLES Dr PRABHAKAR KORE HOSPITAL''

PRINCIPAL INVESTIGATOR:

CO-INVESTIGATOR:

INTRODUCTION AND PURPOSE:

The present study is conducted among patients with rheumatoid arthritis patients attending the out-patient department of medicine and ENT & HNS in KLE's Dr.Prabhakar Kore Charitable Hospital and Medical Research Centre, Belgaum and will be investigated for pure tone audiometry and ESR levels . You are requested to participate in the study and your participation is completely voluntary.

PROCEDURE:

If you agree to participate in this study, the relevant data will be collected as per the proforma and the final diagnosis will be confirmed.

After getting inducted in the study, you will be evaluated for hearing status with Pure tone audiometry and functions of cochlea. Patient will also be investigated for the blood ESR and the association will be studied.

BENEFITS:

Patient will not be eligible for any kind of monetary benefits or free services by virtue of your participation in the study.

RISKS:

Methods applied to do the study are safe.

COST OF PARTICIPATION:

The cost of th e Investigation will be borne by the Study Subject. The other indirect expenses will be borne by the Investigator.

PRIVACY AND CONFIDENTIALITY:

The results of the study may be published in journals for scientific purposes. However, your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY:

You can withdraw from the study at any time if you wish to do so.

AUTHORIZATION TO PUBLISH THE RESULTS:

The researcher may use the information gathered from this study for presentation in scientific meetings. However, your identity will not be revealed.

CONSENT SUMMARY:

I have been explained all the contents of this consent form in my local language and having understood and clarified all my queries about the study to the best of my knowledge, I hereby give my voluntary consent for participation in the study. I do sign the informed consent form in front of an eyewitness whom I recognize.

Name and Signature/ left thumb impression of the participant:

Name and Signature of the interviewer:

Name and Signature/ left thumb impression of the eyewitness (Relative):

Signature of the guide: **Date:**

PROFORMA

ASSESMENT OF HEARING STATUS IN RHEUMATOID ARTHRITIS A ONE YEAR OBSERVATIONAL STUDY

Date:

Name:

Age: OP/IP no:

Sex: Date of assessment:

Address: Date of discharge:

Occupation: Diagnosis:

CLINICAL PROFILE:

Chief Complaint:

History of Present Illness

Past History:

Personal History:

Family History:

Drug history:

DRUGS TAKEN DURATION

NSAIDS		
Steroids		
hydroxychloroquine		
Methotrexate		
Leflunomides		
sulphasalazine		
Other medications		

I) General Physical Examination -

Blood Pressure:

Pulse:

Respiratory Rate:

Pallor

Icterus

Clubbing

Cyanosis

Lymphadenopathy

Edema

Visual analogue scale:

II) ENT Examination

1. EAR EXAMINATION:

	Right	Left
Pinna		
Pre auricular area		
Post auricular area		
External auditory canal		
Tympanic membrane		

TUNING FORK TESTS:

Rinne's test	256 Hz	
	512 Hz	
	1024 Hz	

Weber's test:

Absolute Bone Conduction test:

FACIAL NERVE EXAMINATION:

2. NOSE EXAMINATION

External appearance Root

- Bridge
- Dorsum
- Alae
- Tip
- Columella

Cold spatula test

Anterior Rhinoscopy

Posterior Rhinoscopy

Paranasal Sinus Examination

3 THROAT EXAMINATION:

4.NECK EXAMINATION:

5. JOINT EXAMINATION:

NUMBER OF LARGE JOINTS INVOLVED:

NUMBER OF SMALL JOINTS INVOLVED:

INSPECTION:

PALPATION:

JOINT MOBILITY:

<u>DIAGNOSIS:</u>

<u>BLOOD INVESTIGATION:</u>

ESR-

PURE TONE AUDIOMETRY: **RIGHT**

LEFT

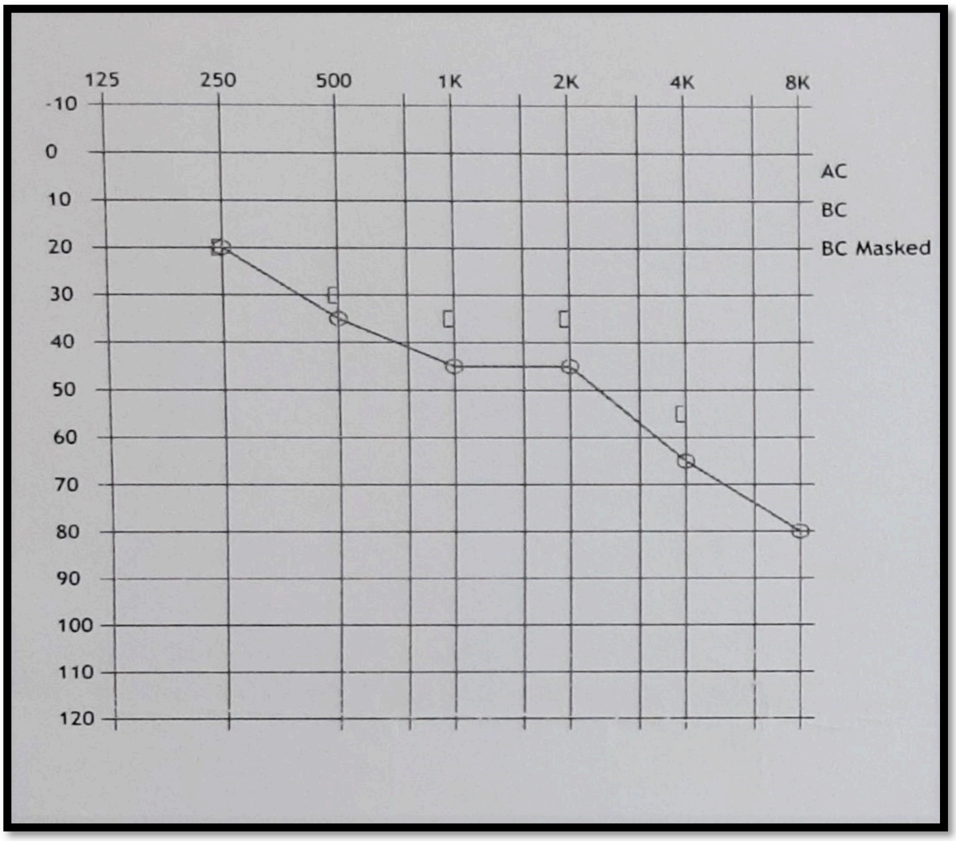
PIC 1 MAICO MA53 AUIOMETER

PIC 2 ESR Analyser

PIC 3 Rheumatoid Factor Test Kit

PIC 4 PTA in Progress

PIC 5 PTA of Right ear showing SNHL Pattern of Hearing Loss



KEY TO MASTER CHART

F	:	Female
M	:	Male
dB	:	decibel
SNHL	:	Sensory Neural Hearing Loss
CHL	:	Conductive Hearing Loss
B/L	:	Bilateral
N	:	Normal
ESR	:	Erythrocyte Sedimentation rate
RA	:	Rheumatoid Arthritis

MASTER CHART

NAME	OP.NO /IP.NO	AGE	SEX	R EAR	L EAR	ESR	Type of hearing loss	Frequency of Hearing Loss	Duration of RA	Drugs	RA factor
Sridhar	3011484	50	M	40	38.3	50	B/L SNHL	High Frequeny (3000 Hz)	4 years	2 years	+
Sattevva	5814913	32	F	16.6	15	48	N	N	6 months	2 months	+
Rajeshwari	5574580	34	F	20	20	58	N	N	2 years	1 year	+
Asfaq	5867484	47	M	21.6	21.6	56	N	N	5 years	3 years	+
Laxmi	5562321	55	M	11.6	15	8	N	N	4.5 years	2 years	+
Shrinath	3582774	28	M	38.3	45	39	B/L SNHL	High Frequency (3000Hz)	1 year	2 weeks	+
Hanumanth	5298870	28	M	30	23.3	32	R mild CHL	Mid Frequency	7 months	4 months	+
Sonakka	993292	38	F	45	15	62	SNHL(R)	High Frequency (2500Hz)	8 years	3 years	+
Rohila	5572424	40	F	25	20	20	N	N	10 years	5 years	+
Suja	456357	33	F	37	29	14	B/L SNHL	High Frequency	2 years	1 year	+
Yallavva	5267777	55	F	43	41	9	B/L SNHL	High Frequency	3 1/2 years	2 years	+
Tangavva	3193016	44	F	39.6	30	39	B/L SNHL	High Frequency	9 years	7 years	+
Sushila	4306591	58	F	20	19	24	N	N	6 months	not started	+
Mrutyunjaya	1056375	34	F	28.5	19.5	20	R mild SNHL	Mid Frequency	6 years	5 years	+
Manjula	3938597	30	F	32.2	13.6	68	R mild SNHL	High Frequency	8 years	71/2 years	+
Roopa	4336603	58	F	28.8	21.3	34	R mild SNHL	High Frequency	22 years	20 years	+
Suvarna	4898374	32	F	15	15	20	N	N	3 months	not started	+
Sureka	1037696	31	F	17.9	18	18	N	N	1 year	not started	+
Vijayalakshmi	1028740	40	F	23	27	96	N	N	7 years	5 years	+
Sham	5925427	38	F	14.7	12.4	42	N	N	5 years	3 years	+
Shashikumar	5494569	22	M	13	17	55	N	N	7 months	not started	+
Nagavva	3852328	35	F	35	24	48	R ear SNHL	High Freqency	4 years	31/2 years	+
Ismail	55593342	54	M	25	29	33	N	N	7 years	2 years	+
Shivaraj	5562614	27	M	13.3	11.6	18	N	N	6 months	not started	+
Anand	5542564	28	M	15.4	17	20	N	N	9 months	2 months	+
Gomathi	5282730	40	F	34	30	20	B/L SNHL	High Frequency	2 months	1month	+

Name	IP/OP no	AGE	SEX	R ear	L ear	Hearing	ESR	RA factor
Mahesh	3011472	47	M	15	16	Normal	2	Negative
Lagmavva	5814923	31	F	16.6	15	Normal	10	Negative
Fathima	5674580	36	F	20	20	Normal	2	Negative
Ramesh	5768484	47	M	21.6	21.6	Normal	12	Negative
Varun	5523321	55	M	11.6	15	Normal	5	Negative
Abishek	3892774	28	M	17	18	Normal	0	Negative
Ragav	5398870	29	M	30	15	Normal	9	Negative
Gauri	982292	40	F	24	15.7	Normal	17	Negative
Nagavva	5902424	42	F	23.7	20	Normal	19	Negative
kartiga	432357	35	F	23.8	23	Normal	13	Negative
Vaishali	5267890	58	F	24	22.3	Normal	14	Negative
Ballava	3193123	44	F	19.6	23	Normal	15	Negative
Yallama	5306591	55	F	20	19	Normal	8	Negative
Keshavi	1056234	34	F	24.5	19.5	Normal	2	Negative
Manisha	3929597	30	F	22.2	13.6	Normal	9	Negative
Ishwari	4336730	58	F	25.8	21.3	Normal	20	Negative
Pradeepa	4894792	32	F	15	15	Normal	18	Negative
Anu	1034396	31	F	17.9	18	Normal	18	Negative
Savitha	1028744	40	F	23	24	Normal	19	Negative
Lakshmi	5455427	38	F	14.7	12.4	Normal	14	Negative
Sanjeev	5494669	22	M	13	17	Normal	5	Negative
Daksha	3847328	35	F	35	24	Normal	15	Negative
Maruthi	5548342	54	M	25	29	Normal	13	Negative
Sanmath	5549614	27	M	13.3	11.6	Normal	18	Negative
Nagaraj	5550564	26	M	15.4	17	Normal	20	Negative
Varsha	5251730	38	F	15	11	Normal	3	Negative