CORRELATION BETWEEN RADIOLOGICAL AND TYMPANOMETRY FINDINGS AMONG PEDIATRIC PATIENTS WITH ADENOID HYPERTROPHY ATTENDING OTORHINOLARYNGOLOGY CLINIC AT MUHIMBILI NATIONAL HOSPITAL

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By

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A Dissertation Submitted in Partial Fulfilment of the Requirements for the Degree of Master of Medicine (Otorhinolaryngology) at

Muhimbili University of Health and Allied Sciences.

October, 2024

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for examination by Muhimbili University of Health and Allied Sciences a dissertation entitled: **‘‘Correlation Between Radiological and Tympanometry Findings Among Pediatric Patients with Adenoid Hypertrophy Attending Otorhinolaryngology Clinic at Muhimbili National Hospital,** in (partial) fulfilment of the requirements for the Degree of Master of Medicine (**Otorhinolaryngology**) of Muhimbili University of Health and Allied Sciences.

_____

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(Supervisor)

Date: _____

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(Co-Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I, Abdulnoor Ismail Mohamed, declares that this **dissertation** is my own 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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With heartfelt gratitude

DEDICATION

"Dedicated to my pillar of strength, my beloved wife **Samaha Abdulrahman**, whose unwavering support and boundless love have been my guiding light throughout this journey. To my cherished children, whose laughter and presence have brought joy to even the most challenging days. To my ever-inspiring big sister, whose wisdom and encouragement have been constant sources of motivation. And to the patients who generously participated in the research, your trust and contribution have been invaluable in advancing our understanding. This dissertation is a tribute to the love, sacrifice, and encouragement of my dear family, and the collaborative spirit of those who make progress possible."

ABSTRACT

Background: The most prevalent cause of nasal obstruction in pediatric patients is adenoid hypertrophy (AH), often leading to symptoms such as snoring, sleep apnea, difficulty breathing, or mouth breathing. Adenoid hypertrophy significantly contributes to the development of otitis media with effusion (OME) in children, with a higher incidence observed as adenoid size increases. The most dependable and cost-effective evaluation method for enlarged adenoids and the determination of the adenoid-nasopharyngeal ratio (ANR) was lateral nasopharynx Xray. Tympanometry test is not a routine test carried out for patients with adenoid hypertrophy at our facility. In this study it was effectively used to detect the middle ear complications associated with adenoid hypertrophy such as otitis media with effusion.

Objective: The main aim of the study was to determine correlation between radiological and tympanometry findings among pediatric patients with adenoid hypertrophy attending the otorhinolaryngology clinic at Muhimbili National Hospital.

Materials and methods: This was a hospital based cross-sectional study design, conducted at otorhinolaryngology departmental clinic at Muhimbili National Hospital from July 2023 to January 2024 among patients aged below 18 years who were diagnosed with AH using lateral nasopharyngeal X-rays. Adenoid nasopharyngeal ratio was used to determine the grade of AH. The patients were sent for a tympanometry test. A designed structured data collecting tool was used for recording patients' demographic data, radiological findings obtained from the lateral nasopharyngeal x-ray radiography as well as tympanometric findings. Data were analyzed by using statistical package for the social science (SPSS) version 24 and presented in cross-tabulations and figures. Correlation coefficient and the Chi-square test were used for statistical associations and compare proportions. P value <0.05 was considered statistically significant.

Results: Majority of patients (53%) were aged 5-8 years, with males' predominance (61.6%). Common symptoms were snoring (32.2%) and mouth breathing (27.6%), while hypo nasal speech was rare (1.5%).Grade III AH was most common (50.4%), followed by grade IV (26.3%), and grade I was least common (1.3%). Tympanometry types varied, with type B most prevalent, right 56.0% and left 57.8%, followed by type A right 33.6% and left 31.0%, and type

Ad least common (0.4%). The study observed a strong correlation between radiological and tympanometry findings with bilateral decrease in the proportion of type A and increase in proportion of type B with increase in radiological grades. ($r = 0.597$ for right ear, $r = 0.643$ for left ear, $p < 0.001$).

Conclusion and recommendations: Adenoid hypertrophy grades III and IV were majority observed in 1 to 4 years. Males predominantly presented with grade I,II and IV, and female with grade III. Tympanometry type B was most commonly observed followed by type A, and least was type Ad bilaterally. The study found a strong correlation between radiological and tympanometry findings, noting a bilateral decrease in the proportion of type A and increase in proportion of type B as radiological grades increases. Implement regular screening for adenoid hypertrophy in pediatric patients aged 1 to 4 years, focusing on those presenting with symptoms snoring, mouth breathing, and hypo-nasal speech. Patients presented with severe adenoid hypertrophy (grades III and IV) accompanied by type B tympanograms, to consider performing adenoidectomy and grommet tube insertion together in a single setting. Standardized clinical guidelines integrating radiological imaging and tympanometry are recommended, with further research needed on longitudinal correlations and adenoidectomy outcomes

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LIST OF ABBREVIATIONS

AA	:	Antroadenoidal diameter
AH	:	Adenoid Hypertrophy
ANR	:	Adenoid Nasopharyngeal Ratio
ATH	:	Adenotonsillar Hypertrophy
ENT	:	Ear, Nose, Throat
ET	:	Eustachian Tube
ETD	:	Eustachian tube dysfunction
MNH	:	Muhimbili National Hospital
MEE	:	Middle Ear Effusion
MUHAS	:	Muhimbili University of Health and Allied Sciences.
OME	:	Otitis media with effusion
TYM	:	Tympanogram
UAO	:	Upper Airway Obstruction

DEFINITION OF TERM

1. **Adenoid hypertrophy** is the enlargement of the adenoids, which are a collection of lymphoid tissue situated in the nasopharynx. In this study, patients with adenoid hypertrophy were diagnosed based on clinical manifestations including nasal obstruction, snoring, mouth breathing, adenoid face, hypo nasal speech, runny nose, nasal obstruction.
2. **Adenoid Nasopharyngeal Ratio (ANR):** A radiological finding parameter on the lateral nasopharyngeal X-ray by using Fujioka method. ANR was used in this study, to determine the grade of adenoid hypertrophy. Grade I, less than 25% of the ANR, Grade II occupies 25-50% of the ANR, Grade III; those occupies 50-75% of the ANR, Grade IV occupies 75-100% of the ANR.
3. **Otitis media with effusion (OME):** is a medical condition marked by the accumulation of fluid in the middle ear. In this study abnormal type B and type Cs curves were regarded as diagnostic for middle ear effusion
4. **Pediatric age:** Refers to age between 0 days to 18 years.
5. **Tympanogram:** is an audiological test used to assess middle ear status. It measures movement of the tympanic membrane in response to changes in air pressure.
6. **Tympanometric findings:** provide important information about the condition of the middle ear function: type A tympanogram indicates normal middle ear function. Type As suggestive of ossicular fixation (otosclerosis or tympanosclerosis affecting the ossicles) with normal Eustachian tube function. Type Ad represent an ossicular subluxation (a partial or full ossicular discontinuity), or a healed tympanic membrane perforation. Type B tympanogram indicates abnormalities, often indicating poor tympanic membrane mobility, possible external ear canal blockage, or middle ear effusion. Type C tympanogram indicates negative middle ear pressure, typically caused by eustachian tube dysfunction or upper respiratory infections. Type Cs indicate a Eustachian tube dysfunction, most likely also means there is some fluid in the middle ear as well as some air.

7. **Abnormal tympanometric findings:** in this study abnormal tympanometric findings were classified as type As, type Ad, type B, type C and type Cs.

CHAPTER ONE

1.0 INTRODUCTION.

1.1 Background

1.1.1 Adenoid hypertrophy

The adenoid is part of the pharyngeal lymphatic ring called Waldeyer's ring in the upper respiratory tract. The ring consists of several lymphoid structures which include the adenoid (pharyngeal tonsil) on the posterior wall of the pharynx, the palatine tonsils, and the lingual tonsil which is located at the base of the tongue. (1)

Adenoid tissue can be identified from the age of 4 to 5 months. It continues to grow from the age of 2 to 14 years and rapidly regresses at the age of 15 years in the majority of the children.(2)The adenoid attends its largest dimension to the volume of nasopharynx once the child reaches the age of 7 years. The immune function of the adenoids is to produce B cells that facilitate in the production of IgG and IgA plasma cells. Oral and nasal exposure to antigens is an important part of childhood innate immunity (2)

Adenoid hypertrophy is one of the common causes of nasal airway obstruction in children. Symptoms of adenoid hypertrophy in children include persistent mouth breathing, hyponasal speech, and snoring. If the condition is left untreated, it can lead to complications such as craniofacial anomalies, obstructive sleep apnea (OSA), hearing loss, cor-pulmonale, failure to thrive, cardiomegaly, and pulmonary edema. Recurring infections together with allergies are risk factors for adenoid hypertrophy. Chronic adenoid tissue infection can act as a source for upper respiratory tract infection (URTI). The inflow of bacteria and viruses from the nasopharynx will result in edema and mechanical impediment to the Eustachian tube (ET) which can lead to an increase in middle ear pressure and cause negative intratympanic pressure. Eustachian tube dysfunction (ETD) plays a vital role in the pathogenesis of OME. It causes inflammation and mucosal swelling. The middle ear mucosa undergoes secretory activity, leading to the formation of middle ear effusion. When the adenoid is exposed to an allergen, it triggers an immune response by releasing mast cells and other allergic mediators which bind to immunoglobulin (IgE) and release histamines and other inflammatory mediators. The release of

mediators affects the mucociliary transport time, ciliary function, and structure. The effects of mediators can contribute to the secretory activity of the middle ear mucosa and the formation of effusion ((3),(4)

One of the most cost-efficient and reliable methods for evaluating the size of the adenoid is a lateral nasopharyngeal X-ray. It is used to determine the absolute sizes of the adenoid and the size of the nasopharyngeal space. The two main factors in assessing nasopharyngeal obstruction give an estimated size of the adenoid in relation to the nasopharyngeal airways. The adenoid nasopharyngeal ration (ANR) of the two sizes can provide a simple arithmetic measure of the nasopharyngeal obstruction. This ratio is used to measure adenoid size in relation to the nasopharyngeal space. (5,6)

1.2.1 Otitis media with Effusion

Otitis media with effusion (OME) is a condition characterized by the accumulation of fluid in the middle ear without signs of acute infection. The fluid build-up occurs in both the middle ear and the Eustachian tube, leading to pressure on the tympanic membrane. This pressure inhibits the vibration of the tympanic membrane and reduces sound conductivity, resulting in hearing loss. Chronic OME is described by the persistence of fluid accumulation in the middle ear for a duration of three months or longer. Acute otitis media (AOM) refers to the inflammation of the middle ear that has an acute onset and rapid progression and is frequently accompanied by fever and otalgia. AOM is considered the second most frequently observed pediatric diagnosis in an emergency visit, followed by upper respiratory infection. (7)

Otitis media with effusion is more predominant in the pediatric age group. Adenoid hypertrophy is one of the etiopathological factors for OME, Others include: recurrent URTI, allergic rhinitis and gastroesophageal reflux. Adenoid hypertrophy could mechanically obstruct the Eustachian tube, leading to anatomical blockage of the ET, consequently, resulting in induced middle-ear negative pressure. Correlation between AH and OME has led to silent, progressive hearing loss in pediatric patients and has impacted their language abilities and behavior.(8)

Acute otitis media is diagnosed when a middle ear effusion (MEE) is visible through pneumatic otoscopy and tympanometry. During otoscopic examination, characteristic signs of AOM include an elevated air-fluid level or a bulging tympanic membrane, indicating acute inflammation in the ear. The tympanic membrane may appear opaque, white, or erythematous, and there may be presence of purulent fluid originating from the middle ear. Symptoms commonly associated with AOM include irritability, otalgia, and fever. OME is a diagnosis based on the accumulation of fluid in the middle ear without the signs or symptoms of an ear infection. The recommended primary diagnostic method for OME is pneumonic otoscope and tympanometry is used for diagnostic confirmation. (9)

Watchful waiting is considered the initial treatment since OME resolves spontaneously. antibiotics and corticoids are not recommended. In cases where symptoms persist, a surgical procedure such as myringotomy with tympanostomy tube insertion is recognized as an effective treatment option. A ventilation tube is used to allow air ventilation into the middle ear and prevent fluid re-accumulation. Adenoidectomy is a current treatment option for cases of OME characterized by obstructive adenoids. Hearing aids can be considered in pediatric patients with hearing loss that impairs language development. (10)

1.3.1 Tympanometry:

Tympanometry involves the use of a device called a tympanometer to assess the structural function of the middle ear. This test is typically performed following an otoscopic examination. During the procedure a probe is inserted into the outer ear canal, emitting a sound tone that reflects off the tympanic membrane and measures pressure within the ear canal. Tympanometry has proven to be effective in evaluating middle ear disorders in children. It is cost effective, widely used by physicians, accepted by patients, and easy to administer. (11)

Tympanometry requires unobstructed ear canals to produce accurate results. The procedure measures the sound signal and middle ear pressure generating a tympanogram graph, displayed on the tympanometer's screen. The peak of the curve represents compliance, the flatness represents gradient, and the position of the peak on the x-axis indicates pressure. The tympanometer also measures the volume of the ear canal, which can provide valuable

information when comparing the volumes of both ears. Partial earwax blockage minimally impacts the measurement, but excessive earwax or improper probe placement can result in inaccurate ear canal volume readings. Ears with perforated eardrums or ventilation tubes typically have larger ear canal volumes, while an occluded ventilation tube appears normal. Quality assurance requires that the curve shape and figures match, and any non-normal curves should be repeated to eliminate artifacts.

Tympanograms are classified according to the Jerger/Fiellau-Nikolajsen classification system which categorizes them into different types based on their shape and characteristics.

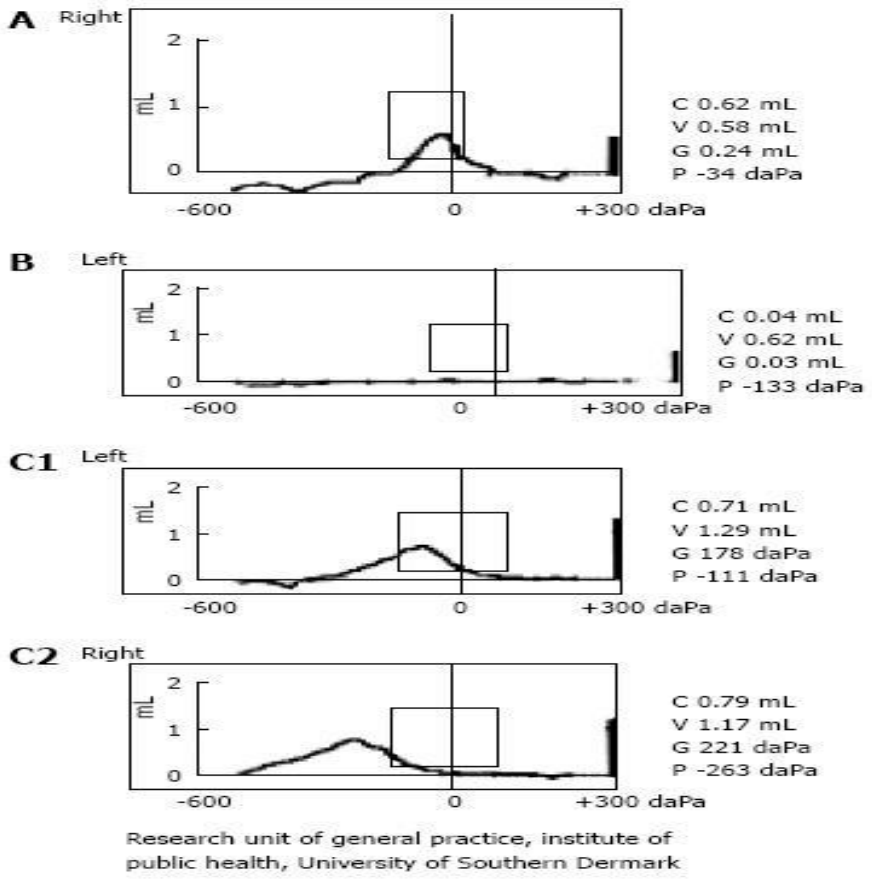


Figure 1: Tympanogram types

Type A represents a normal peaked curve with pressure ranging between +50 and +99 daPa. **Type B:** show a flat curve without a clear peak indicating a rigid tympanic membrane commonly associated with middle ear fluid. The positive predictive value for middle ear fluid is approximately 90%. **Type C1** is a peaked curve with negative pressure ranging from -100 to -199 daPa, often observed in children with nasal congestion. It can be considered an intermediate stage that may progress to either type B or type A. **Type C2**: Similar to type C1, this is a peaked curve; however, it has negative pressure equal to or less than -200 daPa. Certain **type C2** tympanograms indicate a combination of air and effusion in the middle ear. It is important to note that interpretating of a tympanogram should be done in conjunction with the patient's history and objective findings to ensure an accurate assessment.(9)

1.2 Problem statement

Muhimbili National Hospital (MNH) manages the majority of cases involving pediatric patients with adenoid hypertrophy. Routine clinical assessment and radiological investigations have been the primary diagnostic tools for adenoid hypertrophy at MNH. Middle ear effusion is among the potential complications of untreated adenoid hypertrophy. However, the scope of middle ear effusion has yet to be determined. Furthermore, there is no published evidence from Tanzania that addresses the correlation between adenoid hypertrophy (using radiological findings) and middle ear effusion (as assessed by tympanometry).

1.3 Conceptual framework

The purpose of this conceptual framework was to examine and understand the association between radiological results and Tympanometric findings in pediatric patients with adenoid hypertrophy who attend the otorhinolaryngology clinic at Muhimbili National Hospital. The tympanometric findings of the pediatric patients enrolled in the study were identified as the dependent variable, while grades of adenoid hypertrophy according to age and sex were represented as independent variables. The radiological finding parameter used was lateral nasopharyngeal X-ray using the Fujioka method to determine the adenoid nasopharyngeal ratio (ANR) measurements. This was used to assess the existence and severity of adenoid hypertrophy. The severity was recorded in grades and scored as a percentage. Adenoids

occupying less than 25% were grade I, those occupying 25-50% were grade II, those occupying 50-75% were grade III; and lastly those occupying 75-100% of the ANR were considered as grade IV. Tympanogram tests was performed. The findings were recorded as Types A, B, and C. Type A tympanogram indicated normal middle ear pressure with peak between +50 daPa to –200 daPa for children. Type C tympanogram was considered as abnormally the result will show a low middle ear pressure with a peak less than –200daPa for children. Type B tympanogram indicated an abnormality with no pressure peak recorded. The researcher employed this framework to establish objectives, conduct a literature review, and analyze data on pediatric patients diagnosed with adenoid hypertrophy.

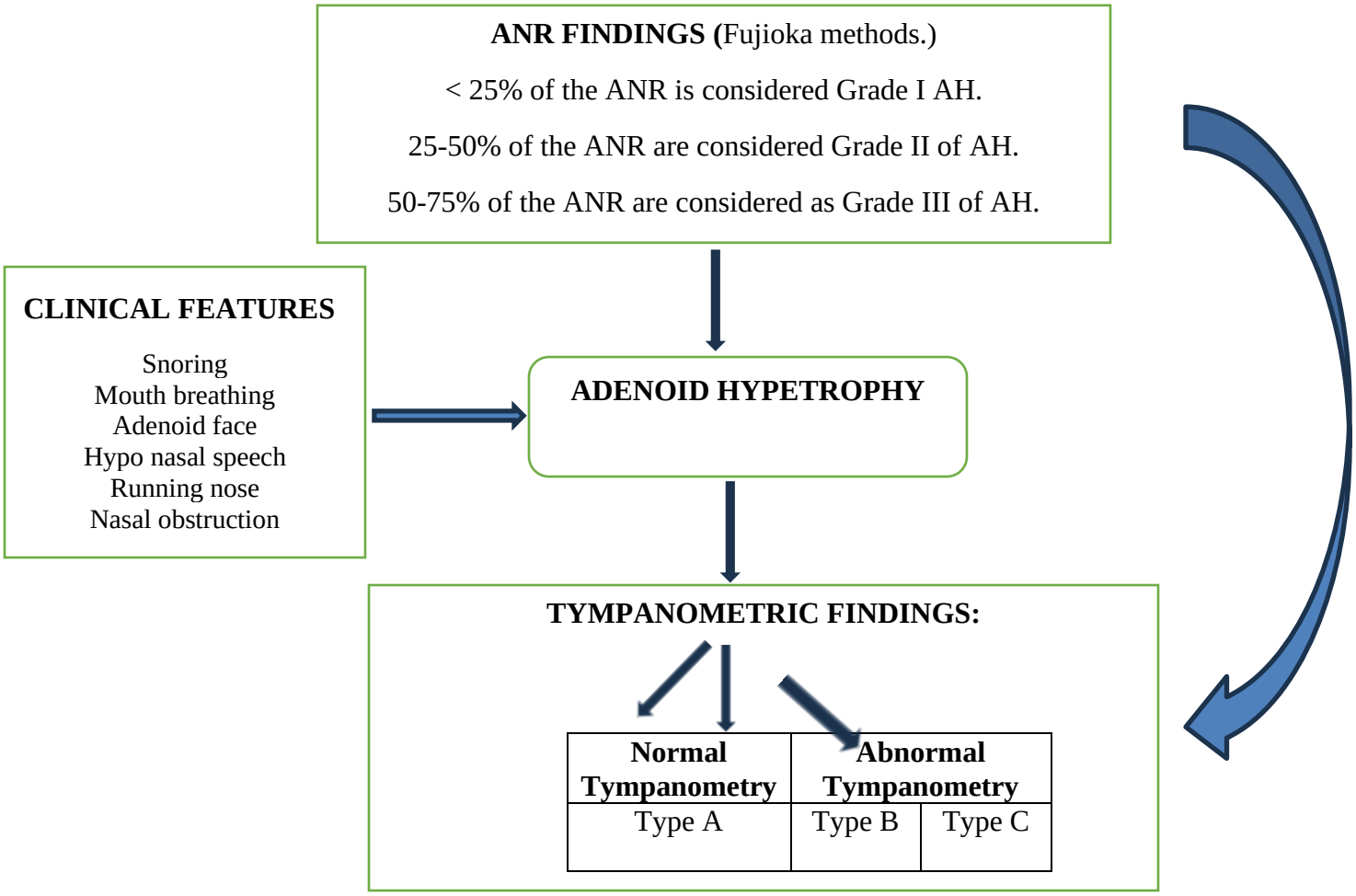


Figure 2: Conceptual frame work

1.4 Rationale of the study

The different types of tympanometry will provide more information about the middle ear status in pediatric patients with adenoid hypertrophy. This will help us determine if there is a need for hearing evaluation and management in all pediatric patients with adenoid hypertrophy. The study aims to establish a standardized procedure that physicians and other healthcare practitioners can utilize to promote early screening in pediatric patients with adenoid hypertrophy, specifically for suspected of middle ear effusion. Early intervention and monitoring can then be implemented to prevent potential repercussions including hearing loss, delayed language development, and cognitive damage. Additionally, this standardized 4procedure will improve patient care and reduce management costs.

1.5 The main research question.

What is the correlation between radiological and tympanometry findings among pediatric patients with adenoid hypertrophy attending otorhinolaryngology clinic at Muhimbili National Hospital?

1.5.1 Research questions.

i. What are the radiological findings among pediatric patients with adenoid hypertrophy attending otorhinolaryngology clinic at Muhimbili National Hospital?
ii. What are the tympanometry findings among pediatric patients with adenoid hypertrophy attending otorhinolaryngology clinic at Muhimbili National Hospital?
iii. What is the correlation between the radiological and tympanometry findings among pediatric patients with adenoid hypertrophy attending otorhinolaryngology clinic at Muhimbili National Hospital?

1.6 Main objective

To determine correlation between radiological and tympanometry findings among pediatric patients with adenoid hypertrophy attending Otorhinolaryngology clinic at Muhimbili National Hospital

1.6.1. Specific objectives

i. To determine the radiological findings among paediatric patients with adenoid hypertrophy attending Otorhinolaryngology clinic at Muhimbili National Hospital
ii. To determine the tympanometry findings among paediatric patients with adenoid hypertrophy attending Otorhinolaryngology clinic at Muhimbili National Hospital
iii. To determine the correlation between the radiological findings and tympanometry findings among pediatric patients with adenoid hypertrophy attending Otorhinolaryngology clinic at Muhimbili National Hospital

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Radiological findings of the paediatrics patients with adenoid hypertrophy

A highly cost-effective and reliable approach to evaluate the size of adenoids involves using lateral nasopharyngeal X-rays which involves assessing both the absolute dimensions of the adenoids and the size of the nasopharyngeal space. The evaluation of nasopharyngeal obstruction primarily hinges on two factors that approximate the size of the adenoids relative to the nasopharyngeal airways. The adenoid to nasopharynx ratio (ANR) is a straightforward mathematical measure of nasopharyngeal obstruction derived from these two sizes, which serves as a gauge for adenoid size in relation to the nasopharyngeal area. (5,6)

Estimating ANR using the Fujioka technique involves measuring two specific distances, first distance is measured from the outermost point of the adenoid's curvature to the spheno/basioccipital (A) and the second distance is from the spheno/basioccipital to the posterior end of the hard palate (N). The ANR is calculated by dividing distance (A) by distance (N) and recorded measurement is then classified as follows: The adenoid nasopharyngeal ratio (ANR) is considered normal if it is 0.25 or below, mildly enlarged if it ranges from greater than 0.25 to 0.5, moderately enlarged if it ranges from greater than 0.5 to 0.75, and severely enlarged if it exceeds 0.75.(6,12)

Studies have been conducted in various regions, including Europe, Asia, and Africa, to assess the severity of adenoid hypertrophy using nasopharyngeal radiological Xray in patients with adenoid hypertrophy. According to the Fujioka method, most studies have reported grade III (0.50-0.75) as the highest level of adenoid hypertrophy (5,13–17). However, a study conducted in Asia and Africa found that grade II (0.25-0.50) was the most commonly recorded grade.(13), Additionally, a study in Tanzania revealed that Grade IV adenoid hypertrophy was the most frequently observed grade.(18). It is worth noting that grade I adenoid hypertrophy (0.25) was recorded least frequently in other studies. (14,15). Furthermore, more males were recruited than females in these studies .(13,16)

2.2 Tympanogram findings of paediatric patient with adenoid hypertrophy

Click or tap here to enter text.The tympanometry test has been used to determine the middle ear status in patient with adenoid hypertrophy with Type B has been the most frequently reported tympanometric type in both ears of patients with adenoid hypertrophy in various studies.(4,16,17,19–21) . Other studies show that Type B was more frequently reported in the case groups than in the control groups. (4,16,20).

Type C was recorded at the highest frequency in unilateral cases of eustachian tube dysfunction (20), in contrast to another study which showed that type A was the most frequently reported in unilateral cases. (22). Another study shows that Type A was the most common reported in the control group compared to the cases. (16)

Type C was least recorded in the control groups compared to the cases (4,16) and was least recorded on the left side of the ear compared to the right. (11,23)

2.3 Correlation between the radiological and tympanometry findings among patient with adenoid hypertrophy

The studies aim to investigate the relationship between the adenoid grades and tympanometry types, in pediatric patients with adenoid hypertrophy.

Abdel Tawab H. et al in Oman, conducted a prospective study which demonstrated a significant association between grade IV adenoid hypertrophy and type B tympanometry. Larger adenoid sizes correlated with a shift from type C to type B tympanometry curves. Furthermore, a strong positive correlation was revealed between mucoid effusion and grade IV adenoid size. Higher grades of adenoid hypertrophy corresponded to increased viscosity of middle ear fluid. (19)

Utama et al in Indonesia, found a significant correlation between the ANR and Tympanometry findings. The significance of $p < 0.001$ indicated a highly significant relationship between these variables. The study also showed the strength of association which resulted in a correlation coefficient (r) of 0.605 the role of which indicated a moderately strong positive correlation.(24)

Orji F et al in Nigeria found that grade IV nasopharyngeal obstruction was associated with type B tympanograms in 48% of cases. (21)

Nwosu et al in Nigeria revealed a significant association between grade III adenoid hypertrophy and OME compared to other grades of adenoid hypertrophy ($p < 0.05$). Bilateral cases of OME were more prevalent in grade III adenoid hypertrophy.(4)

Els et al. in South Africa found a significant correlation between ANR and tympanometry types A, B, and C with increased incidence of type B and C tympanograms for ANR ≥ 0.71 (OR 3.98, $p < 0.05$). No statistically significant relationship was found between adenoid hypertrophy and OME for ANR ≥ 0.71.(25)

Kiama A.M in Kenya, showed that grade II adenoid hypertrophy was associated with type B tympanograms in 56.3% of cases, and grade III adenoid hypertrophy was associated with type B tympanograms in 72.2% of cases. No significant difference in AN ratio was found between pediatric patients with or without OME in grades I and II adenoid hypertrophy. However, grade III adenoid enlargement increased the likelihood of developing OME compared to grade II. (16)

There is a significant correlation between Grade IV and tympanometry type B (19,21,25). These findings differ to the studies which show that there a substantial correlation between grade III and type B tympanometry.(4,16)

Meanwhile other studies reveal no statistically significant ($p > 0.05$) relationship between grade I, II with type B tympanometry. (16,21)

CHAPTER THREE

3.0 METHODOLOGY.

3.1 Study design.

A cross-sectional study

3.2 Study duration

July 2023 to January 2024

3.3 Study setting

This study was carried out at the Otorhinolaryngology Clinic, Audiology unit, and the department of diagnostic radiology within the Muhimbili National Hospital (MNH). Muhimbili National Hospital is a national teaching and referral hospital affiliated with Muhimbili University of Health and Allied Sciences (MUHAS), located in Upanga, Dar es Salaam, Tanzania. It has 32 specialized clinics with 2800 employees and a bed capacity of 1500. Otorhinolaryngology clinic is one of the specialized clinics at MNH which has 17 medical specialists and over 60 other medical carders including resident, registrar and nurses. It serves approximately over 1800 pediatric patients per month. The clinic offers a range of super specialized services, including otology, audiology, head and neck surgery, rhinology, allergology, language, and speech services.

3.4 Study population.

- Pediatric patients aged from birth to 18 years attend Otorhinolaryngology clinic at MNH.

3.5 Sample size

Yamane formula was employed in the calculation of the sample size.(26)

Given by the formula:

$$\textbf{Sample size } n = \frac{N}{(1+N\,\varepsilon^{2})}$$

Given that:

n = The minimum required sample size,

ε = The margin of error, conventionally set as 1.96, resulting in a 5% margin of error for the study.

N=552, the average number of new cases of children attending the ORL clinic at MNH in three months obtained during a pilot study done at the clinic. The minimum sample size was calculated as:

$$n = \frac{552}{1+552X0.05^2}$$

n=232

Therefore, 232 children were considered the minimum sample size for the study**.**

3.6 Inclusion and Exclusions criteria

3.6.1 Inclusion criteria

- Pediatric patients with clinical features suggestive of adenoid hypertrophy aged from birth to 18 years, attending Otorhinolaryngology clinic at MNH.
- Positive radiological findings with clinical features suggestive of adenoid hypertrophy.
- Parental / guardian consent for the study participation.

3.6.2 Exclusion criteria

- Pediatric patients with congenital anomalies (craniofacial malformation, otological-based genetic syndromes)
- Patients with tympanic membrane perforation, grommet, or T tube

3.7 Sampling method

A non-probability convenience sampling method was employed. Pediatric patients were only recruited if they met the inclusion criteria to participate into the study and the recruitment process ceased once the sample size was reached.

3.8 Variables

3.8.1 Dependent variable

Tympanometry findings.

3.8.2 Independent

Grades of adenoid hypertrophy, Age, Sex.

3.9 Data collection tools and technique

Equipment:

- Lateral nasopharyngeal radiographs(X-ray) that were performed at the Muhimbili National Hospital.
- Tympanometer: Amplivox Otowave model 102 CE 0413
- Otoscope with various sizes of aural specula
- Cerumen hook
- Data collection form (socio-demographics, nasopharyngeal x-ray and tympanometric findings)

3.9.1 Method 1: Radiological techniques:

This technique was applied by a trained radiographer at the Radiology Department of MNH. The patients were placed in a supine position with an open mouth and slightly extended neck. Nasopharyngeal radiography was taken, the degree of the adenoid obstruction was defined the adenoid to nasopharyngeal ratio. The X-ray was reported by the principal investigator together with the trained radiologist**.** The estimation of the adenoid nasopharynx ratio (ANR) using the Fujioka method was determined by measuring two distances. The initial distance was from the outermost point of convexity of the adenoid shadow to the basioccipital (A). The subsequent

distance was from the anterior inferior edge of the sphenobasioccipital synchondrosis to the posterior end of the hard palate (N). Adenoid to Nasopharynx Ratio was calculated by taking the distance (A) divide by the distance (N). The measurement was then recorded as follows: The adenoid nasopharyngeal ratio (AN) was categorized as follows: 0.25 or below was classified as normal, greater than 0.25 to 0.5 was classified as mild enlargement, greater than 0.5 to 0.75 was classified as moderate enlargement, and anything exceeding 0.75 was classified as severe enlargement.

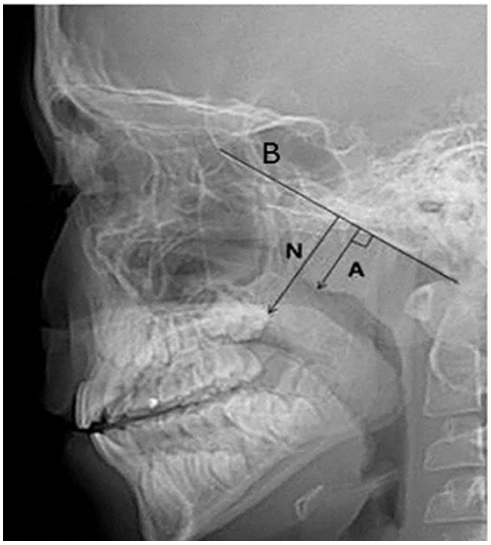


Figure 3: Adenoid measurement:

Represents the distance from the anterior margin of the **basioccipital** to the point of maximal convexity: N: nasopharyngeal measurement represents the distance between the anterior inferior edge of the **sphenobasioccipital synchondrosis** to the posterior superior edge of the hard palate. The ANR is determine by Fujioka method whereby the A/N ratio is obtained by dividing the A by N (6,12)

3.9.2. Method 2: Audiological techniques (tympanogram)

This technique was conducted by the trained audiology specialist at ORL audiology unit located at MNH. Parent or guardian were asked if the patient has any discomfort or pain before the test. The parents were then asked to remove any objects from the patient that may interfere with insertion of the probe (e.g., a hearing aid). For those patients who might require assistance, parents were asked to assist by placing the patient on lap in seated position with one hand securing patient's hands and other holding the patient head against the chest. Otoscopic examination was done to ensure that there were no cerumen impaction, tympanic membrane perforation, grommet, or T tube before the procedure is conducted. The probe was placed in each ear separately and measurements were recorded. The results were interpreted based on depicting various tympanogram tracings on variations according to Jerger classification. Tracing of the type A tympanogram curve shows a normal maximum height that occurs at a pressure near to zero, and the width of the curve is normal. The curved was flattened and had a low static admittance in type B tracing with normal ear canal volume. This finding suggested a reduced tympanic membrane vibration caused by middle ear effusion. (MEE). Type C tracing the curve demonstrated a significant negative pressure in the middle ear, to a retracted tympanic membrane which suggested an eustachian tube dysfunction (ETD) or middle ear with effusion (MEE).

3.10 Data Management and Analysis

3.10.1 Data Collection

Patient radiographic and tympanometric findings were documented on a data collection form which included demographics and clinical characteristics, as well as nasopharyngeal X-ray and tympanometric findings by the principal investigator.

3.10.2 Data analysis

Data collected were entered in analysis statistical package for the social science (SPSS) computer software version 24. A correlation coefficient was used to assess the relationship between radiological findings data and tympanometric findings data. The results were presented in graphs and table to show different variables and their correlations. The results were interpreted range from –1 to +1, where 0 indicates that there is no linear or monotonic association. Accuracy and completeness were determined.

3.11 Ethical Consideration and Approval.

The research proposal was presented to the Otorhinolaryngology department at MUHAS. Ethical clearance to conduct the research was received from MUHAS research and publication committee. Data collection permission was obtained from the MNH research unit. The parent or guardian of the patient was given a satisfied explanation about the study. A written consent was presented to the parent or guardian of the patient for the enrollment in the study in both Kiswahili and English. Initials and codes number were used. The information and the findings were kept confidential during data collection.

3.12 Study limitation and Mitigation

- Poor radiographic image quality was mostly caused by inaccurate and improper placement of pediatric patients. The parent or the guardian were asked to assist in holding and sooth the child to avoid immobility and distraction.

CHAPTER FOUR

4.0 RESULTS

4.1 Demographic and clinical presentation of patient with Adenoid hypertrophy.

4.1.1 Demographic characteristics of patient with Adenoid hypertrophy by age and sex.

A total of 232 pediatric patients with adenoid hypertrophy (AH) were enrolled in this study. Their ages ranged from 4months to 10 years with a median age of 3 years and an interquartile range (IQR) of 3 (4,1). The majority, 53%, were aged 5-8 years with males accounting for 61.6%, and a male-to-female ratio of 1.6: 1. (Table 1)

Table 1: Age and sex distribution of pediatric patients with adenoid hypertrophy attended Otorhinolaryngology clinic

Age Groups (years)	Child's Sex		Total
	Male N (%)	Female N (%)	N (%)
>1	17(85.0%)	3(15.0%)	20(8.6%)
1-4	52 (71.2%)	21(28.8%)	73(31.5%)
5-8	64 (52.0%)	59(48.0%)	123(53.0%)
9-12	10(62.5%)	6 (37.5%)	16(6.9%)
Total N (%)	**143(61.6%)**	**89(38.4%)**	**232(100.0%)**

4.1.2 Clinical presentation among the pediatric patient with adenoid hypertrophy:

Most patients presented with snoring (32.2%) followed by mouth breathing (27.6%), and least presented with hyponasal speech (1.5%). **(Figure 4)**

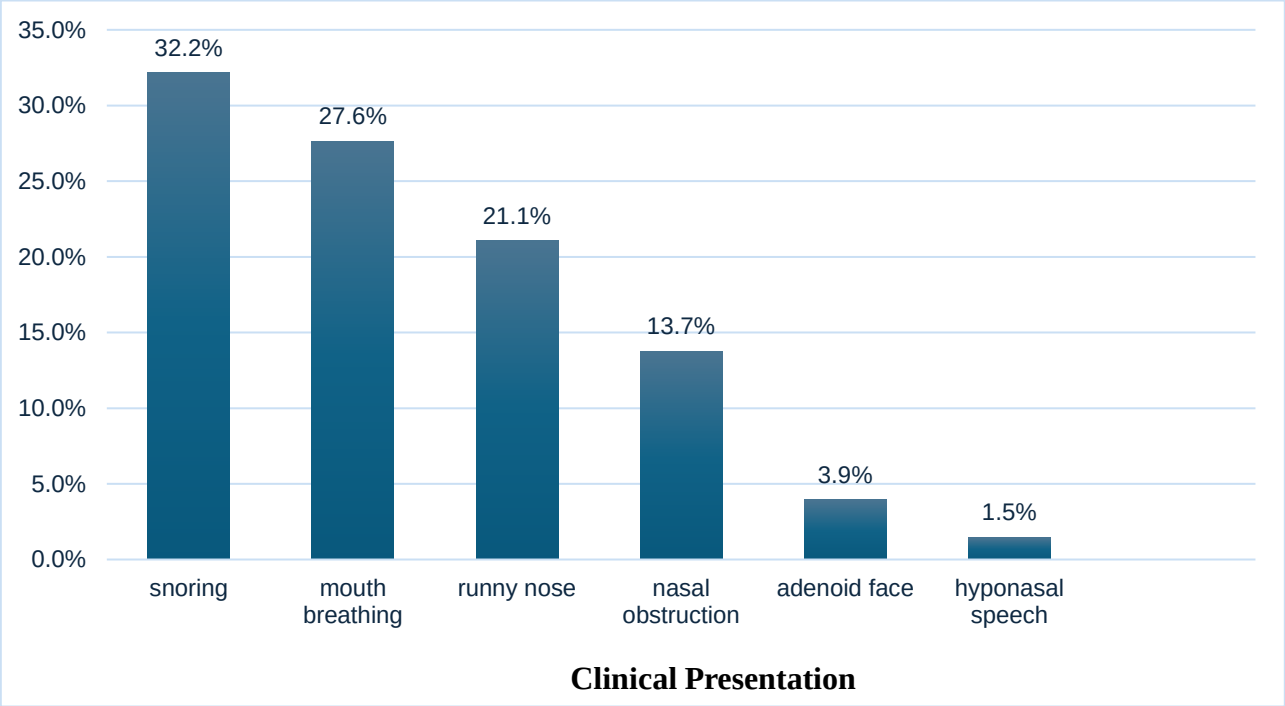


Figure 4: Clinical presentation among the pediatric patients with adenoid hypertrophy

4.2 Radiological findings among paediatric patients with adenoid hypertrophy according to age and sex.

Half of the patients (50.4%) had Grade III AH while only 1.3% had Grade I AH. Grade I and Grade II AH were more prevalent in the 9-12-year age group, accounting for 12.5% and 50.0%, respectively. Notably, no patients with Grade I AH were observed in the 1-4 and 5-8-year age groups. Grade III AH was most frequently observed (54.8%) in the 1-4-years age group, and least common (25.0%) in the 9-12-year age group. Grade IV AH was predominantly found among patients aged <1 year (40.0%), with the lowest prevalence (12.5%) observed in the 9-12-year age group (Table 2).

Grade I (2.1%), II (24.5%), and IV (31.5%) AH were more commonly observed among males, whereas Grade III AH (64.0%) was more commonly observed among females. (Figure 5).

Table 2: Radiological findings by age among the paediatrics patients with adenoid hypertrophy

Age Groups (years)	Radiological Grade				Total
	Grade I N(%)	Grade II N(%)	Grade III N(%)	Grade IV N(%)	N (%)
<1	1(5.0%)	3(15.0%)	8(40.0%)	8(40.0%)	20(8.6%)
1-4	0(0.0%)	9(12.3%)	40(54.8%)	24(32.9%)	73(31.5%)
5-8	0(0.0%)	31(25.2%)	65(52.8%)	27(22.0%)	123(53.0%)
9-12	2(12.5%)	8(50.0%)	4(25.0%)	2(12.5%)	16(6.9%)
Total	**3(1.3%)**	**51(22.0%)**	**117(50.4%)**	**61(26.3%)**	**232(100.0%)**

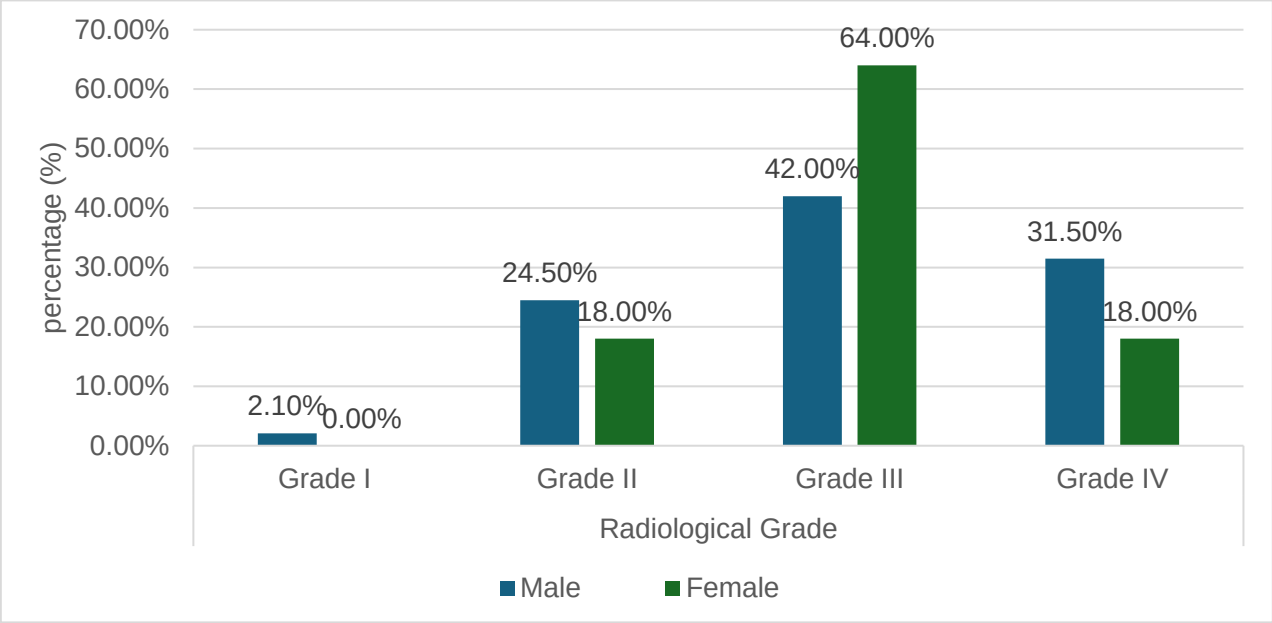


Figure 5: Radiological findings by sex among the paediatric patients with adenoid hypertrophy

4.3 Tympanometry findings among paediatric patients with adenoid hypertrophy according to age and sex.

4.3.1 Tympanometry findings according to the age and sex in the right ear.

The majority had Type B (56.0%), followed by type A (33.6%), with type Ad (0.4%) being the least common. When stratified by age groups, Type A was predominant in the 9-12 years age group (62.5%), while the lowest prevalence was observed in the 1-4 years age group (21.9%). Type As was mostly found in the 1-4 years age group (4.1%), with no occurrences in the other age groups. Type Ad was solely identified in the 1-4 years age group (1.4%). Type B was most prevalent in the <1 year age group (70.0%), with the prevalence decreasing as the age groups increased. Type C was primarily observed in the 1-4 years age group (12.3%), with no occurrences in the 9-12 years age group (Table 3). The observed differences in tympanogram types across the age groups were not statistically significant (p=0.86)

Type A (37.1%), and Type Ad (0.7%) were more commonly observed among males, whereas Type B (60.7%), Type As (3.4%) and Type C (7.9%) were observed more frequently in females. The observed differences in tympanogram types across the sex were not statistically significant (p=0.474) (Figure 6).

Table 3: Tympanogram findings(right) by age among paediatric patients with adenoid hypertrophy

Age Groups (years)	Tympanogram types (right)					Total N (%)	Fisher's Exact Test
	TYPE A N (%)	TYPE As N (%)	TYPE Ad N (%)	TYPE B N (%)	TYPE C N (%)		
<1	5 (25.0%)	0 (0.0%)	0(0.0%)	14 (70.0%)	1 (5.0%)	20(8.6%)	
1-4	16(21.9%)	3(4.1%)	1(1.4%)	44(60.3%)	9(12.3%)	73(31.5%)	
5-8	47(38.2%)	2(1.6%)	0(0.0%)	66(53.7%)	8(6.5%)	123(53.0%)	**0.86**
9-12	10(62.5%)	0(0.0%)	0(0.0%)	6(37.5%)	0(0.0%)	16(6.9%)	
Total	**78(33.6%)**	**5(2.2%)**	**1(0.4%)**	**130(56.0%)**	**18(7.8%)**	**232(100.0%)**	

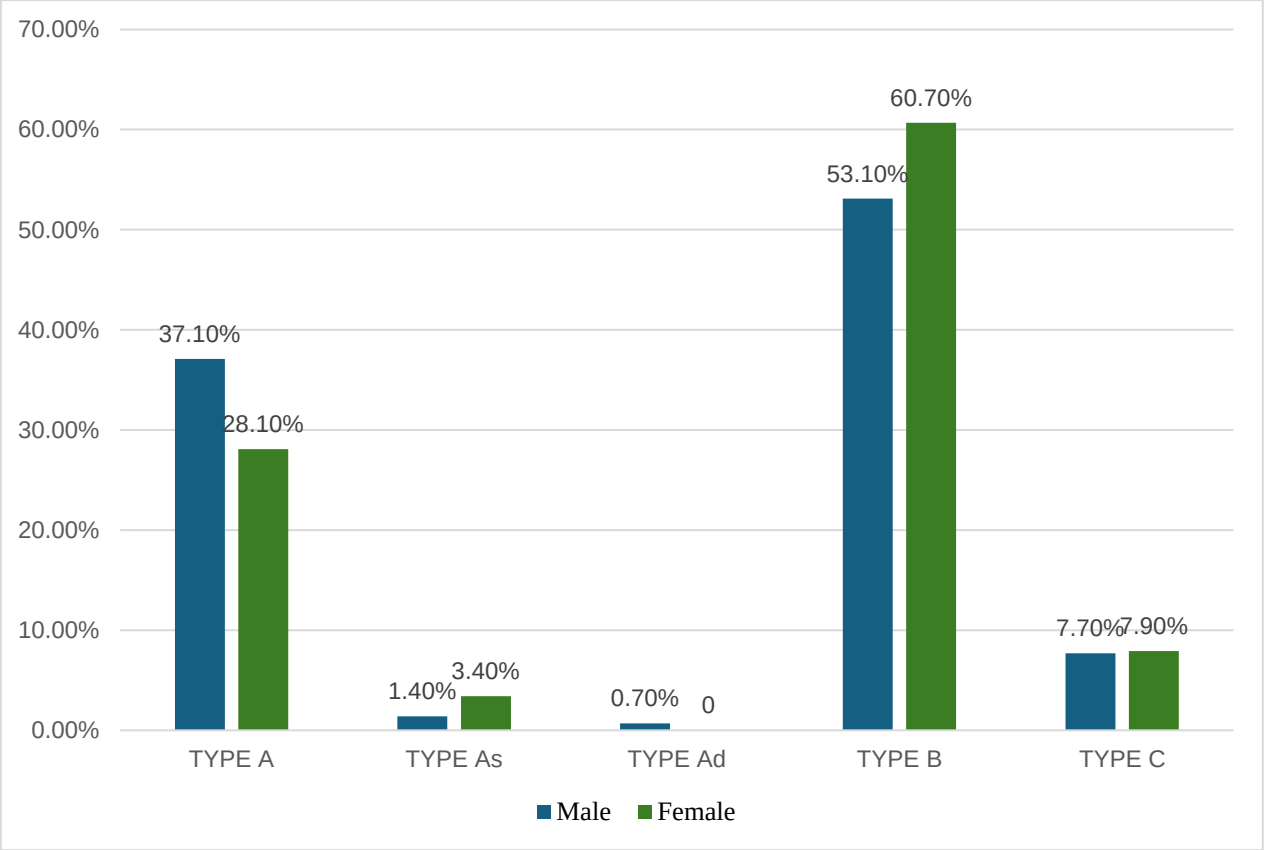


Figure 6: Tympanogram findings(right) by sex among paediatric patients with adenoid hypertrophy

4.3.2 Tympanometry findings according to age and sex in the left ear.

The majority of patients had Type B tympanograms (57.8%), followed by Type A (31.0%), with type Ad being the least prevalent (0.4%). Type A tympanogram was predominantly observed in the 9-12 years age group (62.5%), while the lowest prevalence was noted in the 1-4 years age group (20.5%). Type Ad tympanogram was exclusively identified in the 1-4 years age group (1.4%). Type B tympanogram was most prevalent in the 1-4 years age group (67.1%), with the lowest prevalence observed in the 9-12 years age group (37.5%). Type C tympanogram was primarily observed in the <1 year age group (25.0%), with no instances found in the 9-12 years age group. The observed differences in tympanogram types across the age groups were not statistically significant (p=0.019) (Table 4).

Type A (32.9%), Type Ad (0.7%) and Type C (11.2%) were more commonly observed among males whereas Type B (61.8%) was only observed more frequently in females. The observed differences in tympanogram types across sexes were not statistically significant (p=0.800). (Figure 7)

Table 4: Tympanogram findings(left) by age among paediatric patients with adenoid hypertrophy.

Age Groups (Years)	Tympanogram types (left)				Total N (%)	Fisher's Exact Test
	TYPE A N (%)	TYPE Ad N (%)	TYPE B N (%)	TYPE C N (%)		
<1	5(25.0%)	0(0.0%)	10 (50.0%)	5(25.0%)	20(8.6%)	
1-4	15(20.5%)	1 (1.4%)	49 (67.1%)	8 (11.0%)	73 (31.5%)	
5-8	42 (34.1%)	0(0.0%)	69 (56.1%)	12 (9.8%)	123 (53.0%)	**0.019**
9-12	10 (62.5%)	0 (0.0%)	6 (37.5%)	0 (0.0%)	16 (6.9%)	
Total	**72(31.0%)**	**1 (0.4%)**	**134 (57.8%)**	**25 (10.8%)**	**232 (100.0%)**	

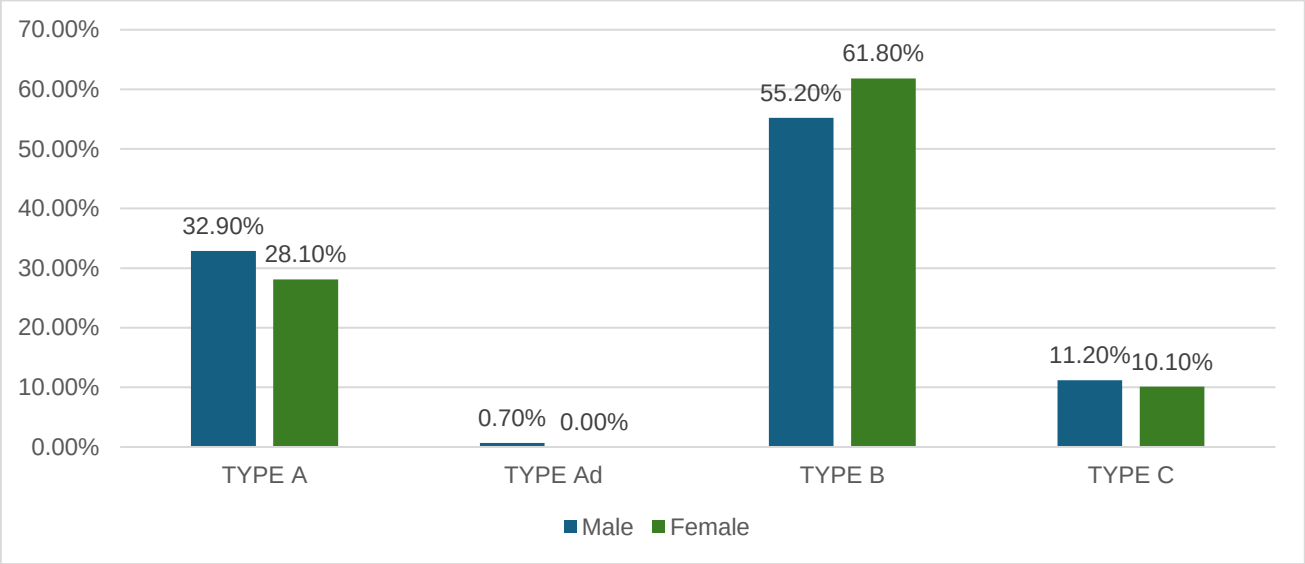


Figure 7: Tympanogram findings(left) by sex among paediatric patients with adenoid hypertrophy.

4.4 Correlation between the radiological findings and tympanometry findings among patients with adenoid hypertrophy.

4.4.1 Correlation of the radiological findings and tympanometry of the right and left ear.

This study shows a correlation between radiological and tympanometry findings with Spearman rank, with moderate correlation coefficient, of the right ear, r, is 0.597 (Figure 8) and strong correlation of the left ear, r, is 0.643(Figure 9) and both were statistically significant (p = <0.001).

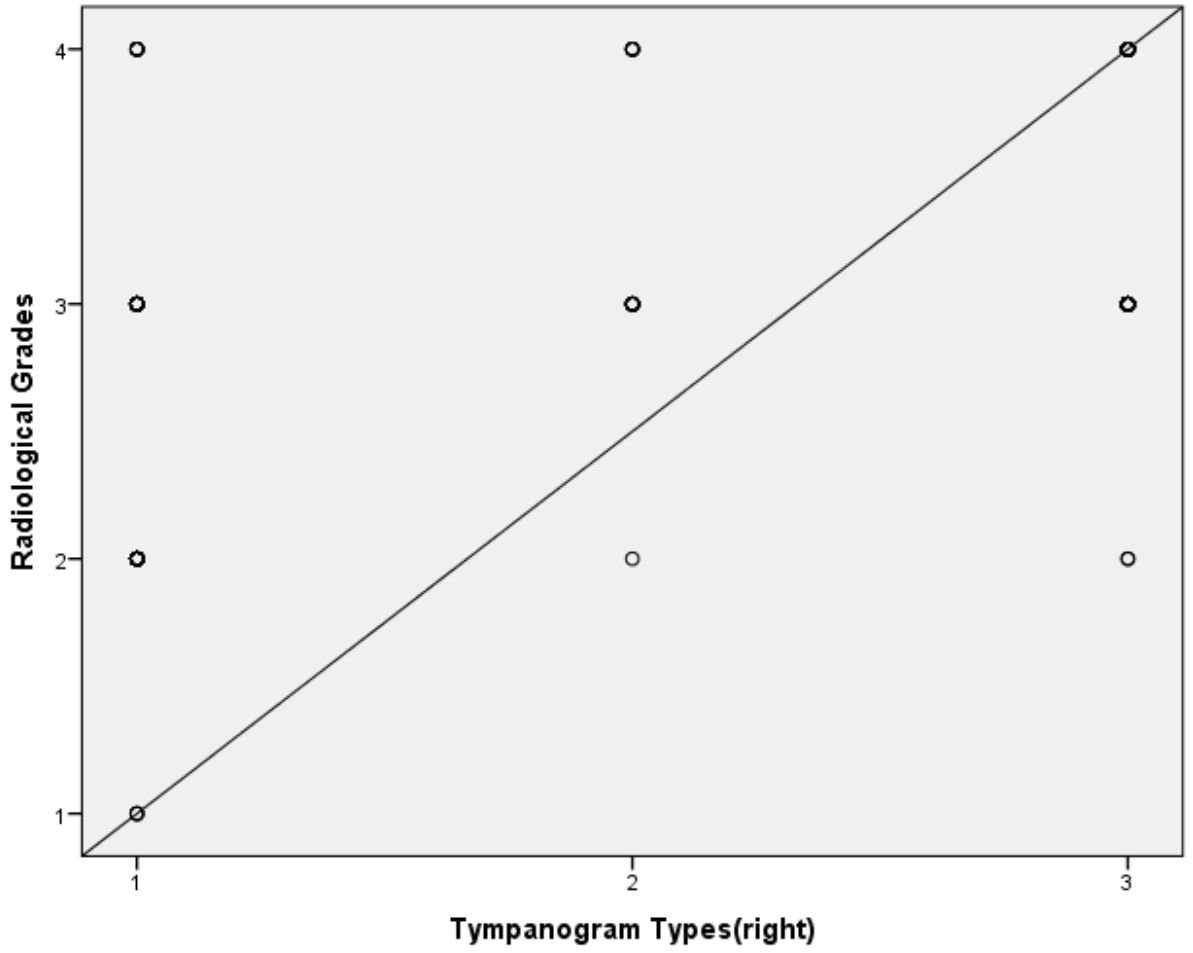


Figure 8: Correlation between radiological grades and tympanogram types (right)

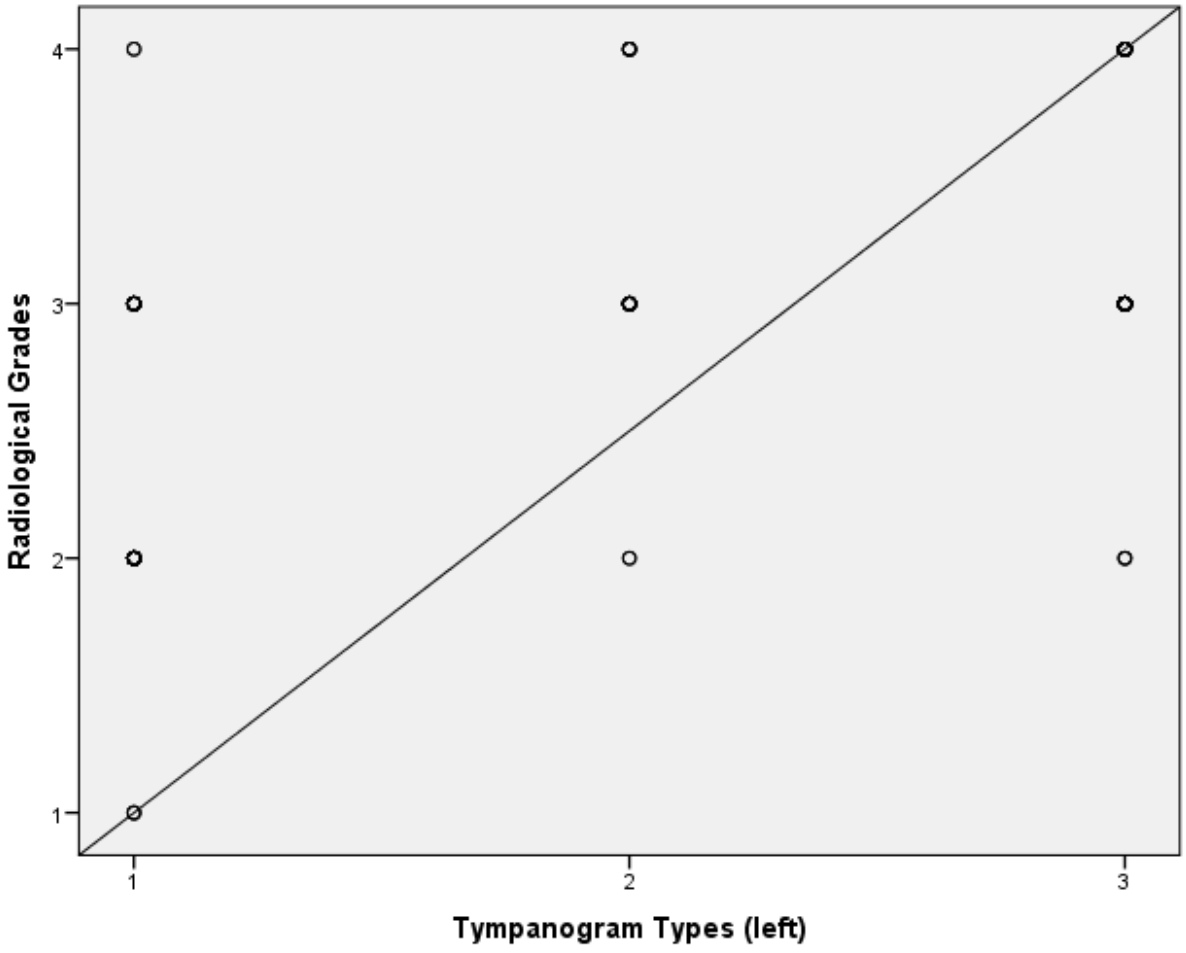


Figure 9: Correlation between radiological grades and tympanogram types (left)

CHAPTER FIVE

5.0 DISCUSSION

Adenoid hypertrophy refers to the enlargement of the adenoid tissues which causes mechanical obstruction of the eustachian tube. The adenoid is a part of the lymphoepithelial tissues located medially to the eustachian tube, superior to the nasopharynx. Together with the palatine and lingual tonsils it forms a structure known as Weldyer's ring. Adenoid size typically increases during childhood, peaking around the age 6 or 7 years before regressing during adolescence.(1,2,27)

In this study, the majority of the pediatric patients with adenoid hypertrophy who attended the ORL clinic at MNH were aged between 5 to 8 years, accounting for 53.0% of the study population. The age range observed in this study is almost similar to studies done by Huang et al in China,(28),Papaioannoe et al in Greece, (29). Diksha et al in India(5)and Mukutu et al in Tanzania (18).

The most commonly presented clinical features in patients with adenoid hypertrophy in this study were snoring (32.2%) followed by mouth breathing (27.6%), and the least commonly presented feature was hypo-nasal speech (1.5%). Such clinical findings are similar to studies done by O.S Jyothirmai et al in India (14), and Utama et al in Indonesia(24). Dissimilar finding appears in a study by Moideen et al in India where the most commonly presented clinical features were nasal obstruction (91.44%) followed by mouth breathing (87.50%) and snoring (79.16%) (30) The observed difference could be attributed to the higher sample size(n=232) ,and the age group range of the participants from >1 to 18 years in this study.

The majority of pediatric patients with adenoid hypertrophy in this study were found to have grade III adenoid hypertrophy (50.4%). The least common was grade I (1.3%). The observed grades range were similar to studies done by Diksha et al in India(5), Solmaz et al in Turkey(13), and Islam et al in Bangladesh(17). Dissimilar findings appear in other studies done by Moideen et al in India (30).and Mukutu et al in Tanzania(18) where grade IV adenoid hypertrophy was the most observed grade. These discrepancies can be attributed to the specific age range >1 to

18 years) and the higher sample size (n= 232) in this study. These observed findings could have influenced the result and contributed to the observed differences

With regards to tympanometry findings, the majority of pediatric patients with adenoid hypertrophy had type B tympanogram, followed by type A tympanogram. The observed tympanogram types were similar to studies done by Abdel Tawab H et al in Oman(19) , Hamza et al in India(20),Islam et al in Bangladesh(17),Nwosu et al (4)and Orji F et al(21) in Nigeria, and Kiama A.M in Kenya(16)

Pertaining to the correlation between radiological and tympanometry findings, this study observed a moderate correlation with a correlation coefficient, of 0.597 for the right ear, and a strong correlation with a correlation coefficient, of 0.643 for the left ear. Both correlations were statistically significant ($p = <0.001$). The findings are consistent with studies done by Abdel Tawab H. et al. in Oman (19),Utama et al in Indonesia(24),Orji F et al (21) and Nwosu et al (4)in Nigeria. Dissimilar findings appear in a study by Els et al. in South Africa, showed no statistically significant relationship between type B and adenoid hypertrophy grade IV ($p > 0.05$). This discrepancy may be due to specific age range of >1 to 18 years and higher sample size in this study (n=232). Nonetheless, there was a significant correlation between the mean average of adenoid nasopharyngeal ratio and tympanograms type (A, B, C) ($p<0.05$). (25)

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Adenoid hypertrophy grades III and IV were predominantly observed in pediatric patients aged 1 to 4 years. Males predominantly presented with grades I, II and IV, while females presented more frequently with grade III. Tympanometry type B was the most commonly observed, followed by type A, with type Ad being the least common bilaterally. The study found a strong correlation between radiological and tympanometry findings, noting a bilateral decrease in the proportion of type A and an increase in the proportion of type B as radiological grades increased.

6.2 Recommendations

1. Implement regular screening for adenoid hypertrophy in pediatric patients aged 1 to 4 years, focusing on those presenting with symptoms snoring, mouth breathing, and hypo-nasal speech, to facilitate early diagnosis and intervention.
2. Patients presented with severe adenoid hypertrophy (grades III and IV) accompanied by type B tympanograms, to consider performing adenoidectomy and grommet tube insertion together in a single setting. These combined approaches will not only address hearing improvement but also prevent speech and language delays that are often associated with adenoid hypertrophy and middle ear effusion.
3. Standardized clinical guidelines integrating radiological imaging and tympanometry are recommended, with further research needed on longitudinal correlations and adenoidectomy outcomes

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APPENDICES

Appendix I: Data collection form (English version).

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)

SCHOOL OF MEDICINE DEPARTMENT OF OTORHINOLARYNGOLOGY

Child age:_____ Sex: Male: ☐ Female: ☐

Address: ☐

Study title:

“ **CORRELATION BETWEEN RADIOLOGICAL FINDINGS AND TYMPANOMETRIC FINDINGS AMONG PEDIATRIC PATIENTS WITH ADENOID HYPERTROPHY ATTENDING OTORHINOLARYNGOLOGY CLINIC AT MUHIMBILI NATIONAL HOSPITAL**. ‘‘

1. **Clinical symptoms and signs:**

Clinical symptoms and signs:	**Tick where applicable**
Snoring	
Mouth breathing	
Adenoid face	
Hypo nasal speech	
Running nose	
Nasal obstruction	

2 RADIOLOGICAL FINDINGS FOR AH

GRADES	**ANR MEASUREMENT**	**TICK WHERE APPLICABLE**
Grade I:	Less than 0.25	
Grade II:	Greater than or equal to 0.25 to 0.5	
Grade III:	Greater than or equal to 0.5 to less than 0.75	
Grade IV:	Greater than 0.75	

3. **TYMPANOMETRY FINDINGS**

TYPES OF TYMPANOGRAMS		**TICK WHERE APPLICABLE**	
		Right ear	**Left ear**
Type A			
Subtypes:	Type As		
	Type Ad		
Type B			
Type C			
Subtypes:	Type Cs		
	Type Cd		

4. ASSOCIATION OF RADIOLOGICAL FINDINGS AND TYMPANOMETRY FINDINGS OF AH

		TYMPANOMETRY FINDINGS							
		Type A		Type B		Type C		Other Subtypes	
		RT	LT	RT	LT	RT	LT	RT	LT
AH GRADES	AH Grade I (<25%)								
	AH Grade II (<50%)								
	AH Grade III (<75%)								
	AH Grade IV (>75%)								

Key: RT: Right, LT: Left

Appendix: II consent form (English version)

PARENTAL/GUARDIAN INFORMED CONSENT FOR PARTICIPATIONS IN THE RESEARCH.

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

SCHOOL OF CLINICAL MEDICINE

OTORHINOLARYNGOLOGY DEPARTMENT

PARENTAL/GUARDIAN INFORMED CONSENT FORM

Patient ID code:

Introduction: I Dr Abdulnoor Ismail Mohamed, a postgraduate student specializing in otorhinolaryngology at Muhimbili University of Health and Allied Sciences. This is to inform you that am conducting a study as part of my postgraduate qualification at the university by the tittle:

Correlation between radiological findings and tympanometric findings among pediatric patients with adenoid hypertrophy attending otorhinolaryngology clinic at Muhimbili National Hospital ‘‘.

Study purpose: The objective of this study is to ascertain, middle ear function in patient with adenoid hypertrophy by assessing the symptomatic patient by using Fujioka method of lateral nasopharyngeal Xray and the tympanogram test. This study is part of the requirement for the completion of the MMed otorhinolaryngology program at the university.

Methodology of the study: The study mainly involves the principal investigator who will establish an initial contact with the patient at ORL clinic and review if the enrollment criteria are satisfied. Then the patient will be referred to the radiological department for a later nasopharyngeal Xray. Then later the patient will be further referred to the audiology department for tympanometry. Both relevant clinical data will be collected and analyzed by the lead investigator.

Study participation in this research: Your participation to this study is entirely voluntary. Your decision to participate or decline will not have any influence on your current treatment. If you decide to take part and provide your consent by signing this document, we kindly ask for a few minutes of your time to conduct an interview and complete the study registration form. It is important to note that you have the right to withdraw from the study at any time without facing any penalties or negative consequences. This document serves as a consent form and provides the necessary information for you to make an informed decision about your participation.

Confidentiality: Please rest assured that all data gathered during the study will be treated with the utmost confidentiality. Your personal information will be kept anonymous, and your privacy will be protected throughout the entire research process.

Benefits : Your involvement in this study will assist us in advancing medical knowledge in the field of Otorhinolaryngology by establishing a connection between radiographic findings and tympanometric findings in children with adenoid hypertrophy. Consequently, the research findings will contribute to enhancing the management of patients.

Risk: Be assured that participating in this study carries minimal risks, and every precaution will be taken to ensure your safety and comfort throughout all procedures.

Cost: Your participation in this study will not receive any benefits or any form of incentive and you will not be required to make any form of payment as well.

Contacts: If you have any questions, concerns, or would like further clarification about the study, please contact the following individuals or entities:

Dr. Abdulnoor I. Mohamed (lead investigator)

a postgraduate student at the Department of Otorhinolaryngology

Muhimbili University of Health and Allied Sciences

P.O. BOX 65001.

Dar es Salaam.

Mobile: +255 0687392051 OR

If you have any queries concerning your rights to participate in this study, you may reach out to:

Dr. Aveline Kahinga (Supervisor)

Otorhinolaryngology specialist Department of Otorhinolaryngology

Muhimbili National Hospital

P.O. BOX 65001.

Dar es Salaam.

Mobile: +255764608917 OR

Dr. Sadam Issa (CO-Supervisor)

Otorhinolaryngology specialist Department of Otorhinolaryngology

Muhimbili National Hospital

P.O. BOX 65001.

Dar es Salaam.

Mobile: +255713687379

Dr Nahya Salim

Director, Directorate of Research and Publications

Muhimbili University of Health and Allied Sciences

P.O. BOX 65001.

Dar es Salam

Mobile: +255713250074

I have carefully reviewed the information presented in this form. I agree / disagree with my child's inclusion to this study.

_____ _____

Child’s Name. Date

_____ _____

Signature: Parent/legal Guardian Date

_____ _____

Signature of lead investigator Date

Appendix III: Consent Form (Swahili Version).

IDHINI YA KIDHIBITI CHA **WAZAZI/MWANGALIZI KWA AJILI YA USHIRIKIANO KATIKA UTAFITI**

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

SHULE YA TIBA,

IDARA YA MASIKIO, PUA NA KOO

FOMU YA IDHINI YA KIDHIBITI CHA WAZAZI/MWANGALIZI

Nambari ya utambulisho wa mgonjwa:

Utangulizi: Mimi, Dkt Abdulnoor Ismail Mohamed, mwanafunzi wa shahada ya uzamili maalum katika tiba ya masikio, pua na koo katika Chuo Kikuu Cha Afya na Sayansi Shirikishi Muhimbili. Ninawajulisha kuwa ninakusanya data kwa ajili ya utafiti wangu kama sehemu ya sifa yangu ya uzamili katika chuo kikuu kwa jina:

"Ushirikiano kati ya matokeo ya uchunguzi radiografia na tympanogramu kwa wagonjwa watoto wenye uvimbe wa koromeo wanaohudhuria kliniki ya tiba ya masikio, pua na koo katika Hospitali ya Taifa Muhimbili."

Lengo la utafiti: Lengo la utafiti huu ni kuchunguza utendaji wa sikio la kati kwa wagonjwa wenye uvimbe wa koromeo kwa kutathmini wagonjwa wenye dalili kwa kutumia njia ya Fujioka ya picha za X-ray ya sehemu ya pua ya nyuma na mtihani wa tympanogramu. Utafiti huu ni sehemu ya mahitaji ya kukamilisha programu ya MMed katika tiba ya masikio, pua na koo katika chuo kikuu.

Njia ya utafiti: Utafiti huu kwa kiasi kikubwa unahusisha mchunguzi mkuu ambaye atawasiliana awali na mgonjwa kwenye kliniki ya ORL na kukagua ikiwa vigezo vya usajili vimekamilika. Kisha mgonjwa atapewa rufaa kwa idara ya mionzi kwa ajili ya Xray ya nyuma

ya puani. Baadaye mgonjwa ataelekezwa kwa idara ya audiolojia kwa ajili ya timpanometri. Data zote zinazofaa kliniki zitakusanywa na kuchambuliwa na mchunguzi mkuu.

Ushiriki katika utafiti huu: Washiriki katika utafiti huu wanaandikishwa kwa hiari. Uamuzi wako wa kushiriki au kukataa hautakuathiri matibabu yako ya sasa. Ikiwa utachagua kushiriki na kutoa ridhaa yako kwa kusaini fomu hii, utaulizwa kwa upole kutenga dakika chache kwa ajili ya mahojiano ili kukamilisha fomu ya usajili wa utafiti. Una haki ya kujiondoa katika utafiti wakati wowote bila kukabiliwa na adhabu au matokeo yoyote. Hati hii inatumika kama fomu ya ridhaa na inatoa habari muhimu ili uweze kufanya uamuzi unaofaa kuhusu ushiriki wako.

Usiri: Tafadhali jipe moyo kuwa data zote zilizokusanywa wakati wa utafiti zitahifadhiwa kwa siri kabisa. Taarifa zako binafsi zitabaki kuwa za kitambulisho, na faragha yako italindwa kwenye mchakato wote wa utafiti.

Manufaa: Ushiriki wako katika utafiti huu utatusaidia katika kuendeleza maarifa ya kitabibu katika uga wa Otorinolaringolojia kwa kuanzisha uhusiano kati ya matokeo ya kipimo cha mionzi na matokeo ya timpanometri kwa watoto wenye uvimbe wa tezi. Kwa hiyo, matokeo ya utafiti yatachangia kuboresha utunzaji wa wagonjwa.

Hatari: Jipe moyo kuwa kushiriki katika utafiti huu kunahusisha hatari ndogo, na tahadhari zote zitachukuliwa ili kuhakikisha usalama na faraja yako katika taratibu zote.

Gharama: Ushiriki wako katika utafiti huu hautapata faida yoyote au motisha yoyote na hautalazimika kufanya malipo yoyote.

Mawasiliano: Ikiwa una maswali, wasiwasi au ungependa ufafanuzi zaidi kuhusu utafiti huu, tafadhali usisite kuwasiliana na wafuatao:

Dkt. Abdulnoor I. Mohamed (Mtafiti Mkuu)
ni mwanafunzi wa shahada ya uzamivu

katika Idara ya Otolaringolojia Chuo

Kikuu cha Muhimbili cha Sayansi na Afya.

S.L.P. 65001. Dar es Salaam.

Simu: +255 0687392051 AU

Ikiwa una maswali yoyote kuhusu haki zako za kushiriki katika utafiti huu, unaweza kuwasiliana na:

Dkt. Aveline Kahinga (Msimamizi)
Mtaalam wa Otolaringolojia Idara ya
Otolaringolojia Hospitali ya Taifa Muhimbili
S.L.P. 65001. Dar es Salaam.
Simu: +255764608917 AU

Dkt. Sadam Issa (Msimamizi Msaidizi)
Mtaalam wa Otolaringolojia Idara ya
Otolaringolojia Hospitali ya Taifa Muhimbili
S.L.P. 65001. Dar es Salaam.
Simu: +255713687379

Dkt. Nahya Salim
Mkurugenzi, Idara ya Utafiti na
Machapisho Chuo Kikuu cha
Muhimbili cha Sayansi na Afya
S.L.P. 65001.
Dar es Salaam.
Simu: +255713250074

Nimesoma na kuelewa maudhui ya fomu hii. Ninaridhia/sipingi ushiriki wa mtoto wangu katika utafiti huu...

Jina la Mtoto. Tarehe

Sahihi ya wazazi au Mlezi wa kisheria au Mhudumu Tarehe

Sahihi ya Mtafiti Mkuu Tarehe

Appendix IV: 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/1925 Date: 03/10/2023

MUHAS-REC-10-2023-1925
ABDULNOOR ISMAIL MOHAMED
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: CORRELATION BETWEEN RADIOLOGICAL AND TYMPANOMETRY FINDINGS AMONG PEDIATRIC PATIENTS WITH ADENOID HYPERTROPHY ATTENDING OTORHINOLARYNGOLOGY CLINIC AT 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: 03/10/2023
EXPIRATION DATE OF APPROVAL: 03/10/2024

STUDY DESCRIPTION:
Purpose:

The purpose of this prospective study is to determine the correlation between radiological and abnormal tympanometry findings among pediatric patients with Adenoid Hypertrophy attending Otorhinolaryngology clinic at 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. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee



Appendix V: 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/K.179/2021 06th November, 2023

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

MUHIMBILI NATIONAL HOSPITAL
RECEIVED
06 NOV 2023
REGISTRY
File No.

Re: **INTRODUCTION LETTER**

We would like to inform you that the bearer of this letter is Abdulnoor Ismail Mohamed with Reg. No. HD/MUH/K.179/2021 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: **"Correlation Between Radiological and Tympanometry Findings Among Pediatric Patients with Adenoid Hypertrophy Attending Otorhinolaryngology Clinic at Muhimbili National Hospital."** he is being supervised by Dr. Aveline Kahinga from MUHAS and Dr. Sadam Issa 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.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c Abdulnoor Ismail Mohamed

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 V: Permission letter

THE UNITED REPUBLIC OF TANZANI

MINISTRY OF HEALTH

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/CRTCU/Perm/2023/551 Date: 07th November, 2023

Head of Department

- Imaging Diagnostic Section
- Otorhinolaryngology

Muhimbili National Hospital Upanga & Mloganzila

RE: PERMISSION TO COLLECT DATA AT MNH

Name of Student	**Abdulnoor Ismail Mohamed**
Title	**"Correlation Between Radiological and Tympanometry Findings Among Pediatric Patients with Adenoid Hypertrophy Attending Otorhinolaryngology Clinic at MNH".**
Institution	Muhimbili University of Health and Allied Sciences
Supervisor	Dr. Aveline Kahinga (MNH)
Co – Supervisor	Dr. Sadam Issa (MUHAS)
Period	07th November, 2023 to 30th April, 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. Aveline Kahinga** (MNH) supervisor.

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

Sincerely,

Dr. Deus Buma

For: 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, DCSS
c.c Dr. Aveline Kahinga
c.c Abdulnoor Ismail Mohamed

Upanga West, Kalenga Street, Plot No. 1048013, P.O. BOX 65000, Dar es Salaam, Tanzania.
Telephone: +255-22-2151367-9, Telephone: +255-22-2151351-2
Email: info@mnh.or.tz, Website: www.mnh.or.tz