PREVALENCE AND SEVERITY OF TEMPOROMANDIBULAR DISORDERS AMONG PATIENTS WITH OTOLOGICAL MANIFESTATIONS ATTENDING MUHIMBILI NATIONAL HOSPITAL.

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By

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A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Medicine in Otorhinolaryngology at

Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that they have read and hereby recommend for acceptance by the Muhimbili University of Health and Allied Sciences a dissertation entitled: **‘‘Prevalence and severity of temporomandibular disorders among patients with otological manifestations attending Muhimbili National Hospital’’**, in partial fulfilment of the requirements for the degree of Master of Medicine in otorhinolaryngology of the Muhimbili University of Health and Allied Sciences.

.....

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Date: …….

…….

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Date: …….

DECLARATION AND COPYRIGHT

I, John Mhando, 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

I would like to dedicate this study to my parents, for their endless and tireless prayers and encouragements and support to my educational achievement and well being of my life and family at large; particularly during my studies. Lastly; proudly and without hesitation I would like to dedicate this work to my wife, sons and daughter; Maria Peter Simbee, Lionel, Jaydon and Julia respectively, for they have been super tolerant and strong during my whole study period.

TABLE OF CONTENTS

CERTIFICATION i
DECLARATION AND COPYRIGHT ii
ACKNOWLEDGEMENT iii
DEDICATION iv
TABLE OF CONTENTS v
LIST OF TABLES viii
LIST OF ABBREVIATIONS ix
DEFINITION OF TERMS x
ABSTRACT xi
CHAPTER ONE 1
1.0 INTRODUCTION 1
1.1 Background 1
1.2 Problem statement 5
1.3 Conceptual framework 6
1.4 Rationale 7
1.5 Research questions 7
1.5.1. Broad Research Question 7
1.5.2. Specific Research Questions 7
1.6. Objectives 8
1.6.1. Broad objective 8
1.6.2. Specific objectives 8
CHAPTER TWO 9
2.0 LITERATURE REVIEW 9
2.1. Prevalence of Temporomandibular disorders 9
2.2. Severity of temporomandibular disorders 10
2.3. Temporomandibular Disorders and Its Otological Manifestations 10
CHAPTER THREE 13
3.0 MATERIALS AND METHODS 13

3.1. Study design and setting....13
3.2. Study population....13
3.3. Study duration....13
3.4. Sample size and sampling techniques....13
3.4.1. Inclusion criteria....14
3.4.2 Exclusion criteria....14
3.4.3. Sampling procedure and technique....14
3.5. Variables....15
3.5.1. Independent variables....15
3.5.2. Dependent variables....15
3.6. Data collection procedures....15
3.7. Data collection tool....16
3.8. Statistical analysis....16
3.9. Ethical issues....17
3.10. Dissemination plan....18
3.11. Study limitations....18
CHAPTER FOUR....19
4.0. RESULTS....19
4.1. Socio-demographic characteristics of study participants....19
4.2. Prevalence of Temporomandibular Disorders among patients with otological manifestation....20
4.2.1. Prevalence of temporomandibular disorders indexed by clinical characteristics of the study participants....20
4.3. Severity of temporomandibular disorders among patients with temporomandibular disorders....22
4.4. Association between number of otological manifestations and severity of temporomandibular disorders....23
4.4.1. Factors associated with diagnosis of Temporomandibular disorders....23

CHAPTER FIVE 29
5.0. DISCUSSION 29
CHAPTER SIX 31
6.0. CONCLUSION AND RECOMMENDATIONS. 31
6.1. Conclusion. 31
6.2. Recommendations. 31
REFERENCES 32
APPENDICES 41
Appendix 1: Informed Consent Form (English version) 41
Appendix 2: consent form (Swahili version) 43
Appendix 3: Data collection tool (English version) 45
Appendix 4: Swahili version of the Data collection tool 48
Appendix 5: Ethical Clearances 51
Appendix 6: Introduction Letter 53
Appendix 7: Permission Letter 54
Appendix 8: Plagiarism 55

LIST OF TABLES

Table 1: Socio-demographic characteristics of study participants (N=288) 19

Table 2: Prevalence of temporomandibular disorders indexed by clinical characteristics of the study participants.....21

Table 3 : Bivariate Analysis of factors associated with diagnosis of Temporomandibular Disorders.....24

Table 4: Multivariable Analysis of factors associated with diagnosis of Temporomandibular Disorders.....26

Table 5: Bivariable Analysis of factors associated with severity of Temporomandibular Disorders.....27

Table 6: Multivariable Analysis of factors associated with severity of Temporomandibular Disorders.....28

LIST OF FIGURES

Figure 1: Proximity between temporomandibular joint, masticatory muscles and the ear.Click or tap here to enter text. 3

Figure 2: Conceptual framework.....

Figure 3 : Distribution of disease severity among Temporomandibular patients 22

LIST OF ABBREVIATIONS

AOM	-	Acute otitis media
COM	-	Chronic otitis media
ENT	-	Ear, Nose, and Throat
FAI	-	Fonseca Anamnestic Index
MNH	-	Muhimbili National Hospital
MUHAS	-	Muhimbili University of Health and Allied Sciences
OMF	-	Oral Maxillo Facial
ORL	-	Otorhinolaryngology
RDC/TMD	-	Research diagnostic criteria for Temporomandibular disorders.
TMDs	-	Temporomandibular disorders
TMJ	-	Temporomandibular joint

DEFINITION OF TERMS

Acoustic -vestibular analyzer-refers to the cochlear and the vestibular apparatus in the human ear.

Aural fullness-Ear pressure or ‘‘clogging sensation’’ of the ears (1). Also referred to as “stuffy ear” or “fluid in the ear”.

Bruxism-Unconscious Excessive teeth grinding when either awake (awake bruxism) or when asleep (sleep bruxism)

Hyperacusis-A term used to describe intolerance to certain everyday sounds that causes significant distress and impairment in social, occupational, recreational and other day to day activities (2).

Orthodontics-correction of mal aligned teeth or malocclusions.

Orthopantomogram-Is an imaging technique(radiograph) used to study hard tissues of the oral cavity e.g. mandible, teeth and the adjacent skeletal structures like the Temporomandibular joint.

Otalgia-Ear pain

Parafunctional habits- Habitual use of the stomatognathic system other than for eating, drinking or speaking.eg biting tongue, cheek or lip; biting foreign objects, nail biting, chewing gum, squeezing mobile phone between the ear and the shoulder (3).

Stomatognathic system-This is the system that consists of TMJs, oral cavity forming bones, soft tissues (gums, mucosa, tongue, cheeks, lips and glands), teeth and muscles involved in chewing and deglutition.

Tinnitus-Perception of sound in absence of an external source (1).

Vertigo- Illusion of spinning motion (1). A subjective sensation that you or the surrounding environment is moving or more correctly spinning.

Clinical characteristics-For the purpose of this study clinical characteristics are; Otalgia, subjective hearing impairment, vertigo, tinnitus, aural fullness, bruxism, parafunctional habits and the number of ontological manifestations.

ABSTRACT

Background: Temporomandibular disorders encompass the temporomandibular joint and stomatognathic muscular disorders. Temporomandibular disorders may have non-otological and otological symptoms mainly due to anatomical, embryological and functional commonness between the ear structures and the masticatory system. There is paucity of data especially in our locality regarding temporomandibular disorders and its manifestations especially the otic ones; thus necessitating determination of its prevalence and severity among patients with otological manifestations and eventually improve management of patients.

Objective: This study aimed at determining the prevalence and severity of temporomandibular disorders among patients with otological manifestations attending Muhimbili National Hospital.

Methodology: A total of 288 patients were enrolled in this cross-sectional study. A structured questionnaire (Fonseca) which had ten anamnestic questions was employed for data collection. The diagnosis was made by comparing the total score to the Fonseca anamnestic index severity categories as mild (20-40), moderate (45-65), and severe (70-100). Patients who had scores of 0-15 were regarded as having 'No temporomandibular disorder' . Other information such as demographics and clinical characteristics were collected. A logistic regression was used to investigate the relationship between number of otological manifestations and diagnosis of Temporomandibular disorder. Similarly, ordinal multinomial logistic regression was conducted to investigate the relationship between the number of otological manifestations and severity of temporomandibular disorders.

Results: The prevalence of temporomandibular disorders was 61.46%. Out of 177 patients who had a diagnosis of temporomandibular disorder; 105 (59.32%) had mild temporomandibular disorder, 51(28.81%) had moderate temporomandibular disorder, and 21(11.86%) had severe temporomandibular disorder. In an adjusted analysis, there was a statistically significant relationship between a number of otological manifestations (Odds

ratio=1.470, p-value=0.0066), parafunctional habit (Odds ratio=2.372,p-value= 0.0143) and the diagnosis of temporomandibular disorder.

In ordinal multinomial logistic regression, being female (Odds ratio=0.514, p-value=0.0307) and the number of otological manifestations (Odds ratio=0.532, p= 0.001) was associated with severity of temporomandibular disorder.

Conclusion and recommendation: Temporomandibular disorders were prevalent (61.46%) from our study. Majority; 105 (59.32%) of patients had mild temporomandibular disorder and few; 21(11.86%) had severe temporomandibular disorder and significant association was found between the number of otological manifestations; diagnosis and severity of temporomandibular disorders .Otorhinolaryngologists should be more vigilant and inquire about symptoms and signs of temporomandibular disorders in patients presenting at Otorhinolaryngology clinic.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Temporomandibular disorders (TMDs) entails a group of disorders involving the temporomandibular joint (TMJ), muscles of mastication and adjacent or associated structures. These components of the stomatognathic system serves the function of chewing, swallowing, speech and breathing (4). The etiology of TMDs is multifaceted and complex. The factors that are involved can be grouped into; predisposing factors, initiating factors and those that foster the progression of the disease; the successful management of TMDs depends on these factors and there are instances where one factor could serve for all the above categories(5).Contributing factors include trauma (macro and micro), parafunctional habits like bruxism, teeth grinding and clinching; psychological disorders like depression, anxiety; orthodontic procedures, exogenous estrogen(6).

The functional and anatomical relationship of the stomatognathic system and the ear may lead to otological manifestations that are not due to ear pathologies but due to other disorders that are beyond the Acoustic-vestibular analyzer thus presenting a challenge to Otorhinolaryngologists (7). It is of paramount importance that Otorhinolaryngologists are equipped with the knowledge and skills to screen and diagnose TMDs and either treat them accordingly or make an early and proper referral to a dentist or oral maxillofacial (OMF)surgeon. Studies have shown that with proper treatment there is improvement of patients with otological manifestations due to pathologies that are not entirely due to affections of the acoustic vestibular analyzer(8–11).Temporomandibular disorders deserve special recognition in otolaryngologic practices because as it has been shown to present a major challenge in diagnosing and evaluating patients with TMDs who presents with otolaryngologic features with a non -yielding or negative findings in the ear during ear, nose and throat(ENT)examination i.e. otoscopic examination and conventional tympanometry and pure tone audiometry(12).

Temporomandibular disorders are prevalent and it is estimated that 60% to 70% of the general population has experienced at least one sign of TMD but only one out of four individuals are aware of these symptoms and seek medical attention (5). Symptoms and signs of TMDs include clicking sounds in the TMJ when opening and closing it, as well as pain in the TMJ and/or muscles of mastication caused by activity i.e. motions of the jaw. Limited mouth opening, mandibular deviation during function, and persistent headaches without an obvious cause are some other signs and symptoms(13).The mechanism or etiopathogenesis of the otological symptoms in patients with TMD is still debatable and is attributed to anatomical proximity between the TMJ and the ear structures and the shared embryological development and innervation by V3 division of the trigeminal nerve; of the masticatory system and the ear structures especially, the middle ear muscles that explains some of the otological symptomatology to patients with TMD. The movement of the TMJ or the mandible is also essential for aiding closure and opening of the Eustachian tube, so limitations of movement of the TMJ can lead to a sensation of ear fullness (14–17).

The diagnosis of TMDs has long been made mostly clinically with exception of some selected cases that might need further evaluation. Imaging may be a useful adjunct to history and physical examination although in most cases it is not preferred in initial stages of management as it mostly doesn't alter the initial management. Plain radiographs e.g. the Orthopantomograms although limited in their use they can be used to rule out some differential diagnoses of the bony TMJ such as fractures, ankylosis, growth or developmental problems as well as tumors (18)(19).There is a wide range variation in TMDs prevalence and TMDs signs and symptoms in different population, this may be accounted for by varieties of study designs, sampling methods, measurement/evaluation equipment and diagnostic criteria(20).

Otological diseases can cause symptoms in the TMJ and vice versa and thus commonly hinder patients from correctly identifying the origin of the pain and thus it becomes a

challenge to practitioners as well(21).Studies have shown that the occurrence of otic symptoms is prevalent

in patient with TMD and strongly associated with progression of the severity of TMDs (16,21,22). Patients with TMDs can present with otic symptoms that includes otalgia, tinnitus, aural fullness, vertigo and subjective hearing impairment. There are myriad of studies that have studied the relationship between otic symptoms and TMDs but attempts to verify the actual origin of these ailments in conjunction with appropriate assessment of the hearing organ has been scarce (17).

Temporomandibular joint syndrome or dysfunction is divided into four severity stages. Stage 1-Early stage with minimal symptoms. Stage 2-Progressive symptoms with occasional joint clicking or popping. Stage 3-Persistent symptoms with limited jaw movement. Stage 4-Severe dysfunction with significant pain, limited jaw movement and possible joint degeneration.

The below pictorial presentation of the TMJ, masticatory muscles, the ear canal give an insight to how close these three are related and thus diseases of the ear may present with signs and symptoms that are sometimes difficult to establish its origin (23).

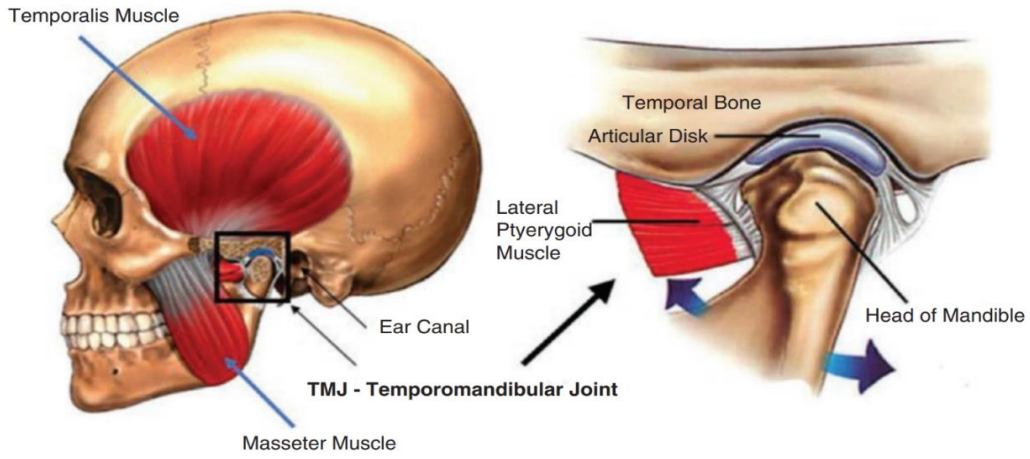


Figure 1: Proximity between temporomandibular joint, masticatory muscles and the ear.

For a longtime the criteria for diagnosis and classification of TMDs has been research diagnostic criteria for temporomandibular disorders (RDC/TMD) but this has its limitation as it cannot categorize patients according to the degree of severity of TMDs which is important as TMDs is a chronic condition. Classification is fundamental in identifying patients from non-patient by determining the relationship between sign and symptoms and the degree of severity (44). For clinicians to be able to determine the symptoms and relate them to the degree of severity, assessing the progression of TMDs and hence individualize treatment there need to be a tool that would assist the clinicians in that. And that led to the popular use of the Fonseca anamnestic index (FAI) in classifying patients as this is cheap, easy to administer, little inter examiner differences(44).The FAI classification uses a 10-item questionnaire each with either "a Yes" or "No" or Sometimes" response and then the scores will be multiplied with an assigned value i.e. YES by 10, NO by zero and SOMETIMES by 5. The total score is compared to anamnestic index categories as proposed by Fonseca et al (20,27,43).

Fonseca's questionnaire

Question	No	Sometimes	Yes
1.Is it hard for you to open your mouth?			
2.Is it hard for you to move your mandible side to side?			
3.Do you get tired/muscular pain while chewing?			
4.Do you have frequent headaches?			
5.Do you have pain on the nape or stiff neck?			
6.Do you have earaches or pain in the craniomandibular joints?			
7.Have you noticed any TMJ clicking while chewing or when you open your mouth?			
8.Do you clench or grind your teeth?			
9.Do you feel your teeth do not articulate well?			
10.Do you consider yourself a tense(nervous) person?			

No TMD	Mild TMD	Moderate TMD	Severe TMD
0-15	20-40	45-65	70-100

Therefore, the aim of this study was to determine the prevalence and severity of TMDs among patients with otological manifestations attending Otorhinolaryngology (ORL) clinic at Muhimbili National Hospital as this will foster awareness, early detection, treatment and timely referral of the patients

1.2 Problem statement

Temporomandibular disorders (TMDs) are prevalent and yet pose a diagnostic challenge to both otolaryngologists and dentists as well, because of an array of sign and symptoms that can mimic ear disease while in fact the pathology is in the stomatognathic system and the vice versa is also true. It is estimated that 60% to 70% of the general population has experienced at least one sign of TMD but only one out of four individuals are aware of these symptoms and seek medical attention. (24). In the Sub-Saharan Africa, a study done in Ekiti; the prevalence of temporomandibular joint disorders was 1.3%, the main otological features were earache and a dull tympanic membrane in 100% and 35.4% respectively(25). A study done in Ilala district on prevalence of craniomandibular disorders which involved 115 participants revealed that 26% of the sample population had at least one subjective symptom; with joint noises being the most frequent symptom(26).Another study done in southeast Tanzania on risk factors for signs and symptoms of TMD it was found that TMJ clicking accounted for 67.5%(13).In both local studies there is paucity of data on otological manifestations among patients with TMDs thus making this study worth undertaking.

1.3 Conceptual framework

TEMPOROMANDIBULAR DISORDERS AND ITS OTOLOGICAL MANIFESTATIONS.

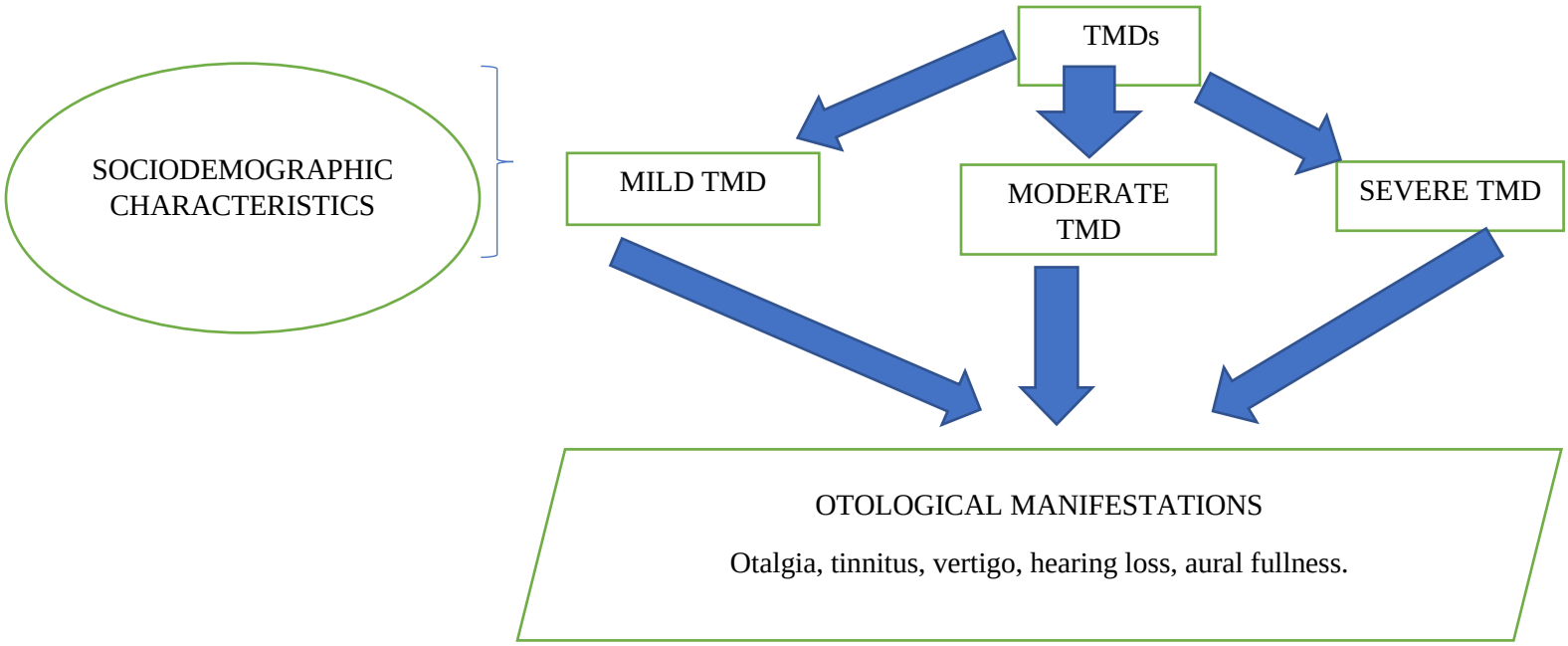


Figure 2: Conceptual framework

Temporomandibular disorders are a group of pathologies affecting the TMJ (secondary to a true articular disease) and its surrounding structures (secondary to myofascial pain and dysfunction), other congenital and developmental anomalies, macro and micro trauma. Typically presents with TMJ pain, mandibular movement restrictions, and TMJ clicking/popping/crepitus sounds. Other manifestations include frequent headaches and otological symptoms such as otalgia, tinnitus, vertigo, aural fullness, subjective hearing impairment due to the shared embryological origin of middle ear structures and the masticatory muscles and the close proximity between the ear and the temporomandibular region. Studies have shown that there is an association between TMDs and sociodemographic characteristics (age, sex, education level, marital status, working status, parafunctional habit and bruxism) of patients with TMDs.

1.4 Rationale

This study will raise awareness to clinicians as to what extent the TMDs are rampant, and enlighten clinicians that we might be misdiagnosing or underdiagnosing these patients especially when they attend ORL clinics with ear complaints that are due to pathologies of the stomatognathic system; hence improving the management of these patients and refer them accordingly for further review and management by OMF surgeons. This study also serves as a partial fulfillment of the requirement for the award of masters of medicine in Otorhinolaryngology at Muhimbili University of Health and Allied Sciences (MUHAS).

1.5 Research questions

1.5.1. Broad Research Question

What is the prevalence and severity of temporomandibular disorders among patients with otological manifestations attending Otorhinolaryngology clinic at Muhimbili National Hospital?

1.5.2. Specific Research Questions

1. What is the prevalence of temporomandibular disorders among patients with otological manifestations attending Otorhinolaryngology clinic at Muhimbili National Hospital?
2. What is the severity of temporomandibular disorders among patients with temporomandibular disorders attending Otorhinolaryngology clinic at Muhimbili National Hospital?
3. What is the association between the number of otological manifestations and severity of temporomandibular disorders among patients with temporomandibular disorders attending otorhinolaryngology clinic at Muhimbili National Hospital?

1.6. Objectives

1.6.1. Broad objective

To determine the prevalence and severity of temporomandibular disorders among patients with otological manifestations attending Otorhinolaryngology clinic at Muhimbili National Hospital.

1.6.2. Specific objectives

1. To determine the prevalence of temporomandibular disorders among patients with otological manifestations attending Otorhinolaryngology clinic at Muhimbili National Hospital.
2. To determine severity of temporomandibular disorders among patients with temporomandibular disorders attending Otorhinolaryngology clinic at Muhimbili National Hospital.
3. To determine association between number of otological manifestations and severity of temporomandibular Disorders among patients with Temporomandibular disorders attending Otorhinolaryngology clinic at Muhimbili National hospital.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1. Prevalence of Temporomandibular disorders

Temporomandibular disorders (TMDs) have recently been recognized as a common pathological condition, and public awareness of them has grown. The term TMDs covers a wide spectrum of diseases affecting the masticatory muscles and related structures that affect the temporomandibular joint (TMJ). Muscle aches and pains, TMJ sounds, deviations in the mandibular range of motion, and headaches are some of the symptoms that define TMDs (17,24). Prevalence of TMDs has been thoroughly researched over the years, but analyzing the findings from a wide range of literature presents a number of challenges (differing skill levels among examiners, inconsistent assessments, and research bias(24).

Temporomandibular disorders are quite prevalent in the general population, with approximately 60%-75% subjects will manifest with one TMD sign and 35% TMD symptom(24,27).In general TMDs are estimated to affect between 5% to 15% of the adult population(18,28).Studies have shown that females are more affected than males with approximately 2:1 female to male ratio i.e. twice as much as it affects male(24,29,30).The exact reason for this is still unknown but this could be attributed to various factors such as hormonal factors, differences in joint collagen type, ligamental laxity and higher intra articular pressure, cultural and social factors, levels of work related stresses, differences in pain sensitivities.(31–33).Temporomandibular disorders seem to be prevalent in adolescents; greatest peak at 20-40yrs(34). and in women of reproductive age in whom there is sharp fall later in the middle age. Temporomandibular disorders are less common in children and elderly ages (24,29,30). Sociodemographic factors have also been shown to be associated with the occurrence of the TMDs (3). In a study done at MNH among patients attending OMF clinic and inpatient wards; which aimed at determining the occurrence of temporomandibular joint disorder (TMJD), it was found that the prevalence was 1.3% (35).

2.2. Severity of temporomandibular disorders

The severity of temporomandibular disorders (TMDs) anamnestically falls into three categories namely mild, moderate and severe. Several studies have shown that severity of TMDs is influenced by various factors such as sociodemographic and psychological factors (anxiety and depression), parafunctional habits, bruxism. In study done in Turkey exploring the presence and severity of symptoms of TMD and its association with psychological and sociodemographic factors, parafunctional habits and bruxism which included 2580 participants it was found that the severity of TMD was greater in patients with sign and symptoms of anxiety and depression($p>0.05$), sociodemographic and psychological data showed an association between the presence and severity of symptoms of TMD and sex (OR 1.52) 95% CI ,parafunctional habits (OR 2.64) ,bruxism (OR 3.14),anxiety(OR 2.30),depression(OR 1.90) all with 95% CI(36).

Most of the studies done revealed that majority of the participants had mild form of the disorder and less had severe form of the disorder. In a study done in Pakistan to assess severity patterns of TMDs in young adults it was shown that among the 162 study participants; 40.15% had mild TMD,35.2% had moderate and 8.6% had severe disease (37). A study in Brazil on otological findings and other symptoms related to TMD in young people it was found that among 251 participants; 177 (70.5%) had some degree of TMD ,49 (19.5%) had moderate symptoms,10 (4%) had severe TMD symptoms(21).A study done in Cairo to assess the prevalence and severity of TMDs involving 593 post graduate students it was also depicted that the mild category was the most common constituting 57% and moderate form had 31.7%, severe form made 11.3%(38).

2.3. Temporomandibular Disorders and Its Otological Manifestations

Patients with TMDs may have otological manifestations that are not solely due to otic pathologies but rather from the stomatognathic system dysfunctions leading to negative otic findings during otorhinolaryngological examinations. A study done in India to evaluate prevalence of otorhinolaryngological symptoms in patients with TMD in which 172 TMD

patients were enrolled both male and female aged 18 to 59 years; it was found that among 172 participants ,74(91.4%) had otological symptomatology (39).

Patients with temporomandibular disorders may have ear discomfort, tinnitus, ear fullness, hearing loss, vertigo, hyperacusis, ear pruritus, a feeling of water in the ear canal, and other symptoms. The prevalence of otological symptoms was found to be 87% among TMD cases in a study conducted in Brazil to assess the relationship between otological symptoms and TMD, which involved 485 medical records of patients attending a diagnostic and treatment center for TMJ and dental facial disorders at Tuiuti University of Parana. The two conditions with the highest prevalence were ear fullness (39%), which was followed by tinnitus (42%). Other complaints included deafness (17.5%), vertigo (30.5%), and imbalance (14.8%). The age range between 41 and 50 had the highest prevalence of otic symptoms (37%), followed by the range between 51 and 60 (32%) (4).

Another study done at university of Pernambuco which enrolled 251 participants with or without TMDs, aimed at studying otological findings and other non otological symptoms related to TMDs in young people significant association was found with tinnitus, ear pain, hearing loss and vertigo($p<0.001$)(21).A study done in Greece to assess aural symptoms in patients with TMJD among 40 participants with TMJD aged 20 to 60 years with mean age of 42.9 years, SD 15;it was found that 60% of the patients had ear pain,72.5% pain around the ear,70% had tinnitus,30% ear fullness,30% reduced hearing acuity. Although using Fischer's exact test among the age groups significant difference was found for the subjects with subjective hearing loss in patients older than 45 years ($p=0.002$) (12).

A study done in Milan, Italy to evaluate prevalence of new onset otological symptoms among patients with TMD, in which 400 patients were included; the new onset otological symptoms was found in 76% of the participants with TMD. Aural fullness was the most common (33.3%), tinnitus (23%), vertigo (19.8%) (1). In Cairo at the El-Sahel teaching hospital a study involving 104 TMD patients and 110 controls was done to assess the otological symptoms and audiometric findings in patients with TMD. Most of patients had combination of otological manifestations (40)

In Tanzania; particularly in our locality; there is paucity of studies regarding TMDs. A study done in Ilala district on prevalence of craniomandibular disorders which involved 115 participants revealed that 26% of the sample population had at least one subjective symptom; with joint noises being the most frequent symptom between the age groups (26). Although otological manifestations were not mentioned in the study which makes this study worth undertaking.

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1. Study design and setting

This was a cross-sectional study. The study was conducted at Otorhinolaryngology (ORL) outpatient clinics at Muhimbili National Hospital located in Ilala district in Dar es salaam. Muhimbili National Hospital is a tertiary and specialized hospital and also is the Academic and research facility for Muhimbili University of Health and Allied Sciences (MUHAS). It has 1500 bed capacity, admits approximately 150 patients daily and about 2000 clients as outpatients. Otorhinolaryngology clinic is amongst many specialized clinics available at Muhimbili National Hospital. Otorhinolaryngology clinic is organized into two firms; each firm runs for two days in a week with an estimate of 70 clients per day per firm. Amongst the 70 patients 1/3(approximately 30 patients per day) of them have otological complaints.

3.2. Study population

All patients with otological complaints aged 18 years and above attending ORL clinic during the study duration.

3.3. Study duration

This was a 6-months study, from October 2023 to March 2024.

3.4. Sample size and sampling techniques.

The sample size "n" of participants was calculated using the Yamane's/Slovin's formula below (41,42)

$$n=N/(1+Ne^2)$$

Where N=size of the population, about 720 pts over the 3 months, involving one of the two firms, this was from a two-week pilot study at ORL clinic.

Ɛ=margin of error; was 5%

Therefore n $=720/(1+720x0.05^2)$

$=257.1428571$

Rounding it off to the next whole number=258

Taking account of non-response rate of 10%, then adjusted sample size given by formula:

$N = \frac{n}{R}$ Whereby N- adjusted sample size for non-response, n-crude sample size, R- response rate 90%=0.9

Therefore: $N = \frac{258}{0.9} = 286.667$

Thus, the estimated sample size for this study was 287.

Though a total of 288 participants were captured. A consecutive sampling technique was adopted.

3.4.1. Inclusion criteria

All Patients aged 18years and above attending ORL clinic during the study period who presented with or complained of ear pain, subjective hearing impairment, tinnitus, aural fullness or a sensation of ear blockage, vertigo and are were willing to participate in the study and had signed an informed consent were enrolled.

3.4.2 Exclusion criteria

Any local ear pathology e.g. otitis externa (OE), acute otitis media (AOM), chronic suppurative otitis media (CSOM); history of ear surgery, patients with cardinal symptoms of throat diseases (sore throat, foreign body sensation, difficult in swallowing, hoarseness of voice and stridor/audible respiration) were excluded as any pathology in the throat or pharynx can lead to referred ear pain, patients with head and neck malignancies, mentally handicapped patients and patients who were unwilling to participate in the study or unable to fully consent were also excluded from the study.

3.4.3. Sampling procedure and technique

This study employed a convenient sampling technique.

3.5. Variables.

3.5.1. Independent variables.

The independent variables were age, sex, education level, marital status, working status, parafunctional habit and bruxism, otalgia, tinnitus, aural fullness, subjective hearing impairment, vertigo.

3.5.2. Dependent variables

Dependent variables were mild TMD, moderate TMD, severe TMD.

3.6. Data collection procedures

There were two research assistants one from each firm who were also sensitizing other staff members at the clinic on the study undertaken so that they were able to identify eligible patients and direct them to a focal person (principal investigator or assistants) for interview. The research assistants and other members of the respective clinic were familiarized with the study undertaken. All Patients aged 18years and above attending ORL clinic during the study period who presented with or complained of ear pain, subjective hearing impairment, tinnitus, aural fullness or a sensation of ear blockage, vertigo, and were willing to participate in the study and had signed an informed consent underwent thorough ENT examination before enrolment to rule out any local ear pathology e.g. otitis externa, acute otitis media ,chronic suppurative otitis media ; history of ear surgery, referred otalgia other than due to TMJ pathology e.g. those with throat complaints, patients with head and neck malignancies, mentally handicapped patients. All eligible participants underwent otoscopic examination to rule out any local ear pathology or condition that would have otherwise excluded the patient from the study. Patients with impacted cerumen were to be followed a week after removal of the cerumen and enrolled into the study if the otological complaints persisted despite removal of the cerumen.

3.7. Data collection tool

A structured questionnaire, part of it adopted from other studies and then modified to suit the needs of the study was employed. The data were filled into the questionnaire by the principal investigator, research assistants, working staff at the clinic and respective residents in the study area. The first part of the questionnaire consisted of sociodemographic characteristics including age, sex, marital status, employment, education level, bruxism, parafunctional habit (biting tongue, cheeck or lip; biting foreign objects, nail biting, chewing gum, squeezing mobile phone between the ear and the shoulder and patient's identification. Self-reported bruxism and parafunctional habits were responded as yes or no. The second part of the questionnaire consisted of Ten TMD screening questions as proposed and validated by Fonseca et al. Each question had a YES, SOMETIMES or NO response and scored 10,5 and 0 respectively. The Sum total of the responses were used to categorize patients. Temporomandibular disorders were classified into four major clinical or anamnestic categories as proposed by Fonseca et al namely as No TMD or absent, mild TMD, moderate TMD, severe TMD (43,44).

The third part of the questionnaire did inquire about the presence or absence of otalgia, tinnitus, sensation of ear fullness or ear blockage, subjective hearing impairment, vertigo as these were the most common reported otological manifestations among patients diagnosed to have TMDs.

3.8. Statistical analysis

Data were collected and entered into statistical package for social science (SPSS) version 23. Categorical variables were presented using frequencies and percentages, and the association between categorical variables were tested using chi-square tests. Non-normally distributed continuous variables were presented using Median and Interquartile Range (IQR). To determine prevalence of temporomandibular disorders patients who were diagnosed to have TMD using the screening tool were run against total number of participants. The severity of TMDs were obtained by running total number of patients in each severity category i.e. mild, moderate or severe as determined by their score from the screening tool; against all patients diagnosed with TMDs.To determine the relationship between number of otological

manifestation and diagnosis of TMD, both bivariable and multiple logistic regression was conducted. Furthermore, the outcome variable(severity) was classified in an ordinal level. Therefore cumulative multinomial logistic regression which takes into account the ordinal arrangement of the outcome levels was employed.Modelling of the outcome was in the direction of mild;thus to determine the relationship between number of otological manifestation and the severity of TMD, both bivariable and multiple ordinal multinomial logistic regression was conducted. For the multivariable model, covariates with p-value <0.3 during bivariable analysis were included in the final model. The analysis of this study was conducted using IBM SPSS Statistics (version 23) and SAS version 9.4 software (SAS, Inst, Cary, NC).

3.9. Ethical issues

The Muhimbili University of Health and Allied Sciences ethical committee and MNH research publication department approved the study in question. Muhimbili National Hospital ORL Clinic granted permission for clinic interviews with clients. Before enrolment into the study all participants were given an informed consent and asked to provide a written consent to participate in the study. Patients confidentiality ensured by using serial numbers or designated special code, as the identification code and not by their names. Upon identification of the patients with features suggestive of TMDs these patients were properly counselled about the probable cause of their manifestations and consequently referred to dental/oral maxillofacial units for further evaluation and management. Patients information and data collected were confidentially kept in accordance with guiding regulation and only the principal investigator and research assistants will have direct access to the collected data. The results of this study will be disseminated to the staff members within the department and when applicable will be published.

3.10. Dissemination plan

These research findings were presented at the ENT department before being put into a report and submitted to the MUHAS through their Directorate of Clinical Services; the Executive Director of MNH will also get a set of copies. A manuscript will be written to publish the research in acceptable national and international publications.

3.11. Study limitations

The study was conducted at a single Centre, which may limit the generalizability of the findings. Additionally, the sample size was relatively small, which may affect the statistical power and precision of the result. Considering how complex the topic is, the diversity of methodologies and the target population, this result should be the interpreted cautiously, requiring further studies that use similar protocols with larger sample sizes.

CHAPTER FOUR

4.0. RESULTS.

4.1. Socio-demographic characteristics of study participants.

A total of 288 patients were recruited for this study. Their ages ranged from 18 years to 87 years with the median age of 40 years (IQR:29-58). Most patients were in the age-group of 25-34 years, 71 (24.7%), and most of the them were females 153 (53.13%). Overall, most patients were married 167 (57.99%), and few were widowed/divorced 25 (8.68%). Most patients had a primary/secondary level of education 158 (54.86%), while those who had no formal education were 9 (3.13%). Overall, the proportions of those who were employed and those who were unemployed were comparable 101 (35.07% versus 101 (35.07%) while the remaining patients were self-employed 86 (29.86%). **Table 1**

Table 1: Socio-demographic characteristics of study participants (N=288)

Characteristic	N (%)
Median Age, IQR 40 (29-58)	
Age categories(years)	
18-24	39 (13.50)
25-34	71 (24.70)
35-44	51 (17.70)
45-54	44 (15.30)
55-64	39 (13.50)
>=65	44 (15.30)
Sex	
Female	153 (53.13)
Male	135 (46.88)
Marital status	
Married	167 (57.99)
Widowed/Divorced	25 (8.68)
Single	96 (33.33)
Education level	
No formal education	9 (3.13)
Primary/Secondary	158 (54.86)
University/College	121 (42.01)
Employment status	
Unemployed	101 (35.07)
Self-employed	86 (29.86)
Employed	101 (35.07)

4.2. Prevalence of Temporomandibular Disorders among patients with otological manifestation

Among 288 patients who were recruited into this study, the prevalence of TMD was 61.46%.

4.2.1. Prevalence of temporomandibular disorders indexed by clinical characteristics of the study participants

Among 37 patients who presented with bruxism 31(83.8%) had TMD while those 251 patients without bruxism 146 (58.2%) had TMD, this difference was statistically significant (p value = 0.0028). Among 143 Patients with otalgia, 111 (77.6%) had TMD, while those 145 patients without otalgia 66 (45.2%) had TMD. This difference was statistically significant (p value= 0.0001). Among 159 Patients who had subjective hearing impairment 86 (54.09%) had TMD while those 129 patients without subjective hearing impairment 91 (70.5%) had TMD; this difference was statistically significant (p value = 0.0043). Among 109 who presented with vertigo 78 (71.6%) had TMD, while among 179 patients without vertigo 99 (55.3%) had TMD. This difference was statistically significant (p value = 0.0060). Among 57 Patients who presented with parafunctional habits 43(75.4%) had TMD, while among 231 patients without parafunctional habits 134 (58.0%) had TMD. This difference was statistically significant (p value = 0.0155). Number of otological manifestations showed statistical significance (p value = 0.0110), whereby among 69 patients with one manifestation 38 (55.0%) had TMD and among 111 patients with two manifestations 61 (54.95%) had TMD; those 85 patients with three manifestations 58 (68.24%) had TMD and Out of 23 patients with four or five manifestations 20(86.96%) had TMD. **Table 2**

Table 2: Prevalence of temporomandibular disorders indexed by clinical characteristics of the study participants

Characteristic	TOTAL (N=288)	TMD YES (N=177)	TMD NO (N=111)	p-value
Bruxism				
Yes	37 (12.85)	31 (83.78)	6 (16.22)	0.0028
No	251 (87.15)	146 (58.17)	105(41.83)	
Otalgia				
Yes	143 (49.65)	111 (77.62)	32 (22.38)	0.0001
No	145 (50.35)	66 (45.52)	79 (54.48)	
Subjective hearing Impairment				
Yes	159 (55.21)	86 (54.09)	73 (45.91)	0.0043
No	129 (44.79)	91 (70.54)	38 (29.46)	
Vertigo				
Yes	109 (37.85)	78 (71.56)	31 (28.44)	0.0060
No	179 (62.15)	99 (55.31)	80 (44.69)	
Parafunctional Habit				
Yes	57 (19.79)	43 (75.44)	14 (24.56)	0.0155
No	231 (80.21)	134 (58.01)	97 (41.99)	
Number of Otological Manifestation				
1	69 (23.96)	38 (55.07)	31 (44.93)	0.0110
2	111 (38.54)	61 (54.95)	50 (45.05)	
3	85 29.51	58 (68.24)	27 (31.76)	
4 or 5	23 (7.99)	20 (86.96)	3 (13.04)	
aural fullness				
Yes	79 (27.43)	50 (63.29)	29(36.71)	0.6944
No	209 (72.57)	127 (60.77)	82(39.23)	
Tinnitus				
Yes	155 (53.82)	95 (61.29)	60 (38.71)	0.9496
No	133 (46.18)	82 (61.65)	51 (38.35)	

4.3. Severity of temporomandibular disorders among patients with temporomandibular disorders

Among 177 patients with TMD, 105 (59.32%) had mild TMD, 51(28.81%) had moderate TMD, and 21(11.86%) had severe TMD. (Figure 3).

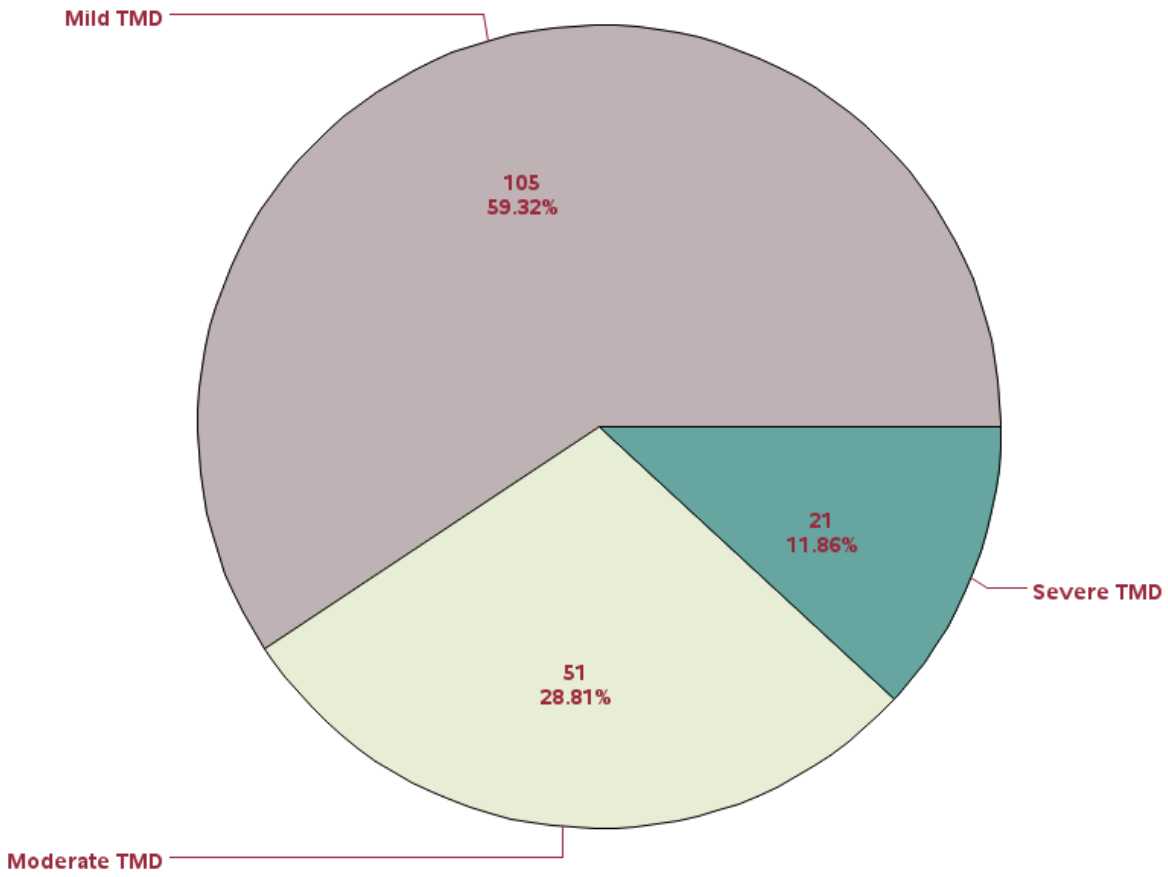


Figure 3 : Distribution of disease severity among Temporomandibular patients

4.4. Association between number of otological manifestations and severity of temporomandibular disorders.

4.4.1. Factors associated with diagnosis of Temporomandibular disorders

Bivariable Logistic Regression

In a crude analysis of factors associated with a diagnosis of TMD, the number of otological manifestations (OR=1.515, 95% CI:1.159-1.981, p=0.0024, and parafunctional habits (OR=2.223, 95% CI:1.152-4.290, p=0.0172) were the only variables that were associated with a diagnosis of TMD). Specifically, a group of patients with one more otological manifestation was 1.52 more likely to be diagnosed with TMD compared to the lower group of patients. Similarly, a group of patients who reported parafunctional habits was 2.22 more likely to be diagnosed with TMD compared to the group of patients who reported no parafunctional habits. Other variables such as age, sex, marital status, education level, and employment status were not significantly associated with the diagnosis of TMD (p>0.05). The results of the bivariable analysis are presented in detail in **Table 3.**

Table 3 : Bivariate Analysis of factors associated with diagnosis of Temporomandibular Disorders

Characteristic	OR (95% CI)	p-value
Age	0.995 (0.981-1.009)	0.4688
Sex		
Female	1.340 (0.832-2.156)	0.2285
Male	ref	
Marital status		
Married	1.231 (0.738-2.052)	0.6876
Widowed/Divorced	1.916 (0.732-5.016)	0.2388
Single	ref	
Education level		
No formal education	2.917 (0.582-14.616)	0.304
Primary/Secondary	1.605 (0.987-2.609)	0.8887
University/College	ref	
Employment status		
Employed	1.332 (0.759 2.337)	0.9002
Self-employed	1.665 (0.916- 3.026)	0.177
Unemployed	ref	
No of Otological Manifestation	1.515 (1.159- 1.981)	0.0024
Parafunctional Habits		
Yes	2.223 (1.152-4.290)	0.0172
No	ref	

Multivariable Logistic Regression

In an adjusted analysis, the relationship between a number of otological manifestations and the presence of TMD remained even after adjusting for sex, marital status, and employment category (OR=1.470, 95%CI: 1.113-1.942, p=0.0066). Specifically, a group of patients with one more otological manifestation were 1.47 times more likely to be diagnosed with TMD compared to a lower group of patients. Similarly, the variable parafunctional habit was significantly associated with a diagnosis of TMD (OR=2.372, 95% CI: 1.189-4.735, p= 0.0143). Specifically, a group of patients who reported parafunctional habits was 2.37 times more likely to be diagnosed with TMD compared to the group who reported no parafunctional habits. The results of the Multivariable logistic regression are presented in detail in **Table 4.**

Table 4: Multivariable Analysis of factors associated with diagnosis of Temporomandibular Disorders

Characteristic	OR (95% CI)	p-value
Sex		
Female	1.152 (0.688-1.928)	0.591
Male	Ref	
Marital status		
Married	1.153 (0.659- 2.016)	0.4916
Widowed/Divorced	2.082 (0.735- 5.898)	0.1917
Single	Ref	
Employment status		
Employed	1.511 (0.815- 2.798)	0.5922
Self-employed	1.706 (0.892- 3.260)	0.2509
Unemployed	ref	
No of Otological Manifestation	1.470 (1.113- 1.942)	0.0066
Parafunctional Habits		
Yes	2.372 (1.189- 4.735)	0.0143
No		

4.4.2. Factors associated with the severity of Temporomandibular Disorders

Bivariable Ordinal Multinomial Logistic Regression

In a crude analysis of factors associated with the severity of Temporomandibular Disorders, only females (OR=0.514, 95%CI: 0.281-0.940, p=0.0307) and a number of otological manifestations (OR=0.532, 95%CI: 0.392-0.722, p= 0.001) was significantly associated with the severity of TMD. Specifically, the estimated odds that a female's score is in the mild TMD direction rather than severe is 0.52 times that of a male. Similarly, for a group of patients with one unit higher in otological manifestation, the estimated odds that a score is score is in the mild TMD direction rather than severe is 0.532 times the estimated odds of lower group. The results of the bivariable Ordinal Multinomial logistic regression are presented in detail in **Table 5.**

Table 5: Bivariable Analysis of factors associated with severity of Temporomandibular Disorders

Characteristic	OR (95% CI)	p-value
Age	1.000 (0.983- 1.018)	0.9809
Sex		
Female	0.514 (0.281-0.940)	0.0307
Male	ref	
Marital status		
Married	0.861 (0.449- 1.650)	0.666
Widowed/Divorced	0.989 (0.341- 2.870)	0.899
Single	ref	
Education level		
No formal education	0.532 (0.122- 2.319)	0.4249
Primary/Secondary	0.902 (0.488- 1.668)	0.6153
University/College	ref	
Employment status		
Employed	0.691 (0.330- 1.450)	0.9802
Self-employed	0.470 (0.224- 0.988)	0.0696
Unemployed	ref	
No of Otological Manifestation	0.532 (0.392-0.722)	0.001
Parafunctional Habits	0.776 (0.397- 1.516)	0.4581

Multivariable Ordinal Multinomial Logistic Regression

In the adjusted analysis of factors associated with the severity of TMD, only the number of otological manifestations (OR=0.541, 95% CI: 0.396-0.741, p=0.0001) was significantly associated with the severity of TMD. Specifically, for a group of patients with one-unit higher (one more) otological manifestation, the estimated odds that a score is in the mild TMD direction rather than severe is 0.53 times the estimated odds of the lower group. The results of the Multivariable Ordinal Multinomial logistic regression are presented in detail in **Table 6.**

Table 6: Multivariable Analysis of factors associated with severity of Temporomandibular Disorders

Characteristic	OR (95% CI)	p-value
Sex		
Female	0.606 (0.320- 1.148)	0.1241
Male	ref	
Employment status		
Employed	0.559 (0.257- 1.215)	0.6122
Self-employed	0.436 (0.202- 0.942)	0.0981
Unemployed	ref	
No of Otological Manifestation	0.541 (0.396-0.741)	0.0001

CHAPTER FIVE

5.0. DISCUSSION

Temporomandibular disorder (TMD) denotes a group of disorders involving the temporomandibular joint (TMJ), chewing muscles, and structures in close proximity e.g. the ears. The aim of this cross-sectional study was to investigate the prevalence and severity of TMDs among patients presenting with otological complaints. The study focused on patients who came to our otorhinolaryngology clinic at Muhimbili National hospital. The prevalence of TMDs in this study was found to be 61.46%, which was relatively high; this finding is in keeping with several studies which did report quite high proportions of TMDs (3,21,45,46). This study used a validated questionnaire (43,44). to diagnose and categorize patients with TMD and did not involve clinical examination and investigations of the masticatory system and temporomandibular joint. However, across literatures there is considerable variations in the reported prevalence which may be accounted for by the differences in the samples or target population and sampling techniques, the methodologies, and the evaluation methods used in the studies (46–48).

With regards to clinical presentation among 177 patients with TMDs;111(62.3%) had otalgia tinnitus 95 (53.7%), subjective hearing impairment 86 (48.6%), vertigo 78 (44.1%), aural fullness 50 (28.2%), parafunctional habits 43 (24.3%), bruxism 31 (17.5%). Otalgia was the commonest presentation among otological manifestations; this is somewhat in agreement with studies that did report that otalgia was the most frequent complaints (7,45,46)

The distribution of severity of temporomandibular disorders among the 177 patients with TMD as determined by the Fonseca anamnestic index severity categories; majority were in the mild category (40.72%) followed by moderate (19%) and the least were in the severe category (2.72%). This finding again showed quite good congruence with several studies which also did depict that mild TMD was the most prevalent and severe TMD the least prevalent (3,45,49).

In the analysis of factors associated with the diagnosis of TMD only the number of otological manifestations and parafunctional habits were significantly associated with the diagnosis of TMD. Studies has been done to assess relationship between various factors such as parafunctional habits, age, sex, emotional stress, anxiety, depression and the TMDs. In these studies statistically significance was found between presence of sign and symptom of TMD with female gender, parafunctional habits, emotional stress, anxiety; also in a study done to verify the relationship between otological symptoms and parafunctional habits in individuals with temporomandibular dysfunction statistically significant association was found between sex and the presence of parafunctional habit as otological symptoms were prevalent among women and individuals with at least one parafunctional habit(49,50). In our study, only parafunctional habits were significantly associated with the diagnosis of TMD in both crude and adjusted analysis but was not significantly associated with severity of TMD. These findings are similar to our finding in that an association is found between TMD and parafunctional habits. The differences that can be seen from other studies when compared to our study can be accounted for by differences in the sample sizes, sampling methods, target populations and the factors studied.

Regarding factors associated with severity of TMD the degree of severity increases as the number of otological manifestations increases. This finding is in keeping with studies done to evaluate the relationship between aural symptoms and TMD severity in which it was shown that as the number of aural symptoms increases so was the severity of TMDs (14,51). In a crude analysis of factors associated with the severity of Temporomandibular Disorders, only being female and a number of otological manifestations was significantly associated with the severity of TMDs although in an adjusted analysis only the relationship between the number of otological manifestations and severity of TMDs remained but other factors like gender, education level, marital status, employment status were not statistically significant.

CHAPTER SIX

6.0. CONCLUSION AND RECOMMENDATIONS.

6.1. Conclusion.

This study revealed that temporomandibular disorders are prevalent; 61.46% among patients with otological manifestations in our setting; majority; 105 (59.32%) of patients had mild temporomandibular disorder,51 (28.81%) had moderate TMD and few; 21(11.86%) had severe TMD and that there is association between the number of otological manifestations, diagnosis of TMD and the severity of TMDs. Specifically, patients with a cluster of otological symptoms or complaints with no apparent ear disease were more likely to be diagnosed with TMD and likewise to have a severe form of TMD.

6.2. Recommendations.

Otorhinolaryngologists should be more vigilant and inquiry about symptoms and signs of TMDs in patients presenting at ORL clinic with insignificant clinical findings on ENT examinations.

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APPENDICES

Appendix 1: Informed Consent Form (English version)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS

Research title: Prevalence and severity of Temporomandibular disorders among patients with otological manifestations attending Muhimbili National Hospital.

PART I: INFORMATION

Introduction

Form No: DATE----------

Greetings. I am Dr John mhando, a postgraduate student of masters in Otorhinolaryngology (MMED-ORL) at Muhimbili University of Health and Allied Sciences. I'm conducting research this research as part of my master's degree program. I kindly invite you to participate in this study. Be assured that your choice whether to participate or not will have no effect on the care and management. Welcome and feel free to ask any question concerning this research.

Aim of the study: To determine otological manifestations related to Temporomandibular disorders among patients attending MNH.

Benefit: The research findings will help in early detection and proper disposal or referral of the patients with Otological manifestations related to temporomandibular disorders as this is essential for better outcome of the treatments available in Oral Maxillo Facial faculty.

Risk: No harm is expected to occur by joining the study.

Withdrawal right: The decision to join this study is completely voluntary. You have the right to decide not to participate or quit immediately, even after signing the consent form and even refuse to respond to any question in the questionnaire.

Confidentiality: Numbers will be used to identify all the participants, so no names required. Only the main investigator will have access to the information collected from participants and after submission of the dissertation report pending the award of a postgraduate degree; the

information will be confidentially kept for two years in accordance to the guiding regulation; after which the information will be properly disposed.

Whom to Contact: If you have any concern or questions about the research, contact the following: Dr John Mhando (P.O.BOX 65001 Dar es Salaam, Tel 0714144026, email address: mhando1410@gmail.com), Dr. Aveline Kahinga (P.O.BOX 65001 Dar es salaam, Tel 0764608917) or Dr Edwin liyombo (P.O. BOX 65001, Dar es Salaam. Tel 0715283569). You can also contact **Dr Nahya Salim,** the Chairperson of the Muhimbili University Senate Research and Publications Committee**, +255713250074** P.O.BOX 65001, Dar es Salaam, for any matters concerning ethical violation of the study.

PARTII: Declaration: I confirm that I have read and understood the purpose and the procedure of this research. Also, I know that my participation is purely voluntary. The questions I had have all been explained and answered, and I have agreed to be a participant in this study.

Participant signature……. Date…… Investigator signature…… date……...

Appendix 2: consent form (Swahili version)
CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

KURUGENZI YA TAFITI NA MACHAPISHO.

Nambari-------- Tarehe----------

SEHEMU YA I: TAARIFA

Utangulizi

Naitwa Dokta John Mhando, mwanafunzi wa shahada ya uzamili ya udaktari idara ya maskio, pua na koo Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili. Nafanya utafiti **kuhusu uhusiano kati ya dalili mbalimbali zinazojitokeza kwenye masikio kutokana na matatizo kwenye taya, misuli ya kutafunia na maungio kati ya taya na fuvu la kichwa kwa wagonjwa wanaohudhuria kliniki ya masikio pua na koo katika Hospitali ya Taifa ya Muhimbili.Nakukaribisha sana kusoma maelezo haya na kisha kutoa ridhaa ya kushiriki kwako katika utafiti huu.**

Kusudi la utafiti

Lengo ni kutafiti kuhusu uhusiano kati ya dalili mbalimbali zinazojitokeza kwenye masikio kutokana na matatizo kwenye taya, misuli ya kutafunia na maungio kati ya taya na fuvu la kichwa kwa wagonjwa wanaohudhuria kliniki ya masikio pua na koo katika Hospitali ya Taifa ya Muhimbili.

Faida za utafiti huu

Matokeo ya utafiti huu yatasaidia kuwatambua mapema wagonjwa wenye matatizo ya masikio yanayosababishwa na matatizo ya taya, misuli ya kutafunia na maungio kati ya taya

na fuvu la kichwa na kuweza kuwapa rufaa mapema kwenda kwa madaktari wa upasuaji wa kinywa taya na uso kwa sababu ni muhimu ili kupata matokeo mazuri ya matibabu

Madhara ya utafiti huu

Hakuna madhara yanayotarajiwa kwa washiriki wa utafiti.

Kujitoa kwenye utafiti

Kushiriki kwako katika utafiti huu ni hiyari, unayo haki ya kujitoa katika utafiti huu wakati wowote na maamuzi yako hayataathiri kiwango na ubora wa huduma atakachopewa mgonjwa

Usiri

Namba zitatumika kwa utambuzi wa washiriki wa utafiti huu na sio majina ya washiriki. Kumbukumbu zote zinazohusiana na utafiti huu zitatunzwa kwa kuzingatia sharia, kanuni na taratibu kabla ya kuharibiwa ipasavyo.

Mawasiliano wakati wa utafiti

Pale ikitokea kuna shida yoyote au maswali, wasiliana na wafuatao; Dr John Mhando (P.O.BOX 65001 Dar es Salaam, Tel 0714144026, email address: mhando1410@gmail.com), Dr. Aveline Kahinga (P.O.BOX 65001 Dar es salaam, Tel 0764608917) or Dr Edwin Liyombo (P.O. BOX 65001, Dar es Salaam. Tel 0715283569). Ikiwa Kuna suala lolote linalohusu mwenendo wa kimaadili wa utafiti, wasiliana na Mwenyekiti wa Kamati ya Tafiti na Machapisho wa Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili **Dr. Nahya salim, +255713250074,** S.L.P 65001, Dar es salaam.

Tamko: Nakubali bila kushurutishwa kwamba mimi……. nimesoma na kuelezewa kwa undani na maswali yangu yamejibiwa kwa ufafanuzi na ninakubali kuwa mshiriki wa huu utafiti.

Saini ya mshiriki---------- tarehe……..

Saini ya mtafiti mkuu/Saini ya mtafiti msaidizi---------- date……

Appendix 3: Data collection tool (English version)

PART I

1. Personal Particulars.

ID no…… Age…. Sex ….

2. Education level…….

1) No formal education
2) Primary/secondary
3) University/college

(circle where appropriate)

3.Marital status…….

1) single
2) married
3) divorced
4) widow/widower

(circle where appropriate)

4.Working status….

1) Student
2) Employed
3) Unemployed
4) Self employed

(circle where appropriate)

5.Parafunctional habit ((biting tongue, cheeck or lip; biting foreign objects, nail biting, chewing gum, squeezing mobile phone between the ear and the shoulder)

1) Yes
2) No

6.Bruxism… (Teeth grinding)

1) Yes
2) No

PART II: TMD SCREENING FAI QUESTIONNAIRE

Questions	No	Sometimes	Yes
Is hard for you to open your mouth?			
Is it hard for you to move your mandible from side to side?			
Do you get tired /muscular pain while chewing?			
Do you have frequent headaches?			
Do you have pain on the nape or stiff neck?			
Do you have earaches or pain in the craniomandibular joints?			
Have you noticed any TMJ clicking while chewing or when you open your mouth?			
Do you clench or grind your teeth?			
Do you feel your teeth do not articulate well?			
) Do you consider yourself a tense(nervous) person?			
Total			

Total score…… severity category…….

1. 0-15 No TMD
2. 20-40 Mild TMD
3. 45-60 Moderate TMD
4. 70-100 Severe TMD

PART III.

OTOLOGICAL SYMPTOMS

1) Subjective hearing impairment-hearing impairment reported by a patient
2) Otalgia-Ear- pain in a patient with no active ear pathology, no history of ear surgery, no cardinal throat complaints.
3) Tinnitus- Perception of sound in absence of an external source.
4) Vertigo- Illusion of spinning motion.
5) Aural fullness- Ear pressure or ‘‘clogging sensation’’ of the ears.

   (circle where appropriate) note that participants can have more than one symptom, please circle accordingly.

   Others(specify)……

   All patients presenting with the above otological complaints and a negative or normal otoscopic/ear examination will be screened for presence or absence of TMDs.

NUMBER OF OTOLOGICAL MANIFESTATIONS.

1) one manifestation
2) Two manifestations.
3) (Three manifestations.
4) Four manifestations.
5) Five manifestations.
6) More than five manifestations.

   (circle where appropriate)

Appendix 4: Swahili version of the Data collection tool

SEHEMU YA KWANZA

1.Taarifa binafsi

Namba ya utambulisho…… umri…… jinsia…….

2.Kiwango cha elimu….

1) Sijasoma
2) Shule ya msingi/sekondari
3) Chuo /chou kikuu

(zungushia panapostahili)

3.Hali yamahusiano

1) Sijaoa/sijaolewa
2) Nimeo/nimeolewa
3) Nimeachana na mwenza wangu
4) Mjane

4.Hali ya ajira

1) Mwanafunzi
2) Nimeajiriwa
3) Sijaajiriwa
4) Nimejiajiri

(zungushia panapostahili)

5.Kung'ata ulimi, mashavu au midomo; kutafuna vitu visivyoliwa, kung'ata kucha, kutafuna bazooka, kupokea simu ikiwa kati ya bega na sikio

1) Ndio
2) Hapana

(zungushia panapostahili)

SEHEMU YA PILI:

DODOSO LA UCHUNGUZI WA MAGONJWA YA MAUNGIO KATI YA TAYA NA FUVU LA KICHWA NA MISULI INAYOHUSIKA NA UTAFUNAJI

Nambari	Swali	Ndio (10)	Hapana (0)	Wakatimwingine (5)
1	Je unapata shida kufungua kinywa chako mpaka mwisho?			
2	Je unapata shida kupeleka taya kulia na kushoto?			
3	Je unahisi kuchoka au maumivu ya misuli wakati wa kutafuna?			
4	Je unapata maumivu ya kichwa mara kwa mara?			
5	Unapata maumivu shingoni au shingo kukaza?			
6	Unapata maumivu ndani ya sikio au kwenye eneo la maungio ya taya lako na fuvu la kichwa?			
7	Je umewahi kusikia mlio kwenye maungio ya taya na fuvu la kichwa unapotafuna au kufungua mdomo?			
8	Je umewahi kujigundua kuwa una saga au kugandamiza meno			
9	Je Unapofumba mdomo unaona meno yako hayakutani vizuri?			
10	Je unajichukulia kama mtu mwenye wasiwasi?			
	Jumla			

Jumla kuu…… Kundi la ugonjwa…….

1. 0-15 hakuna
2. 20-40 kidogo
3. 45-65 wastani
4. 70-100 kali

SEHEMU YA TATU

DALILI ZA MASIKIO

1. kuhisi kutokusikia vizuri au shida ya usikivu

    1) maumivu ya sikio
    2) kusikia kelele masikioni ambazo watu wengine hawazisikii
    3) kuona dunia au vitu vinakuzunguka au unazunguka
    4) kusikia sikio Zito au limejaa Maji

2. Dalili zingine (taja kama zipo) …….

(tafadhali zungushia panapostahili) angalizo; mshiriki anaweza kuwa na dalili zaidi ya moja pia. zungushia kila dalili aliyonayo.

Wagonjwa wote wenye dalili tajwa hapo juu na uchunguzi wa sikio ukaonesha matokeo hasi au kutokuwa na shida yoyote watachunguzwa kujua kama wanashida kwenye maungio kati ya taya na fuvu la kichwa pamoja na misuli inayohusika **na kutafuna.**

IDADI YA DALILI ZA SHIDA YA MASIKIO.

1) **Dalili moja.**
2) **Dalili mbili.**
3) **Dalili tatu.**
4) **Dalili nne.**
5) **Dalili tano.**
6) **Dalili Zaidi ya tano.**

(zungushia panapohusika)

Appendix 5: Ethical Clearances

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/1962 Date: 31/10/2023

MUHAS-REC-10-2023-1962
JOHN MHANDO
COLLEGE OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: PREVALENCE AND SEVERITY OF TEMPOROMANDIBULAR DISORDERS AMONG PATIENTS WITH OTOLOGICAL MANIFESTATIONS ATTENDING MUHIMBILI NATIONAL HOSPITAL.

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: 31/10/2023
EXPIRATION DATE OF APPROVAL: 31/10/2024

STUDY DESCRIPTION:
Purpose:

The purpose of this cross-sectional study is to determine the Prevalence and severity of temporomandibular disorders among patients with otological manifestations attending Muhimbili National Hospital.

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. Kasusu Nyamuryekung'e

Ag. Chairperson, MUHAS Research and Ethics Committee

Appendix 6: Introduction Letter

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/T.192/2021

10th November, 2023

The Executive Director,
Muhimbili National Hospital,
P.O. Box 65000,
DAR ES SALAAM

Re: INTRODUCTION LETTER

We would like to inform you that the bearer of this letter is John Mhando with Reg. No. HD/MUH/T.192/2021 is a student at Muhimbili University of Health and Allied Sciences (MUHAS) "pursuing MMed. Otorhinolaryngology.

As part of his studies, he will be doing an elective research titled: **"Prevalence and Severity of Temporomandibular Disorders Among Patients with Otological Manifestations Attending Muhimbili National Hospital."** he is being supervised by Dr. Aveline Kahinga from MUHAS and Dr. Edwin Lyombo from MNH.

The research has been approved by the Chairman of University Senate.

Kindly provide him the necessary assistance to facilitate the conduct of his research.

We thank you for your cooperation.

Mr. Sebe Mohamed
For: DIRECTOR, POSTGRADUATE STUDIES

c.c John Mhando

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix 7: Permission Letter

THE UNITED REPUBLIC OF TANZANI

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/556 Date: 09th November, 2023

Head of Department

- ENT
- Dental

Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH

Name of Student	**John Mhando**
Title	**"Prevalence and Severity of Temporomandibular Disorders Among Patients with Otological Manifestations Attending MNH".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Aveline Kahinga (MUHAS)
Co – Supervisor	Dr. Edwin Lyombo (MNH)
Period	10th November, 2023 to 31st 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. Edwin Lyombo** (MNH) supervisor.

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

Sincerely,

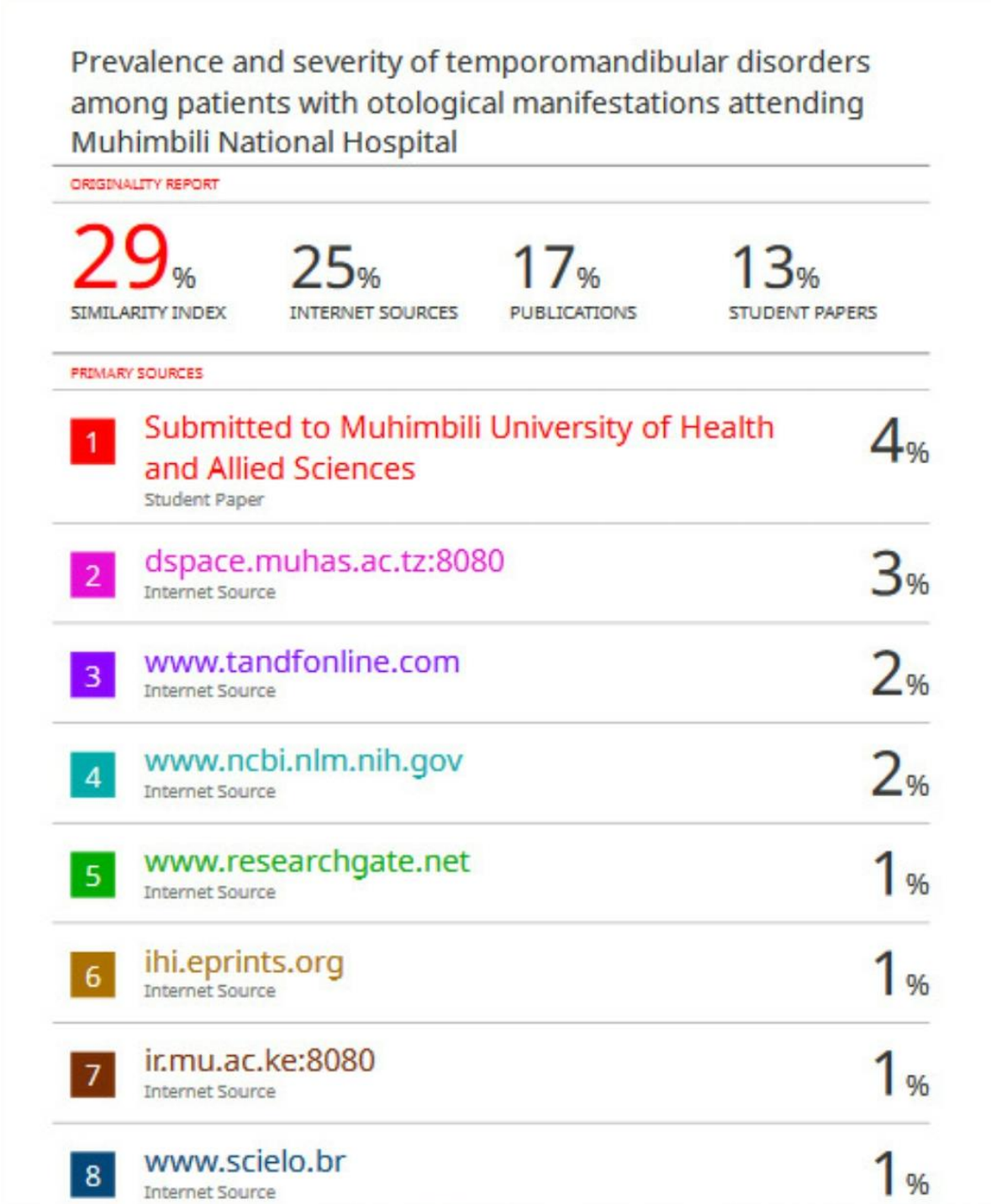
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For: Head of Clinical Research, Training and Consultancy Unit

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Appendix 8: Plagiarism



Prevalence and severity of temporomandibular disorders among patients with otological manifestations attending Muhimbili National Hospital

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