THE PREVALENCE OF HEARING LOSS AMONG PATIENTS WITH HYPOTHYROIDISM AT KENYATTA NATIONAL HOSPITAL

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A dissertation submitted in partial fulfilment of the requirements for the award of degree of Master of Medicine in Otorhinolaryngology, Head and Neck Surgery, University of Nairobi.

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STUDENT'S DECLARATION

I declare that this is my original work and has not been presented for the award of any degree in any research institution or university.

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ABBREVIATIONS

ABR - Auditory Brain Stem Response

Db - Decibel

dBHL - Decibel Hearing Level

CHL - Conductive Hearing Loss

FT_3 - Free T_3

FT_4 - Free T_4

^{131}I - Iodine 131

KENAS - Kenya Accreditation Service

KNH - The Kenyatta National Hospital

MHL - Mixed Hearing Loss

Pmol/L - Picomol per litre

PTA - Pure Tone Audiometry

SD - Standard deviation

SNHL - Sensorineural Hearing Loss

SPSS - Statistical Package for Social Sciences

TSH - Thyroid Stimulating Hormone

T_3 - Triiodothyronine

T_4 - Thyroxine

uIU/L - Microinternational units per litre

UoN - The University of Nairobi

WHO - World Health Organization

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ABSTRACT

Background: The association between hypothyroidism and hearing loss has been well documented. The prevalence of hearing loss in acquired hypothyroidism is 25% and in congenital hypothyroidism it is 35-50%. However, there is paucity of local data on this subject.

Study objective: To determine the prevalence, types, and degree of hearing loss among patients with hypothyroidism at Kenyatta National Hospital

Study setting: The study was carried out at the Kenyatta National Hospital endocrine, surgical thyroid, and Ear, Nose and Throat clinics.

Study duration: This study took twelve months

Study design: This was a cross-sectional study

Study population: A total of 79 patients (18 to 60 years) diagnosed with hypothyroidism by an endocrinologist were recruited.

Methodology: Biochemically hypothyroid individuals had their medical history taken and were physically examined. Hearing was assessed with pure tone audiometry at frequencies of 250 Hz to 8000 Hz.

Data collection and analysis: Data was captured and analyzed by the Statistical Package for Social Sciences (SPSS Version 22.0). Continuous variables were compared using the Student's t-test while Chi-square test was used to analyze categorical variables. A 95% confidence interval was used and a p value of 0.05 considered statistically significant.

Results: There was a prevalence of hearing loss of 9.5% with a statistically significantly high proportion affected at 8000 Hz ($p < 0.05$). Sensorineural hearing loss was noted in 13 ears (86.7%) and mixed hearing loss in 2 ears (13.3%). The degree of hearing loss was predominantly mild and was present in 13 ears (86.7%). Hearing thresholds correlated positively with thyroid stimulating hormone levels, but this was not statistically significant ($p > 0.05$).

Conclusion and Recommendations: There was a 9.5% prevalence of hearing loss among the hypothyroid patients with a predominance of sensorineural type and mild degree of hearing loss. The correlation of thyroid stimulating hormone and hearing thresholds was weakly positive. Routine hearing screening of hypothyroid patients above 50 years is recommended.

1.0 CHAPTER ONE: INTRODUCTION

The World Health Organization (WHO) estimates that about 430 million people worldwide are affected by disabling hearing loss that requires hearing rehabilitation. By 2050, this figure is projected to rise to 700 million[1]. Hypothyroidism has been identified as one of the causes of hearing loss[2].

The prevalence of hearing loss among hypothyroid patients is 25% in patients with acquired hypothyroidism and 35-50% in congenital hypothyroidism[3,4]. Other otological symptoms such as tinnitus and vertigo are also frequent suggesting the involvement of both the auditory and vestibular structures[5].

Whereas the underlying mechanism for congenital hearing impairment is known to stem from developmental anomalies of the middle and inner ears due to thyroid hormone deficiency, the pathophysiology relating to hearing loss in acquired hypothyroidism remains unclear[5]. Existing theories include reduced cellular metabolism within the inner ear and disruption of neuronal transmission at the higher auditory centres among others[5,6].

Audiological assessment of hypothyroid patients by use of pure tone audiometry (PTA) has detected conductive, sensorineural, and mixed hearing loss[7,8]. This suggests that associated lesions may be located within the middle ear, the cochlear, retrocochlear sites or other areas along the ascending auditory pathway[8]. Further assessment by auditory brainstem response (ABR) has confirmed presence of sensorineural hearing loss with the prolongation of absolute latencies of wave V being a consistent finding [9].

Controversy exists in whether thyroid hormone replacement by giving levothyroxine to patients diagnosed with hypothyroidism results in reversal of abnormal audiological findings[8,10]. Cohort studies of hypothyroid patients with hearing loss put on thyroid hormone treatment have yielded variable results[10,11,12].

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Physiology of the auditory system

The auditory pathway starts by the funneling of sound waves into a unidirectional wave directed into the external auditory canal. The sound causes tympanic membrane vibration with the degree of vibration being proportional to the loudness of the sound[13]. The waves are transmitted through the ossicular chain to reach the oval window where the footplate of the stapes impacts. They are then sent up the scala vestibuli passing through the apex of the cochlear duct (the helicotrema) and then travel back the scala tympani to the round window. Vibrations of perilymph within the scala tympani are transmitted to the basilar membrane which moves in corresponding fashion. The organ of Corti (lying on the basilar membrane) converts the signal into an electrochemical signal that is carried by the cochlear division of the vestibulocochlear cochlear nerve to various brain stem nuclei. The signal ultimately projects onto the auditory cortex.

2.2 Hypothyroidism

Hypothyroidism is an endocrine disorder characterized by the presence of thyroid hormone levels below the normal reference ranges. It may exist congenitally or may be acquired due to abnormalities along the hypothalamic-pituitary-thyroid axis[14]. All organ systems may be affected by way of reduced cellular metabolism with symptoms being largely dependent on the degree of hormone deficiency. The prevalence of hypothyroidism in Africa has been estimated at 8.8%[15].

Reduced thyroid hormone synthesis due to environmental iodine deficiency is a leading cause of hypothyroidism. Global estimates indicate that close to 2 billion people have insufficient intake of iodine with sub-Saharan Africa and South Asia being particularly affected [16]. This effectively places a huge population at risk of hypothyroidism.

In iodine-sufficient geographical locations autoimmune conditions cause about 90% of thyroid hormone deficiency[14,17]. Other causes include post-ablative thyroiditis following surgery, ^{131}I administration or therapeutic irradiation, drug-induced thyroid dysfunction (such as the use of interferon alpha, tyrosine kinase inhibitors and interleukin) and thyroid gland infiltration with conditions such as amyloidosis, scleroderma and hemochromatosis among others[14].

Hypothyroidism may be classified as primary, secondary, tertiary or peripheral. Primary hypothyroidism is due to thyroid gland dysfunction that impairs thyroid hormone synthesis. It is the commonest variety of hypothyroidism[18]. Secondary hypothyroidism results from thyroid

stimulating hormone (TSH) deficiency in the setting of an otherwise normal thyroid gland. In tertiary hypothyroidism, there is insufficient thyrotropin releasing hormone (TRH) produced from the hypothalamus. The fourth variety, peripheral hypothyroidism or consumptive hypothyroidism is rare and is caused by aberrant expression of the deiodinase 3 enzyme which inactivates thyroid hormone[14,18].

Hypothyroidism may also be classified as overt or subclinical. Overt hypothyroidism is characterized by high TSH values and free thyroxine levels below the normal reference range. Subclinical hypothyroidism, on the other hand, is defined by serum TSH and free thyroxine levels within the normal range. It may or may not be associated with clinical symptoms[19].

Biochemical tests are central to the diagnosis of hypothyroidism as symptoms tend to be non-specific[20]. A thyroid hormone profile includes triiodothyronine (T_3), thyroxine (T_4) and thyroid stimulating hormone (TSH). Increased serum free TSH is common to all the varieties of hypothyroidism. It is also a sensitive marker of primary hypothyroidism but not of central hypothyroidism[21].

2.3 Hearing loss

Hearing impairment is the inability to comprehend sound. It may be a partial or a complete inability and may affect one or both ears. There are three main types of hearing loss: conductive hearing loss (CHL), sensorineural hearing loss (SNHL) and mixed hearing loss (MHL). The degree of hearing impairment ranges from slight to profound as shown in **Table 1**, below.

Table 1. Grades of hearing impairment from WHO (2021)[22]

Grade of Impairment	Audiometric Value	Performance
0-No impairment	25dB or better (better ear)	No or very slight hearing problems. Able to hear whispers
1- Slight Impairment	26-40 dB (better ear)	Able to hear and repeat words spoken in normal voice at 1 metre
2-Moderate Impairment	41-60 dB (better ear)	Able to hear and repeat words spoken in raised voice 1 metre
3- Severe Impairment	61-80 dB (Better ear)	Able to hear some words when shouted into better ear
4-Profound Impairment including deafness	81 dB or greater (better ear)	Unable to hear and understand even a shouted voice

Disabling hearing loss which encompasses grades 2 and 3 is defined by the WHO as a hearing loss of 35 decibels or more in the better hearing ear[22]. The condition disproportionately affects persons in low and middle-income countries. Counselling, the use of hearing aids, training in sign language and lip reading as well as surgical restorative procedures can be recommended as interventions depending on the type and degree of hearing loss.

2.4 Thyroid Hormone and Hearing

Thyroid receptor alpha 1 (TRa1) and thyroid receptor beta (TRb) are thyroid hormone receptors in the auditory system acting as hormone activated transcription factors. They are encoded by the *Thra* and *Thrb* genes respectively. The binding of thyroid hormone to these receptors is needed for various aspects of middle ear cavity and ossicular bone maturation[23,24]. Congenitally hypothyroid rodent models or those with abnormalities of the thyroid receptors may have persistence of mesenchyme within the middle ear into adulthood, a delay in the ossification of ossicles and enlargement of the ossicles[24].

Thyroid hormone is vital to the process of cochlear maturation. In mice models in which the receptors are absent, there is retardation of cochlear maturation as manifested by malformations of the tectorial membrane, presence of low endonuclear potentials, delayed differentiation of the sensory epithelium and impaired electromechanical transduction in outer hair cells[23]. These abnormalities are the likely basis for the existence of hearing loss in congenitally hypothyroid patients.

Acquired hypothyroidism is postulated to cause hearing loss in several ways. One of the theories proposes that reduced thyroid hormone levels affect cellular metabolism. This in turn impairs the microcirculation within the ear, notably in the stria vascularis and organ of Corti[5,26]. Thyroid hormones have, additionally, been found to control protein synthesis, formation of myelin and enzymes useful in the central nervous system with thyroxine also acting as a neurotransmitter[5]. Many of these functions will likely be adversely affected in presence of thyroid hormone deficiency. Aggravation of autoimmune diseases by hypothyroidism and eustachian tube dysfunction due to submucosal oedema leading to middle ear pathology are other possible causes that have been considered[5,7,27].

2.5 Prevalence, types and degree of hearing loss

Several studies have been carried out over the last few decades to investigate the association between hypothyroidism and hearing loss[8,9,10,11]. The results arising from these studies vary in

the prevalence, degree and types of hearing loss as well as on the reversibility of hearing impairment following administration of levothyroxine.

Tantawy et al carried out a study on audiological findings in patients with thyroid dysfunction categorized as euthyroid, hypothyroid and hyperthyroid[9]. Each category had 20 participants. The results of this study showed statistically significant sensorineural hearing loss in the hypothyroid subjects compared with the euthyroid and hyperthyroid groups but no conductive or mixed hearing loss. Similarly, in Brazil, Santos et al compared audiological findings in 30 patients with acquired hypothyroidism with those of 30 age and sex matched controls[5]. Sensorineural hearing loss was the only type found and was demonstrated in 48.3% of subjects and this was statistically significant.

The findings by Tantawy et al and Santos et al differ from those of Anand et al, Aggarwal et al and Malik et al with the latter investigators demonstrating the presence of conductive and mixed hearing loss in addition to sensorineural hearing loss [7,8,28]. Among 20 hypothyroid patients evaluated by Anand et al, 16 (80%) of them had hearing loss. Out of this, 12 (60%) patients exhibited sensorineural hearing loss and 4 (20%) patients had mixed hearing loss. Aggarwal et al assessed 100 patients with goitrous hypothyroidism in India. Out of the total number, 39 (39%) patients were proven to have hearing impairment; In 8 (8%) of them, the hearing loss was conductive while 15 (15%) had sensorineural hearing loss and 13 (13%) had the mixed type. Malik et al had comparable findings from a sample of 45 patients. Conductive hearing loss was noted in 15 (46%) patients, sensorineural hearing loss in 8 (25%) and mixed hearing loss in 9 (28%). The larger sample sizes by Aggarwal et al and Malik et al may also explain the wider variety of findings compared to the other authors.

The presence of sensorineural hearing loss as a consistent finding in these studies reaffirms the theory that the cochlear and the ascending auditory pathway are affected by the abnormal thyroid hormone levels. The diagnosis of conductive hearing loss by some investigators can be attributed to middle ear pathology. Eustachian tube dysfunction is a possible sequalae of hypothyroidism and the tube has been noted to exhibit congestion and oedema in submucosal tissues in patients known to have thyroid hormone deficiency[27]. One third of patients seen by Malik et al were noted to have retracted tympanic membranes which may explain the large proportion of conductive hearing loss in this study[21].

Whereas some authors have suggested the existence of hearing loss across all frequencies, others have shown that such impairment is only demonstratable at high frequencies. Mahafza et al investigated 41 patients with Hashimoto's thyroiditis using pure tone audiometry[26]. The

results showed the existence of hearing loss across a range of frequencies (250 Hz to 8000 Hz). Tantawy et al and Gupta et al, in contrast, found statistically significant SNHL in hypothyroid patients only at the higher frequencies[9,29]. Tantawy demonstrated hearing loss at frequencies between 4000 Hz and 8000 Hz while Gupta et al found that 42.4% of hypothyroid patients had mild hearing loss in the frequency range of 4000 Hz and 8000 Hz with normal hearing in the frequency range of 500 Hz, 1000 Hz and 2000 Hz. Similar findings were demonstrated by Vinitha et al[30]. This difference may be explained by the nature of patients enrolled in the various studies. All patients evaluated by Mahafza et al had Hashimoto's thyroiditis thus a high likelihood of the autoantibodies characteristic of the disease acting synergistically with the reduced thyroid hormone levels to cause more severe symptoms. The other two investigators recruited general populations of hypothyroid patients that possibly included fewer patients with Hashimoto's thyroiditis.

Regarding the degree of hearing loss, many of the authors have found that the affected patients have mild to moderate hearing loss. In a study carried out in Egypt, Ismail et al found 23% patients with mild sensorineural hearing loss from a sample of 40 hypothyroid patients evaluated[31]. The same findings are recorded by Santos et al in whose study bilateral mild to moderate sensorineural hearing loss was noted in 22 (36.7%) ears. Kumar et al found that in all the 17 (77.3%) patients determined to have hearing loss from a sample of 22 patients, the degree was mild[32]. This consistent finding points to the fact that the impairment arising from hypothyroidism is only partial and patients are unlikely to progress to severe forms of hearing loss.

There is disagreement on the correlation between thyroid hormone levels and hearing thresholds. Half of the participants evaluated by Santos et al had normal thyroxine levels but exhibited changed audiometric thresholds though this was not statistically significant[5]. Tantawy et al observation was that there was no statistically significant correlation between thyroid hormone levels and hearing thresholds. One study, however, does appear to suggest a correlation between levels of hearing and mean TSH levels as mean duration of hypothyroidism[33].

Several attempts have been made to determine the reversibility of hypothyroidism-associated hearing loss through administration of thyroxine with resultant conflicting reports. Sixteen patients found to have hearing loss by Anand et al were put on levothyroxine and reevaluated after 3.7 months[9]. In all the patients, there was an improvement in hearing thresholds as assessed by pure tone audiometry. Three out of the four patients with an initial type B tympanogram, showed normalization of the graph when reassessed after this period.

In an Egyptian study carried out by Hussein et al, 30 hypothyroid patients diagnosed with varying degrees of hearing impairment were put on treatment with levothyroxine and followed prospectively for 6 months[10]. All the patients were re-evaluated by thyroid function tests to confirm that a state of euthyroidism had been achieved. A repeat audiogram and tympanometry were done for each of the patients at this point. There was noted improvement in hearing in 48% of the ears with 15% of them attaining restoration to normal hearing levels. In 52% of the ears, however, there was no change in hearing thresholds. Studies carried out by Post, Devos and Parving et al failed to demonstrate significant improvement in hearing thresholds following treatment of hypothyroid patients with levothyroxine[12,34,35]. Post noted that eight out of forty-two patients with hypothyroidism had sensorineural hearing loss. When these patients were put on thyroid hormone replacement and reevaluated after 6 weeks, there was only questionable improvement in hearing in four of them. The smaller sample size and the shorter duration of follow up as compared to Anand et al and Hussein et al offer a possible explanation. Parving evaluated a much older group of 15 hypothyroid patients with hearing loss with a median age of 76 years. There was no improvement after levothyroxine treatment, a fact that was attributed to the effect of age-related hearing loss.

2.6 Study Justification

Hypothyroidism is associated with a myriad of multi-systemic symptoms including those related to the auditory system[13]. While numerous studies have shown varying degrees of hearing impairment among patients with hypothyroidism, there is paucity of studies carried out within the Kenyan population.

This study aimed to establish the prevalence, types and degree of hearing loss among patients with hypothyroidism as seen at Kenyatta National Hospital and to correlate the degree of the hearing loss with thyroid hormone levels. The study was intended to help determine whether there is need to consider patients with hypothyroidism for routine hearing screening. Moreover, it would provide baseline data upon which future studies can be carried out.

2.7 Study Question

What is the prevalence of hearing loss among hypothyroid patients seen at Kenyatta National Hospital?

2.8 Study Objectives

2.8.1 Broad Objective

To determine the prevalence of hearing loss among patients with hypothyroidism at Kenyatta National Hospital

2.8.2 Specific Objective

To determine the prevalence of hearing loss in patients with hypothyroidism at Kenyatta National Hospital

2.8.3 Secondary Objectives

a) To determine the degree of hearing loss in hypothyroid patients at Kenyatta National Hospital

b) To describe the types of hearing loss among hypothyroid patients at Kenyatta National Hospital

c) To correlate the hearing thresholds with the levels of thyroid hormone in hypothyroid patients at Kenyatta National Hospital

3.0 CHAPTER 3: STUDY METHODOLOGY

3.1 Study Design

This was a cross-sectional study

3.2 Study Setting

This study was carried out in the Kenyatta National Hospital Endocrinology clinic, surgical thyroid clinic and the Ear, Nose and Throat clinic.

3.3 Study Population

The study population comprised patients aged between 18 and 60 years diagnosed with hypothyroidism and confirmed to be hypothyroid by an endocrinologist at the time of enrollment.

3.4. Inclusion criteria

i. Biochemically hypothyroid patients (diagnosed by an endocrinologist)
ii. Aged 18 to 60 years
iii. Patients consenting to participate in the study.

3.5 Exclusion criteria

i. History of preexisting ear disease
ii. Prior history of ear surgery or trauma
iii. Medical illnesses known to cause hearing loss such as hypertension, diabetes mellitus, Human Immunodeficiency Virus (HIV) and autoimmune conditions (SLE, rheumatoid arthritis and others)
iv. Prior history of irradiation to the head and neck
v. Use of ototoxic medication
vi. History of noise exposure

3.6 Sample size Determination

The local prevalence of hearing loss among hypothyroid patients is not known. The study by Aggarwal et al was used to estimate the prevalence (39%)[28].

The sample size will be determined based on the formula below:[36]

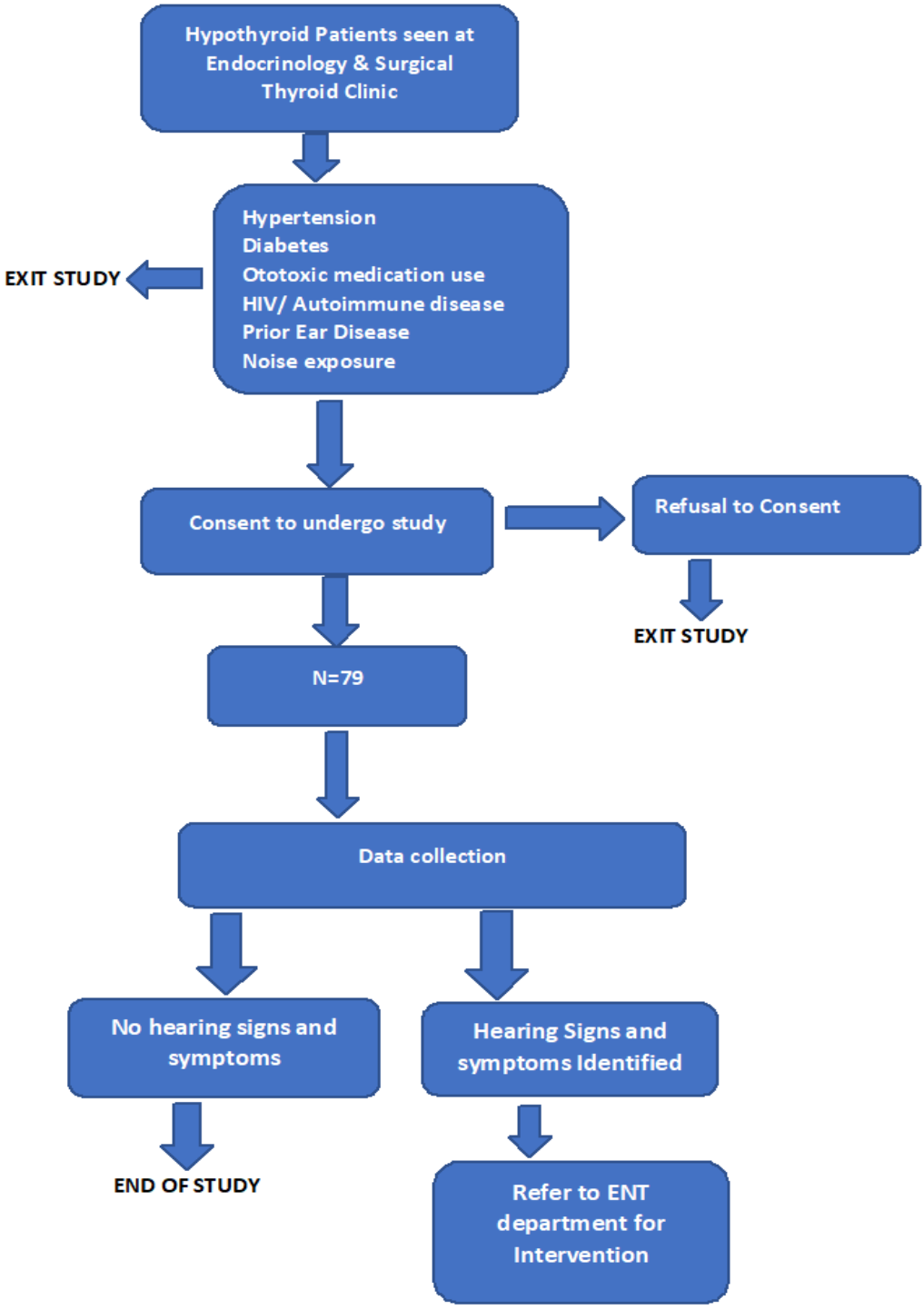
$$n' = \frac{NZ^2P(1-P)}{d^2(N-1)+Z^2P(1-P)}$$

Where;

Z-alpha (standard normal distribution critical value for the desired level of significance; 5%)	=	1.96
P (proportion of hearing impairment in hypothyroid patients)	=	0.39
d (Level of precision of the estimate - usually set at 5% or 0.05)	=	0.05
N (Population size - estimated total patients across the study period)		100

n' (Minimum sample size required for the study) = **79**

3.7 Data collection Flow chart



3.8 study Tools

A demographic and clinical history data sheet was used.

3.9 Study Procedure

All patients who met the inclusion criteria were provided with a written consent prior to enrollment into the study. Those who accepted be enrolled signed the consent form and were

then subjected to a full otolaryngology history and physical examination. The otolaryngology examination included tuning fork tests and otoscopy.

Pure tone audiometry was done using the modified Hughson-Westlake method as per the recommendations of the American Association on Hearing. The testing started with the perceived better ear. The tester presented a pure tone at level that was clearly audible. When the patient responded to the signal, the intensity was then reduced by an intensity of 10 dB and the tone presented at the new level. The participant was asked to give a response once more. This was continued sequentially with reduction of 10 dB at each stage and asking for patient response. It ended when the patient no longer responded. Next, the tone was increased by an intensity of 5 dB until a positive response was attained from the patient. The frequencies tested were 250Hz, 500Hz, 1000Hz, 2000Hz, 4000Hz and 8000Hz. The testing was done both for air and bone condition but the testing for bone conduction only included 500Hz, 1000Hz, 2000Hz and 4000Hz frequencies. The results obtained were be plotted on an audiogram. A pure tone average was then be calculated by adding the thresholds obtained at 500, 1000, 2000Hz and 4000Hz dividing the result by 4. Patients noted to have hearing loss were referred to the ENT clinic for appropriate intervention.

3.10 Data Management and Analysis

Data captured by a data collection form was imported to STATA version 15 for cleaning. Data cleaning helped in identifying and correcting inconsistencies, duplicates and obvious outliers to ensure good data quality. Thereafter, it was transferred to Statistical Package for Social Sciences (SPSS Version 22.0) and analysed. Continuous data were represented by mean ± Standard Deviation (SD) and median depending on the distribution and illustrated using a histogram. Categorical variables were summarized using percentages and frequencies. Illustration of categorical variables was done using bar charts and pie charts as deemed appropriate.

Bivariate analysis was done to determine the crude association between hearing and exposure to hypothyroidism. For continuous predictors, Student's t-test was used in comparing means/medians (depending on the distribution of the continuous variable) of the predictor between the two groups of patients while for categorical predictors, Chi-squared test was used. The prevalence and the corresponding 95% confidence interval and p-value were reported.

3.11 Quality Control

The quality control process was considered at every stage of this study to maximize the validity and reliability of results. A pilot study was first conducted through administration of a pre-test structured questionnaire. This enabled the undertaking of appropriate changes to avoid

misinterpretation of questions and bias. The principal investigator carried out the data collection interviews and physical examination. The data collection tool was then reviewed for completeness and identified errors were corrected. The quantitative and qualitative data were crosschecked for inconsistencies that were rectified when found.

Thyroid function tests were carried out at the Kenyatta National Hospital Chemistry laboratory which is accredited by the Kenya Accreditation Service (KENAS) and has a continuous quality assurance program. There is daily internal quality control and monthly external quality control. The analyser used was the Cobas EG01.

Standard reference ranges will be used as follows: TSH: 0.35 to 4.94 uIU/ml; FT_3: 2.43 to 6.01 pmol/L and FT_4: 9.01 pmol/L to 19.05 pmol/L

Audiological assessment was carried out at the Kenyatta National Hospital's audiological unit by the same specific device and by the same audiologist for all the subjects. The PTA machine to be used was the Interacoustic AC33 clinical audiometer that is calibrated as per ISO standards.

3.12 Ethical Considerations

This research was undertaken following approval by the KNH/UON Ethics and Research committee, ERC. Every patient was provided with a comprehensive verbal explanation of the study as well as written consent. Patients that chose to opt out continued to receive services without discrimination. Patients did not incur any additional costs by choosing to participate in this study. They were anonymized by having an assigned study number aimed at maintaining their confidentiality. Data collection sheets and any copies of results were kept in safe custody of the principal investigator and will not be shared with any unauthorized persons.

At the end of this study, raw data collected will be coded and backed up to be used for any other future study. The results will be presented to the University of Nairobi and the Kenyatta National Hospital as a dissertation. The findings may also be presented in scientific conferences, journals and academic meetings. No conflicts of interest exist on the part of the principal investigator, the supervisors, the university or the hospital.

CHAPTER 4.0 RESULTS

A total of 79 hypothyroid patients were successfully enrolled into the study from the endocrine and surgical outpatient clinics through convenience sampling and underwent audiological assessment. The results were subsequently analyzed.

4.1 Demographics

4.1.1 Age distribution

The mean age of the study population was 47.8 ± 8.89 years with an age range of 28 years to 60 years. The median age was 49 years, and the inter-quartertile range (IQR) was 15.25 years.

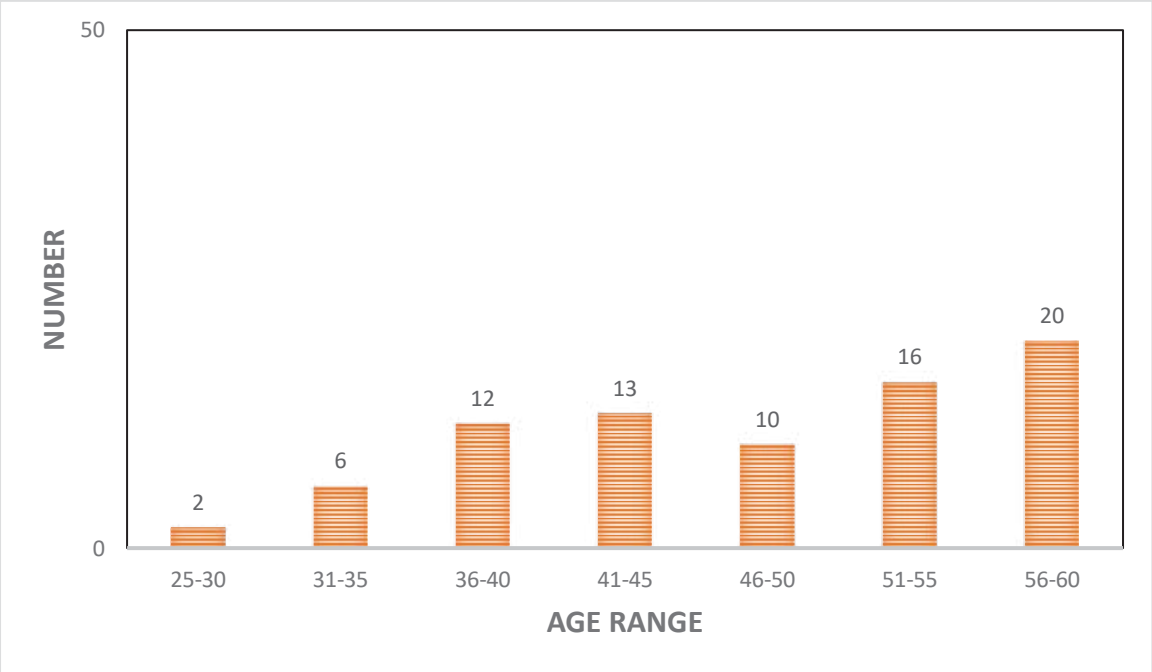


Figure 1. The age distribution graph of recruited patients

4.1.2 Sex Distribution

The number of female patients was 63 (79.7%) while that of the male were 16 (20.2%)

4.2 Thyroid Hormone Levels

All the patients recruited in the study were confirmed to have hypothyroidism at the time of enrollment. Their mean thyroid hormone levels and the respective standard deviations were as shown in table 2 below.

Table 2. Mean thyroid hormone levels

HORMOME	TSH (uIU/mL)	T3 (pmol/L)	T4 (pmol/L)
MEAN LEVELS	14.86 ± 20.05	3.54 ± 1.41	9.05 ± 4.51

4.2.1 Hypothyroidism Treatment History

Among those evaluated, 49 (62%) patients were on thyroid hormone replacement while 30 (38%) had not been initiated on treatment.

4.2.2 Hypothyroidism subtypes

Majority of the patients-36 (45.6%) were post-thyroidectomy. This was followed by those with unknown cause at 31 (39.2%) and Hashimoto's thyroiditis at 9 (11.4%). Other diagnoses made a minor contribution. The various proportions are demonstrated in figure 2.

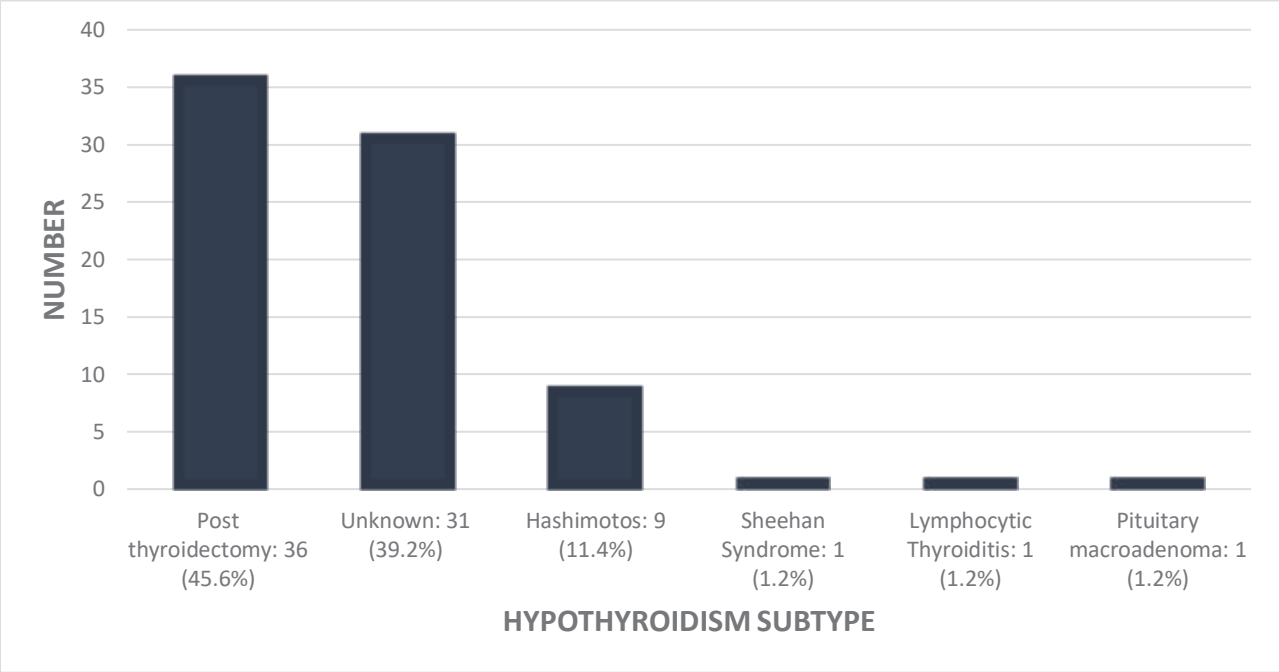


Figure 2. Proportion of hypothyroidism subtypes

4.2.3 Hypothyroidism severity

There were 48 (60.76%) out of 79 patients with subclinical hypothyroidism and 31 (39.24%) with overt hypothyroidism.

4.2.4 Duration since diagnosis of Hypothyroidism

The duration of hypothyroidism varied from 3 months to 15 years with 42 (54.2%) patients having had the condition for less than 5 years. The distribution has been captured on figure 3.

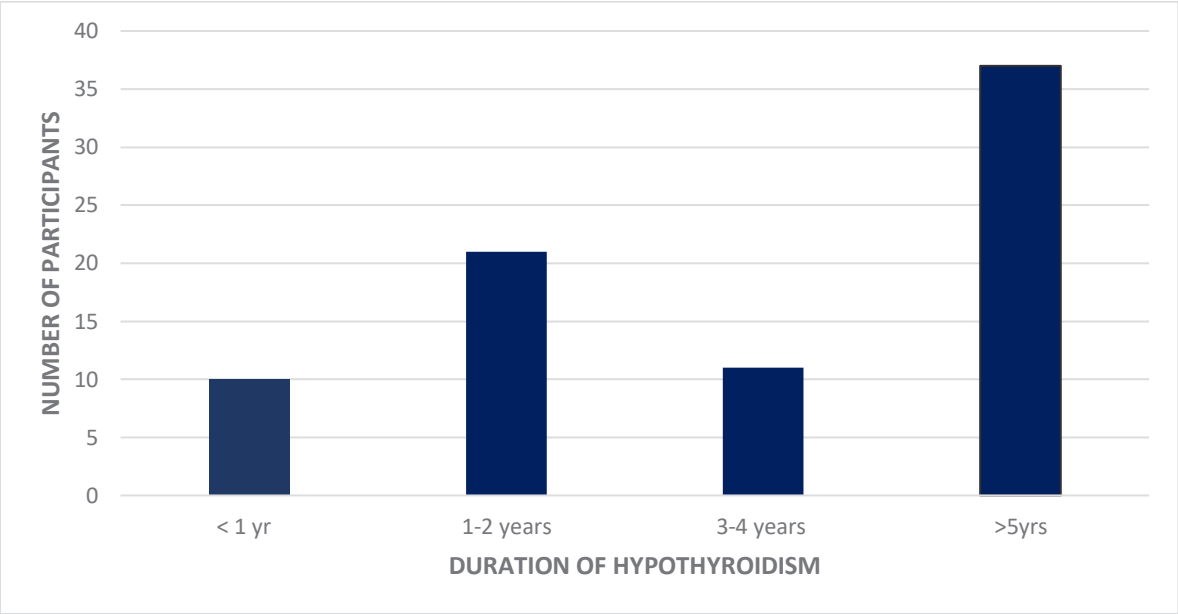


Figure 3. Number of patients by duration since diagnosis of hypothyroidism

4.3 Audiogram Results

Table 3 (below) is a representation of the mean thresholds in decibel hearing level (dBHL) at individual frequencies showing a relatively higher average at 8000 Hz compared to the other frequencies evaluated.

Table 3. Mean hearing level thresholds in dBHL at various frequencies.

TESTED HEARING FREQUENCY	250	500	1000	2000	4000	8000	PURE TONE AVERAGE
MEAN RIGHT EAR dBHL	17.84	17.59	13.73	15.25	17.40	22.34	15.98
SD	9.25	9.43	9.04	10.06	10.61	15.52	8.04
MEAN LEFT EAR dBHL	18.10	17.97	13.92	15	16.96	24.30	15.93
SD	8.33	9.18	9.46	10.09	11.75	15.91	8.29

One-way ANOVA test was performed on the frequency-specific mean hearing thresholds and showed a difference in the mean values. A post-hoc test demonstrated that mean threshold values at 8000Hz were statistically different from the mean values at the other frequencies ($p < 0.0.5$)

4.3.1 Summary Of Abnormal Audiological Findings

Table 4 is a summary of the abnormal findings and indicates the types and grades of hearing loss that were noted in this study expressed as a proportion of all the ears affected.

Table 4. Summary of abnormal audiological findings

	MILD SNHL	MODERATE MHL	MODERATELY SEVERE MHL	TOTAL
RIGHT EARS	6	1	0	7
LEFT EARS	7	0	1	8
TOTAL	13	1	1	15
%	86.6%	6.6%	6.6%	100%

4.3.2 Types of hearing loss

The types of hearing loss included sensorineural and mixed hearing loss, and these were graded as mild to severe. Sensorineural hearing loss was the predominant type and was noted in 6 right ears and 7 left ears. Mixed hearing loss was the only other type and was observed in 1 right ear and 1 left ear. These results are represented in figure 5.

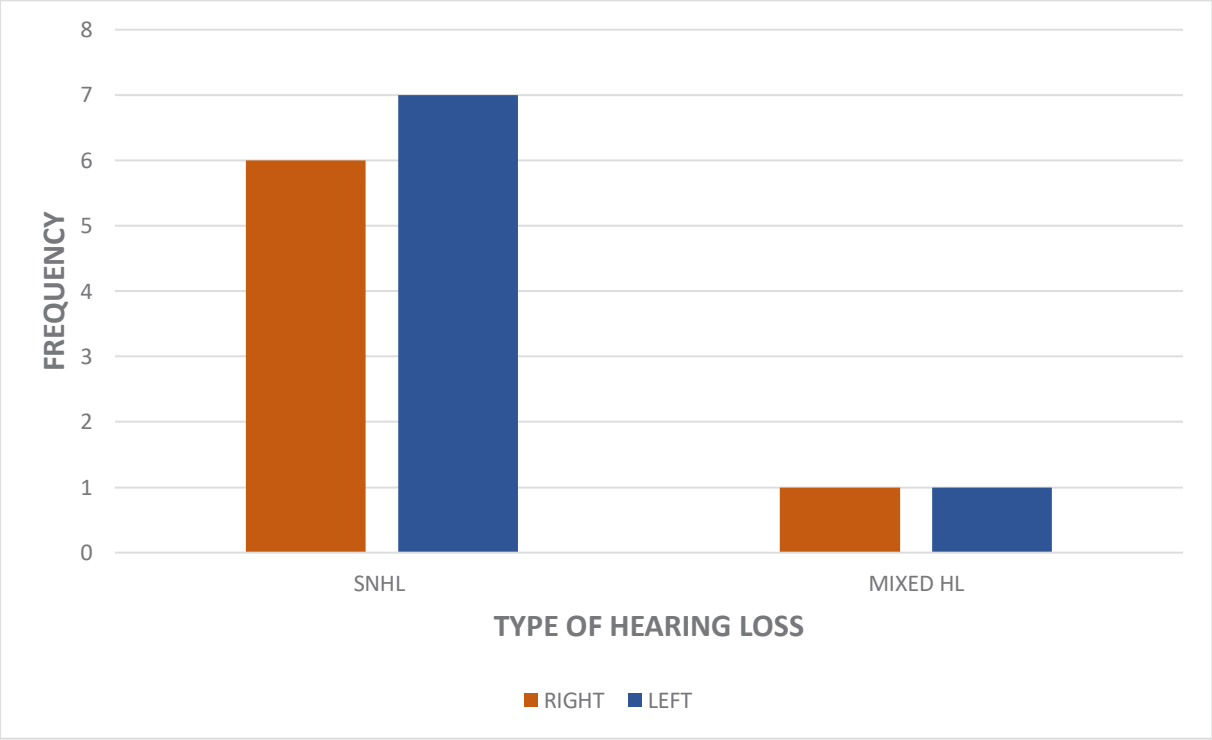


Figure 4. Types of hearing loss

4.3.3 Degree of Hearing Loss

13 ears out of 15 (86.6%) with hearing loss had the mild type. One had moderate hearing loss (6%) and one had moderately severe (6%) hearing loss as displayed on figure 5.

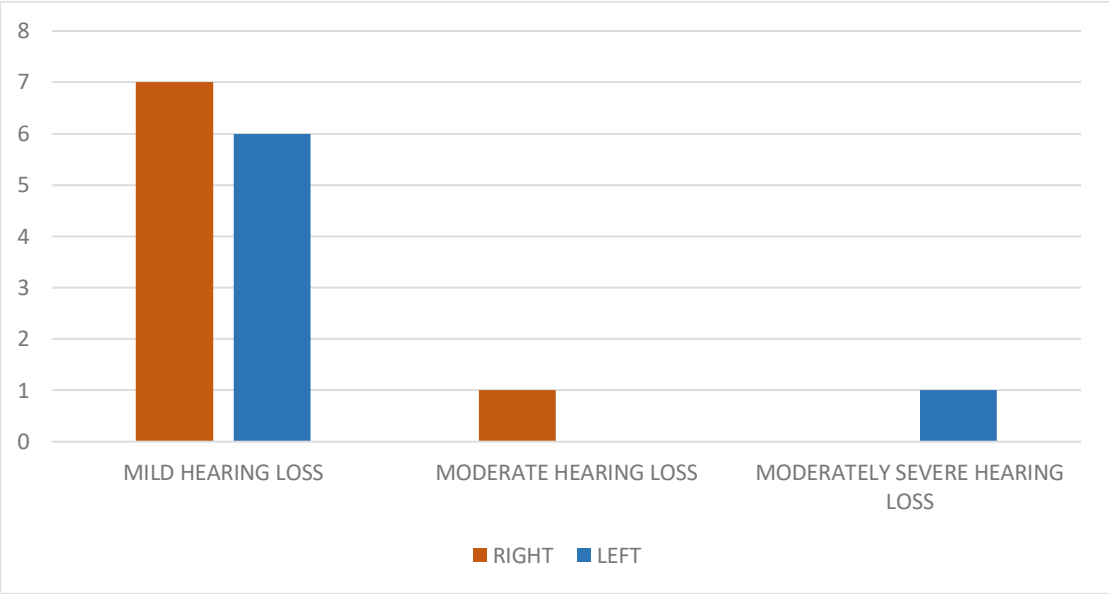


Figure 5. Degree of hearing loss

4.3.4 Prevalence Of Hearing Loss

Of the 158 ears assessed, hearing loss was found in 15 (9.5%) of them. This represented 7 ears on the right and 8 on the left. Nine individuals (7 female and 2 male) with an average age of 52.11 years (SD 8.30) were affected. Six had bilateral involvement while 3 had unilateral hearing loss.

Hearing loss in 4 ears was associated with overt hypothyroidism while in 11 ears it was in patients that had subclinical hypothyroidism. When related to etiology, 5 ears were associated with an unknown cause, 6 were in patients that had had thyroidectomy and 4 were for patients with Hashimotos thyroiditis.

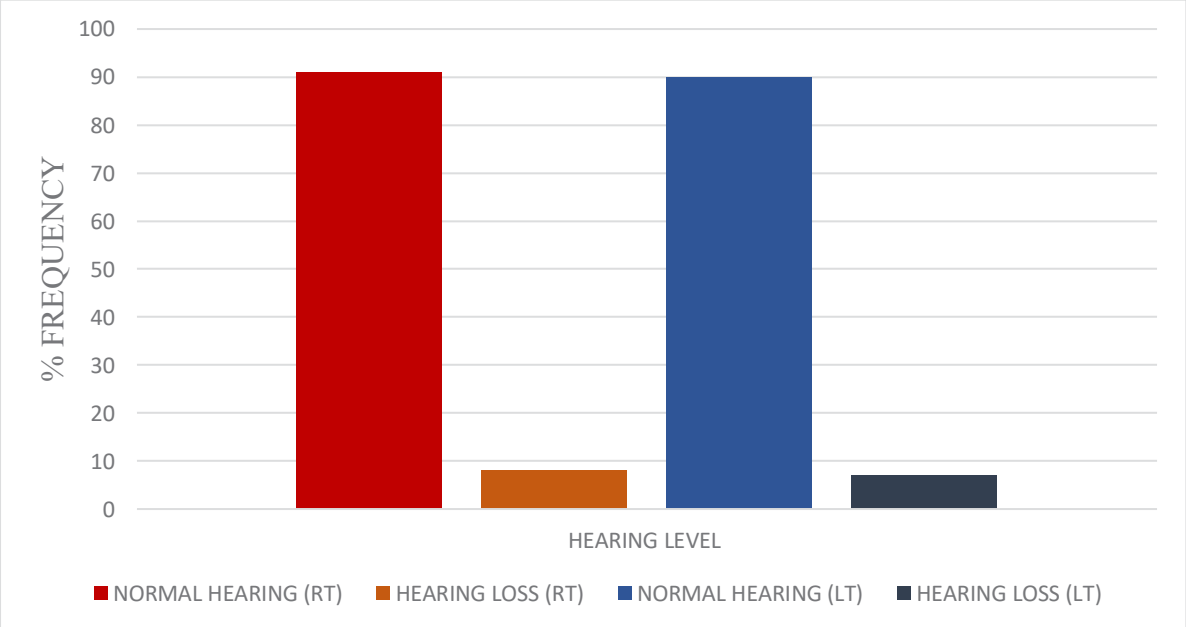


Figure 6. Proportion of patients with hearing loss

4.3.5 Hearing Loss At Specific Frequencies

For the specific frequencies, 8000 Hz showed the greatest hearing loss with 23 (30%) ears showing elevated thresholds on the right and 21 (27%) ears showing elevated thresholds on the left.

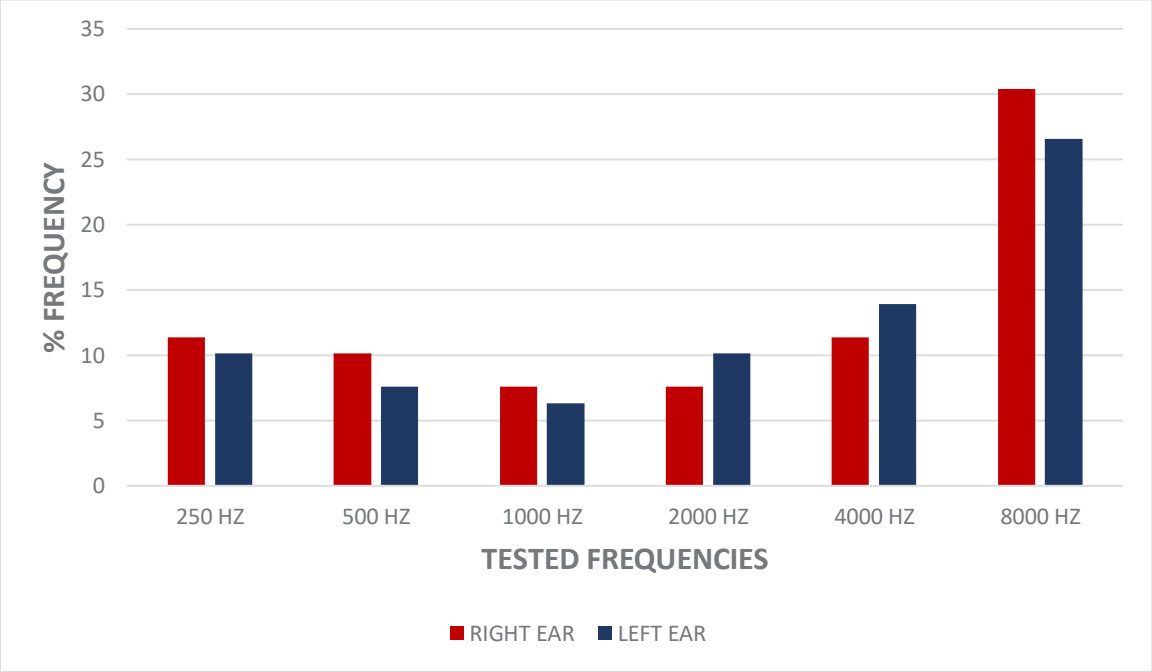


Figure 7. Prevalence of Hearing Loss at Specific Frequencies

4.4 Correlation Between Thyroid Hormones (TSH, T4 and PTA values)

There was a positive correlation between TSH and hearing thresholds and a negative correlation between T4 and hearing thresholds for both ears ($p > 0.05$).

Table 5. Spearman's rank correlation between thyroid hormones and hearing thresholds

	RIGHT EAR		LEFT EAR	
	TSH	**T4**	**TSH**	**T4**
PTA	**0.081**	**-0.07**	**0.07**	**-0.05**
P-value	**0.48**	**0.53**	**0.54**	**0.69**

4.5 Correlation Between Duration Of Hypothyroidism And Hearing Thresholds

There was a positive correlation between the duration of hearing loss and the hearing thresholds, but this was also statistically insignificant ($p > 0.05$).

Table 6. Spearman's rank correlation between duration of hypothyroidism and hearing thresholds

	RIGHT EAR	LEFT EAR
COEFFICIENT	**0.05**	**0.09**
P-VALUE	**0.67**	**0.40**

CHAPTER 5.0: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 DISCUSSION

Hypothyroidism is associated with various audiological symptoms such as hearing loss, tinnitus, and vertigo[5]. The risk has been shown to be present both in the congenital and acquired forms of the condition[3]. With a huge population at risk of hypothyroidism in Africa and Asia, it is needful to investigate the extent to which the hearing loss can be attributed to the condition[16]. This may help develop more focused preventive and therapeutic strategies.

The aim of this study was to determine the prevalence of hearing loss among hypothyroid patients, the type and degree of the hearing loss and whether there is a correlation between the hormone levels and hearing thresholds. The results were intended to inform the need for routine audiological assessment of patients on follow-up for hypothyroidism.

We recruited 79 patients with an age range of 28 to 60 years. The mean age was 47.8 ± 8.89 years, the median 49 years, and the interquartile range (IQR) 15.25 years. The mean age of those with hearing loss was 52.11 ± 8.30 years. Majority of the patients were female at 63 (79.7%). When stratified by age, the largest proportion comprised those in the 56 to 60 years age range (20) followed by those between 51 and 55 years (16) cumulatively making up 45.5% of total patients studied. The finding of a higher proportion of female patients is in keeping with those of other studies reviewed which recorded a range of 83.7%-100%[5,11, 30]. The mean age was similar to that of Karakus et al but was higher than those of Tantawy et al and Santos et al[5,9,11]. Delayed diagnosis of hypothyroidism in our study population may be a contributing factor to the higher mean age which in turn confers a higher risk of presbycusis.

All the patients assessed were confirmed to be biochemically hypothyroid at the time of enrollment. Out of this number, 49 (62%) were already on thyroid hormone replacement while the rest were yet to be initiated on treatment. The mean TSH level was elevated at 14.86 ± 20.05 uIU/mL while T3 and T4 mean values were within normal ranges at 3.54 ±1.41 pmol/L and 9.05 ±4.51 pmol/L respectively. This may have come about due to a high number of subclinical hypothyroid patients who stood at 48 (60.8%) compared to those with overt hypothyroidism who were 31 (39.2%). The proportion of subclinical hypothyroid patients was higher than that of Santos et al that comprised about 50%[5].

The etiology of hypothyroidism was identified as thyroidectomy in 36 (45.6%) and it was unknown in 31 (39.2%). Patients with Hashimotos thyroiditis were 9, representing 11.4 which

was lower than Santos et al who had 70% and Mahafzah et al (100%)[5,25]. This was mainly due to lack of routine determination of thyroid peroxidase antibodies among hypothyroid patients in our population thus a large number were categorized as having an unknown cause of hypothyroidism. Regarding duration of illness, 42 out of 79 (63.2%) had the condition for less than 5 years, a finding that is comparable to other studies[5,33].

Overall, we established presence of hearing loss in 15 ears (7 right and 8 left) representing 9.5% of ears assessed. Out of this, 6 patients had bilateral hearing loss and 3 had unilateral hearing loss. This result compares with the findings of Karakus et al (12.9%) but is far lower than several other studies where the prevalence was 36% -80% [5,8,11,28]. The lower prevalence in our study could be attributed to patient selection where a general population of hypothyroid individuals including post thyroidectomy and those in the unknown cause category were considered with only 11.4% confirmed as having Hashimoto's thyroiditis. Evaluation of hypothyroid patients with Hashimoto's thyroiditis may result in a higher prevalence of hearing loss due to the synergistic effect of low hormone levels and autoimmune injury of the inner ear by autoantibodies [5,28].

The mean hearing thresholds were found to be statistically significantly elevated at 8000Hz compared to the other frequencies both on the right and left ears ($p < 0.05$). This was reflected in the frequency-specific hearing loss analysis with 30% of ears on the right and 27% of ears on the left exhibiting hearing loss. This finding concurred with the results of Tantawy et al Gupta et al and Vinitha et al but differed from those of Karakus et al who found a higher proportion of hearing loss at the lower thresholds and Mahafza et al whose results revealed hearing loss across the entire range of frequencies tested (250 Hz to 8, 000Hz)[9,11,26,29,30].

Sensorineural hearing loss was present in 13 (86.7%) ears while mixed hearing loss was noted in 2 (13.3%) ears. There was no recorded case of conductive hearing loss. Other studies have shown variable results in relation to the type of hearing loss [5,7,9]. Underlying etiology of hypothyroidism appears to bear an influence on the type of hearing loss seen with enrolment of higher numbers of Hashimoto's thyroiditis resulting in a predominance of the sensorineural type[5,11,30]. A smaller number of Hashimoto's thyroiditis patients in our study may have resulted in fewer sensorineural hearing loss cases.

Regarding the degree of hearing loss, 13 ears were found to have mild hearing loss. This represents the majority (86.6%) of ears affected. The remainder (2 ears) showed moderate hearing loss in 1 ear and moderately severe hearing loss in another 1 ear. This finding is in

keeping with most of the reviewed studies in which mild hearing loss is by far the most common form [5,26,29]. A predominantly mild hearing loss may be a reason for underdiagnosis of hypothyroidism-associated hearing loss.

There was positive correlation between the TSH and PTA and negative correlation between T4 and PTA but these were not statistically significant ($p > 0.05$). Santos et al had similar findings but both Srirangaprasad et al and Vinitha et al found a statistically significant correlation between the level of hearing and the serum TSH levels[5,31,33]. A positive correlation between the duration from time of hypothyroidism diagnosis and the hearing thresholds that was not statistically significant was found. This is similar to the findings of Srirangaprasad et al. These findings suggest that the severity of hypothyroidism as well as the duration for which the hormone is suppressed may not necessarily predict the risk of developing hearing loss.

5.2 CONCLUSION

There was a hearing loss of 9.5% among patients with hypothyroidism at Kenyatta National Hospital with sensorineural hearing loss being the predominant type. Hearing loss was noted to disproportionately affect the high frequencies (8000 Hz) and was predominantly of mild degree. A positive correlation between TSH and T4 levels and the hearing thresholds was noted, but this was not statistically significant.

5.3 RECOMMENDATIONS

1. We recommend that hypothyroid patients above 50 years of age undergo routine screening for hearing loss.
2. The study can be repeated with the exclusive evaluation of individuals with Hashimoto's thyroiditis to have a specific prevalence for this subset of patients.
3. A cohort study involving hypothyroid patients diagnosed with hearing loss can be carried out to determine whether there is improvement in hearing thresholds upon administration of levothyroxine.

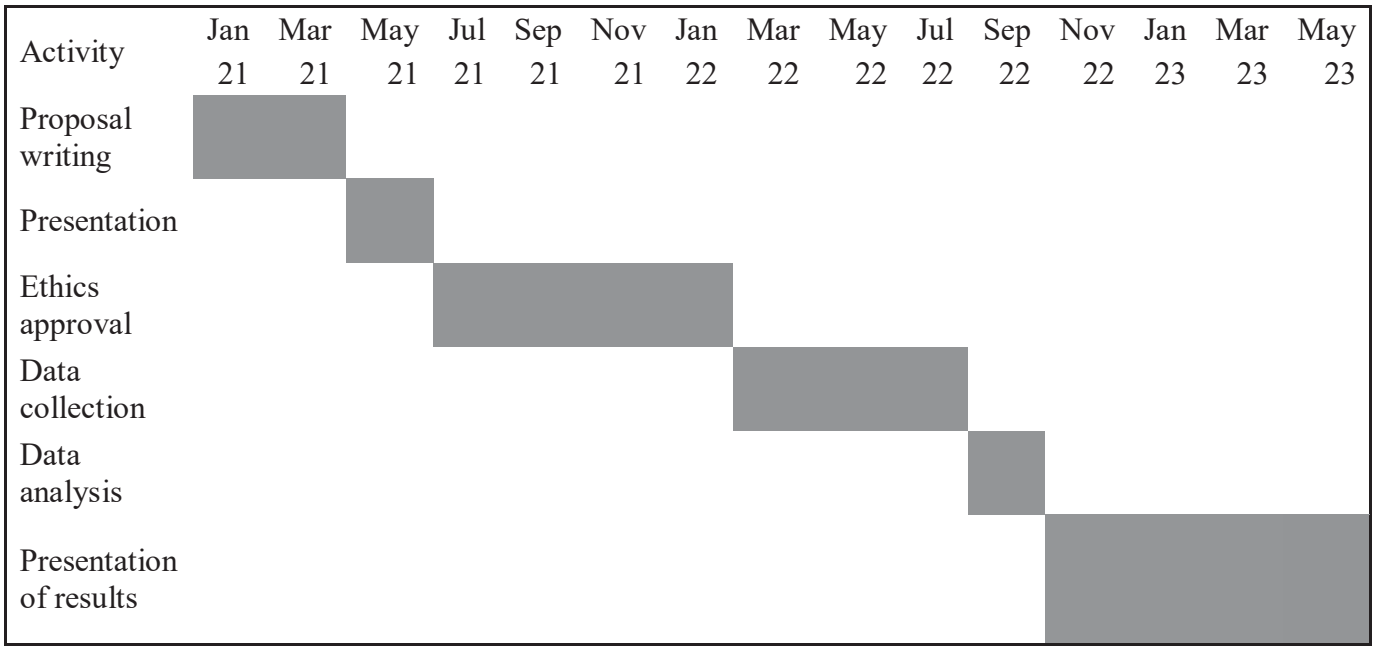
5.4 STUDY LIMITATIONS

The limitations of this study included the following:

1. Up to 39.2 % of the patients were classified as having an unknown cause of hypothyroidism as no clear cause of the hypothyroidism had been identified at the time of enrollment into the study. Thyroid peroxidase antibodies and/or ultrasonographic features to suggest Hashimoto's thyroiditis had not been carried out.

2. Some of the patients were on treatment even though their levels of TSH were high (thus biochemically hypothyroid) at the time of enrollment into the study. This may have acted to alter their hearing thresholds.
3. The absence of age and sex matched controls limits the interpretation of the results obtained.

TIME FRAME



BUDGET AND FUNDING

Table 3: Budget

ITEM		**AMOUNT (Kenya shillings)**
STATIONERY, PRINTING & BINDING	-	20,000
PURE TONE AUDIOMETRY	@800	61,600
BIOSTATISTICIAN	-	30,000
MISCELLANEOUS	-	20,000s
TOTAL		**131, 600**

This study was funded by the Kenyatta National Hospital Research Department.

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APPENDICES

APPENDIX I (a): GENERAL INFORMATION SHEET

Participant Study Number: …….……

Study Title: The prevalence of hearing loss among patients with hypothyroidism at Kenyatta National Hospital

Principal Investigator: Dr. Evans Ongoko Malenje (Mmed student in Otorrhinolaryngology, Head and Neck Surgery, University of Nairobi)

Supervisors: Dr. Peter Mugwe, ENT Consultant

Dr. Sheikh, ENT Consultant

Dr. Stanley Ngare Endocrinologist, KNH

Ms. Serah Ndegwa, Consultant Audiologist, UoN

Introduction

This is an explanation of the study being conducted by the above listed researcher. Hypothyroidism is a condition resulting from reduced thyroid hormone production in the body or inability of the hormone to exert its effects in the body. This may be the result of reduced dietary intake of iodine or may be caused by other conditions affecting the brain or the thyroid gland. Low thyroid hormone results in low energy levels within various cells in the body and these cells are therefore, rendered incapable of carrying out their functions. One of the areas that may be affected by low thyroid human levels is the ear and this results in loss of hearing among those affected.

The researcher is trying to investigate the prevalence of hearing loss among persons diagnosed with hypothyroidism. This will be carried out by recruiting known hypothyroid patients and carrying out hearing assessment within the Ear, Nose and Throat Clinic at Kenyatta National Hospital.

In this form, we have provided information that is required for the research. We request you to go through it and ask any questions that you may have before agreeing to participate in this study.

As some information may be sensitive, you may request more privacy and limit the interaction to only two people that is you and the principal investigator.

Purpose of the study

The results of this study will help determine whether there is significant hearing loss among patients with hypothyroidism at the Kenyatta National Hospital. If significant, it will be used in deciding on the routine hearing assessment of hypothyroid patients and make appropriate referrals for rehabilitation.

Description of study

Before being enrolled to participate in this study, you will be permitted to raise questions about the study. The investigator will be available to answer all your concerns and it is only after you are satisfied that a written consent will be availed to you for signing as an affirmation that you accept to take part in the study. A number of personal details will be taken by the researcher or their research assistant. This will include your demographic data, your occupation, any illnesses suffered in the past or presently, surgical procedures undergone in the past or whether you have taken any medications in the past or are taking them presently. You will then be subjected to a physical examination that consist of a general exam as well as examination of the ear, nose and throat. Hearing assessment will then be carried out to find out whether there is hearing loss.

Risks Involved

This study will be conducted ethically. There are no health risks associated with taking part in this study. No additional charges will be incurred by the patients and no treatments will be withdrawn if you chose not to take part in the study or if you drop out from the study for whatever reason.

Benefits

Patients will get an opportunity to know the status of their hearing and those in whom hearing loss is diagnosed, appropriate referrals to audiologists or otolaryngologists will be done.

Confidentiality

To ensure confidentiality, every participant will use a code number. Names will not be used so as to guarantee confidentiality for all patients.

Payments

Patients will not incur any extra costs above normal treatment and there are no monetary benefits.

Use of Data Collected

The information coming out of this study will be shared only upon authorization by the KNH – UON Ethics committee. It is to be used for advancement of scientific knowledge through conferences, journals and specialities meetings.

Rights as a participant

Patients can voluntarily withdraw from this study at any time without suffering any penalties

Investigator's declaration

I, as the principal investigator, declare that I have not received any financial payments, nor the supervisors, from any company or institution, to finance this study. Such action will and may compromise the study.

In case you have any questions please feel free to seek information through the contacts given below;

Principal Investigator:
Dr. Evans Ongoko Malenje,
Otorrhinolaryngology, Head and Neck Surgery,
School of Medicine, UoN.
P.O. Box 60142-00200, Nairobi.
Email: emalenje@gmail.com
Mobile Number: 0724632094

Signature…….. Date……

Supervisors:

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Consultant Audiologist and Lecturer,
Department of Surgery,
University of Nairobi.

KNH-UoN ERC Secretary,
Phone 2726300 ext. 44102,
email uonknh_erc@uonbi.ac.ke

APPENDIX 1 (b): CONSENT FORM - ENGLISH

I……freely give consent to take part in the study conducted by Dr. Evans Ongoko Malenje, the nature of which has been explained to me by her or her research assistant. I have been informed and I have understood that my participation is entirely at my own will. I comprehend that if I so wish, I can freely withdraw from the study and this will not in any way alter the care being given to me. The results of the study may directly be of benefit to me, my kin and other patients.

Signature/ left thumb print (self)……

Date……

Witness: Name: …….

Signature: ……..

APPENDIX I (a) – KARATASI YA HABARI YA JUMLA

Utangulizi

Yafuatayo ni maelezo kuhusu utafiti unaofanywa na mtafiti aliyejitambulisha awali. Maradhi ya *hypothyroidism* yanatokana na upungufu wa homoni ya *thyroid* mwilini au mwili kutokuwa na uwezo wa kuitumia homoni hiyo. Upungufu wa homoni ya *thyroid* unasababisha seli za mwili kukosa nguvu kiasi cha kutotekeleza majukumu mbali mbali ya kimetaboliki. Baina ya viungo vinavyoadhirika na upungufu wa homoni hii ni vile vinavyowezesha kusikia. Utafiti umebaini ya kwamba baadhi ya watu walio na tatizo la *hypothyroidism* wana upungufu wa kusikia.

Mtafiti anawania kubaini ni watu wangapi kati ya walio na tatizo la *hypothyroidism* wana upungufu wa kusikia na kulinganisha matokeo hayo na matokeo yatakopatikana kwa sampuli ya watu wasiokuwa na shida ya *hypothyroidism*. Mpangilio wa utafiti huyo utajumuisha kutathmini viwango vya homoni ya *thyroid,* kisha washiriki katika utafiti huu watafinywa vipimo vya kusikia katika kliniki ya Ear Nose and Throat, hospitali kuu ya Kenyatta.

Katika fomu hii, tumetoa habari zitakazohitajika kutekeleza utafiti huu.Tunakusihi uyasome maelezo haya na uyaulize maswali yatakayoibuka kabla ya kukubali kushiriki katika utafiti huu.

Baina ya maelezo yatakayohitajika yatakuwa ya kibinafsi. Ikiwa utahitaji usiri zaidi, unaweza ukaomba mazungumzo yatekelezwe baina yako na mtafiti mkuu pekee.

Lengo la utafiti

Tunatumai kwamba utafiti huu utasaidia kuangazia uwepo wa upungufu wa kusikia kati ya wagonjwa wanaougua ugonjwa wa *hypothyroidism* katika hospitali kuu ya Kenyatta. Iwapo tatizo hili lipo, utafiti huu utasaidia kutoa uamuzi wa kufanya uchunguzi wa kusikia kwa wagonjwa wote walio na upungufu wa homoni ya *thyroid*. Kando na haya, wagonjwa watakaopatikana na matatizo ya kusikia watapewa rufaa ya kumuona mtaalamu wa maswala ya kusikia ili kupata usaidizi.

Maelezo ya utafiti

Kabla ya kuanza kushiriki katika utafiti huu, utakubiliwa kuuliza maswali yote yanayohusiana na utafiti huu. Mtafiti atayajibu maswali yako. Ni baada tu ya hilo ndipo utatia sahihi idhini ya kukubali kushiriki. Matafiti au mzaidizi wake atahitaji maelezo kadhaa ya kibinafsi yatahitajika na haya yatajumuisha taarifa za kibinafsi kama umri, ajira, historia ya maradhi, upasuaji na matibabu mengine yaliyofanyika au yanayoendelea kwa sasa. Mshiriki atafanyiwa uchunguzi wa mwili na masikio, mapua na koo. Sampuli ya damu itachukuliwa ili kupima viwango vya homoni ya *thyroid*. Utathmini wa viwango vya kusikia utafanywa ili kubaini iwapo kuna upungufu wa aina yoyote.

Hatari zinazohusika

Utafiti huu unapaniwa kufanywa kwa njia ya uadilifu inayoambana na muongozo wa kamati ya uadalifu ya hospitali kuu ya Kenyatta na Chuo kikuu cha Nairobi. Hakuna madhara ambao yatatokana na kushiriki kwako katika utafiti huu. Hakuna gharama yoyote itatokana na kuwa mshiriki na iwapo utachagua kujiondoa hutapata adhabu au kunyimwa majtibabu kwa namna yoyote.

Faida

Waashiriki katika utafiti huu watapata fursa ya kufahamu afya ya kusikia. Watakaopatikana na upungufu watapewa rufaa ya kuwaona wataalamu wa kusikia.

Usiri

Ili kuwahakikishia washiriki usiri wa habari zao za kibinafsi, nambari maalum zitatumika kuwatambulisha. Majina rasmi hayatumika ili kumuhakikishia mshiriki usiri.

Gharama

Hakuna gharama yoyote zaidi ambayo mshiriki atapata kwa kuhusika katika utafiti huu. Washiriki hawatapata malipo ya aina yoyote kutokana na kukubali kwao kujumuishwa kwenye utafiti huu.

Matumizi ya Data

Matokeo ya utafiti yatakoibuka yatasambazwa tu ikiwa usambazaji huo utaidhinishwa na kamati ya maadili ya hospital kuu ya Kenyatta na Chuo Kikuu cha Nairobi. Usambazaji waweza ukahitajika kwa minajili ya kukuza ujuzi wa kisayansi na hilo litafanyika kupitia makongamano mbalimbali, machapisho ya kisayansi na mikutano ya wataalamu.

Uhuru wa mshikiri.

Mshiriki ana uhuru wa kujiondoa kwa hiari wakati wowote. Hakuna adhabu yoyote itakayotolewa kufuatia uamuzi huo.

Tamko la Mtafiti

Mimi kama mchunguzi mkuu natangaza ya kwamba sijapata malipo yoyote ya kifedha kutoka kwa usimamizi wa hospitali kuu ya Kenyatta, kampuni yoyote ya dawa au nyingine yoyote ili kufanya utafiti huu. Iwapo utahitaji kupata maelezo zaidi, waweza kufanya hivyo kupitia kwa anwani zifuatazo;

Mtafiti Mkuu:

Dkt Evans Ongoko Malenje

Idara ya Upasuaji (Kichwa na Shingo)

Shule ya Matibabu, UoN

Sanduku la Posta 60142-00200, Nairobi.

Barua pepe: emalenje@gmail.com

Rununu: 0724632094

Wasimamizi:

Dkt Peter Mugwe

Mtaalamu wa upasuaji sehemu ya Kichwa na Shingo, Mhadhiri

Chuo Kikuu cha Nairobi, Idara ya Upasuaji.

Simu: 0722513778

Barua pepe: drmugwep@gmail.com

Dkt. Abdifatah Sheikh,

Mtaalamu wa E.N.T, Kichwa na Upasuaji wa Shingo,

Hospitali Kuu ya Kenyatta.

Dkt Stanley Ngare,

Mwanaendokrinolojia,

Hospitali Kuu ya Kenyatta.

Bi Serah Ndegwa

Mtaalamu wa Maswala ya Kusikia

Idara ya Upasuaji

Muhadhiri, Chuo Kikuu cha Nairobi

KNH-UoN ERC Secretary,
Simu: 2726300 ext. 44102,
Barua pepe: uonknh_erc@uonbi.ac.ke

APPENDIX I(b): FOMU YA MAKUBALIANO

Tamko la mshiriki

Mimi.....nimesoma au nimesomewa yaliyochapishwa katika fomu hii. Nimepata maelezo kutoka kwa mtaalamu wa utafiti. Maswali yangu yamejibiwa kwa lugha ninayoelewa. Ninaelewa ya kwamba, kushiriki kwangu katika utafiti huu ni kwa hiari yangu na ninaweza kujiondoa kwa wakati wowote bila kupata adhabu yoyote. Nimekubali kwa hiari yangu kuhusishwa katika utafiti huu. Matokeo ya utafiti huu yaweza kunifaidi mimi, jamii yangu na hata wagonjwa wengine.

Sahihi ya Mshiriki/ Kidole gumba ……

Tarehe ……

Jina la shahidi …….

Sahihi / kidole cha gumba …….

APPENDIX II: DATA COLLECTION FORM

PART A

Study Number…….. Date ……..

PATIENT

A. BIODATA:

1. Age (years) ……..
2. Sex ……..
3. Residence ……..

B. HISTORY

1. **Symptoms**

	Yes		No	
	Right Ear	Left Ear	Right Ear	Left Ear
1. Hearing loss				
2.Tinnitus				
3.Vertigo				
4.Ear Pain				

2. **Thyroid Function Tests** TSH……..

T3……

T4…….

3. **Diagnosis** Hypothyroid ☐ Euthyroid ☐ Hyperthyroid ☐

4. **Subtype** (a) Hashimoto's ☐ Other Thyroiditis ☐ Post Thyroidectomy ☐

Unknown cause ☐

(b) Overt hypothyroidism ☐ Subclinical hypothyroidism ☐

Past Medical and Surgical History

i. **On treatment Yes** ☐ **No** ☐

ii. Duration since diagnosis……..

6. Ear Examination **Right Ear** **Left Ear**

i. Otoscopy

External auditory canal

a. Patent ☐ ☐

b. Stenosed ☐ ☐

Tympanic membrane

a) Normal ☐ ☐

b) Retracted ☐ ☐

c) Bulging ☐ ☐

ii. Rinne's

a) Positive ☐ ☐

b) Negative ☐ ☐

iii. Weber's

Lateralizes to the left ☐

Lateralizes to the right ☐

Central ☐

7. Hearing Assessment **Right Ear** **Left Ear**

i. Level of hearing in dB …….. ……..

ii. Type of hearing loss …… …….

iii. Grade of hearing loss ……. …….