PREVALENCE OF HEARING LOSS AND ASSOCIATED FACTORS AMONG PATIENTS WITH RHEUMATIC DISEASES ATTENDING MUHIMBILI NATIONAL HOSPITAL AND MUHIMBILI ORTHOPEDICS INSTITUTE.

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PREVALENCE OF HEARING LOSS AND ASSOCIATED FACTORS AMONG PATIENTS WITH RHEUMATIC DISEASES ATTENDING MUHIMBILI NATIONAL HOSPITAL AND MUHIMBILI ORTHOPEDICS INSTITUTE

BY

DEOGRATIAS RUTAIHWA

A Dissertation Submitted in (partial) Fulfillment of the Requirement of the Degree of Master of Medicine (Otorhinolaryngology) of the Muhimbili University of Health and Allied Sciences
October 2024.

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by the Muhimbili University of Health and Allied Sciences a dissertation title **"Prevalence of hearing loss and associated factors among patients with rheumatic diseases attending Muhimbili National Hospital and Muhimbili Orthopedics Institute**" in (partial) fulfillment of the requirement for the Master of Medicine in Otorhinolaryngology of the Muhimbili University of Health and Allied Sciences.

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Date_____

DECLARATION AND COPYRIGHT

I, **Deogratias Rutaihwa,** declare that this **Dissertation** is my original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature: _____ Date: _____

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DEDICATION

To my late father, lovely mother, Sister, my son and Mmed ORL graduates class of 2022.

ABSTRACT.

Background: Hearing loss in patients with rheumatic diseases is common. Studies show the prevalence of hearing loss in rheumatic diseases, ranges from 6-72% depending on the type of rheumatic disease. Data from WHO show the trend of rheumatic diseases is increasing at 3%-6% annually every year, hence the population of people with high risk of hearing loss is also increasing. Despite this fact, there is no data in Tanzania, on the prevalence of hearing loss, but also most studies done in other parts of the world have not assessed the factors contributing to hearing loss in these patients. This study will bring data on the prevalence and associated factors that contribute to hearing loss among RD patients attending rheumatology clinics at Muhimbili National Hospital and Muhimbili Orthopedics Institute.

Objective: To determine prevalence and associated factors of hearing loss among patients with rheumatic diseases attending Muhimbili National Hospital and Muhimbili Orthopaedics Institute**.**

Methods: This was a cross-sectional study**,** in patients with established diagnosis of specific rheumatic disease, at Muhimbili national hospital rheumatology clinic and Muhimbili orthopaedics institute. Patient information including socio-demographics data, and data on hearing thresholds were taken, thereafter hearing loss was categorized into types and severity and recorded in a data sheet.

Data was entered and analyzed using Statistical Package for Social Sciences version 25. Categorical variables were summarized using percentages; Numerical variables which are not normally distributed were summarized using median and interquartile ranges. Differences between groups were assessed using the chi-square test. A univariate logistic regression model was used to assess the association between dependent and independent variables. A p-value ≤ 0.05 was considered significant**.**

Results; This study enrolled 88 patients with different rheumatic diseases, 27 with rheumatoid arthritis, 43 with systemic lupus erythematosis and 18 with ankylosing spondylitis. Patients age ranged from 15 to 74 years, the median age was 44 years. Percentage of females was 76.1 while 23.9% were males with female to male ratio of 3.1; 1. Hearing loss was found in 37.5 % (n=33) of patients with 69.7% (n=23) being

females and 30.3 %(n=10) being males. Sensorineural hearing loss was most prevalent accounting 78.8%, conductive hearing loss proportion was 15.2% and mixed hearing loss was least represented with proportion of 6%.

Rheumatoid arthritis patients had the highest proportion of hearing loss 59.3% (n=16), in systemic lupus erythematosus the proportion was 20.9% (n=9) and in ankylosing spondylitis the proportion was 44.4% (n=8).Bilateral hearing loss was common accounting 75.8% and unilateral hearing loss 24.2% of which 15.2% was right sided and 9% was left sided. Regarding severity of hearing loss this study found only mild and moderate forms of hearing loss with proportions of 45.5% and 54.5% respectively .with 75% of patients aged 57 and above having moderate hearing loss. Several factors were found to have statistical significant contribution in hearing loss among rheumatic disease patients these are age (p=0.002), active disease (p=0.001) and longer disease duration (p=0.003).

Conclusion. This study found the prevalence of hearing loss among rheumatic patients to be high at 37.5% as other studies in other parts of the world, patients with active disease, advanced age; longer disease duration are at high risk. Bilateral sensorineural hearing loss was predominant of mild to moderate level.

Recommendation; Rheumatic diseases patients with risk factors should undergo periodic audiologic evaluation

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LIST OF ABBREVIATIONS.

AC	Air conduction.
AS	Ankylosing spondylitis.
BASDAI	Bath ankylosing spondylitis disease activity index
CHL	Conductive hearing loss
DAS-28	Disease activity score- 28
dB	Decibel.
DMARDS	Disease modifying anti-rheumatic drugs.
HZ	Hertz.
IM	Incudo malleolar joint.
IS	Incudostapedial joint.
KHZ	Kilohertz.
MHL	Mixed hearing loss.
MNH	Muhimbili National Hospital
MOI	Muhimbili Orthopaedics Institute.
NSAIDS	Non-steroidal anti-inflammatory drugs.
PTA	Pure tone audiometry.
Q-SLAQ	Quick Systemic lupus disease activity questionnaire
RA	Rheumatoid arthritis.
RD	Rheumatic diseases.
SLE	Systemic lupus erythematosus.
SS	Sjogren syndrome.
Ssc	Systemic sclerosis.
SSNHL	Sudden sensorineural hearing loss.

DEFINITION OF TERMS

Hearing loss (HL): Is a partial or total inability to hear in the normal hearing range, patients will be termed to have hearing loss when their hearing thresholds are equal or above 25dB (1).

Rheumatic diseases. Are connective tissue disorders characterized by chronic autoimmune inflammation driven by an antibody or T-cell response directed against a self-antigen antibody affecting muscles, joints and skin (2).

Conductive hearing loss. Is a type of hearing loss characterized by having better hearing thresholds for bone- conducted signals compared with air-conducted signals, patients with air conduction levels above 25 dB, normal bone conduction thresholds i.e. below 25dB and air bone gap above 15 dB will be termed to have conductive hearing loss (1).

Sensorineural hearing loss. Is a hearing loss that occurs as a result of damage in the cochlea or beyond, patients with air conduction thresholds and bone conduction thresholds above 25dB with air bone gap below 15dB will be termed to have sensorineural hearing loss (1).

Mixed hearing loss. Is a type of hearing loss that has a combination of conductive and sensorineural damage in the same ear, patients with hearing thresholds above 25dB with air bone gap above 25dB (1)

Decibel dB; is a unit of measuring intensities of sound.

Hertz (Hz).refers to the change in amplitude of sound wave of one cycle per second (3)

Ototoxicity. Refer to the process by which a number of therapeutically useful drugs, certain environmental agents such as industrial solvents, and bacterial toxins cause damage to the peripheral end-organs of hearing and balance (3).

CHAPTER ONE.

1.0 INTRODUCTION.

1.1 BACKGROUND.

Hearing loss is a growing global issue; the WHO estimates that by 2050, roughly 2.5 billion people will be deaf (4).Rheumatic diseases are among the medical conditions known to cause hearing loss in these patients. The prevalence of hearing loss ranges from 6-72% depending on the type of rheumatic disease, making RDs one of the most common medical conditions to cause hearing loss. Hearing loss caused by RDs is easily managed if detected early(5)

Most epidemiological data on hearing loss in RD patients is from Europe and America, with few studies in Africa, all being done in North Africa. Georgios et al. in Greece investigated 133 patients with various RDs (RA, SLE, SS, and Ssc) for hearing loss and found the highest prevalence of 75% in Systemic sclerosis and the lowest prevalence of 31.7% in systemic lupus erythematosus patients. The overall prevalence of hearing loss was 39%, with a slight female preponderance(6)

Massimo et al. reported hearing loss in SLE patients ranging from 6-70%, with females being the most afflicted; 25-72% in RA patients, and 1-28% in systemic sclerosis patients(7) in their retrospective cohort among the Taiwanese population. Chung-Ming et al. discovered that the incidence of hearing loss in RA patients was 3.08 per 1000 persons, compared to 1.62 per 1000 people in the general population, indicating that having an RD predisposes a patient to hearing loss(8)

Data on hearing loss in RD patients in Africa is significantly scarce, with a few studies done in Egypt by Nada et al. in 95 patients with RA, of which 81 were females, finding hearing loss in 68.2% of subjects (9). Mahmoud et al. studied 50 patients with RA and 50 patients with SLE and found 82% hearing loss in RA and 54% in SLE patients(10)Works by Furia et al.and Adelowo et al. are the only literature from sub-Saharan Africa on rheumatic diseases; however, their main focus is on epidemiological and clinical patterns of RDs rather than hearing loss aspects of RDs.(11,12).

Hearing loss in RD patients is caused by a number of factors, most notably an autoimmune attack on the inner ear, which leads to vasculitis of the labyrinthine artery, which causes cochlear ischemia. Other processes include damage to outer and inner hair cells by inflammatory cytokines and arthritis of the middle ear ossicles. These pathognomonic mechanisms explain why SNHL is more common than other types of hearing loss, as the inner ear is more affected than the middle and outer ear (5, 13–15).

The majority of the research lists ototoxicity as one of the risk factors for hearing loss in people with RDs. Long-term use of analgesics (NSAIDS) used to treat pain crises associated with RDs has been linked to sensorineural hearing loss (SNHL) (16–18). Hydroxychloroquine is another medicine used to treat RD patients, hydroxychloroquine-induced ototoxicity, on the other hand, is only transient, with hearing returning to normal following withdrawal (18–20). In patients with RDs disease related factors like disease duration, disease activity and RD type have been shown to be significant factors.

Disease activity in rheumatic diseases is determined using internationally validated tools for each disease with patients being grouped into two groups active disease and disease remission i.e. DAS 28 for RA, Q SLAQ(symptom score) questionnaire for SLE and BASDAI for AS, disease remission; those with disease activity scores of ≤ 2.6 for DAS 28, ≤ 4 for BASDAI and Q SLAQ score of ≤ 2,while active disease group has patients with DAS 28 $\geq$ 2.7, BASDAI $\geq$ 4.1 and Q SLAQ $\geq$ 3 this study will investigate how the aforementioned factors contribute to hearing loss in RD patients.

1.2 Problem statement.

Hearing loss in patients with rheumatic diseases is common, studies show the prevalence of hearing loss in RDs, ranges from 6-72% depending on the type of RD, data from WHO show the trend of RDs is increasing at 3%-6% annually every year, hence the population of people with high risk of hearing loss is also increasing, despite this fact ,there is no data in Tanzania on the prevalence of hearing loss, but also most studies done in other parts of the world have not assessed the factors contributing to hearing loss in these patients. This study will bring data on the prevalence and associated factors that contribute to hearing loss among RD patients attending

rheumatology clinics at Muhimbili National Hospital and Muhimbili Orthopedics Institute and hence close the knowledge gap.

1.3 Conceptual framework

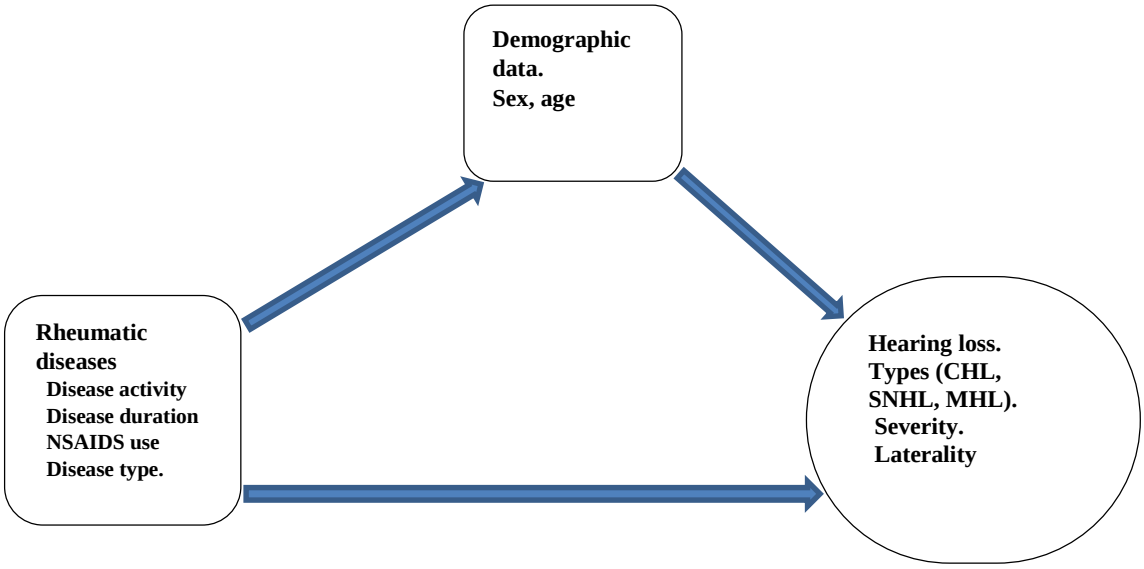


Figure 1: Conceptual frame work.

1.3.1 Description of conceptual framework.

Hearing loss in patients with rheumatic diseases is associated with factors such as disease activity, disease duration NSAIDSs ototoxicity may play role, hearing loss is described in three patterns the type of hearing loss which could be CHL, MHL or SNHL, severity of hearing loss could be mild, moderate, severe and profound with the lateralization being described by which ear is affected one ear or if both ears are involved.

1.4 Rationale.

The results of this study will highlight the significance of hearing loss screening in patients with rheumatic diseases, as well as those caring for and attending patients with hearing loss, to have a high index of suspicion of rheumatic disease and refer patients for early management of the disease. The study will help in updating of guidelines on hearing loss management through incorporating rheumatic diseases as medical conditions that should be considered during management of hearing loss, but also adding management of hearing loss in patients with rheumatic diseases.

The research will serve as a prerequisite for the award of Masters in Medicine Degree in ear, nose, and throat surgery from Muhimbili University of Health and Allied Sciences.

1.5 Research Questions

1.5.1 General research question

What is the prevalence of hearing loss and associated factors among patients with rheumatic diseases attending MNH and MOI clinics?

1.5.2 Specific research questions

1. What is the prevalence and types of hearing loss among patients with rheumatic diseases?
2. What is the laterality of hearing loss among patients with rheumatic diseases?
3. What is the severity of hearing loss among patients with rheumatic diseases?
4. What are factors associated with hearing loss among patients with rheumatic diseases?

1.6 Objectives

1.6.1 Broad Objective

To determine the prevalence and associated factors of hearing loss among patients with rheumatic diseases attending MNH and MOI clinics.

1.6.2 Specific objectives

1. To determine the prevalence and types of hearing loss in each rheumatic disease.
2. To describe the laterality of hearing loss in patients with rheumatic diseases
3. To describe the severity of hearing loss in patients with rheumatic diseases
4. To determine factors associated with hearing loss among patients with rheumatic diseases.

CHAPTER TWO

2.0 LITERATURE REVIEW.

2.1 The prevalence and types of hearing loss in patients with rheumatic diseases.

The proportion of hearing loss varies from one rheumatic disease to another, from small proportions of 6% to proportions of up to 72%. Generally, rheumatoid arthritis has the highest prevalence of hearing loss out of all RDs, with studies showing a prevalence ranging from 25% to 72%; prevalence in SLE ranges from 8 to 66%; and prevalence in AS ranges from 28.6% to 48%. Most studies on hearing loss in RDs are on these diseases; other diseases are more reported in case reports due to their rarity among RDs.

Most studies in rheumatoid arthritis patients have shown that hearing loss is in this disease ranging from 25% to 72% (13). Dionicio et al.(15) in Mexico found the proportions of hearing loss in rheumatoid arthritis patients that were enrolled to be 36.8%, 68.4%, and 94.9% at low, middle, and high frequencies, respectively.

Huang C-M et al.(8) in their retrospective cohort among Taiwanese patients, found the incidence density of hearing loss among RA patients was 3.08 per 1000 persons, and the estimated cumulative incidence of hearing loss in the RA cohort was 1.5% greater than in the non-RA cohort (3.3% vs. 1.8%). Another study by N.M. Gamal et al. in Egypt found that mild to moderate sensorineural hearing loss ranged in prevalence among RA patients from 29.5% to 68.2%. (9).

In research by Torsten and colleagues found out that sensorineural hearing loss being the most common in almost all vasculitis, only very small proportions of conductive and mixed hearing loss were found among these patients in their study (17) in systemic lupus SLE, the proportion of hearing loss ranges from 6-70% , the hearing loss may be unilateral or bilateral, affect all frequencies, and resemble the age related hearing loss pattern (18–20)**.**

Flora Yan et al.(21) found the proportion of hearing loss in AS patients to be 42.4%. They also discovered that people with AS have a 4.65 higher risk of having hearing

loss than those without AS. Ajmani et al. did a study in India and assessed 100 patients with AS, and they found 48 (48%) patients with AS had hearing loss, with conductive hearing loss leading in proportion, followed by mixed hearing loss, and a few cases of sensorineural hearing loss.(22)

Patients with rheumatic diseases may present with any of three types of hearing loss; most studies show that patients with RA are affected by sensorineural hearing loss compared to the other two types. (6,16,21,23). Conductive hearing loss in this population has been reported in very small proportions in some studies, and in most studies, it was not found totally. Individuals with RA experience a bilateral, fluctuating sensorineural hearing loss pattern in acute exacerbations of the disease.

Patients with SLE present almost exclusively with SNHL in most studies, often affecting low and medium frequencies. High-frequency SNHL was found by Maciaszczyk et al. and Roverano et al. Khalid et al. characterized SNHL as involving mid- and high-frequency bands. (19,20). Systemic vasculitis, on the other hand, has been shown to cause more SNHL than other types of hearing loss; in Kawasaki vasculitis, SNHL of up to 36% was found.

In systemic lupus (SLE), SNHL is more prevalent than other types of hearing loss; the hearing loss may fluctuate and, in some patients, may be sudden, unlike in other types of rheumatic diseases. Different reports have reported variable presentations of types of hearing loss in AS patients, but SNHL has been shown in many reports to be predominant compared to CHL and MHL. However, Ajmani et al. found CHL to be in a higher proportion of 60.4%, MHL of 33.3%, and SNHL accounted for only 3% of hearing loss.(22,24–26).

2.2 Lateralization of hearing loss in rheumatic diseases

Most rheumatic diseases cause bilateral hearing loss in patients; however, there are rare exceptions. SLE encompasses a broad spectrum of laterality of hearing loss, with unilateral and bilateral patterns reported in some patients. (9) Sperling et al. discovered bilateral and unilateral lateralization patterns, with the hearing loss progressing gradually. (29).

RA patients have been observed to have bilateral sensorineural hearing loss that affects all frequencies.(22,23,25) studies in patients with AS showed a bilateral pattern of hearing loss among subjects with AS.(24–26).

2.3 Severity of hearing loss in rheumatic diseases.

RA patients may have subclinical hearing loss since high frequencies are implicated in the early stages of the disease. Several studies have found that patients with RA experience mild to moderate hearing loss affecting both ears equally.(13,27,28). Also it has been found that people with RA are more likely to experience acute sensorineural hearing loss compared to healthy people.(29).Systemic lupus erythematous has been shown to cause SNHL hearing loss in all frequencies, with majority of reports showing mild to moderate hearing loss.

Hearing loss in systemic vasculitis varies in severity from one entity to another. In Cogan's syndrome, hearing loss has been shown to range from mild to profound and even deafness in up to 50% of patients, whereas other forms of vasculitis tend to manifest with mild forms of hearing loss. Ankylosing spondylitis causes mild hearing loss affecting all frequencies and is primarily SNHL, making it subclinical in most cases, as reported by Erbek et al. Sajal et al. discovered mild-to-moderate hearing loss in 48 of the 100 AS patients enrolled in the study. (24,30).

2.4 Factors associated with hearing loss among patients with rheumatic diseases

Ototoxicity due to NSAIDS is one of the factors associated with hearing loss in patients with RD. Studies show chronic NSAIDS leads to mild to moderate SNHL hearing loss.(31–33), however in rheumatic patients most studies have not shown statistical significant relationship between NSAID use and hearing loss.(8,9,14,34,35).

In patients with rheumatic diseases, disease activity and duration are crucial disease related factors for developing hearing loss; however, findings regarding disease activity and duration, as well as their relationship with the development and severity of hearing loss have conflicting results with some studies showing strong relationship between disease activity and duration with hearing loss in RD patients and others showing no relationship.

In RA disease, activity and duration have an influence on the severity and occurrence of hearing loss in RA patients. In other rheumatic diseases, there have been conflicting results, with some studies showing that disease activity influences hearing loss and others showing that there is no statistical difference in hearing loss between patients with active disease and those whose disease is under control.(9,22,25,36,37)

An Egyptian study found a statistical significant relationship between long RD duration and hearing loss .(10). However results from studies by Abbas et al and Erbek et al are divergent from this finding.(24,34).

CHAPTER THREE

3.0 METHODOLOGY.

3.1 Study design

This was a cross-sectional hospital-based study**.**

3.2 Study duration

This research was carried out for 6 months from October 2023 to March 2024.

3.3 Study population

All rheumatic disease patients who visited the MNH and Muhimbili Orthopaedic Institute's rheumatology clinic were included as study participants.

3.4 Study area

This study was conducted at MNH rheumatology clinic and MOI where most AS patients are seen. Muhimbili National Hospital is a Dar es Salaam-based tertiary hospital. With a capacity of 1500 beds and sees roughly 2000 patients each day, with 1000 to 1200 patients admitted per week. Currently there are 113 patients with confirmed diagnoses of different rheumatic diseases attending clinic at MNH and MOI.

3.5 Inclusion and exclusion criteria

3.5.1 Inclusion criteria.

1. All patients with confirmed diagnosis of rheumatic disease and consented to be study participants.

3.5.2 Exclusion criteria.

1. Patients with external ear deformities, that prohibit fitting of audiometer headphones.
2. Patients with history of head injury**.**
3. Patients with history of chronic ear discharge.
4. Patients with family history of hearing loss.

3.6 Sampling technique

Patients were enrolled by non-probability consecutive sampling method until the study sample size was attained

3.7 Sample size estimation

Sample size was estimated using formula for finite population by Taro Yamane (38).

$$n = \frac{N}{N + 1e^2}$$

Where N is the sample/study population

In this case the number of patients at MOI and MNH rheumatology clinics is

113 patients.

e is the margin of error which is 5% or 0.05 so plugging these variables in the formula

$$113/ (1 + 113*0.05^2)$$

88.1 patients

This approximates to 88 patients.

3.8 Study variables.

Independent variables are	**Dependent variables**
Age.	Type of hearing loss.
Sex.	Severity of hearing loss.
Disease activity.	Laterality.
Disease duration.	
NSAIDS use.	
RD type.	

3.9 Data collection techniques

The study enrolled participants with established diagnosis of rheumatic disease who agreed to complete the informed consent and assent form. Participants' information, including age, sex, and drugs they are taking was collected and recorded in a questionnaire. Piloting of study tools was done on 9 patients prior to commencing the research.

Study participants underwent ENT examination by the principal investigator, all patients were taken blood samples for CRP, ESR, and disease activity for each specific rheumatic disease was calculated using validated international scores for each disease i.e. DAS 28 for RA, Q SLAQ (symptom score) questionnaire for SLE and BASDAI for AS final scores to determine the state of disease activity were documented on case record sheet and interpreted. Finally, patients underwent audiometric assessment by an audiologist at MNH audiology unit.

Audiological assessment.

All audiometric tests were done in a sound proof room at the MNH audiology clinic, an audiologist tested all participants using a pure-tone audiometer (Corso stati unit 35127, Padova, Italy), and the results were entered on a data collecting sheet.

An audiometer (Corso Stati unit 35127, Padova, Italy) and supra-aural headphone was used to perform pure tone audiometry on each participant's ear in a at frequencies of 250Hz, 500Hz, 1 KHz, 2 KHz, 4 KHz, 6 KHz, and 8 KHz and air conduction and bone conduction in the left and right ears, with a decibel range of 0 to 120 decibel levels were examined.

For audiometric measurements, various sound pressure levels ranging from 0 to 120 decibels and frequency ranges of 250 to 8000 Hertz were used.

The kind and degree of HL were recorded on the audiogram. The three types of HL are sensorineural (air conduction and bone conduction thresholds above 25 decibels, without an air-bone gap), conductive (air conduction above 25 decibels, normal bone conduction threshold, with an air-bone gap), and mixed (air conduction and bone conduction thresholds above 25 decibels, with an air-bone gap).

The WHO categorizes HL into five categories: mild (thresholds 26 to 40 decibels), moderate (thresholds 41 to 55 decibels), moderate-severe (56 to 70 decibels), severe (thresholds 71 to 90 decibels), and profound (thresholds exceeding 91 decibels). The outcomes were used to complete the datasheet

3.9.1 Research tools.

1. Otoscope and ear specula of different diameters.
2. Audiometer.
3. Spirit, cotton wool and boric acid eardrops.
4. Cerumen hook.
5 Data gathering form.

3.9.2 Internal validity and external validity.

These were ensured by using a standard questionnaire to obtain the history and examination data, which in the pilot study proved to be effective in capturing all the information. The investigator used a Heine otoscope for ear examination, disease activity was calculated using internationally validated scores for each RD, and PTA was performed in a quiet environment using a calibrated PTA machine.

3.10 Data Management and Analysis plan.

Data was analysed according to the objectives, before analysis, the data was inspected for accuracy, and internal consistency. Data was entered and analyzed using Statistical Package for Social Sciences version 25. Categorical variables were summarized using percentages; numerical variables which were not normally distributed were summarized using median and interquartile ranges. Differences between groups were assessed using the chi-square test and univariate and multivariate logistic regression modes were used to assess the association between dependent and independent variables. A p-value ≤ 0.05 was considered significant**.**

3.11 Ethical Consideration

Ethical clearance and approval to carry out this study was sought from the directorate of research and publications at MUHAS. Administrative permission for conducting the study was sought from the MNH Institute of Academics, Research, Publications, and Ethics Committee. All study participants gave their written informed consent prior to

being enrolled in the study. Patients who were able to read and write were given consent forms read through them and then signed. Mature minors got assent from their guardians or parents. Patients who were not able to read and write consent forms were read aloud, and their consent was obtained by their thumb. Confidentiality was ensured by keeping paper-based records in a secure location; identifiers were removed from study-related information; and computer-based information was accessible to personnel related to the study by means of passwords.

3.12 Study limitation.

Since this was one hospital-based study henceforth the sample was not representative of all rheumatic patients in Tanzania.

CHAPTER FOUR

4.0 RESULTS

4.1 Characteristics of the study participants

A total of 88 patients with different rheumatic diseases were enrolled in this study, of which 76.1% (n = 67) were females, with a female-to-male ratio of 3.1:1. Half of the study participants (n = 44) were between the ages of 36 and 56, with a median age of 44 years and an interquartile range of (35, 58). Among these 88 patients, SLE patients accounted for 48.9% of the study participants (n = 43).

Table 1: Characteristics of the study participants.

Variable	**Frequency (n)**	**Percent (%)**
Age range (years).		
15 – 35	25	28.4
36 – 56	**44**	**50.0**
≥ 57	19	21.6
Median age in years (IQR)	44 (35, 58)	
Sex		
Male	21	23.9
Female	**67**	**76.1**
Type of rheumatic disease		
Ankylosing spondylitis (AS)	18	20.5
Rheumatoid arthritis (RA)	27	30.7
Systemic lupus erythematosus (SLE).	**43**	**48.9**
Total	88	100%

Key; IQR interquartile range.

4.2 Prevalence of hearing loss in each rheumatic disease.

Out of 88 study participants, hearing loss was found in 37.5% (n = 33) of participants, in patients with rheumatoid arthritis the prevalence was 59.3%, in ankylosing spondylitis the prevalence was 44.4% and patients with systemic lupus erythematosus had the lowest prevalence of 20.9%. Males had higher proportion of hearing loss compared to females 85.4% versus 72.6% (p= 0.27).

Table 2A: Prevalence of hearing loss in each rheumatic disease by age and sex.

Variable	**Hearing loss**			
	Present (%)	**Absent n (%)**	**Total**	***P*-value**
Age group (years)				
15 – 35	3 (12.0)	22 (88)	25 (28.4)	
36– 56	18(40.9)	26 (59.1)	44 (50)	0.002
≥ 57	**12 (63.2)**	7 (36.8)	19 (21.6)	
Total	**33 (37.5)**	55(62.5)	88(100)	
RD type				
AS	8(44.4)	10(55.6)	18(20.4)	
RA	**16(59.3)**	11(40.7)	27(30.7)	0.004
SLE	9(20.9)	34(79.1)	43(48.9)	
Gender				
Male	10(85.4)	11(14.8)	21(51.3)	
Female	**23(72.6)**	44 (27.4)	67 (48.7)	0.272
Total	**33(37.5)**	55(20.8)	88(100)	

Key; RA rheumatoid arthritis AS ankylosing spondylitis SLE systemic lupus erythematosus.

Table 2(B) Types of hearing loss by age and sex among rheumatic patients with hearing loss N=33

	Type of hearing loss				
Variable	**Conductive n(%)**	**Sensorineural n(%)**	**Mixed n(%)**	**Total n (%)**	**p-value**
Age group					
15-35	**2(66.7)**	1(33.3)	0(0.0)	3(9.1)	
36-56	2(11.1)	**14(**77.8**)**	2(11.1)	18(54.5)	
≥57	1(8.3**)**	**11(91.7)**	0(0.0)	12(36.4)	0.002
Total	5(15.2)	**26(78.8)**	2(6.1)	33(100)	
RD type					
AS	2(25)	**5(62.5)**	1(12.5)	8(24.2)	
RA	3(18.8)	**12(75)**	1(6.25)	16(48.5	0.004
SLE	0(0.0)	**9(100)**	0(0)	9(27.3)	
Total	5(15.2)	**26(78.8)**	2(6.0)	33(100)	
Sex					
Male	2(20)	**7(70)**	1(10)	10(30.3)	
Female	3(13.0)	**19(82.6)**	1(4.3)	23(69.7)	0.272
Total	5(15.2)	**26(78.8)**	2(6.1)	33(100)	

Key. RA rheumatoid arthritis AS ankylosing spondylitis SLE systemic lupus erythematosus.

4.3 Lateralization of hearing loss among rheumatic disease patients

In this study bilateral hearing loss was found to be more common contributing 75.8% (n=50 ears),it was predominant across all age groups with highest proportion in patients aged 57 and above 84% (n=9) in terms of sex bilateral hearing loss was more common in females with proportion in females being 84.7% (n=36).

In patients with unilateral hearing loss right sided hearing loss accounted 15.2% of ears (n=5), overall proportion of unilateral hearing loss was 24.2 % (n=8) ears, there is a statistical significance in the difference between unilateral and bilateral hearing loss (p = 0.03).conductive hearing loss

Table 3. Laterality by age and sex per ear in rheumatic disease patients.

	Lateralization of hearing loss				
Variable	**Right only n(%)**	**Left only n(%)**	**Bilateral n (%)**	**Total n (%)**	**P-Value**
Age groups					
15-35	0 (0.0)	1(33.3)	**4 (66.7**)	5(9.1)	
36-56	2 (11.1)	2(11.1)	**28(77.7**)	32 (54.5)	0.003
≥ 57	**3 (25)**	0(0.0)	**18(84)**	21 (36.4)	
Total	**5 (15.2**)	3 (9.0)	**50(75.8**)	58 (100)	
Gender					
					0.005
Male	2(6.7)	1(10.0)	14(70.0)	17 (55.3)	
Female	**3(7.1**)	2 (8.2)	**36(84.7)**	41(44.7)	
Total	5(15.2)	3 (9.0)	**50** (75.8)	58 (100)	

4.3 Severity of hearing loss in rheumatic diseases.

Among 33 patients with hearing loss, moderate hearing loss was found to be more prevalent with proportion of 54.7% (n=18) mild hearing loss contributed 45.5% other forms of severity of hearing loss were not found in this study.

4.4 Factors associated with the hearing loss among rheumatic disease patients.

In this study; age was found to be an important factor for hearing loss, as seen from age group 15-35 the proportion of hearing loss was 12.0%, in patients aged 36-56 the proportion was 40.9% and highest proportion in the age group 57 and above was 63.2 with a statistically significant p value of 0.002, there was no statistical significant difference in hearing proportions of males and females (p= 0.27). Disease activity was also found to have strong relationship with hearing loss with the highest proportion of hearing loss in patients with active disease 65.9% versus 12.8% (p=0.001). This study also found out that patients with longest disease duration in the context of this study more than 5 years had the highest proportion of hearing loss of 51.9% versus 42.9% and 5.3% in patients with duration of 2-4 and less than 2 years respectively (p=0.003).

The use of NSAIDS was found to be related with hearing loss among RD patients the proportion of hearing loss in NSAID users being 50% and 35.1% in non NSAID users

(p=0.272). The proportion of hearing loss in patients with rheumatoid arthritis was highest 59.3% (p= 0.004) compared to 44.4% in ankylosing spondylitis and 20.9% in systemic lupus erythematosus.

Table 4: Factors associated with hearing loss among rheumatic disease patients

	Hearing loss		
Variable	**Present (%)**	**Absent (%)**	**p - value**
Age group (years)			
15 – 35	3 (12.0)	22 (88.0)	**0.002**
36 – 56	18 (40.9)	26 (59.1)	
≥ 57	**12 (63.2)**	7 (36.8)	
Sex			
Male	10 (47.6)	11 (52.4)	0.272
Female	23 (34.3)	44 (65.7)	
Disease activity			
Active disease	**27 (65.9)**	**14 (34.1)**	**< 0.001**
Disease remission	6 (12.8)	41 (87.2)	
Disease duration (years)			
< 2	1 (5.3)	18 (94.7)	**0.003**
‘ 2 – 4	18 (42.9)	24 (57.1)	
≥ 5	14 (51.9)	13 (48.1)	
Use of NSAIDs			
Yes	7 (50.0)	7 (50.0)	0.292
No	26 (35.1)	48 (64.9)	
Type of rheumatic disease			
Ankylosing spondylitis (AS)	8 (44.4)	10 (55.6)	**0.004**
Rheumatoid arthritis (RA)	**16 (59.3)**	**11 (40.7)**	
Systemic lupus erythematous (SLE)	9 (20.9)	34 (79.1)	

Key; NSAIDS Non-steroidal anti- inflammatory drugs.

CHAPTER FIVE

5.0 DISCUSSION.

5.1 Discussion

Patients with rheumatic diseases frequently experience hearing loss; studies show that this prevalence varies from 6-72% depending on the type of RD. WHO reports indicate that the trend of RDs is rising at a rate of 3% to 6% year over year, which means that the population at high risk of hearing loss is also growing. However, in Tanzanian data on the prevalence of hearing loss in this high-risk group is lacking. The prevalence of hearing loss in RD patients visiting rheumatology clinics at MNH and MOI was examined in this study, as well as disease related factors that may contribute to it.

This study found the overall prevalence of hearing loss to be 37.5% these findings are comparable to findings in a study by Tsirves et al who got the prevalence of 39% among 133 patients with various RDs(6), the prevalence of hearing loss among RA patients in the current study was 59.3% which is comparable to findings of Mohamed et al who got prevalence of 54.5% (39). Halligan et al found the prevalence to be 59% (40) and Jabbar et al found prevalence to be 59.5%.(41)

Among SLE patients the prevalence was 20.9% which is comparable to findings of Kastanioudakis et al who found prevalence of 22.5%.(42). However in Iran Abbasi et al found the prevalence to be 26.7% which is slightly higher than in this study (34) this difference is attributed by shorter mean duration of our study participants

In AS sub group the prevalence was found to be 44.4% which is slightly higher than that found by Flora yan et al 42.4% .(21), and lower than that of 48% found by Ajmani et al in India.(22). Amor dorado et al in Spain got the highest prevalence of 58% (35). This difference could be explained by the short mean disease duration and age of our study participants.

Sensorineural hearing loss has been found to be prevalent across all RDs this study found prevalence of SNHL to be 62.5% in AS, 75% in RA and 100% in SLE this predominance of SNHL is also reported in other different studies done among these patients.(19,21,24,25,34,35,40,41), findings of study by Ajmani et al in India among

AS patients are divergent for they show predominance of CHL of 60.4% (22). This predominance of SNHL agrees with McCabe hypothesis that RDs cause SNHL.

Only mild and moderate forms of hearing loss were discovered in this study, with mild hearing loss accounting for 45.5% and moderate hearing loss for 54.5%. These findings are consistent with findings from other studies conducted in Greece, India, Egypt, Sudan, and the United States.(6,9,22,39–41). Moreover these findings are what is expected of severity of hearing loss caused by RDs.

In our study bilateral symmetrical pattern of hearing loss was found in 75.8% of, right sided in 15.2% and left sided in 9%. Gamal et al found bilateral symmetrical in 69.3%, Jabbar et al reported bilateral symmetrical loss in 46.2% while unilateral in 13.7%. (9,41).

In the current study age was found to be one of associated factor for developing hearing loss among RD patients comparing to patients in age group 15-35 the proportions of hearing loss in patients with age groups 36-56 and 57 and above were 40.9% and 63.2% which were statistically significant (p=0.002) these findings are in agreement with findings from other studies.(6,8,19,22,40,41). It is worthwhile mentioning that old age is related to hearing loss a physiological change in auditory system called presbycusis so this could partly explain why older RD patients had higher hearing loss thresholds compared to young patients

Disease activity in RD is another associated factor for hearing loss, patients with active disease had higher proportion of hearing loss compared to patients in disease remission 65.9% versus 12.8% respectively and this was statistically significant (p=0.001) there have been conflicting findings regarding disease activity and hearing loss, in their studies Takatsu et al. Tsirves et al and Gamal et al found a relationship between disease activity and hearing loss.(6,9,27) moreover Ajman et al. Dagli et al and Mohamed et al had divergent results.(22,26,39).

According to this study, patients with longer-lasting rheumatic diseases had a higher proportion of hearing loss; this proportion increased with the duration of the disease; the proportions for patients with less than two years' disease, two to four years' disease, and five years' disease or more were 5.3%, 42.9%, and 51.9% respectively (p=0.003).

These findings are similar to those of study done in Egypt by Mohamed et al (10). Moreover Abbas et al in Egypt and Erbek et al in Turkey found no relationship between longer disease duration and hearing loss (24,34).

Very few studies have compared rheumatic disease type in relation to hearing loss, Soliman et al in Egypt(43) studied 99 with different rheumatic diseases RA,SLE and Behcet disease. The prevalence of hearing loss in RA patients was 43.7% while it was Twenty seven point eight percent and twenty six point seven percent in SLE and Behcet respectively, though the level of statistical significance was not tested.

Tsirves et al (6) studied 133 patients with various RDs found proportion of hearing loss in RA was significant in comparison to other RDs ($p < 0.05$) these findings are in agreement with findings of this study.

CHAPTER SIX

6.0 CONCLUSSION AND RECOMMENDATIONS

6.1 Conclusion

This study, found the prevalence of hearing loss in RD patients is high at 37.5%. RD patients with advanced age, active disease, and long disease duration were found to have high risk of developing hearing loss. Bilateral symmetrical sensorineural hearing loss in mild to moderate forms was most prevalent.

6.2 Recommendations.

i. Rheumatologist should consider audiologic evaluation as part of patient follow-up.

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APPENDICES

APPENDIX I: CONSENT INFORMATION.

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)
SCHOOL OF MEDICINE.DIRECTORATE OF RESEARCH AND PUBLICATIONS.

Ear, nose and throat surgery department (ENT)

CONSENT FORM WITH INFORMATION.

ID-NO---------- DATE----------

TITLE: Prevalence of hearing loss and associated factors among patients with rheumatic diseases attending Muhimbili National Hospital and Muhimbili Orthopedics Institute.

INTRODUCTION: I'm a doctor named Deogratias Rutaihwa. I'm pursuing a Masters of Medicine at Muhimbili University of Health and Allied Sciences in ear, nose, and throat surgery.

Please grant me permission to enrol you in the study mentioned above. Please read the provided information. You are welcome to talk to your family and friends about this, and I'll be happy to address any concerns they may have

STUDY OBJECTIVES: to assess the prevalence, pattern of hearing loss and associated factors among rheumatology patients receiving care at Muhimbili National Hospital and Muhimbili Orthopaedics Institute.

STUDY PARTICIPANTS: all patients with rheumatic diseases

HOW YOU WILL PARTICIPATE: Should you decide to take part in this study, your role is like this. You will be interviewed then a look over your hospital attendance to determine the diseases diagnosis date and present course of management. There also will be an otological examination.

At the MNH audiology unit, you will have a screening hearing exam. We will pay for the testing. Analysis will be done using the results from each participant.

BENEFITS: Even though participating in this study may not directly benefit you, it will significantly advance our understanding of how rheumatic disorders affect hearing.

RISKS: The risk of taking part in this study is anticipated to be zero. Your decision to take part in this investigation or not will not compromise the quality of your management.

VOLUNTARISM: Participating is optional.

STUDY PARTICIPANTS RIGHTS: You have the right to default enrollment or end you. Participation in this investigation any time.

REMUNERATION: Participants in the study will not receive any financial or tangible compensation.

CONFIDENTIALITY: At all times, strict discretion shall be upheld. Your name will not be associated with your test results, and each test result will only be published as a total of all results.

Please sign the consent form if you understand everything said and are willing to participate.

WHO TO CONTACT: Please get in touch with these individuals mentioned down here if you have any worries or inquiries concerning the study:

Dr Deogratias Rutaihwa (P. O. BOX 65001 Dar es Salaam, Tel 0763690709, email address: deo2016ngaiza@gmail.com), Dr Willybroad Massawe (P.O.BOX 65001 Dar es salaam, Tel 0769228424),Dr Perfect Godfrey Kishevo (P.O BOX 65001 Dar es salaam,Tel 0787709516) or Dr Daudi Ntunaguzi (P.O. BOX 65001, Dar es Salaam. Tel 0687 365 208). You can also contact Professor Bruno Sunguya the Chairperson of the Muhimbili University Senate Research and Publications Committee, P.O.BOX 65001, Dar es Salaam, for any matters concerning ethical violation of the study.

APPENDIX II: CONSENT FORM.

ENROLLMENT NUMBER _____

I _____ hereby consent to be among patients who will be investigated as described to me by Dr Deogratias Rutaihwa.

By signing, I certify that I am aware of the aim of this investigation and that any details i give will be considered classified.

Furthermore, i declare that no money or materials have been offered to me as an exchange for taking part in this investigation.

Patient/caregiver

Signature_____ Date_____

Main researcher/ research assistant signature _____

Date_____

KIAMBATANISHO III: FOMU YA MAELEZO KUHUSU IDHINI YA MGONJWA

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

KURUGENZI YA TAFITI NA UCHAPISHAJI

RIDHAA YA KUSHIRIKI KWENYE UCHUNGUZI.

Namba ya usaili……. Tarehe…….

KICHWA CHA HABARI: Uchunguzi wa upana wa usikivu hafifu kwa wagonjwa wenye magonjwa ya rheumatizimu

UTANGULIZI: Salaam, ninaitwa Daktari Deogratias Rutaihwa niko katika mafunzo ya Shahada ya Uzamili ya upasuaji wa masikio, pua na koo katika Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili.

Naomba ridhaa yako ili nikusajili katika uchunguzi huu. Unaruhusiwa kusoma maelezo haya, na niko tayari kujibu maswali yoyote, ukihitaji kushauriana na jamaa na familia.

DHUMUNI LA UCHUNGUZI: Kuangalia upana wa usikivu hafifu Kwa wagonjwa wenye shida ya rheumatizimu

WASHIRIKI WA UTAFITI: Wagonjwa wenye shida za rheumatizimu.

NAMNA YA KUSHIRIKI: Tutachunguza masikio yako ya nje na kuangalia kuwa sikio ni safi, kisha kiwango chako cha usikivu kitachukuliwa kwa kipimo chausikivu kilichopo katika hospital ya taifa muhimbili. Hutatoa fedha yoyote kugharamia kipimo hicho maana zimeshalipiwa na mtafiti. Tutakuhoji ili kupata taarifa fupi kuhusu ugonjwa wako, vilevile tutachambua takwimu za hospitali ili kupata historia ya matibabu yako na maendeleo ya matibabu yako.

FAIDA: Matunda ya utafiti huu yanaweza yasikuguse moja kwa moja wewe lakini matokeo ya uchunguzi huu yatasaidia kupanua wigo wa ufahamu wetu juu ya shida ya usikivu kwa wagonjwa wenye rheumatizimu

ATHARI: Hutapata madhara yoyote kwa kuwa sehemu ya uchunguzi huu.

- **HIARI:** ushiriki wako katika uchunguzi huu ni kwa matashi yako

HAKI: waweza kijitoa kwenye utafiti mda wowote

FIDIA: Washiriki wa utafiti huu, hakuna pesa au chochote kile kitatolewa.

USIRI: Usiri wakati wote utahakikishwa.

Ninaomba uweke sahihi yako kwenye fomu ya idhini tafadhali kama kiashiria cha kukubali kuwa sehemu ya watu watakaochunguzwa

MAWASILIANO: na upatapo dukuduku au maswali basi piga namba zifuatazo;

Dr Deogratias Rutaihwa (S. L. P 65001, Dar es Salaam, simu 0763690709, email deo2016ngaiza@gmail.com) au Dr. Willybroad Massawe (S, L.P 65001,0713872522 Dar es salaam) au Dr Daudi Ntunaguzi (S.L.P 65001, Dar es Salaam, simu 0687 365 208). Ikiwa kuna suala lolote linaloashiria kuharibu mwenendo wa kimaadili wautafiti, wasilianana Mwenyekiti wa Kamati ya Tafiti na Machapisho wa Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili Dr. Bruno Sunguya, S.L.P 65001, Dar es salaam.

KIAMBATISHO IV: KIBALI CHA UTAFITI

NAMBARI YA UTAFITI……...

Mimi ndugu_____ nimeridhia kuwa sehemu ya watu watakaochunguzwa katika uchunguzi huu baada ya kufafanuliwa na daktari Deogratias Rutaihwa

Uwepo wa saini yangu katika karatasi ni kithibitisho kuwa nimekubali yote niliyoelezwa na mtafiti,kuhusu utafiti huu.

Vilevile ninakiri sijapatiwa au kuahidiwa fedha au zawadi ili kushiriki katika uchuguzi huu

Mgonjwa/Mbadala

Sahihi…….

Tarehe…….

Sahihi ya mtafiti /mtafiti msaidizi……

APPENDIX V: CHILD ASSENT FORM

English version

I am Dr DEOGRATIAS RUTAIHWA a masters student pursuing MMed Otorhinolaryngology at Muhimbili University of Health &Allied Sciences (MUHAS). I am doing a study on **PREVALENCE OF HEARING LOSS AND ASSOCIATED FACTORS IN PATIENTS WITH RHEUMATIC DISEASES ATTENDING MUHIMBILI NATIONAL HOSPITAL AND MUHIMBILI ORTHOPEDICS INSTITUTE''.** I am asking you to take part in the research study because you have been selected to represent other children.

For this research I will examine your ears including performing otoscopic examination using a hand-held Otoscope and assessing your hearing thresholds using a Diagnostic Audiometer.

During this procedure you may experience discomfort and mild pain especially when performing otoscopy but this is temporary and it will resolve soon after the procedure.

I will keep your results in private, and I will not show them to your parents. Only I and your parents/guardian will be allowed to see the results.

If your results will be abnormal I will referrer you to the ENT specialist of your choice for further management. I will also provide you with a copy of all test results of your hearing status for you to keep it, or to show to the ENT doctor of your choice for further consultation.

You should know that:

- You do not have to be to be in this study if you do not want to. You won't get into any trouble if you say no.
- You may stop being in the study at any time.
- Your parents/guardians will be asked if it is OK for you to be in the study. Even if they say it's OK, it is still your choice whether or not to take part.
- You can ask any questions you have, now or later. If you think of a question later, you or your parents can contact me at mobile no 0763690709

Sign this form only if you:

- Have understood what you will be doing for this study.
- Have had all your questions answered.
- Have talked to your parents/guardian about this study and
- Agree to take part in this study.

.....	.....	.....
Your Signature.	Printed Name.	Date.

APPENDIX VI: SWAHILI VERSION

Habari, naitwa Dr DEOGRATIAS RUTAIHWA mwanafunzi wa shahada ya uzamili ya udaktari wa pua, koo na masikio katika Chuo Kikuu cha Sayansi na Afya Shirikishi (MUHAS).Ninafanya utafiti unayohusiana na **'UPUNGUFU WA USIKIVU NA VISABABISHI KWA WAGONJWA WENYE MAGONJWA YA RHUMATIZIMU KATIKA HOSPITALI YA MUHIMBILI NA TAASISI YA MIFUPA MOI.**

Nitakupa maelezo na kukualika kushiriki katika utafiti huu kwakua ni miongoni mwa watoto waliochaguliwa kushiriki. Kabla ya kuamua kushiriki unaweza kuongea na mtu yeyote kupata maelezo ya kutosha,na kama kuna maneno hujaelewa vizuri unaweza kumuuliza moja kati ya wataalamu wa afya.

Utafiti huu unajumuisha kuchunguza na kupima uwezo wa kusikia kwa kutumia vifaa maalum navyo ni otoscope na audiometer.

Wakati wauchunguzi unaweza usijisikie vizuri wakati wa kuingiza kifaa masikioni, na pia unaweza kupata maumivu kidogo ambayo yataisha punde tu uchunguzi utakapoisha.

Matokeo ya uchunguzi wa masikio yako yatakua siri baina yangu, wewe na wazazi/walezi wako na hakuna mwingine yeyote ataweza kuyaona ikiwemo walimu wako.

Kama matokeo ya uchunguzi wa masikio yako yatakua na shida nitakutuma kwenye hospitali yenye madaktari bingwa wa pua,koo na masikio kwa ajili na matibabu zaidi.Na pia nitakupatia ripoti ya uchunguzi wa masikio yako ukae nayo au ukamuonyeshe daktari mwingine wa pua ,koo na masikio mtakayemchagua.

Pia unatakiwa utambue kua:

- Hulazimishwi kushiriki katika utafiti huu kama hutaki.Hutapata matatizo yoyote kwa kutokushiriki.Unaweza kuacha kushiriki utafiti mda wowote kama ukitaka kufanya hivyo.
- Kama wazazi wako wakikubali ushiriki na wewe hutaki kushiriki sisi tutafuata maamuzi yako.
- Unaweza kuuliza swali lolote kuhusu utafiti kupitia simu namba 0763690709.

Utasaini fomu hii kama:

- Umeelewa kuhusu utafiti huu.
- Maswali yako yote kuhusu utafiti yamejibiwa.
- Umeongea na wazazi/walezi wako kuhusu utafiti huu na wamekubali.

……..... …… ……..……...……....

Sahihi yako Jina Lako Tarehe

APPENDIX VII: QUESTIONNAIRE

"INFORMATION GATHERING TOOL FOR ASSESSMENT OF HEARING LOSS AND ASSOCIATED RISK FACTORS AMONG PATIENTS WITH RHEUMATIC DISEASES ATTENDING MNH AND MOI"

INSTRUCTION- Please fill the spaces according to the response of the subject.

A. Demographic data:

1. Date ……/……. /……
2. Study ID…….
3. Hospital Registration……...
4. Age…….....
5. Sex: Male……. Female……...

3. Laboratory investigation (results)

(i) ESR…….

(ii) CRP……

B. Associated factors for hearing loss

(i) Rheumatic disease type (name.)

……..

(ii)Disease activity in rheumatic disease.

(a) Disease activity in RA (by DAS 28 score)

Score……

Interpretation of score…… (Remission, active disease).

(b) Disease activity in SLE (by Q- SLAQ score)

Score…….

Interpretation of score…… (Remission, active disease)

(c) Disease activity in AS (by BASDAI score)

Score……

Interpretation of score……. (Remission, active disease)

(ii) Disease duration.

…….

(iv) NSAID use currently for past 7 days.

Yes ( )

No ( ).

2. Pattern of hearing loss. (Please put a tick in appropriate box)

PTA	**Type of hearing loss**	**RT EAR**	**LT EAR**
	Sensory neural hearing loss		
	Conductive hearing loss		
	Mixed hearing loss		
	Severity of hearing loss	**RT EAR**	**LT EAR**
	a. Normal hearing (0-25)		
	b. Mild hearing loss(26-40dB)		
	c. Moderate hearing loss(41-60dB)		
	d. Severe hearing loss(61-80dB)		
	e. profound hearing loss (81dB and above)		

APPENDIX VIII DAS 28 TOOL FOR RHEUMATOID ARTHRITIS.

HOSPITAL NUMBER DATE

Global assessment (GH) scale (max score 10/10)
None……...**Severe.**

Right side		Joint	Left side	
Tender	Swollen		Tender	Swollen
YN	YN	Shoulder	YN	YN
YN	YN	Elbow	YN	YN
YN	YN	Wrist	YN	YN
YN	YN	MCP 1	YN	YN
YN	YN	MCP 2	YN	YN
YN	YN	MCP 3	YN	YN
YN	YN	MCP 4	YN	YN
YN	YN	MCP 5	YN	YN
YN	YN	PIP 1	YN	YN
YN	YN	PIP 2	YN	YN
YN	YN	PIP 3	YN	YN
YN	YN	PIP 4	YN	YN
YN	YN	PIP 5	YN	YN
YN	YN	Knee	YN	YN
		Total		

Tender (TEN)……Swollen (SW)…….

Patient tender joint count……

Patient swollen joint count……..

ESR level……

Global assessment ……

DAS 28= 0.56√(TEN 28) + 0.28√(SW 28) +0.7lnESR+0.014 (GH)

APPENDIX IX Q SLAQ TOOL FOR SLE.

Q- SLAQ SYMPTOM QUESTIONAIRE TOOL FOR DETERMINING DISEASE ACTIVITY IN SLE.

SLAQ item (name of variable)	**Any positive response (mild/moderate/severe)**	**No positive response**
Weight loss, unintentional	1	0
Fatigue	1	0
Fever (>38,5 º C)	1	0
Lymphadenopathy	1	0
Rash on cheeks (shape like a butterfly	1	0
Rash or feeling sick after going out in the sun	1	0
Sores in mouth or nose	1	0
Alopecia	1	0
Shortness of breath	1	0
Chest pain w/deep breath	1	0
Abdominal pain	1	0
Forgetfulness	1	0
Signs of depression	1	0
Unusual headaches	1	0
Muscle weakness	1	0
Muscle pain	1	0
Join pain or stiffness	1	0
Swollen joints	1	0

This score results in a score of 18, with score of≤2 showing disease remission and score of ≥3 signifying active disease.

BASDAI SCORE TOOL FOR DISEASE ACTIVITY IN ANKYLOSING SPONDYLITIS.

Please place a mark on each line to indicate your answer to each question relating to THE PAST WEEK. SCORE /10

1.How would you describe your overall level of FATIGUE/TIREDNESS you have experienced?

NONE. VERY SEVERE

2. How would you describe the overall level of NECK, BACK or HIP pain you have had?

NONE VERY SEVERE

3. How would you describe the overall level of pain/swelling in joints OTHER THAN neck, back

Or hips you have had

NONE VERY SEVERE

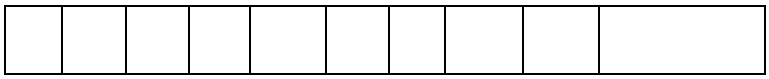
4.How do you describe the overall level of DISCOMFORT you have had from any areas tender

To touch or pressure?

NONE VERY SEVERE

Total of Q1 to Q4 (out of 40) {A}

5. How would you describe the overall LEVEL of MORNING STIFFNESS you have has from the time you wake up?



NONE VERY SEVERE

6. HOW LONG does your MORNING STIFFNESS last from the time you wake up?



0 1/2 1 1 1/2 2+ hours

Total of Q5 to Q6 divided by two (out of 10) B

Total score out of 50 A+ B

BASDAI (A +B) divided by five (score out of 10)

APPENDIX X ETHICAL CLEARANCE LETTER

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1919 Date: 03/10/2023

MUHAS-REC-10-2023-1919
DEOGRATIAS RUTAIHWA
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: HEARING LOSS IN PATIENTS WITH RHEUMATIC DISEASES ATTENDING MUHIMBILI NATIONAL HOSPITAL AND MUHIMBILI ORTHOPEDIC INSTITUTE.

Reference is made to the above heading,

I am pleased to inform you that the Chairperson has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 03/10/2023
EXPIRATION DATE OF APPROVAL: 03/10/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this cross-sectional study is to determine the prevalence of hearing loss and its associated risk factors among patients with rheumatic diseases attending Muhimbili national hospital and Muhimbili orthopedics institute.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014801.pdf and in the MUHAS archives

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee



APPENDIX XI: APPROVAL FOR STUDY

MOI
MUHIMBILI ORTHOPAEDIC INSTITUTE

Ref. PA.382/401/01/49 **26th January, 24**

Muhimbili University of Health and Allied Sciences
P.o.box 65001
Dar es salaam
Tanzania.

RE: APPROVAL FOR STUDY

Reference is made to your letter dated on 19th January 2024 for research study with reference no. HD/MUH/T.256/2019

On behalf of the Management I would like to officially inform you that, your permission has been granted for your student **Deogratias Rutaihwa** to conduct study at Muhimbili Orthopaedic Institute (MOI). His study titled **HEARING LOSS IN PATIENTS WITH RHEUMATIC DISEASES AATTENDIND MUHIMBILI NATIONAL HOSPITAL (MNH) AND MUHIMBILI ORTHOPAEDIC INSTITUTE (MOI)**

This letter will introduce you to the Director of clinical support. It's my hope that your stay at MOI will be fruitful. For any clarification contact CRTM +255713764522.

Dr. Joel J Bwemelo, CRTM
For: MOI Executive Director

MUHIMBILI ORTHOPAEDIC INSTITUTE P. O. Box 65474 DAR-ES-SALAAM

Cc: Director Postgraduates

Cc: Supervisor

APPENDIX XII: PERMISSION LETTER

THE UNITED REPUBLIC OF TANZANI

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/543 Date: 30th October 2023

Head of Department

ENT

Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH.

Name of Student	**Deogratias Rutaihwa**
Title	**"Hearing Loss in Patients with Rheumatic Diseases Attending at Muhimbili National Hospital and Muhimbili Orthopaedic Institute".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Perfect Kishevo (MUHAS)
Co – Supervisors	Dr. Wilybroad Massawe (MNH)
Period	27th October, 2023 to 30th January, 2024

Approval has been granted to the above principal investigators to collect data at MNH. Dissemination of study findings at MNH shall be overseen by **Dr. Wilybroad Massawe** (MNH) supervisor.

Kindly ensure the named principal investigator abide to the ethical principles and other conditions of the research approval.

Sincerely,

Dr. Jessie Mbwambo
Head of Clinical Research, Training and Consultancy Unit

HEAD, TEACHING, RESEARCH & CONSULTANCY UNIT
P.O. Box 65000
DAR-ES-SALAAM
MUHIMBILI NATIONAL HOSPITAL

c.c DSS

c.c Dr. Wilybroad Massawe

c.c **Deogratias Rutaihwa**

Upanga West, Kalenga Street, Plot No. 10480/3, P.O. BOX 65000, Dar es Salaam, Tanzania.
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Email: info@mnh.or.tz, Website: www.mnh.or.tz

CamScanner