CORRELATION BETWEEN CLINICAL AND RADIOLOGICAL FINDINGS IN PAEDIATRIC PATIENTS WITH ADENOID HYPERTROPHY ATTENDING OTORHINOLARYNGOLOGY SERVICES AT MUHIMBILI NATIONAL HOSPITAL

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Department of Otorhinolaryngology

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By

Serah Mumbi Mutuku

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

Muhimbili University of Health and Allied Sciences
October, 2021

CERTIFICATION

The undersigned certifies that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; **"Correlation between Clinical and Radiological Findings in Pediatric Patients with Adenoid Hypertrophy attending Otorhinolaryngology services at Muhimbili National Hospital'',** in (partial) fulfillment of the requirements for the degree of Master of Medicine (Otorhinolaryngology) of Muhimbili University of Health and Allied Sciences.

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Dr. Daudi C. Ntunaguzi (MD, MMed)

(Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I, **Serah Mumbi Mutuku**, 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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I would like to extend my gratitude to all the unnamed patients whose enthusiastic participation enabled the completion of this work.

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DEDICATION

This dissertation is dedicated to my lovely Sister Miss Gladys' Wavinya Mutuku, you supported this life-changing pursuit. A better definition of love never existed.

Also to my guardian angel, mum: You told me to pursue knowledge with the fervor of a possessed girl; it's not over. It's your prayers that keep me going.

To all adenoid hypertrophy patients: your plight shall be my motivation.

ABSTRACT

Background

The significance of radiological assessment in the treatment plan of patients with adenoid hypertrophy cannot be undermined. This study evaluated the correlation between clinical symptoms and radiological findings in the clinical assessment of patients with adenoid hypertrophy.

Objective: The study aimed to determine the correlation between clinical and radiological findings in pediatric patients with adenoid hypertrophy.

Methodology: A hospital-based, cross-sectional study was conducted at Muhimbili National Hospital by recruiting 201 children, aged between 1 to 7 years from November 2020 to May 2021. with signs and symptoms of adenoid hypertrophy. Clinical assessment was performed through structured questionnaires prepared for primary caregivers, which were filled by the investigator. Radiographic findings were obtained through lateral nasopharyngeal radiographs. This data was analyzed using Statistical Package for social sciences version 24, results presented in frequency, tables and figures. Clinical scores were calculated with a P-value <0.05 being considered statistically significant.

Results: A total of 201 children were involved in this study, their mean and median age was 4 years, age ranged from 1 to 7 years. Most of the children 126(62.7%) were in the age group 3-4 years followed by 5-7 years 42(20.9%). Majority 117(58.2%) were male, and the prevalence of children with adenoid hypertrophy was 140(69.7%). Also snoring 131(65.2%) was the most common clinical presentation. On the other hand, clinical score of severe adenoid hypertrophy and radiological finding of grade IV adenoid hypertrophy were recorded as the highest findings in all age groups. A strong positive correlation between clinical score and radiological findings was found with Spearman's rank correlation, $r_s=0.771$.

Conclusion and recommendation

The present study has demonstrated that lateral radiograph of the nasopharynx is sensitive in evaluating children suspected to have adenoid hypertrophy in accordance with their clinical symptoms and thus provides an objective measure of the pathology.

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LIST OF ABBREVIATIONS

AH	-	Adenoid Hypertrophy
ANPS	-	Adenoid Nasopharyngeal Space
ANR	-	Adenoid Nasopharyngeal ratio
AO	-	Airway Obstruction
ATH	-	Adenotonsilar Hypertrophy
ENT	-	Ear, Nose, and Throat
ERC	-	Ethical Research committee
MCO	-	Measures of Choanal Obstruction
MNH	-	Muhimbili National Hospital
MUHAS	-	Muhimbili University of Health and Allied Sciences
NpT	-	Nasopharyngeal Tonsil
NST	-	Nasopharyngeal Soft Tissue
ORL	-	Otorhinolaryngology.
P	-	Prevalence / Proportion
PNS	-	Postnasal space
R	-	Ratio
SP	-	Soft Palate
UAO	-	Upper Airway Obstruction

DEFINITIONS OF KEY TERMS

Adenoid: Lymphoid tissue in the nasopharynx.

Basiocciput: The portion of the occipital bone that extends anteriorly from the anterior rim of the foramen magnum and fuses with the sphenoid bone.

Cavum: the nasal cavity: Cavum radiograph is a postnasal space.

Child: every human being below the age of 18 years.

Cor-pulmonale: Disease of the heart characterized by hypertrophy and dilatation of the right ventricle and secondary to disease of the lungs or their blood vessels.

Synchondrosis: a type of cartilaginous joint in which the cartilage is usually converted into bone before adult life.

Video nasopharyngoscopy: Use of an endoscope to view the pharynx.

Snoring: Vibration of respiratory structures and resulting sound due to obstructed air movement during breathing while asleep.

Mouth breathing: Act of breathing through the mouth due to an obstruction to breathing through the nose.

Sleep disturbance: Inability to fall asleep that results in functional impairment throughout the following day.

Cessations of breath: Transient cessations of respiratory airflow caused by blockage of airways.

Hypo-nasal speech: Sound of speech that results from too little air escaping through the nose (sounds like talking with a stuffy nose).

Upper respiratory tract: Consists of the nose, nasal cavity, nasopharynx and the larynx. The structures that allow us to breath and speak.

Upper respiratory tract infections: Any disease that mainly involves the upper respiratory tract and is associated with fever, cough, sore throat and rhinitis. More than 6 episodes of severe disease a year is defined as recurrent respiratory tract infection.

Adenoid facies: A disorder that refers to the open-mouthed face of children who have long facies with adenoid hypertrophy. It is associated with a narrow nose, shortened upper lip, narrow palate, high palate vault and dental crowding.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background Information

Adenoid hypertrophy is among the leading causes of nasal obstruction in children worldwide. It is observed in children who present with varying clinical signs and symptoms, including mouth breathing, snoring, hypo-nasal speech, and resultant infections such as recurrent otitis, rhino-sinusitis, and adenoiditis. Severe cases of adenoidal hypertrophy present with obstructive sleep apnea, poor performance at school, and impairment of cognitive functions. Adenoid is a lymphoid tissue located in the roof and posterior wall of the nasopharynx behind the soft palate. Adenoid hypertrophy is an obstructive condition due to an increased size of adenoids. Normally being a resistance center against upper respiratory infections, it may become a source of the recurrent and chronic infection itself. Adenoid hypertrophy is a common childhood disease(1).

Applied anatomy

Understanding the knowledge of adenoids is very important in the pathophysiology and management of adenoid hypertrophy. Development of adenoids is from mesodermal cell origin at 16 weeks of intrauterine life by subepithelial infiltration of lymphocytes. Adenoid along with other lymphoreticular tissue of Waldeyer's lymphatic ring traps virus, bacteria, allergen, etc, contributes to immunological homeostasis. At the time of birth, it is small in size and becomes active between 3 years to 7 years of age. It is clinically felt like a bag of worms. It starts its involution by adolescence. Histologically it is constituted by respiratory epithelium with cilia, crypts, and germinal center(2).The adenoids, along with the faucial tonsils, lingual tonsils, and tubal tonsils of Gerlach make up what is known as Waldeyer's ring. Together, these tissues function as an essential part of the human immune system. Antigens, introduced through the oral and nasal cavities, come into contact with the immune cells of Waldeyer's ring. These cells can then produce immunologic memory of the antigens and fight them by producing IgA antibodies; this is thought to result in a "priming" of the immune system in infancy.

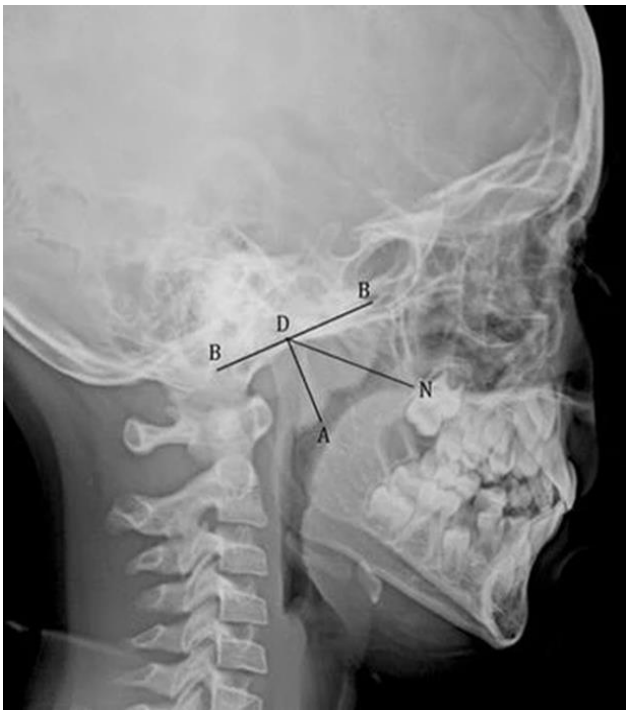
Adenoids are present at birth and enlarge throughout childhood, reaching peak size by age seven. In most individuals, they will regress in size during puberty and maybe nearly absent by adulthood. For this reason, adenoiditis is commonly a problem of childhood. Adenoids help fight against infections. They trap bacteria and viruses entering the body through the nose, causing the tonsils to swell and become inflamed. They return to normal once an infection subsides. The risk factors associated with adenoid hypertrophy are recurrent throat infections or tonsils, contact with airborne viruses, germs, and bacteria(3)

An enlarged adenoid can occlude the choana, especially when sleeping in a supine position. Symptoms due to airway obstruction like mouth breathing, hypo-nasal speech, and snoring in children are observed. Obstruction of the Eustachian tube, may also cause otitis media with effusion and accompanying conductive hearing loss, and in the most serious cases, obstructive sleeping apnea and accompanying growth retardation and cor-pulmonale. The significance of radiological assessment in the treatment plan of patients with adenoid hypertrophy cannot be undermined. Owing to its easy accessibility, availability, and non-invasiveness, radiographic imaging has been the gold standard to assess obstruction of the nasopharyngeal airway by enlarged adenoids. Several radiological parameters are assessed on the radiographic image of the lateral nasopharyngeal soft tissue that assesses the size of the adenoid and the degree of nasopharyngeal airway obstruction(4).

Various methods have been used for the diagnosis of adenoid hypertrophy. There are gold standard invasive methods that necessitate the use of anesthetic agent either local or general anesthesia, that is used to assess adenoid hypertrophy, but they are commonly used in adult patients in our setting. These methods include nasal pharyngoscopy and nasal endoscopy. Some restrictions and side effects are encountered when using nasal pharyngoscopy and nasal endoscopy in 1 year to 7 years' age group. These restrictions and side effects include allergic reactions to anesthetic agents, unpleasant taste, irritation, cough, numbness sensation, vocal cord spasms which can lead to breathing problems and hoarseness of voice. During the introduction of these scopes, they can injure and cause ulceration of the nasal, oral, pharyngeal

and laryngeal mucosa. These complications are not encountered in the use of radiography in assessing adenoid hypertrophy.

On the other hand, the un co-operative state of the pediatric patient in an awake procedure state restricts the doctor to assess adenoid hypertrophy using nasal pharyngoscopy and nasal endoscopy, because this patient cannot withstand seeing the doctor introduce a scope through their noses. For instance, a lateral radiograph of the nasopharynx may be useful to assess the adenoid size and its association with the size of the nasopharynx, as the clinical examination can be notoriously unreliable in young children. It provides valuable information regarding correct patient selection for adenoidectomy, thus eliminating the possibility of unnecessary surgical intervention. Lateral plain X- ray of the nasopharynx gives an idea about the size of adenoid and its relation to the size of the nasopharynx. The adenoid is considered small if it takes nearly 25% of the nasopharynx, moderate if it takes nearly 50% and large if it takes more than 75% of the nasopharynx(5).



Adenoid Nasopharyngeal Ratio ANR: Ratio between adenoid and nasopharyngeal space.
Adenoid (A): greatest distance between a line drawn along the straight part of the inferior margin of the basiocciput and the point of maximal convexity of the anterior outline of the adenoid.
Nasopharyngeal space(N): distance between the posterior and superior edge of the hard palate and posteroinferior margin of the sphenobasiocciput synchrondosis.
ANR calculated by dividing AD with ND.

Figure 1: Radiograph of the post nasal space for Fujioka et al assessment method

1.2 Problem statement

At MNH various approaches have been used in assessing clinical findings and management of adenoid hypertrophy among pediatric patients receiving ORL services. Yet no study has been done to correlate clinical findings and radiological findings of AH. Little is known in our country regarding the correlation between the clinical and radiological findings of adenoid hypertrophy patients receiving services at ORL departments. Lateral nasopharyngeal x-ray is the most reliable evaluation tool in patients suspected to have AH. However, despite the widespread reliance on its findings, several controversies remain. Therefore, the study was aimed to determine the correlation between clinical and radiological findings in pediatric patients with Adenoid hypertrophy attending ORL services at Muhimbili National Hospital.

1.3 Rationale of the study

Adenoid hypertrophy is more common in children than in adults that occur without an acute condition or chronic infection of the adenoids. Therefore, the study finding is expected to present baseline data to be used for further research by the public and private organizations, policy makers, and ministry of health for planning the best diagnosis method for Adenoid hypertrophy among children aged one to seven years. Also, the study findings generated in this study will be expected to strengthen the existing knowledge on the clinical presentations that may be used to shed the light on competence and skills that are needed to develop an accurate diagnosis of AH at ORL department in MNH, as well as included in the curriculum for educating the physicians and allied health professionals.

This study is also a partial fulfillment of the requirements for the award of a Masters in Medicine degree in Otorhinolaryngology at Muhimbili University of Health and Allied Sciences (MUHAS).

1.4 Conceptual framework

The framework was designed to describe the correlation between clinical and radiological findings in pediatric patients with Adenoid hypertrophy attending ORL services at Muhimbili National Hospital. In this framework, pediatric patients with Adenoid hypertrophy were used to describe the dependent variable while the parameters in clinical presentation and radiological finding represented the Independent variables. The clinical presentation parameters consisted of mouth breathing, snoring, cessations of breath, sleep disturbances, hypo-nasal speech, adenoid facies, and recurrent respiratory tract infection. The radiological finding parameters were the X-ray nasopharyngeal radiograph (Fujioka ANR-measurements) and presence of adenoid hypertrophy, including the radiographic evaluate for enlargement of the adenoid tissue which involved the following grades, Grade I(mild) AH occupying (25%) of PNS, Grade II(moderate) AH occupying 25-50% of PNS, Grade III(moderately severe) AH occupying 50-75% of PNS and Grade IV(severe) AH occupying 75-100% of PNS. Therefore, the framework was used by the researcher in this study to formulate objectives, conducting analysis and literature review among children diagnosed with adenoid hypertrophy.

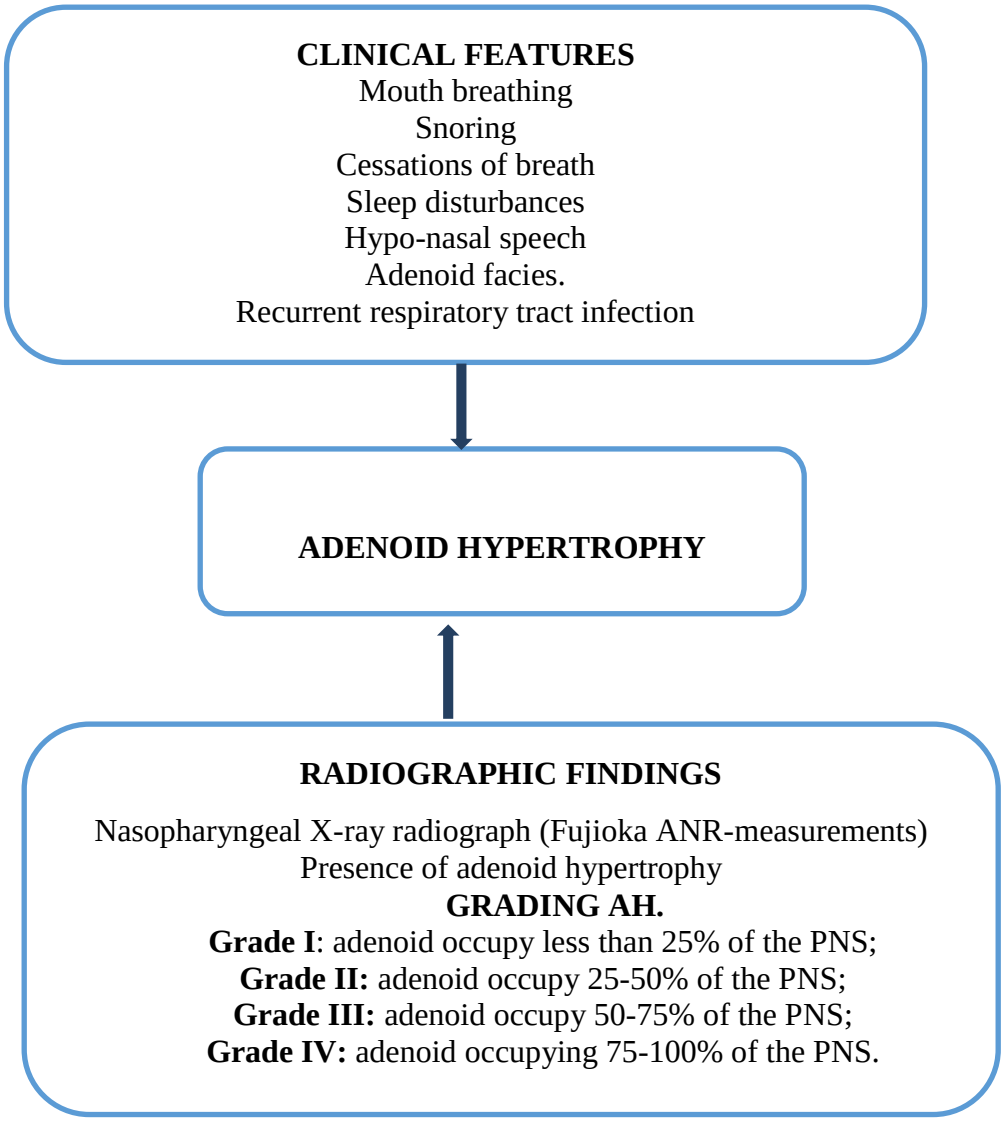


Figure 2: Conceptual framework

1.5 Main research question

What is the correlation between clinical and radiological findings of adenoid hypertrophy in patients receiving ORL services at MNH?

1.5.1 Research questions

i. What is the prevalence of adenoid hypertrophy in patients receiving ORL services at MNH?
ii. What are the clinical features of adenoid hypertrophy in patients receiving ORL services at MNH?
iii. What are the radiological findings of pediatric patients with adenoid hypertrophy attending ORL services at MNH?
iv. What is the relationship of lateral nasopharyngeal x-ray score with clinical presentations of AH?

1.7 Main objective

To determine the correlation between clinical and radiological findings in pediatric patients with Adenoid hypertrophy attending ORL services at Muhimbili National Hospital.

1.7.1 Specific objectives

i. To determine the prevalence of adenoid hypertrophy in pediatric patients attending ORL services at MNH.
ii. To assess the clinical presentation of pediatric patients with adenoid hypertrophy attending ORL services at MNH.
iii. To assess the radiological findings of pediatric patients with adenoid hypertrophy attending ORL services at MNH.
iv. To establish the relationship between the clinical and radiological diagnosis of adenoid hypertrophy in pediatric patients attending ORL services at MNH.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Prevalence of Adenoid Hypertrophy

Generally, the prevalence of adenoid hypertrophy among children aged 6 months to 15 years has been reported to be 19 to 58% worldwide. Studies conducted in Canada showed that the prevalence of adenoid hypertrophy in children was 49.70%. One among these studies composed of 1,132 subjects observed a frequency of 27% for children between 5 and 7 years, and 19% to 20% for children between the age of 8 and 14 years(8). A study done in London documented a prevalence of 54% (21).

In a study done in Kartal, consisting of 79 children (48 male and 31 female) between 5 and 14 years of age, the prevalence of adenoid hypertrophy was found to be 66.4%. In three primary schools in Turkey, the prevalence of adenoid hypertrophy was 27%, 19.5% and 19.9% of age strata of 5-7years, 8-10 years and 11-14 years respectively(9). Another study done in Turkey reported an overall prevalence of 66.4% (19) and another study done in Brazil reported prevalence of 64.9% (20). A meta-analysis study done in Italy revealed that among a general pediatric population the prevalence of AH ranged from 42% to 70% (22).

The study conducted in Nigeria by Ezil and Aydin et al. on adenoid hypertrophy showed a prevalence of 7.7% and 27% among 5-10 years, 19.5% in 8-10 years and 19.9% in 11-15-year-old children, while another study conducted in Enugu, South East Nigeria, out of 2010 children, 26 had adenoid hypertrophy, giving a prevalence of 1.3%, with male children predominance and the majority coming from low social-economic class (10). Studies conducted in Kenya, among children aged 1 to 8 years, showed the prevalence of adenoid hypertrophy was 9.4 %, and another study finding conducted in Bugando medical center in Tanzania shows that in 113 patient with allergic rhinitis, there were 88(46.3%) patients with adenoid hypertrophy(7). Therefore this highlights the need to understand the correlation between clinical and radiological findings of adenoid hypertrophy among children receiving ORL services at the age range 1 to 7 years.

2.1 Clinical presentation of Adenoid Hypertrophy

Adenoid hypertrophy is a significant clinical entity as the cause of recurrent symptoms. The study conducted in Massachusetts, showed recurrent symptoms incidence of 54%, with clinical manifestations that included nasal obstruction, obstructive sleep disorder, rhinosinusitis, recurrent otitis media, and otitis media with effusion among children aged 2 months to 7years. Snoring, sleep disturbance, frequent arousal, nasal obstruction, mouth breathing, and recurrent respiratory tract infection were the commonest symptoms according to a study done in India (11).

Another study in India on pediatric patients showed mouth breathing and snoring were the commonest reported clinical presentation (25). A study done in Saudi Arabia found snoring was the most common complaint, followed by mouth breathing**,** adenoid facies and lastly was sleep apnea(24). Amato *et al.* study's in Brazil showed children who underwent treatment with mometasone furoate reported snoring which was strongly associated with the presence of adenoid hypertrophy (26).

Mouth breathing was a clinical presentation of concern in another study done in Philippine that showed chronic mouth breathing leads to ‘adenoid facies’. This was characterized by incompetent lip seal, narrow upper dental arch, increased anterior face height, steep mandibular plane angle, and a retrognathic mandible(12). According to a study done in Nigeria, adenoid hypertrophy was characterized by more disturbed nocturnal sleep than excessive daytime sleepiness, more behavioral problems, school problems, hyperactivity, nocturnal enuresis, sleep terrors, depression, insomnia, and psychiatric problems (13). And another study done in South East Nigeria reported only 38.4% presented with snoring while cough was as high as 73.1%, allergy 57.7% and fever 50.0% (10).

2.2 Radiological findings of pediatric patients with adenoid hypertrophy

Imaging is important in the assessment of children with suspected AH since these children are often difficult to examine physically. Establishing a rapport with the child is challenging, due to the child’s fear and irritabilities. In addition, symptoms described by the patient’s parents

are often very subjective and vary based on the parent's emotions or understanding of the child's condition. A postnasal space radiograph demonstrates the hypertrophic adenoid and the narrowed nasopharyngeal and oropharyngeal airway (14). Consequently, it is a more objective assessment method for adenoid hypertrophy than clinical assessment. Several methods to objectively assess and standardize the interpretation of these radiographs have been developed. Fujioka et al method (ANR) measure the distance of the adenoid at its greatest diameter, against the size of the nasopharyngeal space. Cohen et al method (AC : SP) measures the size of the air column in the nasopharynx, 10mm from the hard palate, against the soft palate thickness at this level. Johannesson (NpT (mm) measures the greatest width of the adenoid tissue perpendicular to the bony roof of the nasopharynx. Crepeau at el (AA) measures the shortest width between the adenoid tissue and the posterior maxillary wall. Maw et al (PA) measures the shortest width from the anterior adenoid to the soft palate. Mlynarek et al (AO) measure the Johannesson dimension against the width of the nasopharynx (15).

2.3 Relationship between clinical and radiological diagnosis of adenoid hypertrophy in pediatric

A radiological and clinical correlation study of adenoid size in children with symptomatic obstructive adenoid hypertrophy done in Swaziland, where lateral soft tissue neck x-ray were analyzed, showed a good correlation between adenoid sizes on x-ray films, making x-ray a helpful diagnostic tool (16).

Adenoid hypertrophy is a common cause of nasal obstruction in pediatric patients. This is according to a study done by Sharma K. at el in India, that showed the correlation between clinical and radiological findings were carried out so as to make a protocol for early diagnosis of adenoid hypertrophy. The mean age at presentation was 5 years, where patients gave a history of mouth breathing followed by snoring. X-ray soft tissue nasopharynx for adenoids was done that showed either grade III or IV adenoid hypertrophy (17). A study done in Saudi Arabia found grade III AH were majority among 4 to 5 years age group (28).

Another study conducted in India showed that the anatomical site of adenoid hypertrophy makes the adenoids difficult to assess, this makes the use of lateral neck X-ray adenoid-nasopharynx(A/N) ratio, as an evaluation tool, to correlate the patients' clinical presentation with radiological evaluations and compare obstructed and non-obstructed children relative to the assessment method(6). Measuring the size of adenoids and establishing their connection by correlating with the child’s given symptom, according to a study done in India, was more difficult, basically due to the location of adenoids in the nasopharyngeal cavity. Diagnostic efficacy of lateral view x-ray nasopharynx, had a sensitivity of 79.41% and specificity of 75%, and was used to evaluate the size of the adenoids in patients having adenoids hypertrophy(18).

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This was a cross-sectional hospital-based study.

3.2 Study population

Children attending Otorhinolaryngology services at Muhimbili National Hospital.

3.3 Target population

Children with clinical features of adenoid hypertrophy.

3.4 Study duration

The study was conducted for a period of 6 months from January 2021 to June 2021.

3.5 Study setting

The study was conducted at the Muhimbili national hospital, located at Ilala Municipal in the Dar es Salaam region of Tanzania. The selection of the study setting based on the fact that is the national referral hospital in Tanzania receives patients referred from the surrounding hospitals, self-referral, and regional's hospitals in the country. The hospital has 1500 beds with a significant number of 2,000 patients a day with all medical specialists (Muhimbili National Hospital publications, The United Republic of Tanzania, 2020).

The department of Otorhinolaryngology at MNH is comprised of rhinology, otology, head and neck surgery, audiology, speech and language therapy units.

3.6 Inclusion criteria

Children aged from 1 year to 7 years.

3.7 Exclusion criteria

i. Children who present with grade III and IV tonsils.
ii. Children with other conditions like allergic rhinitis, otitis etc.
iii. Children who had developmental diseases (e.g. genetic syndromes, craniofacial anomalies, and neuromuscular diseases).
iv. Adenoid hypertrophy patients that also had major confounding variables/comorbidities (e.g., morbid obesity, cor-pulmonale or cardiopulmonary associated diseases) were excluded in an attempt to eliminate confounding factors like obesity.
v. Negative X-ray findings.

3.8 Sample size estimation

The sample size was calculated from Fisher's formula;

$n=Z^2P\ (1-P)/E^2$

Where: n= minimum required sample size,

Z = (1.96) at 95% was assumed Confidence Interval for the study.

P = Proportion of those with the characteristic of interest of which it's the estimated proportion of patients with AH which was 13.5% in this study, taken from a study done in Kenya, with the age of equal or less than 6 years.

ε = Margin of error which was conventionally taken as the sampling error at 1.96 and was thus taken as 5% in this study.

$N=1.96^2 \times 0.14(1-0.14)/0.05^2 = 185$

The minimum sample size was **185** children.

3.9 Sampling method

A convenient sampling method was utilized for all children presented at MNH in the ORL department (inpatients and outpatients) after fulfilled the criteria for adenoid hypertrophy clinically.

3.10 Data collection techniques

The American Academy of sleep medicine, adenoid hypertrophy clinical diagnostic criteria were used in data collection. Children aged 1 to 7 years were assessed according to this diagnostic criterion. According to the criteria guidelines a child meets adenoid hypertrophy score when his/her clinical presentations were: 1 to 2 symptoms-mild adenoid hypertrophy. 3 to 4 symptoms-moderate adenoid hypertrophy. 5 to 6 symptoms moderately severe adenoid hypertrophy, and above 6 symptoms-severe adenoid hypertrophy. A patient's questionnaire was used to identify the presence of adenoid hypertrophy symptoms as specified by the adenoid hypertrophy diagnostic criteria, and this was done by the principal investigator, trained senior residents (residents in their second or third year of postgraduate studies), and/or specialists from ORL department.

Data collection was done using this American Academy of sleep medicine, adenoid hypertrophy clinical diagnostic criteria which was filled by the investigator and image evaluation. Data collection included patients' demographic data, asked from the patients' guardian/caretaker. Clinical symptoms which included snoring, mouth breathing, sleep disturbance, recurrent respiratory tract infection, hypo-nasal speech, and adenoid facies were assessed. The clinical scoring tool of more than two weeks' symptoms duration of adenoid hypertrophy, where the symptoms were listed, was filled by the principal investigator during the patient's clinical assessment time. After, which the symptoms were graded as: mild-1 to 2 symptoms, moderate-3 to 4 symptoms, moderately severe-5 to 6 symptoms, and severe above 6 symptoms. This scoring tool was from The American Academy of sleep medicine.

Radiographic features included adenoid size, nasopharyngeal depth and adenoid nasopharyngeal ratio by Fujioka et al method. Patients in the research underwent nasopharyngeal radiography in the Radiology Department of MNH. The radiographs were obtained with the children in the supine position and their neck slightly extended and closed mouth. The X-ray machine used was digital Philips, DR/712310, Eindhoven-Best, The Netherland. and the x-ray field was collimated to the nasopharynx. The radiographs were taken by a trained radiographer. Only radiographs taken within two weeks of recruitment into

the study, taken from MNH or in another health facility and with good contrast were included in this study. The nasopharyngeal depth was taken as the average of three measurements, where, three lines were drawn from the posterior nasal spine; first line to posterior superior sphenobasioccipital area, second line to the nearest adenoidal point, and third to basion of the occipital bone. The degree of obstruction was assessed by the adenoid to nasopharynx ratio, proposed by Fujioka et al. and the measurements were taken by the principal investigator.

The adenoid nasopharyngeal ratio of < 0.25 was normal, >/= 0.25 to < 0.5 was mild enlargement, >/= 0.5 to < 0.75 was moderate enlargement and adenoid nasopharyngeal ratio more than 0.75 was severe enlargement.

3.11 Data management

This was done using SPSS computer software version 24.

3.12 Data analysis

Descriptive analysis on the correlation between radiological score and clinical score was determined by using Spearman correlation by taking clinical score as screening tests and radiological score as the gold standard for diagnosing adenoid hypertrophy. The p-value <0.05 was considered statistically significant. Data was then presented in figures and tables.

3.13 Variables

3.13.1 Independent variables

Include the clinical presentations and risk factors of adenoid hypertrophy eg. mouth breathing, snoring, hypo-nasal speech, sleep disturbances, recurrent respiratory tract infection, cessations of breath, adenoid facies and the grades of AH.

3.13.2 Dependent variables

The dependent variable was the pediatric patients with adenoid hypertrophy

3.14 Ethical Considerations and Approval

The proposal was presented to the Department of Otorhinolaryngology of the Muhimbili University of Health and Allied Sciences. Ethical clearance was sought from the Research and Publication Committee of the School of Medicine and the Senate Research and Publications Committee of the Muhimbili University of Health and Allied Sciences. Administrative permission to conduct the study was obtained from Muhimbili National Hospital as per the hospital management protocols.

Consent and assent were obtained for all patients who fulfilled clinical features criteria for AH. Names of all the participants who joined the study were not required but rather identified using their initials, a number which was coded and the mobile phone numbers taken were used only by the principal investigator for close contact tracing. The information obtained during data collection was kept under a strict locked environment where it was only the researcher who had the access and will be destroyed after the dissertation has been submitted and accepted for the award of my postgraduate degree.

3.15 Study limitations

Children were usually restless during imaging and therefore it was difficult in ensuring that the position was correct for obtaining the right measurements.

3.16 Study mitigations

The limitation for this study was mitigated when the X- rays were performed with the parent or guardian around to minimize errors.

CHAPTER FOUR

4.0 RESULTS

4.1 Demographic characteristics

A total of 201 children were involved in this study, their mean and median age was 4 years, ranged from 1 to 7 years. Most of the children 126 (62.7%) were in the age group 3-4 years followed by 5-7 years 42 (20.9%). There were 84 (41.8%) females and 117(58.2%) males, with female to male ratio 1:1.4 (Table 1).

Table 1: Demographic characteristic of children attended ORL service, N=201

Age group (years)	Sex		Total
	Female N (%)	Male N (%)	N (%)
1 – 2	10 (30.3)	23 (69.7)	33(16.4)
3 - 4	52(41.3)	74(58.7)	126(62.7)
5 – 7	22 (52.4)	20 (47.6)	42(20.9)
Total	**84(41.8)**	**117(58.2)**	**201(100)**

4.2 Prevalence of children with adenoid hypertrophy

The prevalence of adenoid hypertrophy was 140 (69.7%). The prevalence was higher 36 (85.7%) among children aged 5-7 years, as compared to other age groups and this was statistically significant (p-value= 0.04). In terms of gender, adenoid hypertrophy was more prevalent 67 (79.8%) among females than males, the difference being statistically significant (p-value = 0.01) (Table 2).

Table 2: Prevalence of adenoid hypertrophy (AH) by sex and age

Age group	Adenoid hypertrophy		Total	p-value
	No	Yes	N (%)	
	N (%)	N (%)		
1 – 2 years	12 (36.4)	21(63.6)	33(16.4)	
3 -4 years	43(34.1)	83(65.9)	126(62.7)	0.04
5 – 7 years	6(14.3)	36(85.7)	42(20.9)	
Total	**61(30.3)**	**140(69.7)**	**201(100)**	
Sex				
Female	17(20.2)	67(79.8)	84(41.8)	
Male	44(37.6)	73(62.4)	117(58.2)	0.01
Total	**61(30.3)**	**140(69.7)**	**201(100)**	

4.3 Clinical presentation of pediatric patients with adenoid hypertrophy

In terms of clinical presentation, the most frequently reported clinical presentation was snoring 131 (65.2%), followed by mouth breathing130 (65.0%) and the least was sleep disturbance 125 (62.2%) (Figure 3).

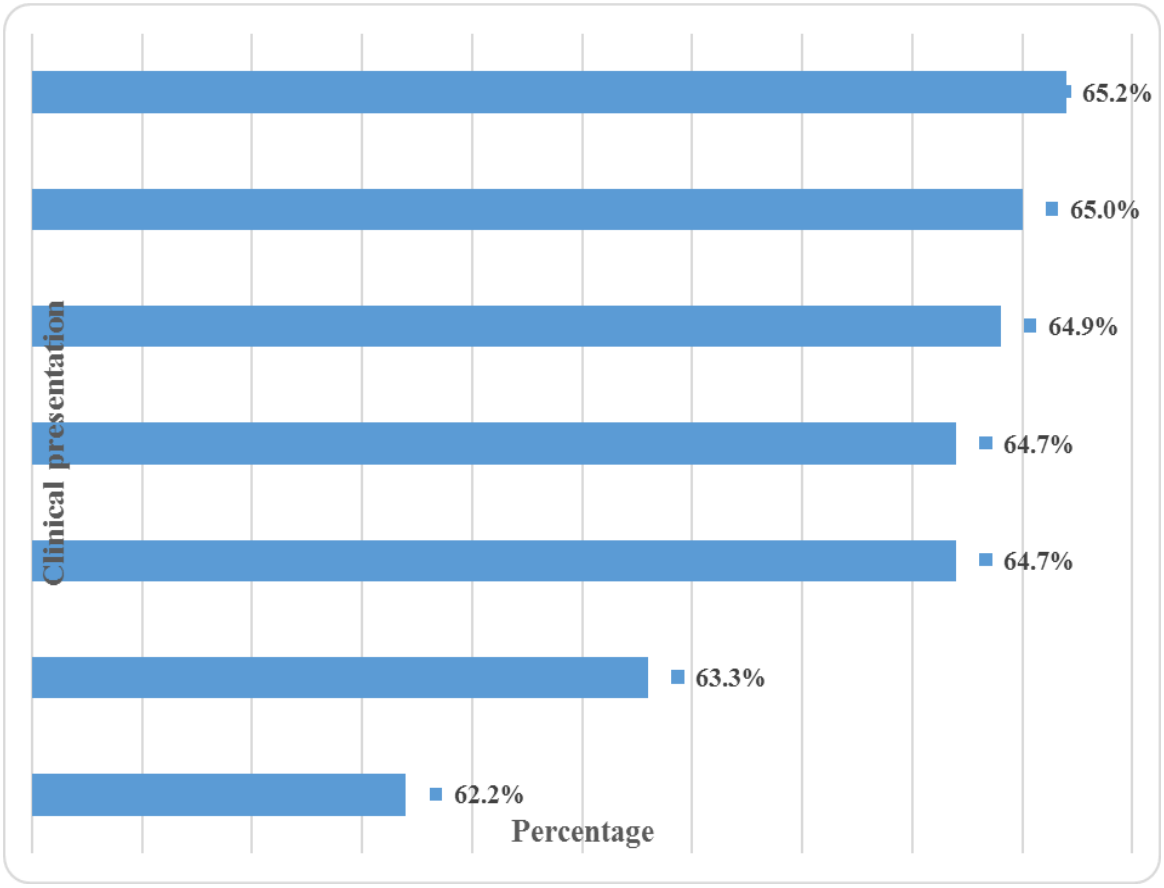


Figure 3: Clinical presentation of pediatric patients with adenoid hypertrophy

4.3.1 Clinical score of pediatric patients with adenoid hypertrophy

Of the clinical scores discovered, severe AH was recorded highest in all age groups, i.e. 11 (52.4%) in 1-2 years, 62 (74.7%) in 3-4 years and 29 (80.6%) among 5-7 years. The difference between age groups and clinical scores was statistically significant (p-value=0.002). Based on gender, severe AH was reported highest in males 55 (73.55%), with a (p-value=0.5) not statistically significant compared to females (Table 3).

Table 3: Clinical score of pediatric patients with adenoid hypertrophy

Variable		**Clinical score**				**Total**	**P-value**
		Mild N (%)	**Moderate N (%)**	**Moderately severe N (%)**	**Severe N (%)**	**N (%)**	
Age group	1-2 years	3(14.3)	3(14.3)	4(19.0)	11(52.4)	21(15.0)	
	3-4 years	0(0.0)	3(3.6)	18(21.7)	62(74.7)	83(59.3)	
	5-7 years	2(5.6)	4(11)	1(2.8)	29(80.6)	36(25.7)	**0.002**
	Total	**5(3.6)**	**10(7.1)**	**23(16.4)**	**102(72.9)**	**140(100)**	
Sex							
	Female	2(3.0)	7(10.4)	11(16.4)	47(70.1)	67(47.9)	
	Male	3(4.1)	3(4.1)	12(16.4)	55(73.5)	73(52.1)	**0.5**
	Total	**5(3.6)**	**10(7.1)**	**23(16.4)**	**102(72.9)**	**140(100)**	

4.4 Radiological findings of pediatric patients with adenoid hypertrophy

Radiological findings showed grade IV was recorded highest in all age groups, i.e.13 (61.9%) among 1-2 years, 60 (72.3%) among 3-4 years and 27 (75.0%) for those aged 5-7 years, the difference between age and radiological findings was statistically significance (p-value=0.02). Based on gender grade IV AH was recorded highest in females 50 (74.6%) with a (p-value=0.6) not statistically significant compared to males (Table 4).

Table 4: Radiological findings of pediatric patients with adenoid hypertrophy

Demographic	Radiological findings			Total N(%)	P-Value
	GRADE I N(%)	GRADE II N(%)	GRADE III N(%)	GRADE IV N(%) Total	
Age: 1-2 years	0(0.00)	4(19.0)	4(19.0)	13(61.9)	21(15.0)
3-4 years	0(0.00)	3(3.6)	20(24.1)	60(72.3)	83(59.3)
5-7 years	2(5.6)	1(2.8)	6(16.7)	27(75.0)	36(25.7)
Total	**2(1.4)**	**8(5.7)**	**30(21.4)**	**100(71.4)**	**140(100)**
Sex: Female	1(1.5)	2(3.0)	14(20.9)	50(74.6)	67(47.9)
Male	1(1.4)	6(8.2)	16(21.9)	50(68.5)	73(52.1)
Total	**2(1.4)**	**8(5.7)**	**30(21.4)**	**100(71.4)**	**140(100)**

4.5 Correlation of clinical score and radiological findings

By use of Spearman's rank correlation this study showed a strong positive correlation between clinical score and radiological findings with a (Spearman's rank correlation, r_s=0.771).

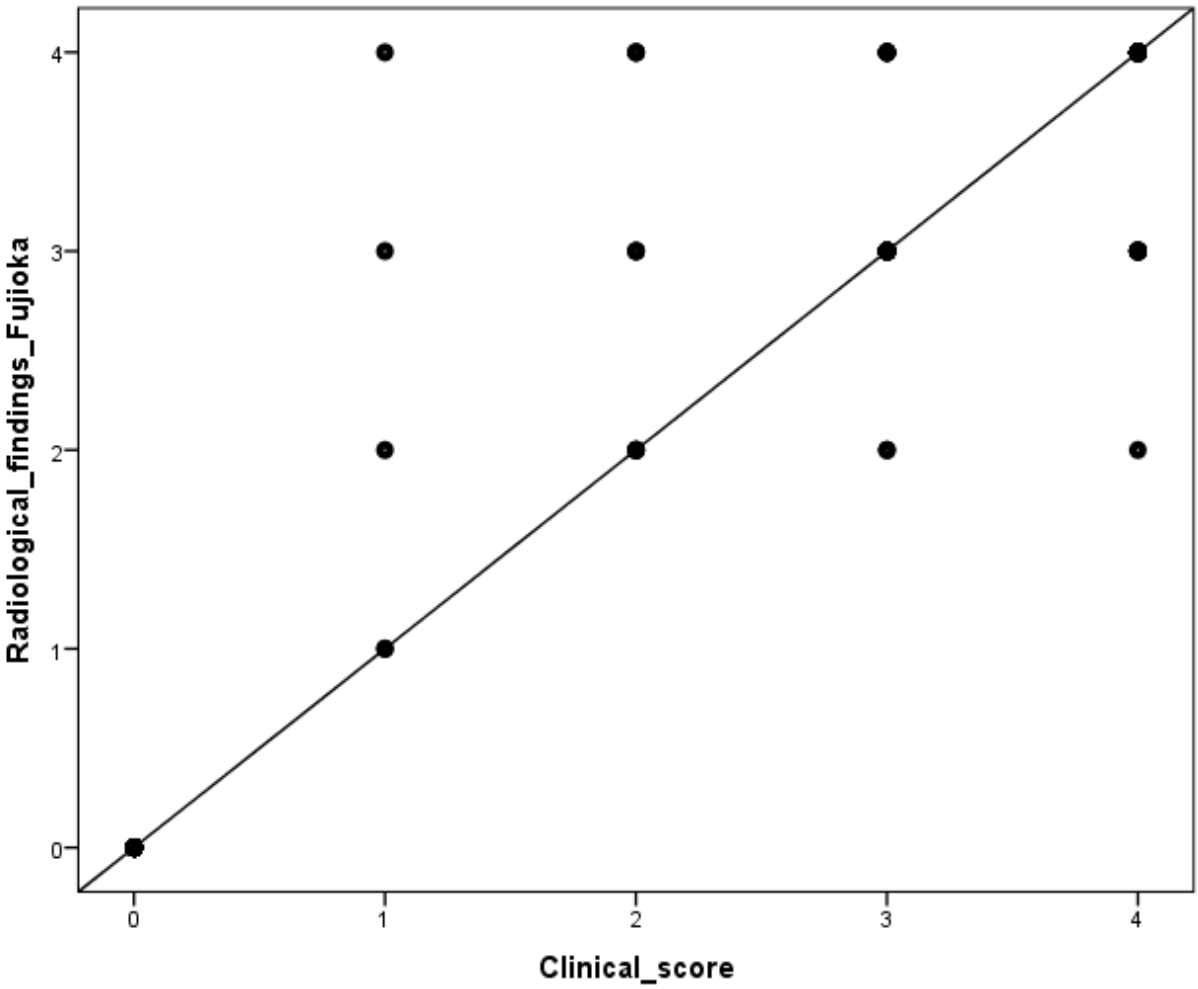


Figure 4: Relationship between clinical score and radiological findings

CHAPTER FIVE

5.0 DISCUSSION

Hypertrophic adenoids may block the posterior nasal space which interferes with nasal airflow and the drainage of secretions. Adenoid hypertrophy (AH) poses a major health problem, substantially affecting the quality of life of children, severe cases of adenoidal hypertrophy present with obstructive sleep apnea, poor performance at school, and impairment of cognitive functions. This study sought to find the correlation between clinical and radiological findings in pediatric patients with adenoid hypertrophy attending Otorhinolaryngology services at Muhimbili National Hospital.

In this study it was found that the prevalence of adenoid hypertrophy was high 69.7%. It was more prevalent among children aged 5-7 years and among females. The findings of this study are similar to a study done in Turkey which reported an overall prevalence of 66.4% (19), and a study in Brazil which reported prevalence of 64.9% (20), also a study done in London which documented a prevalence of 54% (21). A meta-analysis study reviewing the studies on prevalence of adenoid hypertrophy done in Italy, revealed that among a general pediatric population the prevalence of AH ranged from 42% to 70% (22). In terms of AH according to age groups, the study in Turkey had the same findings with this study i.e. 5-7 years were more affected (8). The affect by gender showed females were more affected, this is contrary to a study done in Kenya(23).

In this study snoring**,** mouth breathing and adenoid facies were the most reported clinical presentations among children with AH. This finding is similar to a study done in Saudi Arabia where snoring was the most common complaint, followed by mouth breathing**,** adenoid facies and lastly was sleep apnea(24). Another study in India on pediatric patients is congruent with this study where mouth breathing and snoring were the commonest reported clinical presentation (25). Amato *et al.* study's in Brazil showed children who underwent treatment with mometasone furoate reported snoring which was strongly associated with the presence of adenoid hypertrophy (26). However, a study in South East Nigeria which studied children who

attended outpatient clinic, reported only 38.4% presented with snoring while cough was as high as 73.1%, allergy 57.7% and fever 50.0% (10).

Clinical score of pediatric patients with adenoid hypertrophy showed that severe AH was more found among patients compared to other scores. This finding was similar to studies done in India, Nepal and Nigeria ((4, 10, 16, 27)).

In this study, majority of the patients were found to have grade IV adenoid hypertrophy. This was in accordance to studies done in India (5, 17, 27). Contrary to the study done in Saudi Arabia were grade III AH were majority among 4 to 5 years age group (28).

In this study, a strong correlation between clinical scores and radiological findings was reported. This was in accordance with a study done by Aljahdali et al. in Saudi Arabia, which observed a positive correlation between clinical scores and radiological findings (16). Contrary to a study done in Iran which found a weak correlation between lateral nasopharyngeal x-ray and clinical scores, because of a smaller sample size (29).

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

i. The present study has demonstrated a good correlation between lateral radiograph of the nasopharynx and clinical presentations in evaluating children suspected to have adenoid hypertrophy thus providing an objective measure of the pathology.

6.3 Recommendation

i. There is a need for more comprehensive studies in future on larger samples, with the inclusion of a greater number of clinical presentations in patients suffering from adenoid hypertrophy.

ii. The present study highlights that a single clinical presentation is not enough to determine disease severity, and that the presence of various clinical features should be assessed to determine disease severity and clinical scores.

iii. There is need for short training programs like seminars, workshops for the high level of agreement in interpretation of nasopharyngeal plain radiography among trained raters in the evaluation of patients with hypertrophied adenoids.

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APPENDICES

Appendix I: Questionnaire – English Version

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES (MUHAS)

SCHOOL OF MEDICINE

DEPARTMENT OF OTORHINOLARYNGOLOGY

QUESTIONNAIRE FORM

IDENTIFICATION NO.: _____

DATE:_____ PHONE NO:_____

Title of the study:

"Correlation between Clinical and radiological findings in pediatric patients with adenoid hypertrophy attending ORL services at MNH.''

Childs' Age_____ SEX: Male ☐ Female ☐

1.PRIMARY CARE GIVER

PLEASE TICK APPROPRIATELY WHERE IT CORRESPONDS WITH THE CHILD:(Adenoid Hypertrophy Clinical score tool adapted from the American academy of sleep medicine).

No	AH CLINICAL PRESENTATION FOR THREE MONTHS DURATION.	YES	NO
1.	Does your child have mouth breathing		
2.	Does your child experience loud snoring three or more nights per week		

3.	Does your child experience episodes of breathing cessations witnessed by another person three or more days per week		
4.	Does the child experience sleep disturbances three or more days per week		
5.	Does your child get recurrent respiratory tract infections three or more days per week		
6.	Does your child get hypo-nasal speech		
7.	Does the child have adenoid facies ie: -Incomplete lip seal -Narrow upper dental arch -Increased anterior face height -Steep mandibular plane angle -Retrognathic mandible		

CLINICAL DIAGNOSIS CRITERIA:

Clinical presentations:1 to 2 symptoms-mild adenoid hypertrophy.

3 to 4 symptoms-moderate adenoid hypertrophy

5 to 6 symptoms-moderately severe adenoid hypertrophy

above 6 symptoms-severe adenoid hypertrophy.

2. ADENOID HYPERTROPHY RADIOGRAPHIC DIAGNOSTIC SCORING TOOL

ADENOID NASOPHARYNGEAL RATIO (ANR) MEASUREMENT	**AH GRADE**	**DIAGNOSIS**	**PLEASE TICK WHERE APPLICABLE**
< 0.25	Grade I (<25%)	Normal adenoids	
>/=0.25 to 0.5	Grade II (<50%)	Mild enlargement	
>/=0.5 to <0.75	Grade III (<75%)	Moderate enlargement	
ANR >0.75	Grade IV (>75%)	Severe enlargement	

Adenoid nasopharyngeal ratio (ANR) of:

< 0.25 was normal,

>/= 0.25 to < 0.5 was mild enlargement,

>/=0.5 to <0.75 was moderate enlargement

INR more than 0.75 was severe enlargement.

Appendix II: Questionnaire – Swahili Version

CHUO KIKUU CHA SAYANSI NA AFYA SHIRIKISHO MUHIMBILI (MUHAS)

CHUO CHA UDAKTARI

IDARA YA PUA, SIKIO NA KOO

DODOSO NA FOMU YA UKUSANYAJI

Namba ya utambulisho:…… Namba ya simu……

Kichwa cha habari cha utafiti:

“Uhusiano kati ya ugonjwa wa uvimbe wa nyuma ya pua kwa watoto na picha husika”.

MAELEKEZO KWA MZAZI WA MTOTO MHOJIWA

WEKA ALAMA YA KUSAHIHISHA AU KUKANA KULINGANA NA HALI YA MTOTO.

No.	**HALI YA MTOTO**	**NDIO**	**LA**
1.	Je mtoto wako anapumua kwa kutumia mdomo (badala ya pua)		
2.	Je mwanao anakoroma angalau siku tatu au zaidi kwa wiki wakati wa usiku		
3.	Je mwanao akilala anapata hali ya kukosa kupumua unaoshuhudiwa na mtu mwengine siku tatu au zaidi kwa wiki		
4.	Je mwanao anapata shida kulala siku tatu au zaidi kwa wiki		
5.	Je mwanao anapata homa za pua mara kwa mara siku tatu au zaidi kwa wiki		
6.	Je sauti ya mwanao akiongea inatokea puani		
7.	Je maumbile ya uso wa mwanao yamebadilika		

Appendix III: Consent Form (English version)

PARENTAL PERMISSION FOR CHILD PARTICIPATION IN RESEARCH.

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

SCHOOL OF MEDICINE

DEPARTMENT OF OTORHINOLARYNGOLOGY

INFORMED PARENTAL CONSENT FORM

Childs' Identification No.: _____

Introduction:

Hello, my name is Dr Serah Mumbi Mutuku, a postgraduate student in the department of Otorhinolaryngology at Muhimbili University of Health and Allied Sciences.

As part of my postgraduate program at this university, I am conducting a study titled; "Correlation between Clinical and Radiological findings in pediatric patients with adenoid hypertrophy attending Ortorhinolaryngology services at Muhimbili National Hospital''.

Study purpose:

This study aims to determine, how Fujioka radiographic assessment method of AH in symptomatic children at ORL-MNH compare with the clinical symptom assessment.

It is also conducted as a partial fulfillment for the completion of MMed Otorhinolaryngology.

Methodology of this study:

This study mainly involves responding to a questionnaire consisting of standardized questions.

The child will be examined after initial contact is made with Otorhinolaryngologist and the criterion for enrollment is met. The availed nasopharyngeal radiographs will be interpreted by the principal investigator.

Participation in this study:

Participation in this study is absolutely voluntary. If you choose to participate and give consent by signing this form, you will be required to spend few minutes for an interview in order to fill and complete the questionnaire. However, if you choose not to participate, rest assured the treatment for your disease will not be affected nor compromised in any way; that is to say you will receive the treatment that you are entitled to. Furthermore, you are allowed to withdraw from participation at your own will and at any time even if you have already given consent initially and you will not be penalized for such decision.

Confidentiality:

All data collected as well as information obtained during this study will be handled with utmost confidentiality and will not be revealed to anybody outside the research team.

Benefits:

By participating in this study, the information you provide will help us to correlate the radiographic findings among children with adenoid hypertrophy and presenting symptoms. Thus the research outcomes will help to improve patients' management.

Risk:

By participating in this study, we do not anticipate any risks nor intend any harm on you while conducting the study.

Cost:

By participating in this study, you will not be required to make any payments and no payment will be made to you as well.

Contacts:

For further information, questions or queries regarding this study or any concerns with respect to your participation, you may kindly contact the following:

Dr. Serah Mumbi Mutuku (Principal investigator)
Otorhinolaryngology postgraduate student
Department of Otorhinolaryngology
Muhimbili University of Health and Allied Sciences
P.O. BOX 65001. Dar es Salaam.
Mobile: +255 745 786 148 OR

In case you have questions about your rights of participation in this study you may contact;

Dr. Daudi Cheche Ntunaguzi (Supervisor)
Otorhinolaryngology specialist
Department of Otorhinolaryngology
Muhimbili National Hospital
P.O. BOX 65001.
Dar es Salaam.
Mobile: +255687365208

Dr Bruno Sunguya
Director, Directorate of Research and Publications
Muhimbili University of Health and Allied Sciences
P.O. BOX 65001.
Dar es Salaam.
Mobile: +25576755484

I have read / been informed the contents of this form and have understood its meaning clearly.

I consent / do not consent for my child to participate in this study.

_____	_____
Name of Child.	Date
_____	_____
Signature of parent(s) or Legal Guardian or Caretaker	Date
_____	_____
Signature of Principal Investigator	Date

Appendix IV: Assent Form (English Version)

CHILD PERMISION TO PARTICIPATE IN RESEARCH

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

SCHOOL OF MEDICINE

DEPARTMENT OF OTORHINOLARYNGOLOGY

INFORMED ASSENT FORM FOR MINORS

Title: "Correlation between Clinical and Radiological findings in pediatric patients with adenoid hypertrophy attending Ortorhinolaryngology services at Muhimbili National Hospital''.

Hello, I am Dr Serah Mumbi Mutuku, a postgraduate student in the department of Otorhinolaryngology, conducting a research on Correlation between Clinical and Radiological findings in pediatric patients with adenoid hypertrophy attending Ortorhinolaryngology services at Muhimbili National Hospital.

A research is a way to learn about people and if you decide you want to be a part of this study, you and/or your caregiver will be asked a few questions. If you do not want to be in this research, you will continue to receive the treatment and care that you need.

The reports and documents will not have your identity on it and whatever information you give us will be kept confidential.

You do not have to be in this study if you do not want to. If you decide to stop after we begin it is okay also.

If you decide you want to be in this study, please sign your name.

I, ---------- want to be in this study.

Appendix V: Consent Form (Swahili version)

FOMU YA IDHINI KWA MZAZI KUMRUHUSU MTOTO KUSHIRIKI KWENYE UTAFITI HUU

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI (MUHAS)

CHUO CHA UDAKTARI

IDARA YA PUA, SIKIO NA KOO

FOMU YA IDHINI KWA MTOTO

Namba ya mtoto ya utambulisho: _____

Utangulizi:

Habari, kwa jina naitwa Dkt. Serah Mumbi Mutuku, ni mwanafunzi daktari katika idara ya pua, sikio na koo katika chuo kikuu cha afya na sayansi shirikishi Muhimbili.

Kama sehemu ya mafunzo yangu katika chuo hiki, ninafanya utafiti wenye kichwa cha habari "Uhusiano kati ya ugonjwa wa uvimbe wa nyuma ya pua kwa watoto na picha husika".

Lengo la utafiti huu:

Utafiti huu una lengo la kufahamu njia ya kusoma picha ya nyuma ya pua ili kusaidia katika matibabu ya shida husika.

Utendaji wa utafiti huu:

Utafiti huu sana sana unahusu kujibu dodoso inayojumuisha maswali yenye viwango vya uhusiano kati ya ugonjwa wa uvimbe wa nyuma ya pua kwa watoto na picha husika

Mtoto atapimwa na daktari katika klinik na picha ya nyuma ya pua itasomwa.

Ushiriki katika utafiti huu:

Ushiriki katika utafiti huu ni wa hiari kabisa. Kama utachagua kushiriki na kutoa idhini kwa kusaini fomu hii ya ridhaa, utatakiwa kutumia dakika chache kwa ajili ya mahojiano ili kujaza na kumaliza dodoso. Hata hivyo kama utachagua kutokushiriki, uwe na tumaini kwamba matibabu ya ugonjwa wako hazitoathirika kwa namna yoyote; kusema hivyo ni kwamba utapata matibabu unayostahiki. Zaidi ya hapo, unaruhusiwa kujitoa kushiriki kwa hiari yako mwenyewe na wakati wowote hata kama ulishatoa idhini mwanzoni na wala hautatukosea kwa hayo maamuzi.

Usiri:

Maelezo yote yatakayokusanywa pamoja na majibu yatakayopatikana wakati wa utafiti huu yatashughulikiwa kwa usiri wa hali ya juu na hayatafunuliwa kwa mtu yeyote nje ya timu ya watafiti wahusika.

Faida:

Kwa kushiriki katika utafiti huu, itatusaidia kuelewa vizuri zaidi jinsi ya kusoma picha ya nyuma ya pua ili kusaidia katika matibabu ya shida husika.

Madhara:

Kwa kushiriki katika utafiti huu, hatutarajii mahatarishi yoyote wala kukusudia madhara yoyote juu yako wakati wa kufanya utafiti.

Gharama:

Kwa kushiriki katika utafiti huu, hautahitajika kulipia malipo yoyote na pia wewe hautalipwa.

Mawasiliano:

Kwa habari, maswali au maelezo zaidi kuhusu utafiti huu au wasiwasi wowote kuhusu ushiriki wako, unaweza kuwasiliana na wafuatao:

Dkt. Serah Mumbi Mutuku (Mtafiti mkuu)

Mwanafunzi daktari wa pua, sikio na koo

Idara ya pua, sikio na koo
Chuo kikuu cha afya na sayansi shirikishi Muhimbili
S. L.P. 65001. Dar es Salaam
Simu: +255 745 786 148 AU

Dkt. Daudi Cheche Ntunaguzi (Msimamizi)
Daktari bingwa wa pua, sikio na koo
Idara ya pua, sikio na koo
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Dkt. Bruno Sunguya
Mkurugenzi
Kurugenzi la Utafiti na Uchapishaji
Chuo kikuu cha afya na sayansi shirikishi Muhimbili
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Mimi, nimesoma / nimejulishwa yaliyomo kwenye fomu hii na nimeelewa maelezo yake kwa wazi.

Mimi natoa idhini / sitoi idhini mtoto wangu kushiriki katika utafititi huu.

_____ _____

Jina la Mtoto. Tarehe

_____ _____

Sahihi ya Mzazi mshiriki Tarehe

_____ _____

Sahihi ya mhojaji (Mtafiti mkuu / Matifiti msaidizi): Tarehe

Appendix VI: Assent Form (Swahili version)

FOMU YA IDHINI KWA MTOTO KUSHIRIKI KWENYE UTAFITI HUU CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI (MUHAS

KICHWA CHA HABARI. UTAFITI KUHUSU "UHUSIANO KATI YA UGONJWA WA UVIMBE WA NYUMA YA PUA KWA WATOTO NA PICHA HUSIKA".

Habari, naitwa Dkt. Serah Mumbi Mutuku, mwanafunzi wa shahada ya uzamili ya udaktari wa masikio, koo na pua katika Chuo cha Sayansi Shirikishi cha Muhimbili.

Nafanya Utafiti kuangalia "uhusiano kati ya ugonjwa wa uvimbe wa nyuma ya pua kwa watoto na picha husika". Nitakupa maelezo na kukualika kushiriki katika utafiti huu, kabla ya kuamua unaweza kuongea na mtu yeyote kupata maelezo ya kutosha, kama kuna maneno hujaelewa vizuri unaweza kumwuliza daktari au muuguzi yeyote.

Utafiti ni njia ya kujifunza juu ya watu na ikiwa unaamua unataka kuwa sehemu ya utafiti huu, wewe na/au mlezi wako ataulizwa maswali machache. Utahitaji kipimo cha lateral nasopharyngeal X-ray (kipimo cha ufanyaji kazi wa mfumo wa umeme kwenye pua) ,ambavyo ni sehemu ya uchunguzi stahiki kwa wagonjwa wenye uvimbe wa nyuma ya pua.

Ikiwa hutaki kuwa katika utafiti huu, utaendelea kupata matibabu na huduma unayohitaji. Ripoti na nyaraka hazitakuwa na utambulisho wako juu yake na taarifa yoyote unayoyotoa itachukuliwa siri. Ni hiari yako kuwa katika utafiti huu na ikiwa hutaki hutalazimishwa kutaka. Ikiwa utaamua kuacha baada ya kuanza, hiyo ni sawa pia.

Ikiwa unaamua unataka kuwa katika utafiti huu tafadhali saini jina lako.

Mimi, ---------- nataka kuwa katika utafiti huu.

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Andika jina lako hapa Tarehe

Appendix VII: Approval of ethical clearance

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR - RESEARCH AND PUBLICATIONS

Ref. No.DA.282/298/01.C/

Date: 25/02/2021

MUHAS-REC-02-2021-499

DR. Serah Mumbi Mutuku
MMed – Otorhinolaryngology,
School of Medicine
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: CLINICAL AND RADIOLOGICAL FINDINGS IN PAEDIATRIC PATIENTS WITH ADENOID HYPERTROPHY ATTENDING OTORHINOLARYNGOLOGY SERVICES AT MUHIMBILI NATIONAL HOSPITAL.

Reference is made to the above heading.

I am pleased to inform you that the Chairman 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: 25/02/2021
EXPIRATION DATE OF APPROVAL: 24/02/2022

STUDY DESCRIPTION:
Purpose:
The study will strengthen the existing knowledge on the clinical presentations that may be used for more accurate diagnosis of AH at ORL department in MNH. This will help the ministry of health to know the prevalence of patients with AH at MNH which will project the prevalence of AH country wide.

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-%20354.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. Bruno Sunguya
Chairman, MUHAS Research and Ethics Committee

Cc: Director of Postgraduate Studies

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research & Publications
Box 65001

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1038; Direct Line:+255-22-2152489;Telefax:+255-22-2152489;E-mail:drp@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix VIII: 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.104/2018

26TH February, 2021

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

Re: INTRODUCTION LETTER

The bearer of this letter is Dr. Serah Mumbi Mutuku, a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing MMed. Otorhinolaryngology.

As part of her studies she intends to do a study titled: "***Clinical and Radiological Findings in Paediatric Patients with Adenoid Hypertrophy Attending Otorhinolaryngology Services at Muhimbili National Hospital.***"

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

Kindly provide her the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Sharifa Kamby
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School of Medicine, **MUHAS**
cc: Dr. Serah Mumbi Mutuku

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 IX: Permission letter to conduct data at MNH

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/TRCU/Perm/2021/045 **Date: 2nd March, 2021**

Head of Department
ENT
Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH.

Name of Student	**Dr. Serah Mumbi Mutuku**
Title	**"Clinical and Radiological Findings in Paediatric Patients with Adenoid Hypertropia Attending Otorhinolaryngology Services at Muhimbili National Hospital".**
Institution	**Muhimbili University of Health and Allied Sciences**
Supervisors	Dr. Daudi Cheche Ntunaguzi
Period	2nd March 2021, to 3rd July, 2021

Approval has been granted to the above mentioned student to collect data at MNH.

Kindly ensure that the student abide to the ethical principles and other conditions of the research approval.

Sincerely,

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

Reid B. Mchome
Coordinator –Teaching, Research and Consultancy Unit

c.c DSS
c.c **Dr. Serah Mumbi Mutuku**

Upanga West, Kalenga Street, Plot No. 10480/3, P.O. BOX 65000, Dar es Salaam, Tanzania.
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