ASSESSMENT OF VESTIBULAR FUNCTION IN PATIENTS WITH CHRONIC SUPPURATIVE OTITIS MEDIA AT THE KENYATTA NATIONAL HOSPITAL

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Head and Neck Surgery , University of Nairobi

DECLARATION

I hereby declare that this research work titled: ASSESSMENT OF VESTIBULAR FUNCTION IN PATIENTS WITH CHRONIC SUPPURATIVE OTITIS MEDIA AT THE KENYATTA NATIONAL HOSPITAL, is my original work. Any reference to work done by other researchers have been duly cited. I also declare that this research work has not been submitted for publication in any journal nor has it been presented for a degree award at any other university.

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LIST OF ABBREVIATIONS

BPPV	Benign positional paroxysmal vertigo
CHL	Conductive Hearing Loss
COM	Chronic Otitis media
CSOM	Chronic suppurative otitis media
dB	Decibels
EEV	European evaluation of vertigo score
ENT	Ear nose and throat
ENG	Electronystagmography
Hz	Hertz
HRCT	High resolution computed topography
KNH	Kenyatta National Hospital
MMP	Matrix metalloproteinases
MRI	Magnetic resonance imaging
PTA	Pure tone audiometry
RCT	Rotational chair testing
SCC	Semicircular canal
SNHL	Sensorineural Hearing loss
SVV	Subjective visual vertical test
SPSS	Statistical package for social sciences
TM	Tympanic membrane
UON-KNH ERC	University of Nairobi-Kenyatta National Hospital ethics and research committee
VOR	Vestibulo-ocular reflex
VCR	Vestibulo-colic reflex
VEMP	Vestibular evoked myogenic potential
VNG	Videonystagmography
VSR	Vestibulospinal reflex
WHO	World Health Organization

CLINICAL DEFINITIONS

Gait Test – This test is done by observing how the subject walks towards the examiner and away from the examiner. Unilateral peripheral disorders generally cause patients to lean or fall towards the side of the lesion.

Fukuda Stepping Test: The examiner asks the subject to march on the spot arms outstretched with their eyes closed. Rotation of 45 degrees or more following 50 steps is suggestive of a peripheral vestibular hypo-function to the side of rotation.

Nystagmus: A rhythmic, slowly forward-quickly backward movement of the eyes.

Romberg's test: In this test, the subject is asked to stand with their feet together eyes closed for 30 seconds. The subject will sway towards the ipsilateral side in those presenting with a unilateral peripheral vestibular or cerebellar disorder. This test may be sharpened by asking the subject to stand with one foot in front of the other, the sharpened Romberg's test.

Spontaneous Nystagmus: In this test, the examiner observes the patient's eyes for nystagmus usually the fast phase of nystagmus is away from the peripheral vestibular lesion.

Gaze Test: The subject fixes gaze on an object and the examiner observes for nystagmus.

Saccades Test: In this test, saccades are examined by asking the patient to alternately fixate, with the head still, on the examiner's nose and then on the finger held at different locations approximately 15 degrees away from the primary position. Inability to quickly and accurately follow the target indicate a central problem.

Smooth Pursuit Test: The subject follows a target without moving the head. The tests results should resemble a smooth sinusoid. The presence of a normal pursuit rules out a central vestibular disorder.

Head Thrust Test: The examiner asks the subject to stare at the examiner's nose as he briskly turns the patient's head from one side to the other while observing eye position. A normal result is obtained when the patient's eyes remain fixed on the target. When the eyes make a compensatory movement after the head is stopped to reacquire the target (a refixation saccade), the test results are abnormal.

Head Shaking Test -The patient is instructed to shake the head vigorously approximately 30 times horizontally. The patient may wear frenzel lenses to inhibit visual fixation. After the

shaking is stopped abruptly, the eyes are observed for nystagmus. With a unilateral loss of labyrinthine function, vigorous nystagmus is typical.

Dynamic Visual Acuity Test: This involves asking a subject to read a Snellen chart at rest and then with their head shaken at 0.2 Hz. A greater than 3-line drop is suggestive of a peripheral vestibular deficit.

Dix-Hallpike Maneuver: This is a positional maneuver test done to elicit vertigo. When the patient is sitting the neck is extended and turned to one side. The patient is then placed supine rapidly, so that the head hangs over the edge of the bed. The patient is kept in this position until 30 seconds have passed if no nystagmus occurs. The patient is then returned to upright, observed for another 30 seconds for nystagmus, and the maneuver is repeated with the head turned to the other side

Epley's Maneuver: Patient is placed into the Dix-Hallpike position for the affected side and inducing vertigo. The head is then turned in two 90-degree increments towards the opposite side, stopping until any nystagmus resolves, until the nose is pointing 45 degrees from the ground. The patient is then brought into a sitting position. The maneuver is repeated until no further nystagmus is elicited.

Semont Maneuver: The patient's head is turned 45 degrees to the unaffected ear while in the sitting position. The patient is then rapidly swung sideways onto the involved side provoking vertigo. After the vertigo subsides the patient is rapidly swung sideways to the uninvolved side through a 180-degree motion. This is done so as to dislodge otoconia from the cupula and move them out of the posterior semicircular canal into the vestibule where they are harmless

ABSTRACT

Background: Chronic suppurative otitis media is a chronic inflammation of the middle ear and mastoid cavities. It may be associated with inner ear functional damage resulting in disorders of hearing and balance. The pathological factors which diffuse through the round window causing cochlear damage can also cause vestibular damage.

Objective: This study evaluated the vestibular functions of patients presenting with Chronic suppurative otitis media at the Kenyatta National Hospital.

Study Design and setting: This was a cross-sectional prospective study on patients presenting with Chronic suppurative otitis media at the Kenyatta National Hospital Ear Nose and Throat department.

Methodology: Patients aged eighteen years and above who were recruited in the study were eighty. Convenient sampling technique was used to recruit participants. History and physical examination including pure tone audiometry were done followed by clinical vestibular assessment tests.

Data Management and analysis: Data was expressed as means and standard deviation. Correlations of the variables and presence of vestibular disorders were established by use of chi squared test and odds ratios with a p value of <0.05 being significant.

Results: Among eighty patients recruited into the study,15 (18.75%) had a positive history of vertigo. Patients with a vestibular disorder from the clinical vestibular tests done were 6(7.5%)**.** There was spontaneous nystagmus and gaze evoked nystagmus in 2(2.5%) of the patients, abnormal dynamic visual acuity in 4(5%), head shaking nystagmus in 5(6.3%), positive head thrust test in 6(7.5%) and an abnormal fukuda step test in 5(6.3%) of the patients. Duration of disease, sensorineural type of hearing loss and a positive fistula test were the risk factors identified as associated factors to vestibular disorders. The mean duration of disease for the patients with vestibular disorders was 51.7±10.8 years while for those without vestibular disorders was 20.4±16.5 years with a p value <0.001. Patients who had a fistula test were 5(6.3%) all of whom were diagnosed with a vestibular disorder with a p value <0.001.

Conclusion: Patients with a longer duration of CSOM, sensorineural hearing loss and a positive fistula test were more likely to develop vestibular disorders and should have routine vestibular assessment done.

1.0 CHAPTER ONE: INTRODUCTION

Chronic suppurative otitis media (CSOM) is defined as a chronic inflammation of the middle ear and mastoid cavities[1]. The WHO definition requires only two weeks of otorrhea. CSOM is characterized by recurrent or persistent ear discharge through a Tympanic Membrane (TM) perforation with a permanent pars tensa or pars flaccida abnormality. Chronic Otitis Media (COM) may be classified as mucosal, squamous or healed. The mucosal and squamous subtypes may further be classified as either active or inactive.

CSOM usually develops in the first years of life but may also persist to adulthood. Every year, there are 31 million new cases,22.6% of whom is in children below 5 years [2]. According to a study done by Simoes et al in 2015 in Kenya, the prevalence of chronic otitis media is 15/1000 of which the highest prevalence was in rural Rift Valley schoolchildren with a prevalence of 24/1000 [3].

The most commonly isolated organisms in CSOM are Pseudomonas Aeruginosa followed by Staphylococcal aureus [4] .Locally, in a study done by Aduda et al [5] the predominant micro-organisms were Proteus followed by Enterococcus, Staphylococcal Aureus and Pseudomonas while Mwaniki et al [6] found the most predominant microorganism to be isolated to be staphylococcus followed by Pseudomonas, Proteus and Escherichia coli.

Patients with CSOM clinically present with otorrhea and hearing loss. The hearing loss can be of different types either Conductive hearing loss (CHL), Sensorineural hearing loss (SNHL) or Mixed hearing loss. SNHL occurs when inflammatory mediators enter the inner ear through the round window causing hair cell loss. Diagnosis of CSOM is based on history and clinical examination which includes otoscopic examination. On otoscopy, perforations seen can either be central or marginal, total or subtotal. A 512-Hertz (Hz) Tuning fork test is a critical part of the diagnosis to establish if there is hearing loss and whether it is conductive or sensorineural. Pure Tone Audiometry (PTA) should be done in all patients with CSOM to establish the type and degree of hearing loss.

Due to anatomical proximity, the pathologic factors causing SNHL in CSOM may affect the vestibular system thus causing vestibular disorders [7][8][9] .These vestibular disorders adversely affect the quality of life of the patient hence vestibular assessment tests should be routinely done in patients with CSOM who are at risk of developing vestibular disorders.

1.1 Vestibular Disorders in CSOM

1.1.1 Pathophysiology of vestibular disorders in CSOM

Recurrent infections in CSOM may lead to the accumulation of toxins within the middle ear. These toxins may pass into the inner ear causing an alteration of proteins subsequently leading to cochlea and vestibular damage. In addition, presence of a cholesteatoma may cause erosion of the bony labyrinth due to the associated osteolytic enzymes leading to a labyrinthine fistula. This labyrinthine fistula may consequently cause vertigo. Topical aminoglycoside antibiotics have also been implicated in causing vestibular injury.

1.1.2 Clinical Presentation of Vestibular Disorders in CSOM

Chronic ear discharge and hearing loss are a common presentation in CSOM. The peripheral vestibular deficit occurs gradually and many patients are initially able to compensate without overt symptoms. Once the peripheral vestibular deficit is present; the patients present with vertigo and may also have nausea or vomiting which correlate with the vertiginous attacks.

The European Evaluation of Vertigo scale (EEV) is a physician-administered questionnaire which assesses vestibular syndrome symptoms which include illusion of movement, duration of illusion, motion intolerance, neurovegetative signs, and instability [(10)] .Each symptom is scored between zero and four with zero being presence of no symptoms and four being worsened symptoms.

1.1.3 Clinical Vestibular Assessment Tests

Clinical examination of eye movements may help differentiate between peripheral and central vestibular disorders. Once the vestibular system is involved in CSOM, the input from the Semicircular canals (SCC) cause the eyes to turn attempting to compensate for the head rotation which has been perceived. The eyes are unable to continue to rotate in the same direction for prolonged periods. Quick resetting movements then occur that take the eyes back to their neutral position causing nystagmus which is defined as a rhythmic, slowly forward-quickly backward movement of the eyes[(11)]. The direction of nystagmus is described according to the direction of the fast phase. The eyes appear to "beat" in the phase of the fast direction. This kind of nystagmus, which is often labeled “spontaneous nystagmus”, continues until the asymmetry of vestibular activity is restored to normal or until the central nervous system adapts to the vestibular lesion[(11)].

Examination of abnormal eye movements can be accurately performed using frenzel lenses whose main function is to inhibit visual fixation during vestibular examination. The tests which test for the vestibulo-ocular reflex include includes the spontaneous and gaze nystagmus test, dynamic visual acuity test, saccades test, smooth pursuit test, head shake test, head thrust test tests and the Dix Hallpike positional maneuver test. Other tests which test for the vestibulospinal reflexes include the gait test, Romberg's test and fukuda stepping test.

1.1.4 Laboratory Vestibular Assessment Tests

These tests include Electronystagmography (ENG), bithermal caloric test which evaluates the integrity of the lateral semicircular canals, the Rotatory chair test (RCT), Vestibular evoked myogenic potentials (VEMP) and computerized platform posturography. Bithermal caloric test is very sensitive to unilateral lesions of the peripheral vestibular system as each ear is stimulated separately by the examiner.

1.1.5 Management of Vestibular Disorders in CSOM

Management of vestibular disorders in CSOM involve vestibular rehabilitation therapy, medication and/or surgery. In the case of CSOM causing Benign Paroxysmal Positional Vertigo (BPPV), the aim of treatment is to move otoconia from the SCC through the crus communis back into the utricle through repositioning maneuvers such as the Epley's maneuver and the Semont maneuver [(11)].

Medication used in management of vestibular disorders include vestibular suppressants which reduce the intensity of vertigo and nystagmus and antiemetics which control vomiting and nausea. Vestibular suppressants include anticholinergics, antihistamines like betahistine and benzodiazepines

In the case of cholesteatoma causing vestibular disorders, mastoidectomy is indicated which may either be a canal wall down mastoidectomy or a canal wall up mastoidectomy (12)(13). Cholesteatoma is removed with great care from the canal fistula if there is presence of a labyrinthine fistula(14). The labyrinthine fistula is then repaired with bone dust or fascia.

2.0 CHAPTER TWO: LITERATURE REVIEW

The vestibular system comprises parts of the inner ear and brain sections that process the sensory information involved in regulating balance and eye movements. The vestibular system forms the basis for the vestibulocollic reflex (VCR), the vestibulospinal reflex (VSR) and the vestibulo-ocular reflex (VOR) [(1)]. These reflexes stabilize posture and facilitate gait.

The VOR mechanism occurs when vestibular system activation induces eye movement and stabilizes images on the retina. The semicircular canals detect head rotation, they then send their impulses through the vestibular ganglion via the vestibular nerve which end in the brainstem's vestibular nuclei. Fibers then cross into the abducens nucleus of the contralateral side and synapse with a pathway which projects to the lateral rectus of the eye. They also synapse with a pathway that projects by the medial longitudinal fasciculus to the oculomotor nucleus of the contralateral side which then activates the medial rectus [(11)].

The VSR coordinates the head and neck movement with the body with the aim of maintaining the head in an upright position. The vestibular nuclei receive information about changes in the head's orientation through the vestibulocochlear nerve after which they relay motor commands via the vestibulospinal tract. The vestibulospinal tract consists of the lateral vestibulospinal tract and the medial vestibulospinal tract. The medial vestibulospinal tract stabilizes the head position while the lateral vestibulospinal tract helps maintain upright and balanced posture[(11)].

Vestibular disorders can occur as a complication of CSOM. The same pathologic material penetrating to the inner ear and causing SNHL also affect the vestibular system. In the presence of vestibular dysfunction, the vestibular system's function for sensing head movement and countering them with reflexive eye movements and postural adjustments is impaired. Recurrent infections in CSOM may lead to the accumulation of toxins within the middle ear. These toxins are produced by the bacterial organisms in CSOM and can be either exotoxins or endotoxins [(15)]. The round window is the major pathway through which toxic substances pass from the middle to the inner ear in CSOM [(16)(17)]. Other routes of spread of toxic substances into the inner ear include through the oval window, the blood vessels and lymphatics [(18)(19)] . Once in the inner ear, the toxins cause an alteration of proteins subsequently leading to cochlea and vestibular damage. These toxins also spread to the semicircular canals by damaging the macule of the utricle whereby they release otoconias eventually forming BPPV.

Inflammation from the middle ear in CSOM affects the vestibular labyrinth leading to erosion of the bony labyrinth. This usually occurs when there is presence of a cholesteatoma in which cells produce cytokines as a response to various inflammatory processes. These cytokines include tumor necrosis factor alpha (TNF-α) and interleukin-1β (IL-1β) which cause osteoclast mediated bone resorption thus causing erosion of the bony labyrinth [(20)]. In addition to this, in cholesteatoma, there is an imbalance in Matrix Metalloproteinases (MMP) regulation with an overall up-regulation of MMP expression and a decrease in MMP inhibitors leading to degradation of the extracellular matrix and increased bone destruction [(20)]. Cholesteatoma especially of the posterior-superior pars tensa variety is the most frequent cause of lateral canal fistulae. The lateral semicircular canal is more susceptible to erosion because it lies in the path of an enlarging cholesteatoma and also because of its prominence in the aditus [(21)]. Labyrinthine fistulas permit extension of the middle ear infection into the perilymph and the resultant circumscribed labyrinthitis causes vertiginous attacks. The presence of spontaneous nystagmus indicates presence of a fistula and it beats towards the non-diseased contralateral ear.

Some of the topical antibiotics used in management of CSOM particularly the aminoglycoside antibiotics have been implicated in causing vestibular injury [(22,23,24)]. Once the aminoglycosides have been instilled, there may be active and passive transport of them through the round window. Vestibular disease mostly occurs in the crista ampullaris of the semicircular canals [(22)]. The vestibular injury may occur early on with positional nystagmus and may lead to disequilibrium and oscillopsia if there is severe vestibular toxicity.

Previous studies have been done to evaluate the vestibular function of patients with CSOM. In a literature review of current evidence on peripheral vestibular symptoms secondary to otitis media ,several studies involving patients with COM were evaluated [(25)]. Patients who had complaints of dizziness with or without vertigo were 48.36%. Patients who had ENG tests performed and found to have spontaneous nystagmus were 56%. Of the patients who underwent caloric tests ,34.3% had abnormal caloric responses on the affected side. Clinically, there was no significant relation between the presence of vestibular symptoms and abnormal caloric results. In Rotatory chair testing, abnormal responses were positively associated with the presence of vertigo. Most of the tests performed e.g., ENG, VEMP and RCT were found to be affected by the middle ear status. Tests which were not affected by the status of the middle ear included clinical tests such as gait testing, static and dynamic postural

testing, vestibulo-ocular reflex testing, cerebellar function testing, neurologic assessment, the video-head impulse test among others.

In a study done by Mostafa et al[26], he found that there was a correlation of vestibular disorders with CSOM. He assessed the vestibular functions in 60 patients with CSOM in his study. These patients underwent various vestibular tests which included the gait test, spontaneous nystagmus testing, the head impulse test, the head shake test and positional vestibular testing. Instrumental vestibular tests which were done were Infra-red VNG, Rotatory chair test, Computed dynamic posturography and VEMP. The findings were, in 53.5% of the patients, there was a positive history of vertigo,61.65% of the patients had caloric hypofunction while 70% of the cases had Rotatory chair abnormalities and 25% of the patients had abnormal VEMPs+. Duration of the disease had a positive correlation with vestibular dysfunction. Wang et al[27] similarly found a correlation with vestibular disorders and COM in which the VEMP response was significantly affected by COM.

Siampara et al [28] assessed the audio vestibular functions of 75 patients with unilateral COM. Findings of any spontaneous or positional nystagmus were noted if present. Audiological evaluation using PTAs of these patients was then done followed by vestibular assessment tests; cold air caloric tests and ENG tests. ENG recording of saccades and bithermal caloric induced nystagmus revealed canal paresis on the diseased side in 5.3% of the patients who had 15 years history of otorrhea showing that longer the duration of COM the more likelihood for vestibular dysfunction to be present.

Gianoli et al [29]) in his study to determine the incidence of caloric and rotational chair testing (ROT) abnormalities in 25 patients with CSOM found that 76% of the patients had abnormal Caloric tests and 72% of the patients had abnormal Rotational chair testing. 44% of the patients had positive history of vertigo. Similarly, Paparella et al[30] found abnormal caloric response in patients with COM.

Lee in Sik et al [31] evaluated 25 patients with unilateral COM for vestibular dysfunction. Vestibular function was assessed using head-shaking nystagmus test, vibration-induced nystagmus test, air caloric testing and subjective visual vertical (SVV) tests.24% of the patients had canal paresis on COM-sided ears while two patients had canal paresis on the contralateral side. There was pathologic head shaking nystagmus in 48% of the patients, pathologic vibration induced nystagmus in 28% of the patients. Overall,80% of the patients had abnormal vestibular function tests.

Wang et al [11] in his study on vestibular evoked myogenic potentials in COM before and after surgery found that middle ear pathology of COM affected the VEMP response.

Masters and Marsh [(32)] and Schaaf [(33)] recognized vestibular disorders as a possible sequela to COM. Schaaf found that children with history of otitis media had a significantly higher incidence of vestibular disorders than those without such a history. Bhatia and Deka [(34)] reported in their study of vertigo cases that 3:6% of vertigo results from middle ear disorders with conductive deafness.

One of the pathophysiological aspects of how CSOM causes vestibular disorders has been shown to be through the labyrinthine fistulas. These fistulas occur when the bony labyrinth in patients with CSOM is eroded. Busaba et al[(35)]showed that in COM, labyrinthine fistulas occur almost exclusively in the presence of cholesteatoma.56% of the patients with COM complicated with labyrinthine fistula had dizziness on presentation while 97% of the patients had cholesteatoma. He thus concluded that in COM, labyrinthine fistulas occur almost exclusively in the presence of a cholesteatoma.

Kazuo et al[(36)] evaluated 23 patients with COM between the ages of 25 to 71 years for vertigo. The patients consisted of 11 males and 12 females. The most common complaint in these patients was a whirling type of vertigo. Under wearing frenzel glasses, he observed spontaneous nystagmus in 40% of the patients, positional nystagmus in 27% of the patients and positioning nystagmus in 32% of the patients. Under electronystagmography, the detection rate of nystagmus was increased. Saccadic or unidirectional saccadic pursuit was found in 30%. Positive fistula sign was not observed preoperatively even though two of the cases had a fistula in the lateral semicircular canal during surgery.

Kazmierczack et al[(37)] in his study did ENG testing in 60 adult patients with COM . The results showed that dysfunction of the inner ear was found mainly in cases of cholesteatoma indicating a positive correlation between COM and vestibular dysfunction.

No studies have been done on prevalence of vestibular disorders in patients with CSOM locally. Studies done on CSOM reveal a high disease burden which suggests an equally high prevalence of vestibular disorders in CSOM.

2.1 Study Justification

CSOM causes vestibular dysfunction once functional damage to the inner ear occurs. The vestibular disorders in CSOM cause the patients to present with dizziness, vertigo and gait unsteadiness and this can adversely affect the patient's quality of life as they impair the ability to perform normal daily activities. Most patients being managed for CSOM are not routinely evaluated for vestibular disorders. This study sought to establish the prevalence of vestibular dysfunction in patients with CSOM at KNH and will form a substantive basis for whether vestibular assessment should be routinely performed in patients with CSOM and will also evaluate the extent of labyrinthine involvement in patients with CSOM.

2.2 Research Question

What is the prevalence of vestibular disorders in patients with Chronic suppurative otitis media at the Kenyatta National Hospital?

2.3 Objectives

2.3.1 Broad Objective

a) To determine the prevalence and risk factors for vestibular disorders in patients with chronic suppurative otitis media at the Kenyatta National Hospital.

2.3.2 Specific Objectives

a) To determine the prevalence of vestibular symptoms in patients with chronic suppurative otitis media.

b) To determine the signs and symptoms associated with vestibular disorders in patients with chronic suppurative otitis media.

c) To determine the risk factors for vestibular disorders in patients with chronic suppurative otitis media.

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was a Prospective Cross-sectional study.

3.2 Study Site

The study was conducted at the Kenyatta National Hospital ENT clinic.

3.3 Study population

The study population included patients on follow-up for chronic suppurative otitis media.

3.4 Inclusion Criteria

a) Adults ≥18 years with Chronic Suppurative Otitis Media.

b) Patients who consented to the study.

3.5 Exclusion Criteria

a) History of previous ear surgery

b) History of head trauma

c) Patients with disabilities that prevented them from following instructions.

d) Patients with history of diabetes

e) Patients with history of hypertension

f) Patients with metabolic disorders e.g., Gout

3.6 Sample Size Calculation

Sample size was calculated using the Cochran formula [38]

$$n = \frac{z^2 p(1-p)}{d^2}$$

Where n = calculated sample size

z = statistic representing 95% confidence level=1.96

p =prevalence of vestibular vertigo that found prevalence to be 4.9% (39)

d = desired level of precision

$$n = \frac{1.96^2 \times 0.049 \times (1-0.049)}{0.05^2}$$

n=71.6 rounded off to 72

Add 10% to take care of those who drop out

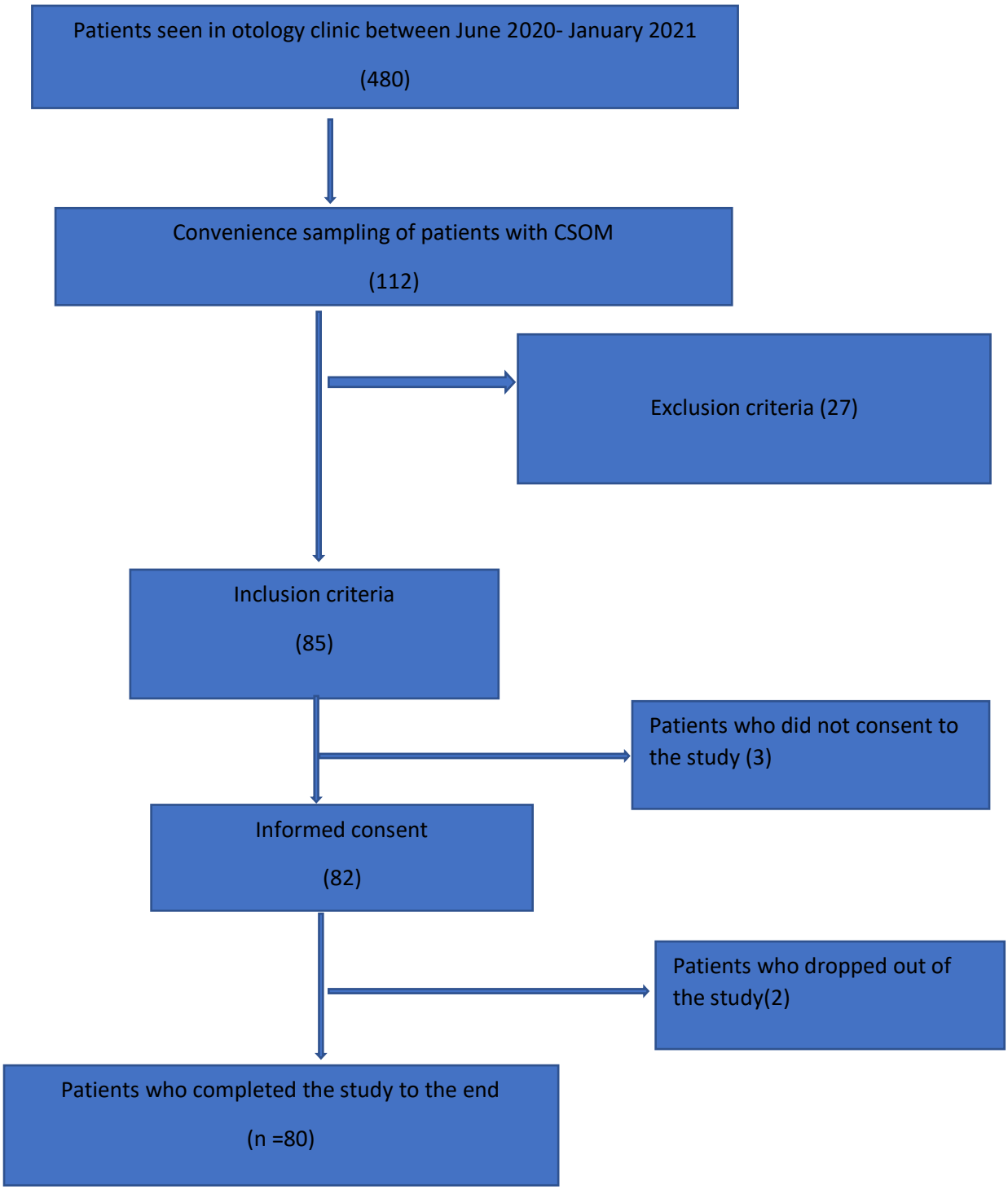
72+ (72×10/100) =79.2 rounded down to 79

n=79

3.7 Sampling Technique

Sample recruitment was done by a convenience sampling technique until the desired sample size was reached.

3.8 Flow Chart for patient selection



3.9 Study Tools

a) Data collection sheet (Appendix 111)

b) Pneumatic otoscope

c) 512 Hz Tuning fork

d) Pure tone audiogram (AC33)

e) Snellen chart

f) Frenzel glasses

3.10 Procedure and Data Collection

Patients who met the inclusion criteria and gave consent were recruited into the study. The recruited patients with CSOM then underwent complete history taking which included filling in the European evaluation of vertigo questionnaire(10)(Appendix 1V). Both ears were then examined using an otoscope followed by tuning fork tests examination. Fistula tests using a pneumatic otoscope was then done by applying pressure to the subject's ear canal using the Siegel's speculum and observing eye movements for nystagmus using frenzel lenses.

The subjects then proceeded to have PTAs done by one audiologist and the same equipment was used for each test to reduce interpersonal and inter instrument bias. PTA for both air conduction and bone conduction was done in a sound proof audiology room. The subjects were then explained to that they would hear tones of short duration in the ear that was being tested and that these tones would become faint and they would be expected to signal when they hear the tone by pressing a button once as they hear the tone however faint it would be. Head phones were then placed on the subject's ears and each ear was tested separately.

The audiometer used was the Interacoustics Clinical Audiometer AC33.Threshold determination was done using the Hughson-Westlake method by beginning with the better ear at 1000Hz and a clear audible signal of 60db was then presented to the ear. If this tone was not heard, the intensity was increased in steps of 5 dB until a response was obtained with the duration being 1-2 seconds. The intensity was also decreased in steps of 10 dB up to when it was inaudible and when the subjects failed to respond, the increase and decrease was then done until 2 responses at the same level and for other frequencies 2000Hz, 4000Hz, 8000Hz, 500Hz and 250Hz in that order were obtained and plotted on the audiogram.

The pure tone average was then obtained by averaging the 4 mid frequencies of 500Hz, 1000Hz, 2000Hz and 4000Hz. The other ear was also tested in the same order. Bone conduction test was done by placing a thin metal head band attached to a small bone vibrator on the patients head so that the vibrator part rested on the mastoid bone. This was done if there was a difference of 25db or greater in hearing levels between the two ears. Masking was done when indicated. The findings were then recorded in a data collection sheet (Appendix 1V)

After the PTA, the clinical vestibular assessment tests were done and the data was collected in the data collection sheet for vestibular assessment tests (Appendix V)

The vestibular assessment commenced by assessing the subjects balance while the subject was standing with the following tests:

a) Gait test– This was done by observing how the subject walked towards the examiner and away from the examiner for a distance of 10 meters. If the subject staggered or consistently leaned or fell towards one side; this would indicate a unilateral peripheral lesion on the side on which the subject leaned or fell towards[39].

b) Romberg test – The subject was asked to stand upright with feet together, eyes closed and hands by their side. If the subject tended to sway and lose balance while the eyes were closed the Romberg's test was positive and this would indicate a vestibular disorder[40].

c) Fukuda test– A small piece of tape was put on the floor in front of the subject's toes then the subject was asked to step in place for 20-30 seconds with arms outstretched and eyes closed. After performing the test, a small piece of tape was placed on the floor along the front of the subject's toes and the angle of this line with the initial line was measured. Rotation of the subject for greater than 45 degrees showed a positive fukuda test and indicated a unilateral loss of vestibular tone in the side to which the subject had rotated[40].

The subject then proceeded to do the Dynamic visual acuity test. This involved asking the subject to read a Snellen chart at a 3metres distance at rest and then with their head shaken. A greater than 3-line drop was suggestive of a peripheral vestibular deficit [40].

The subjects were then seated down and the following eye examination tests were done using frenzel lenses in place

a) Spontaneous nystagmus test– The eyes were observed for nystagmus whether it was present or not. Spontaneous nystagmus for peripheral lesions beats in the direction of the fast phase[11].

b) Gaze test – This was done by having the subject fix gaze on an object. Right lesion has left beating nystagmus (towards the unaffected ear). Gaze to the left makes the nystagmus even worse [11].

c) Saccades test – The subject with the head still was asked to alternately fixate on the examiner's nose and then on the finger held at different locations approximately 15 degrees away from the primary position[11]

d) Smooth pursuit test- The subject was asked to follow an object being moved across their full range of horizontal and vertical eye movements. The subject was meant to follow the object without moving their head. The test results should resemble a smooth sinusoid. Abnormal pursuit and vertigo indicate a central lesion. Normal pursuit and vertigo indicate a peripheral lesion[11].

The subject was then asked to sit on an examination couch and the additional vestibular tests which were done with frenzel lenses in place were;

a. Head -shake test: The subject was instructed to shake the head vigorously 30 times horizontally. After the shaking had stopped abruptly, the eyes were observed for nystagmus[11].

b. Head -thrust test: The subject was asked to gaze steadily at a target in the room. The examiner then briskly moved the subject's head from one side to the other while observing the eye position. A normal result was when the subject's eyes remained fixed on the target and abnormal when the eyes made a compensatory movement after the head had stopped to reacquire the target[11].

c. Dix -Hallpike maneuver test: the subject while seated on an examination couch, had their neck extended by the examiner and the neck was then turned to one side. The subject was then placed supine quickly in order for the head to hang over the edge of the examining couch and was then kept in this position for around 30 seconds and the eyes were observed for nystagmus. The subject was then returned to upright position, observed for another 30 seconds for nystagmus and the maneuver was then repeated with the head turned to the other side[40]

3.11 Quality Control

This was a continuous process throughout the study to ensure that the results are valid and can be replicated. The principal investigator did all the history taking, clinical examination which included the vestibular assessment tests while the audiologist performed the Pure Tone Audiograms using the same Interacoustics clinical audiometer AC33. The audiometer was switched on for ten minutes every day before being used to allow the electronic circuits to stabilize under room temperature prior to their usage. The questionnaire was pretested prior to commencement of study and appropriate changes were made. Data quality control and assurance measures were conducted to ensure integrity of data during collection and analysis.

3.12 Data Management

All data collected from filled questionnaires was sorted, cross checked and cleaned by eliminating outliers and then keyed into the statistical package for social sciences (SPSS) version 22 for analysis. The folder containing the data set was password coded and back up was done daily to prevent missing information.

3.13 Data Analysis

Data analysis was done using SPSS version 22. This entailed both the descriptive and the inferential statistics. In descriptive statistics, the characteristics of the participants was put in percentages and mean scores. Standard deviations were calculated for the continuous variables; ages of the patients and duration of the disease. The categorical variables which included the signs and symptoms of the patients was analyzed by calculating the percentage of subjects in each level of the categorical variables. Chi squared test and odds ratio was used to calculate the associated factors in CSOM which predispose to development of vestibular disorders. Statistical significance was based on a p value of less than 0.05.

3.14 Ethical Considerations

The study commenced after approval from UON-KNH ERC (approval letter KNH-ERC/ A/125). Recruitment of participants was by consent, the participants received full disclosure of the nature of the study. Patients who declined to give consent were not be victimized in any way and they continued to receive treatment as prescribed for their condition. Patients participating in this study did not incur any extra cost. The patients were identified by study numbers and not their names so as to maintain confidentiality throughout the process of data

collection. All the data collection sheets and soft copy data were kept safely by the principal researcher and were not shared to unauthorized persons.

The results of the PTA and findings of the clinical vestibular assessment was shared with the participants and those who were found to have vestibular disorder were referred to the otology clinic for management. At the end of the study the raw data was coded and stored for further study.

3.15 Study Result Dissemination Plan

The results of the study will be submitted to the university in form of a thesis. The Findings of the study will also be shared during presentations in meetings, seminars, conferences, journals and other scientific forums. Hard copies of the study will be availed at the UON department of surgery, college of health science library and the ENT department library. A soft copy will also be available on the University of Nairobi online portal for reference and dissemination. A manuscript will be prepared and submitted for publication in a journal as part of the partial fulfillment of the degree on masters of medicine in ear nose and throat surgery.

4.0 CHAPTER FOUR: RESULTS

4.1 Demographic Characteristics of Study Population

A total of 80 participants were recruited into the study. Among these, males constituted 35 (43.8%) and females 45 (56.3%). The mean age of participants was 38.8±14.6 and ranged from 18 to 73 years. The median age was 37 years with an interquartile range of 27.3-50 years. The frequency distribution of the population is demonstrated in figure 1.

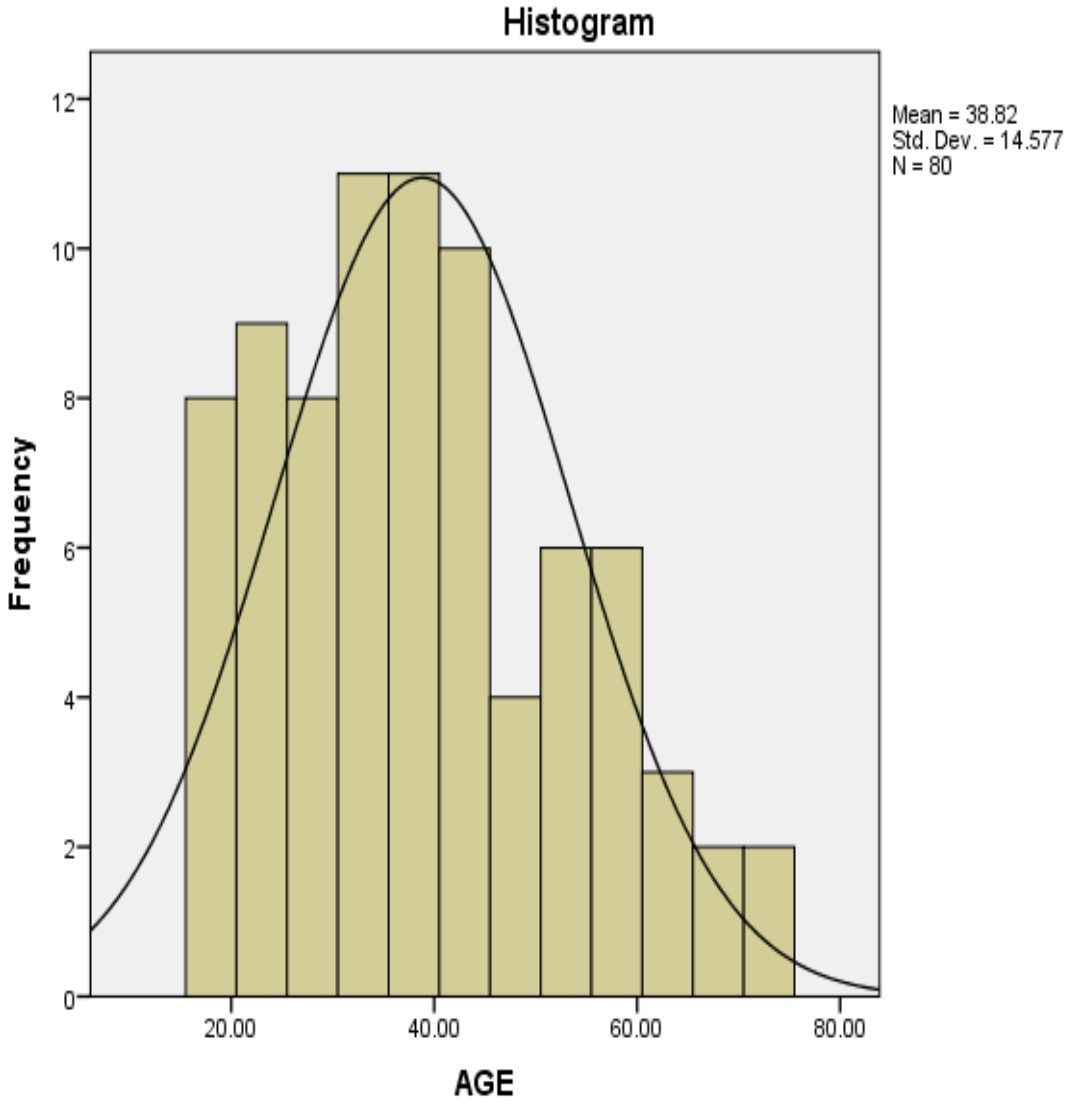


Figure 1: Age distribution

4.2 Gender Distribution across Age Groups

Most of the females were in the age group 41-50 years and constituted 11(13.7%) of the study population while most of the males in the study population were in the age group 31-40 years at 14 (17.5%) as depicted in figure 2.

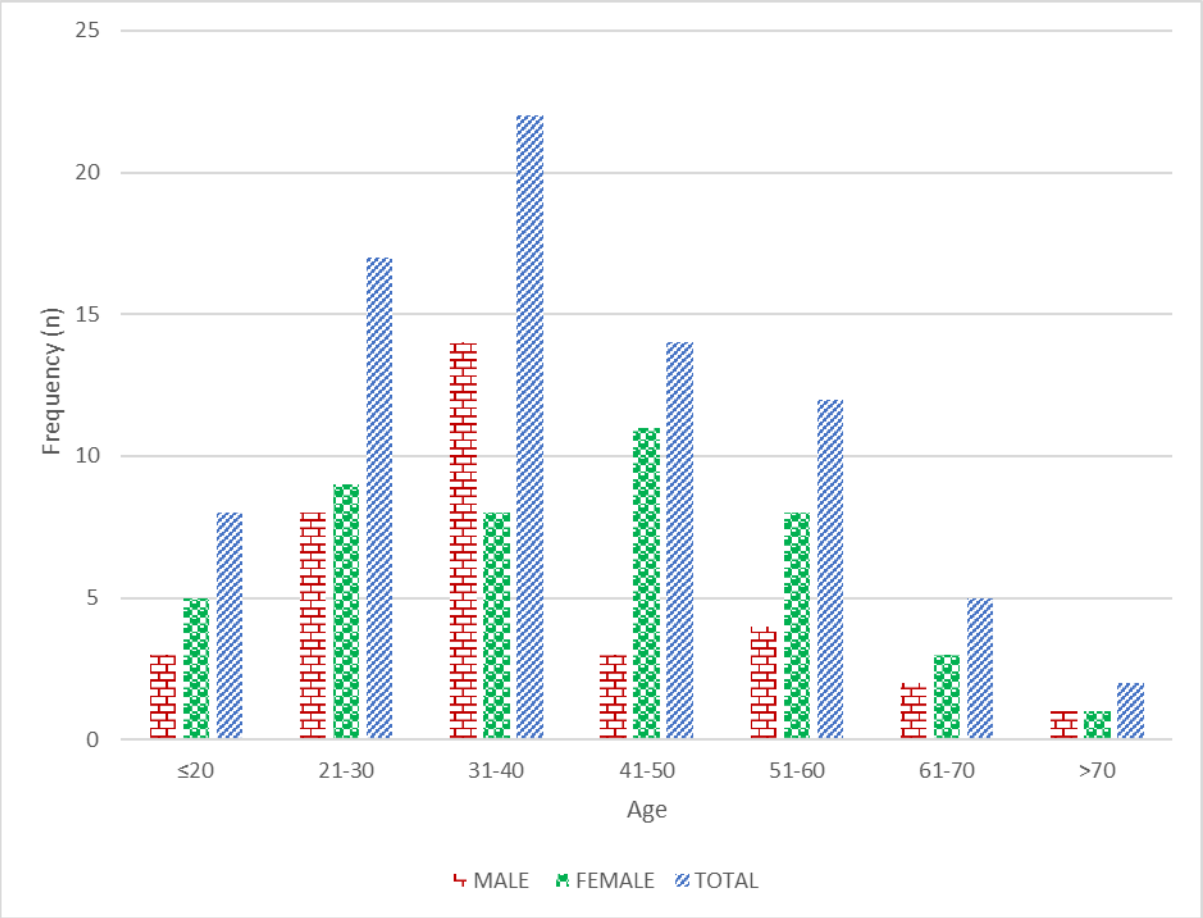


Figure 2: Gender Distribution

4.3 Ear Affected by Chronic Suppurative Otitis Media

Patients who had bilateral CSOM were 19(23.8%) while those who had unilateral CSOM were 61(76.2%). Of the unilateral CSOM,32(40%) was right sided and 29(36.2%) was left sided.

4.4 Type of Tympanic Membrane Perforation

The most common type of tympanic membrane perforation was subtotal perforation seen in 50 (31.3%) of the ears followed by 30(18.8%) ears which had a central perforation.16 (10%) of the ears had a marginal perforation and 13(8.1%) of the ears had a total perforation.

Table 1:Types of tympanic membrane perforation

Type	Right Ear	Left Ear	Total
None	27(38.8%)	24(30.0%)	51(31.9%)
Marginal	10(12.5%)	6(7.5%)	16(10.0%)
Central	14(17.5%)	16(20.0%)	30(18.8%)
Subtotal	21(26.3%)	29(36.3%)	50(31.3%)
Total	8(10%)	5(6.3%)	13(8.1%)

4.5 Type of Hearing Loss

Of all the ears examined and found to have CSOM ,36% had a sensorineural type of hearing loss ,46 % of the ears had a conductive hearing loss and 18% were a mixed type of hearing loss.

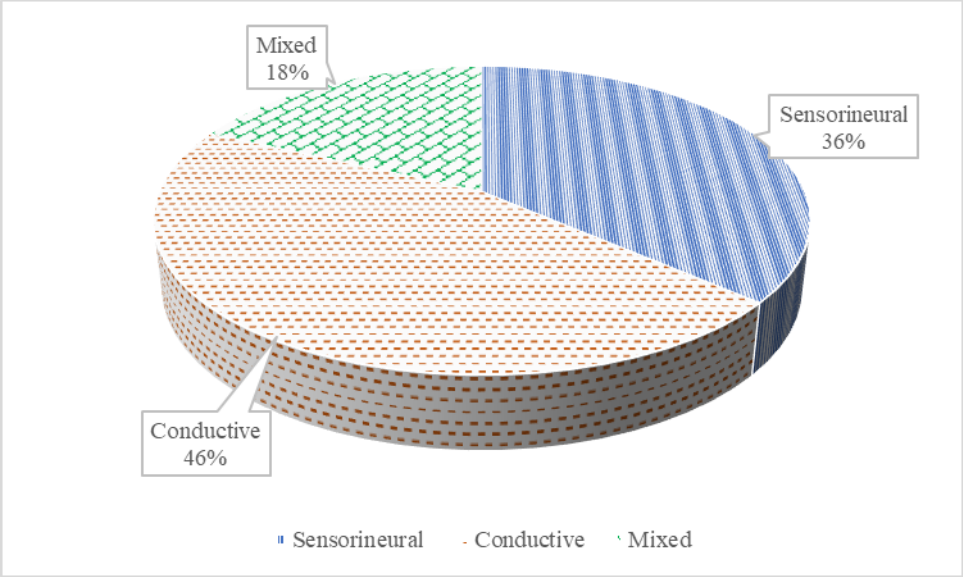


Figure 3: Type of hearing loss

4.6 Severity of Hearing Loss

In our study, of all the ears with CSOM, 33(33.3%) had a moderate hearing loss ,29(29.3%) ears had a mild hearing loss, 19(19.2%) ears had a moderate to severe hearing loss were, severe hearing loss were in 17 (17.2%) ears and profound hearing loss was found in 1 (1.1%) ear.

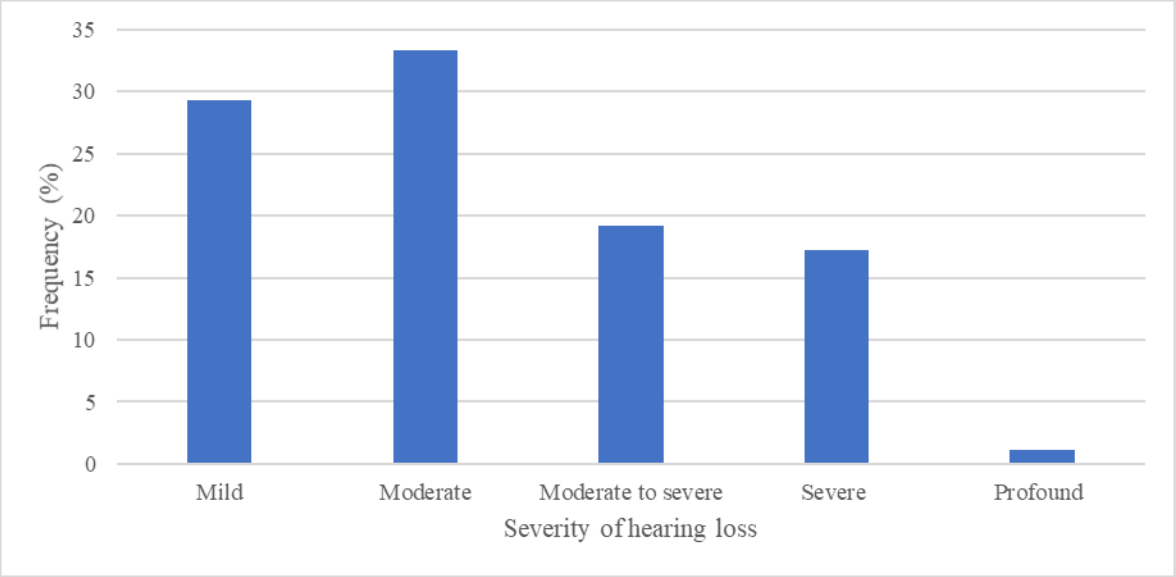


Figure 4: Severity of hearing loss

4.7 Prevalence of Vestibular Symptoms

Patients who had a history of vertigo were 15 (19%) of the population. Patients who had no history of vertigo were 65 (81%). Of all these patients who had vertigo, the vertigo lasted a duration of one minute to one hour when it occurred.

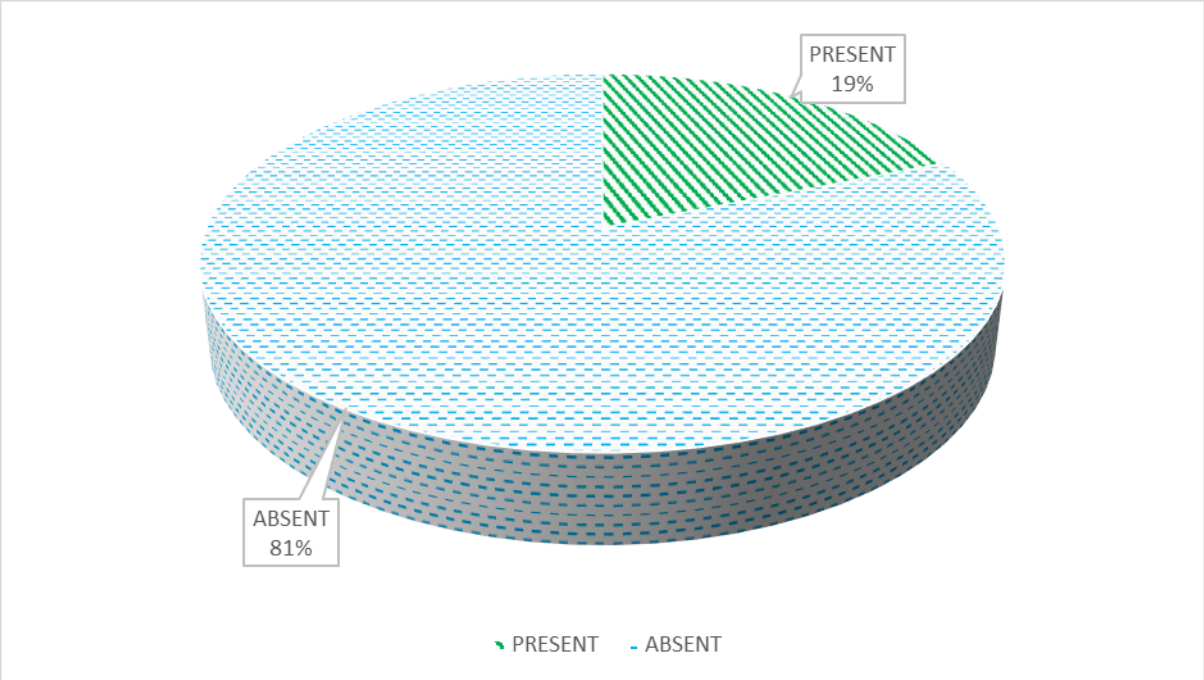


Figure 5: Presence of vertigo

4.8 Symptoms Associated with Vestibular Disorders

Patients who had a positive history of vertigo were 15 (18.75%). Patients who had a history of nausea correlated with vertigo were 5(6.3%), those who had dizziness were 4 (5%) while

those who reported a history of instability were 5(6.3%). In all the patients with a history of instability there were no history of falls or interference with daily activity. Patients who reported history of tinnitus were 7(8.8%).

Table 2: Symptoms associated with vestibular disorders

Symptoms	**Frequency (%)**
Vertigo	15(18.8%)
Dizziness	4 (5%)
Motion intolerance	12(15%)
Instability	6(7.5%)
Tinnitus	7 (8.8%)
Nausea correlated with vertigo	5(6.3%)

4.9 Clinical Vestibular Assessment Tests

Using Frenzel lenses, spontaneous nystagmus and gaze evoked nystagmus were seen in 2 (2.5%) of the population. Patients who had a positive Romberg's test were 2(2.5%) while those who had an abnormal dynamic visual acuity were 4(5%). An abnormal Fukuda test was seen in 5(6.3%) of the patients. Head shaking nystagmus was present in 5(6.3%) of the study population and in all these patients it was horizontal. Head thrust test was positive in 6(7.5 %) of the study population of which 66.7% was positive to the right side and 33.3% was positive to the left side. All the patients had normal smooth pursuit, normal saccades test, normal Dix Hallpike maneuver and normal gait. Overall, vestibular disorders were seen in 6 (7.5%) of the study population out of which 4(5%) had a right vestibular disorder and 2(2.5%) of the patients had a left vestibular disorder.

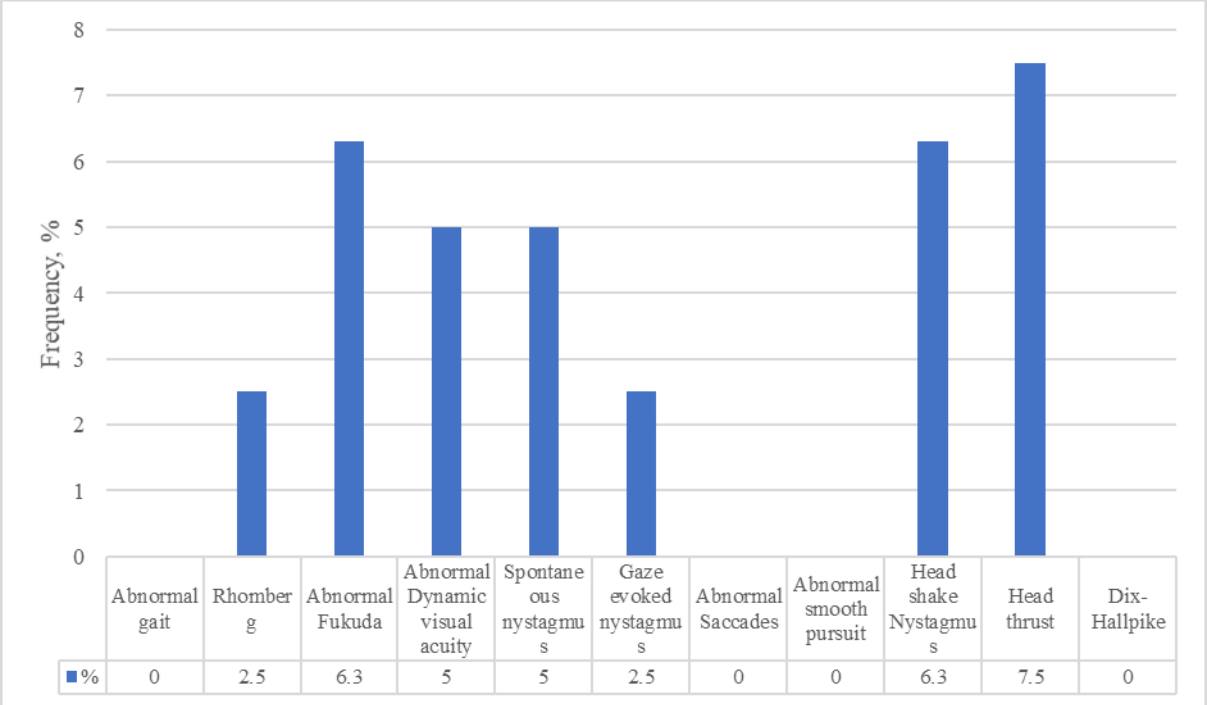


Figure 6: Vestibular assessment tests for the whole study population

Of the patients who had a positive history of vertigo, 6(40%) had a positive head thrust test, 5(33.3%) had a head shaking nystagmus and an abnormal Fukuda test. The patients who had a positive Romberg's test, a spontaneous nystagmus test and gaze evoked nystagmus were 2(13.3%) as shown in figure 7 below. Overall, vestibular disorders were present in 6(40%) of the patients who had history of vertigo.

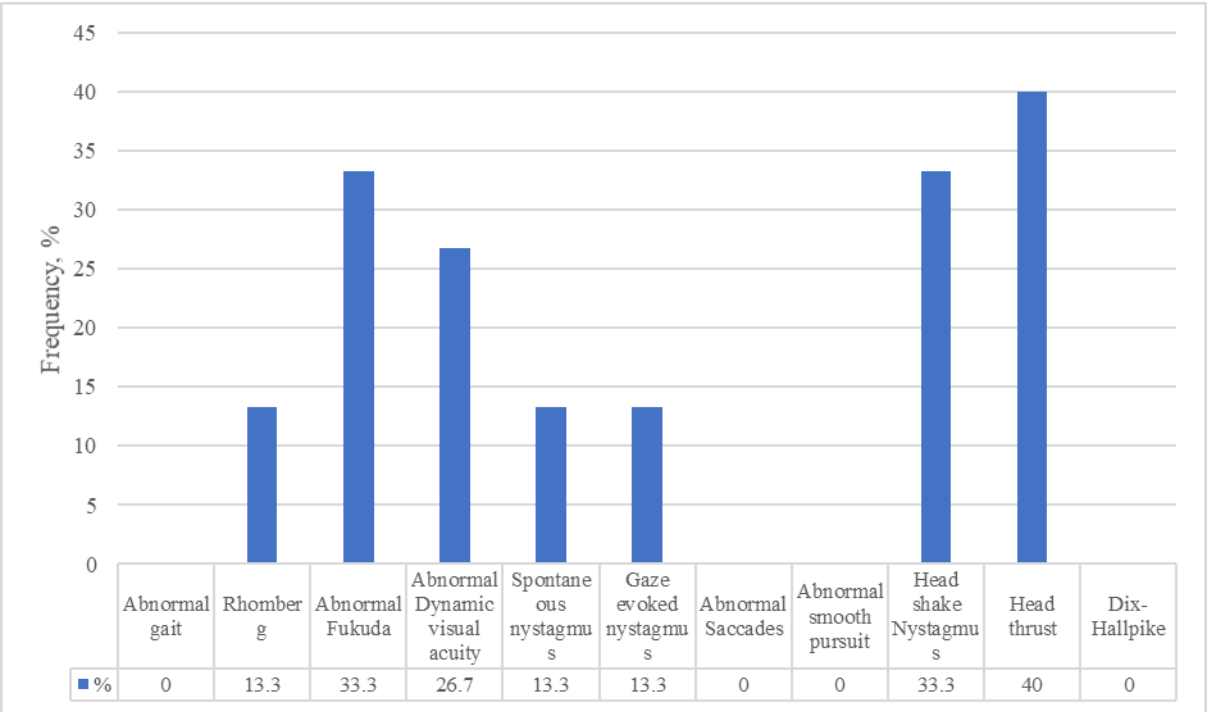


Figure 7: Vestibular assessment test for the patients with vertigo

4.10 Duration of Disease

The mean duration of CSOM in years for all the patients was 22.7±18.7. The disease duration ranged from 3months to 60yrs. The mean duration of disease in years for the patients diagnosed with vestibular disorders was 51.7±10.8 while those for the patients who had no vestibular disorder was 20.4±16.5. This was statistically significant with a **p value <0.001** as depicted in figure 7 below.

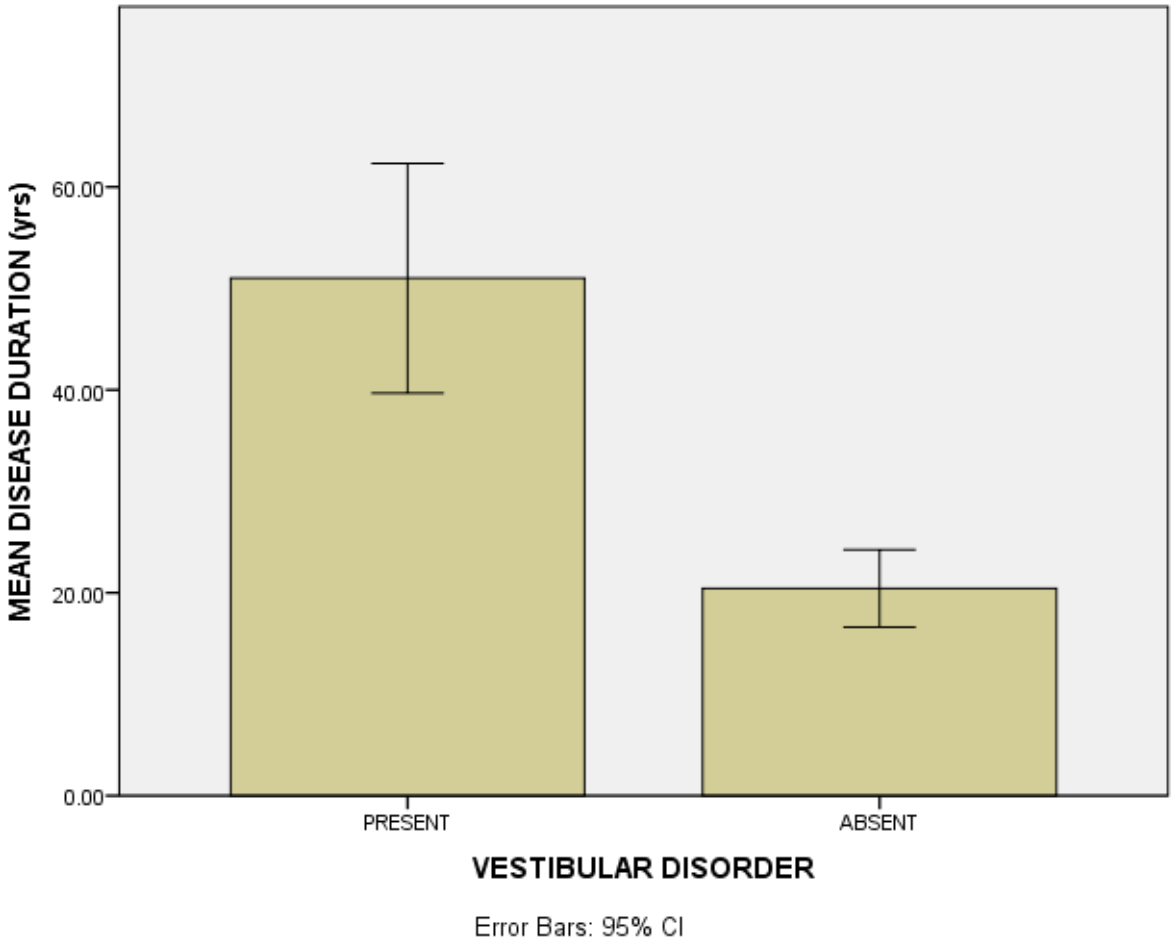


Figure 7: Mean duration of CSOM

4.11 Risk Factors Associated with Vestibular Disorders

Risk factors associated with vestibular disorders included gender, duration of disease, presence of sensorineural hearing loss and having a positive fistula test. More females had vestibular disorders than males with an odds ratio of 0.61 though the relationship was not statistically significant. Patients with vestibular disorders had a greater duration of disease with a mean of 51.7±10.8 years compared to patients who had no vestibular disorders who had a duration of disease of 20.4±16.5 years which was statistically significant, p<0.001. All the patients with vestibular disorder had a sensorineural type of hearing loss and was statistically significant with p value of 0.03. The probability of the patients with a positive fistula test having a vestibular disorder was extremely high with p<0.001 as shown in the table 3.

Table 3: Risk Factors Associated with Vestibular Disorders

Variable		**Vestibular disorder**		X^2	**OR**	**95%CI**	**P-value**
		Absent	**Present**				
Gender	Female	41(91.1%)	4(8.9%)	0.29	0.61	0.1-3.6	0.69 (0.05)
	Male	33(94.3%)	2(5.7%)				
Duration of disease	Mean ±SD	20.4±16.5	51.7±10.8				**<0.001 (0.05)**
SNHL	Present	38(86.4%)	6(13.6%)	5.3			**0.03(0.05)**
	Absent	36(100%)	00				
Fistula test positive	No	74(98.7%)	1(1.3%)	65.8			**<0.001(0.05)**
	Yes	00	5(100%)				

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION & RECOMMENDATIONS

5.1 Discussion

Chronic suppurative otitis media (CSOM) can be associated with functional damage to the inner ear due to the close anatomical relationship between middle ear and inner ear which makes it easy for disease to spread to the inner ear. The pathologic factors which diffuse through the round window causing cochlear damage can also lead to vestibular damage. Our study assessed the vestibular function of eighty patients with chronic suppurative otitis media.

In our study, positive history of vertigo was reported in 15 patients (18.75%) of the patients. In contrast, Mostafa et al [26] while evaluating the vestibular function of patients with CSOM found 53.5% of the patients to have history of vertigo. The difference could be attributed to the study setup as he was evaluating patients with CSOM presenting at the vestibular unit of the hospital. In our study, other associated vestibular symptoms were found to be dizziness in 4(5%) of the patients, nausea correlated with vertigo in 4(5%) of the patients, instability in 6(7.5%) of the patients, tinnitus in 7(8.8%) and motion intolerance in 12(15%) of the patients. None of the other studies we have come across evaluated the associated vestibular symptoms other than vertigo.

Clinical vestibular assessment tests done in our study using Frenzel glasses were spontaneous nystagmus, gaze evoked nystagmus, dix hallpike maneuver, saccades test, smooth pursuit test, head shaking nystagmus test and head thrust test. Additional tests done included dynamic visual acuity, gait test, fukuda test and Romberg's test. Patients found to have spontaneous nystagmus in our study were 2(2.5%) and patients with gaze evoked nystagmus were 2 (2.5%). On the other hand, Kazuo et al [36] observed spontaneous nystagmus in 40% of the patients. The difference could be attributed to the small sample size of 23 patients that he used.

Head shaking nystagmus was seen in 5 (6.3%) of the patients in our study and was horizontal in all of them. In contrast Lee in sik et al [31] found head shaking nystagmus in 48% of the patients. The difference could be attributed to the fact that Lee in sik used the videonystagmograph to measure the nystagmus. Head thrust test was positive in our study in 6(7.5%) of the patients. On the contrary, Mostafa et al [26] found the head shaking test and the head thrust test to be normal in all patients. This could be attributed to the fact that Mostafa et al[26] did not use frenzel lenses for these tests.

All patients had a normal saccades test, normal smooth pursuit test, normal gait test and negative Dix Hallpike test in our study. Similarly, Mostafa et al [26] found all patients had a normal smooth pursuit, normal saccades test and normal positional tests. In our study, positive Romberg's test was seen in 2 (2.5%), abnormal dynamic visual acuity in 4(5 %) of the patients and fukuda step test was abnormal in 5(6.3%) of the patients with a rotation of more than 45 degrees affected to the side affected by CSOM. None of the other studies we have come across evaluated the fukuda step test, Romberg's test or the dynamic visual acuity test.

Overall, 6 (7.5%) of the patients had abnormal findings through these set of vestibular function tests. This is in contrast to lee in sik et al[31] who found overall 80% of the patients to have vestibular disorders. This difference can be attributed to the fact that in addition to using clinical vestibular tests he also used laboratory vestibular tests like air caloric test and the videonystagmograph to measure nystagmus.

The variables evaluated and their influence on being risk factors for development of vestibular disorders in our study were gender, duration of disease, presence of sensorineural hearing loss and a positive fistula test. In our study, patients with vestibular disorders had a greater duration of disease with a mean of 51.7±10.8 years compared to patients who had no vestibular disorders who had a mean duration of disease of 20.4±16.5 years. This was found to be statistically significant, with a p value < 0. 001.These findings are similar to those by Mostafa et al [26] and Siampara et al [28] whereby they both found a positive association between duration of CSOM and presence of vestibular dysfunction and in both studies, this was statistically significant with a p value <0.001. In our study, presence of sensorineural type of hearing loss was found to contribute to presence of vestibular disorders with a p value of 0.03 and was found to be statistically significant. Similarly, Mostafa et al [26] found the presence of sensorineural type of hearing loss to have a strong association of 57.1% of causing vestibular disorders but not to be statistically significant in patients with vestibular disorders

In our study,5(6.25%) of the patients had a positive fistula test and all these patients were diagnosed with a vestibular disorder from the clinical vestibular assessment tests done. This was statistically significant with a p value < 0.001. Similarly, Busaba et al [35] showed that in CSOM, there was a positive correlation between a positive fistula test and vestibular disorders. In contrast, Kazuo et al [36] did not observe any positive fistula sign in the patients he was evaluating for vertigo.

5.2 Conclusion

In our study we found patients with a longer duration of CSOM and with sensorineural hearing loss were more likely to present with vestibular disorders and this was statistically significant. In addition to this, chronicity of the disease was associated with a positive fistula test which also led to patients presenting with a vestibular disorder.

5.3 Recommendations

All patients with a longer duration of CSOM should be assessed for vestibular dysfunction. Furthermore, vestibular assessment should be done in patients with CSOM while being prepared pre-operatively for surgery especially those with a positive fistula test for them to have an informed consent as to the extent of the disease and risks involved in surgery. Lastly, the vestibular assessment tests done pre-operatively in patients with CSOM will also be of help to the surgeon for medicolegal purposes.

5.4 Limitations

The limitations experienced were lack of the laboratory vestibular assessment tests to test for the presence of vestibular disorders in patients with CSOM. Laboratory vestibular assessment tests would assist in the definitive diagnosis of patients with vestibular disorders as they are more sensitive.

TIMELINE

TASK	Jan – June 2019	July 2019	November -April 2020	May 2020-January 2021	February 2021	March - April 2021	May-August 2021
Proposal writing							
Proposal presentation							
Ethics approval							
Data collection							
Data analysis							
Results presentation							
Submission for marking and publication							

BUDGET

ITEM	COST (KSH)
Statistician	40000
Stationery	40000
Research assistant	30000
Pure Tone Audiometry tests	56000
Internet	6000
Publishing costs	30000
Miscellaneous	14000
TOTAL	216000

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APPENDICES

Appendix I: General Patient Information Form and consent form (English version)

My name is Dr Esther Wambui Kimani, I am the principal researcher in this study. The study has been approved by the KNH/UON Ethics and Research Committee.

I am conducting a study entitled **"ASSESSMENT OF VESTIBULAR FUNCTION OF PATIENTS WITH CHRONIC SUPPURATIVE OTITIS MEDIA AT KENYATTA NATIONAL HOSPITAL**"

The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research:

i) Your decision to participate is entirely voluntary
ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities.

We will give you a copy of this form for your records.

May I continue? YES / NO

How you will participate?

a) I will ask you questions regarding your current complains and the history of your condition
b) I will carry out a complete Ear, Nose, Throat, Head and Neck examination.
c) Pure tone audiometry test will be conducted on you followed by vestibular assessment tests.
d) You will incur no extra financial costs and the confidentiality will be maintained at all times.
e) There will be no monetary benefits for participating in the study and it will be purely on a voluntary basis.
f) You will be informed about investigations and importance of the results.
g) You will reserve the right to withdraw from the study at any time without discrimination

Are there any risks involved?

There are no known risks anticipated in your participation in this study.

Is there any penalty for refusing to participate in the study?

No, there are no penalties and the patient will receive treatment as prescribed

What benefits will I get for participating in the study?

Any abnormalities found in the vestibular assessment test and the pure tone audiometry will be attended to by an ENT specialist.

What about confidentiality?

All the information that we obtain will be kept confidential.

Are there any extra costs involved?

There are no extra costs involved in the participation in this study. The patient will however be subject to any standard fees charged by the Kenyatta National Hospital as part of their management.

Are you satisfied with the information provided?

In case of any questions or inquiries, contact the following:

A. Principal Investigator:

Dr. Esther W. Kimani
Department of Surgery,
College of Health Sciences,
University of Nairobi.
P.O. BOX 2134-00100 Nairobi.
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B. Supervisors:

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Dr. Catherine Irungu
Consultant Ear, Nose and Throat Surgeon,
Lecturer,
Department of Surgery
University of Nairobi.
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Ms. Serah Ndegwa MSc
Lecturer and Consultant Audiologist
Department of Surgery
University of Nairobi

Consent by Patient

Patient study number: ……

I……. of……do hereby give consent to be included in this study on assessment of vestibular function in patients with chronic suppurative otitis media at Kenyatta National Hospital.

The nature of the study has been explained to me by the doctor.

I Dr……...confirm that I have explained to the patient the nature of the study.

Date……...Signed…….

Thumb print

Patient /next of kin:

Date ……Signed …….

Contacts

Principal Researcher:

Dr. Esther Wambui Kimani

Post graduate Student Mmed otolaryngology/head and Neck Surgery,

University of Nairobi

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Kenyatta National Hospital.

Dr. Catherine Irungu

Consultant Ear, Nose and Throat Surgeon,

Lecturer,

Department of Surgery,

University of Nairobi.

Department of Surgery

University of Nairobi

If you have any questions on your rights as a participant contact the *Kenyatta National Hospital/UON- Ethics and Research Committee (KNH/UON-ERC)* by calling *2726300 Ext. 44355*.

Appendix II: General Patient Information Form and consent form (Swahili version)

Fomu ya maelezo:

Utangulizi

Mimi ni daktari Esther Wambui Kimani. Mimi ni mwanafunzi katika idara ya upasuaji wa maskio, pua na koo. Ninakuomba idhini yako kushiriki katika utafiti huu

Utashiriki jinsi gani

- **a)** Nitakuuliza maswali kuhusu malalamiko yako ya sasa na historia ya hali yako
- **b)** Nitapima hali ya ugonjwa wako wa kichwa na shingo
- **c)** Nitafanya kipimo ya "pure tone audiometry" na pia kipimo ya uswa wa sehema ya "vestibular "
- **d)** Hutakuwa na gharama za ziada za kifedha na usiri utahifadhiwa wakati wote
- **e)** Hakutakuwa na faida ya fedha kwa ajili ya kushiriki katika utafiti na itakuwa tu kwa msingi wa hiari.
- **f)** Utatambuliwa kuhusu uchunguzi na umuhimu wa matokeo.
- **g)** Utakuwa na haki ya kujiondoa kwenye utafiti wakati wowote bila ubaguzi.

Kushiriki kutakuathirije?

a) Utafiti huu hautakuathiri kwa njia yoyote

Kuna hatari yoyote katika ushiriki wako au kutoshiriki kwako?

a) Hakuna

b) Kukataa kushiriki katika utafiti huu hautaathiri ubora wa huduma utakayopokea.

Tutafanya nini na habari tutakayopata

Tutashiriki matokeo yetu na watu wengine kufanya masomo sawa na tunaweza kuchapisha matokeo yetu katika magazeti ya kisayansi au kuwasilisha katika mikutano ya kisayansi. Usiri wa wagonjwa wote utahifadhiwa.

Je, unastahili na taarifa iliyotolewa?

Ikiwa umeridhika na ufafanuzi wetu na uko tayari kushiriki, basi tafadhali saini fomu ya ridhaa hapa chini.

SEHEMU YA PILI: Fomu ya makubaliano

Numbari ya utafiti: ……

Kibali cha utafiti:

Mimi Bi/Bwana…… nimekubali kushiriki katika utafiti huu.

Sahihi yangu ni thibitisho ya kwamba nimeelewa umuhimu wa utafiti huu na kwamba habari yoyote nitakayotoa itawekwa siri.

Tarehe……Sahihi ……...

Mimi daktari …… nadhibitisha ya kwamba nimeeleza mgonjwa kuhusu utafiti huu.

Tarehe ……...Sahihi……...

Mtafiti mkuu:

Daktari Esther Wambui Kimani

Mwanafunzi wa upasuaji wa masikio,mapua na koo,
Chuo kikuu cha Nairobi,
Simu: 0726486275
Barua pepe: drkimaniesther@gmail.com

Wasimamizi:

Daktari Mary Omutsani

Daktari wa upasuaji wa Masikio, mapua na koo
Idara ya upasuaji,
Hospitali kuu ya Kenyatta

Daktari Catherine Irungu

Daktari wa upasuaji wa Masikio, mapua na koo
Idara ya upasuaji,
Chuo kikuu cha Nairobi

Bi Serah Ndegwa
Mtaalam wa audiologia
Idara ya upasuaji
Chuo kikuu cha Nairobi

maswali yeyote kuhusu utafiti yanaweza kutumwa kwenye *Kenyatta National Hospital/UON-Ethics and Research Committee (KNH/UON-ERC)* by numbari *2726300 Ext. 44355*.

Appendix III: Data Collection Sheet

Code……..... **Age (years) ……...** **Sex- Male/Female**

1.Occupation/s.....

2.Duration of disease (chronic suppurative otitis media) ……

3.Use of ototoxic drugs .....

Characteristics of Otorrhea (YES OR NO)

Right		**Left**	
Scanty Copious	☐ ☐	Scanty Copious	☐ ☐
Foul smelling Not foul smelling	☐ ☐	Foul smelling Not foul smelling	☐ ☐

Ear exam, otoscopy and tuning fork test (Indicate if normal or the specify findings)

	Right		Left
a. Pinna			
b. EAC			
c. Tympanic Membrane	1.Discharge present-YES/NO 2.Type of perforation……. 3.Position of perforation…….		1Discharge present-YES/NO 2.Type of perforation……. 3.Position of perforation…….
d. Fistula test			
e. Rinne's test			
f. Weber's test	Right	Central	Left

PTA will then be done and attached

Type of hearing loss	
Severity of hearing loss	

Appendix IV: European Evaluation of Vertigo Questionnaire

IllMOV	ILLUSION OF MOVEMENT
0	No illusion
1	.....
2	Feeling of swaying to the right or left, ascending or descending movements, light-headedness, listing, rolling.
3	.....
4	Impression of spinning (either of self or of the environment)

DurILL	DURATION OF THE ILLUSION
0	None
1	Less than 1 minute
2	1 minute to 1 hour.
3	1 hour to 3 hours
4	3 hours to 24 hours

MotINT	MOTION INTOLERANCE
0	No motion intolerance
1	Rarely or few
2	Sometimes or moderate
3	Often or marked
4	Always or intense.

NeuVEG	NEUROVEGETATIVE SIGNS
0	No neurovegetative signs
1	Nausea uncorrelated with attacks of vertigo
2	Nausea correlated with attacks of vertigo
3	Nausea associated with one or two episodes of vomiting
4	Intractable vomiting

InsTAB	INSTABILITY (including when under illusion)
0	No instability
1	Instability but no falls and no interference with daily life activity
2	Instability, without falls, but interferes with daily life activity
3	Instability with occasional falls, either when standing or when walking
4	Instability with falls as soon as the patient stands up

Appendix V: Vestibular Assessment Tests

Oculomotor Examination

Extraocular muscle movement NORMAL / ABNORMAL

If abnormal, type of abnormality ……

Ear affected by Chronic otitis media? .....

TEST	RESULT		INTEPRETATION
1.Spontaneous nystagmus	YES ☐ NO ☐		
2.Gaze holding nystagmus	Right	YES ☐ NO ☐	
	Left	YES ☐ NO ☐	
3.Smooth pursuit	Right	NORMAL ☐ ABNORMAL ☐	
	Left	NORMAL ☐ ABNORMAL ☐	
4.Saccadic eye movement	Right	NORMAL ☐ ABNORMAL ☐	
	Left	NORMAL ☐ ABNORMAL ☐	
5.Head shaking nystagmus	Horizontal	YES ☐ NO ☐	
	Vertical	YES ☐	

		NO ☐	
6.Head thrust test	Right	POSITIVE ☐ NEGATIVE ☐	
	Left	POSITIVE ☐ NEGATIVE ☐	
7.Dix-Hallpike test	Right	POSITIVE ☐ NEGATIVE ☐	
	Left	POSITIVE ☐ NEGATIVE ☐	
8.Gait test	NORMAL ☐ ABNORMAL ☐		
9.Romberg's test	POSITIVE ☐ NEGATIVE ☐		
10.Fukuda step test	NORMAL ☐ ABNORMAL ☐		
11.Dynamic Visual Acuity test	NORMAL ☐ ABNORMAL ☐		

Diagnosis: Right Vestibular system…….

Left Vestibular system……

Final diagnosis ……

Appendix VI : KNH/UoN-ERC Letter of Approval

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/125

9th April 2020

Dr. Esther Wambui Kimani
Reg. No.H58/88069/2016
Dept. of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Kimani

RESEARCH PROPOSAL – ASSESSMENT OF VESTIBULAR FUNCTIONS OF PATIENTS WITH CHRONIC SUPPURATIVE OTITIS MEDIA AT THE KENYATTA NATIONAL HOSPITAL (P1004/12/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 9th April 2020 – 8th April 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Dept.of Surgery, UoN
Supervisors: Dr. Catherine Irungu, Dept.of Surgery, UoN
Ms. Serah Ndegwa, Dept.of Surgery, UoN

ASSESSMENT OF VESTIBULAR FUNCTION IN PATIENTS WITH CHRONIC SUPPURATIVE OTITIS MEDIA AT THE KENYATTA NATIONAL HOSPITAL

by Dr. Esther Wambui Kimani

Submission date: 28-Apr-2021 02:06AM (UTC-0700)
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DEPARTMENT OF SURGERY
COLLEGE OF HEALTH SCIENCES
Ext. 43773

ASSESSMENT OF VESTIBULAR FUNCTION IN PATIENTS WITH CHRONIC SUPPURATIVE OTITIS MEDIA AT THE KENYATTA NATIONAL HOSPITAL

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