PREVALENCE AND PATTERN OF SENSORINEURAL HEARING IMPAIRMENT AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS AT THE KENYATTA NATIONAL HOSPITAL

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A STUDY SUBMITTED TO THE UNIVERSITY OF NAIROBI SCHOOL OF MEDICINE IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF MASTERS DEGREE IN OTORHINOLARYNGOLOGY, HEAD & NECK SURGERY
DECLARATION

I hereby declare that this is my original work and has not been presented for the award of any academic credit in any Research institution or University.

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Neville Okwiri.

Signature _____________________ Date ______________

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ACKNOWLEDGEMENT

I wish to acknowledge those whose efforts resulted in the completion of this study. I am very grateful to my supervisors Prof. Isaac Macharia and Dr. Catherine Irungu for their guidance throughout the study period together with all other faculty members of the Department of E.N.T, Head and Neck Surgery for their review and positive criticism during the study duration.

This study was made possible by partial financial grants from the Extension and Research committee of the Kenyatta National Hospital and the Deans Committee Research Grant (DCRG) of the University of Nairobi.
ABBREVIATIONS

ABR – Auditory Brainstem Response

ANSI American National Standards institute

BMI – Body Mass Index

DM – Diabetes Mellitus

dbHL – decibel hearing level

ENT – Ear, Nose and Throat

Hz - Hertz

KNH - Kenyatta National Hospital

PTA - Pure Tone Audiometry
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ABSTRACT

BACKGROUND

Type 2 Diabetes Mellitus is an illness in which insulin secretion and action is impaired. In 2014 the global prevalence of diabetes was estimated to be 9% among adults. In Africa the prevalence of diabetes has been estimated to range from 1% in rural Uganda to 12% in urban Kenya. Patients with diabetes have been shown to have worse hearing as compared to healthy individuals.

AIM

To determine the prevalence and pattern of sensorineural hearing impairment among patients with type 2 diabetes mellitus at the Kenyatta National hospital.

METHODS

Study setting: Kenyatta National Hospital ENT, Head and Neck Surgery outpatient department, Diabetic outpatient clinic and Nairobi Audiology Centre.

Study design: This was a hospital-based cross sectional survey that was carried out for a duration of three months between the months of February and May 2016.

Methodology: A total of 78 patients between 22 – 55 years of age on follow up for type 2 Diabetes Mellitus were recruited into the study. Pure tone audiometry was carried out at 250, 500, 1000, 2000, 4000, 6000 and 8000 Hz. The participants then underwent Auditory Brainstem Response (ABR) testing. Demographic, anthropometric, clinical and laboratory data was collected on a preformatted questionnaire. Data was analyzed using SPSS. Descriptive statistics was used for the population demographic characteristics. Univariate and multivariate analysis was used to determine correlates of risk factors to hearing impairment in diabetes mellitus patients.
**RESULTS**

A total of 78 patients were recruited into the study and overall 39.7% of patients with type 2 diabetes were found to have hearing loss. Mild sensorineural hearing loss accounted for 90.3% of those with hearing loss with a majority of them having high frequency hearing loss.

The ABR wave I, III & V absolute latencies were found to be significantly shorter as compared to normative data. However, the interpeak latencies were similar to normative data.

**CONCLUSION AND RECOMMENDATION**

The hearing loss associated with type 2 diabetes was shown to be mild and as such, the evidence we have as of now, doesn’t justify the added cost to advocate for routine hearing assessment in patients with type 2 diabetes.
CHAPTER 1: INTRODUCTION

11. BACKGROUND

The dysfunction in type 2 diabetes is characterised by hyperglycaemia that occurs as a result of insulin resistance, inadequate insulin secretion, and inappropriate glucagon secretion. Patients with type 2 diabetes mellitus retain some ability to secrete insulin (1).

The complications that contribute to morbidity and mortality in diabetes mellitus include; hypoglycaemia, increased risk of infections, microvascular complications, neuropathic complications, and macrovascular disease. Hyperglycaemia which is a wholemark of all forms of diabetes mellitus affects the microvasculature and nerves, that are integral in hearing.

The chronic hyperglycaemia leads to diabetic microvasculopathy in the peripheral nerves, renal glomerulus, and retina. These lead to blindness, end stage kidney disease, and debilitating neuropathies (2). Diabetes also leads to increased incidence of macrovascular atherosclerosis resulting in a higher risk of myocardial infarction, stroke and limb amputation (3). Molecularly the hyperglycaemic vasculopathy seems to stem from over production of superoxide by the mitochondrial electron transport chain (4).

A post mortem examination of 8 temporal bones of diabetics who had been known to have worse hearing as compared to age and sex matched controls revealed microangiopathy (5). Histologically other studies showed artherosclerotic changes in the cochlea (6).

There is a marked similarity between the cochlear stria vascularis and the renal nephrons (7, 8), hence the vasculopathy that leads to renal failure could also be responsible for hearing loss in diabetic individuals (9).

The displacement of the cochlea is highly frequency specific (10). Maximal displacement for higher frequencies is at the basal end while lower frequencies are at the apex. A number of studies have shown that hearing loss among diabetics predominantly involves the high frequencies (8,11,12). This is similar to presbyacusis, that affects higher frequencies first (13,14). Sensory hair cell loss and cochlea neuron loss at the basal turns are thought to be responsible for presbyacusis (15,16). Nakae et al (17) made similar observations in an animal model of diabetes mellitus. High frequency hearing impairment is associated with difficulties understanding speech and thus impacting negatively on ones life (18).
The Central auditory system begins at the cochlea nuclei and in addition to transmission of acoustic information to higher centres is responsible for critical functions such as sound localization (19). The brainstem auditory evoked response (ABR) was first described by Sohmer and Feinmesser in 1967 (20). The ABR has seven waves. Activity in the cochlear nerve is represented by waves I & II. Waves III & IV represent activity in the cochlea nucleus and superior olivary complex respectively. Wave V is the most robust and represents activity generated primarily from neurons located within the lateral Lemniscal tracks (21).

ABR is commonly used to estimate peripheral hearing sensitivity of patients who cannot (eg infants & young children) or will not (eg malingerers) cooperate with behavioural testing. ABR is also useful in otoneurological assessment. Generally this is accomplished by examining the morphology and latencies of the click evoked ABR measured using high level stimuli. There are several different ways in which the click evoked ABR is altered by the presence of retrocochlear pathology. For example, an ABR that is absent in an ear with audiometric thresholds in the normal to moderate range, an ABR that is characterised only by early peaks, or an ABR with a wave V amplitude that that is much smaller than the amplitude of wave I have all been interpreted as evidence of potential abnormality (22,23). Such grossly abnormal ABR morphologies are thought to reflect partial conduction block or significant loss of cross fiber synchrony along the neural pathways between the cochlear and the inferior colliculus. A second measure that is commonly used to diagnose potential retrocochlear pathology is prolonged interpeak or absolute latencies. In most persons, a high level click stimulus will generate an ABR with a wave V latency of approximately 5.5 msec and with a I-V interpeak latency of approximately 4.0 msec (24). The presence of retrocochlear pathology may slow neural conduction velocities. The presence of changes in central auditory and cognitive processing have also been documented in subjects with diabetes (25).

**EPIDEMIOLOGY**

In 2009 the prevalence of DM in Kenya was estimated to be 4.2% (26). However a marked difference was noted between the rural and urban populations. The prevalence ranged from a high of 12.2% in Nairobi to 2.2% in rural areas. These findings were similar to a study by Mathenge et al in 2010 (27). A study by Ayah R & Otieno CF (28) in Kibera, found the age
adjusted prevalence of diabetes to be 5.3%. Noteworthy in this study was the presence of very high concomitant, major, cardiovascular disease risk factors of cigarette smoking and alcohol abuse. The overall prevalence of diabetes is expected to rise due to increased rural to urban migration and the adaptation of a much more sedentary urban lifestyle (28).

**DIAGNOSIS**

The current WHO diagnostic criteria for diabetes is fasting plasma glucose >7.0mmol/l or a 2 hour post prandial plasma glucose > 11.1 mmol/l (1).

Hearing loss in adults defined as the pure tone average of the frequencies 500, 1000, 2000 and 4000 Hz greater than 25 db hearing level in the worse ear (29).

**MANAGEMENT**

Glycaemic control is achieved via diet and lifestyle modification, oral hypoglycaemics and exogenous insulin administration. Control of lipids and hypertension helps reduce macrovascular complication risk.

Management of patients with hearing impairment depends on the degree. Hearing aids are the main option for patients with mild, moderate or severe impairment. Cochlea implants are indicated for patients with profound hearing loss.
CHAPTER 2: LITERATURE REVIEW

In a survey of 5,742 participants patients with diabetes mellitus were found to have greater hearing loss as compared to non-diabetics (30). Cheng YJ et al (31) showed that the prevalence of hearing impairment among adults without diabetes aged 25 to 69 years from 1971 to 2004 in the United States decreased from 27.9% to 19.1% but among adults with diabetes there was no significant change (46.4% to 48.5%). In a systematic review by Akinpelu et al (32) in 2014 found the prevalence of hearing loss ranging from 44% to 69.7% for diabetic subjects and from 20% to 48.6% for non-diabetic controls. A study by Mozaffari et al among diabetic patients less than 60 years found a 45% prevalence of sensorineural hearing loss in the diabetics versus 20% in controls (33).

Hearing thresholds in patients with diabetes have been reported to correlate with diabetic complications, poor glycaemic control and diabetes duration (7, 34) however other studies didn’t have similar findings (8, 35, 36). In the general population cardiovascular disease and its risk factors have been associated with hearing impairment (37, 38). A study of diabetics (39) among a population based sample showed that nephropathy was associated with hearing impairment.

Sensorineural hearing loss has been attributed to diabetic neuropathy (40). Duck et al (41) reported that co-existing diabetes may intensify hypertensive end organ disease of the cochlea.

Kakarlapudi et al (42) in a chart review of diabetics found that creatinine levels were associated with severity of hearing loss. Other reports have found that severity of hearing impairment is positively associated with urine albumin excretion rate in patients with type 2 diabetes (43). The association between chronic hyperglycaemia and increased risk of microvascular complications in patients with type 1 diabetes mellitus was demonstrated in the Diabetes Control and Complications Trial (DCCT) (44). This has been corroborated by the epidemiology of diabetes intervention and complication study that has demonstrated continued benefit from intensive treatment (45,46). Studies have shown an association between glycaemic control, as assessed by HbA1c levels, and hearing loss (47).

A study by Durmus et al (48) assessed neural conductance along the auditory pathway in diabetic patients and controls with normal hearing. ABR recordings revealed that absolute latencies of waves I, III & V were prolonged in the diabetic group as compared to controls. Toth in 2003 (49) revealed a difference in the interpeak latencies I – III & I – V between diabetic
patients and healthy controls. Gupta et al in 2010 (50) found the latency of wave I to be equal in diabetics and controls. The latency of waves III & V were delayed. The interpeak latencies I – III, III – V, and I – V were delayed in the diabetic group. Longer disease duration and severity were associated with abnormalities in the ABR.

<table>
<thead>
<tr>
<th>Author</th>
<th>Type of study</th>
<th>N (DM/Controls)</th>
<th>Remarks</th>
<th>Method of Hearing assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheng YJ (2009)</td>
<td>Cross sectional NHANES</td>
<td></td>
<td>No change in prevalence of HL among diabetics</td>
<td>PTA</td>
</tr>
<tr>
<td>Akinpelu (2014)</td>
<td>Systematic review</td>
<td>29 articles reviewed</td>
<td>➢ High frequency HL</td>
<td>N/A</td>
</tr>
<tr>
<td>Mozaffari (2010)</td>
<td>Case control</td>
<td>80/80</td>
<td>Prevalence 45% Diabetics vs 20% controls</td>
<td>PTA</td>
</tr>
<tr>
<td>Dalton DS (1998)</td>
<td>longitudinal</td>
<td>344/3227</td>
<td>Nephropathy associated with hearing loss</td>
<td>PTA</td>
</tr>
<tr>
<td>Panchu (2008)</td>
<td>Case control</td>
<td>41/41</td>
<td>HbA1c &gt; 8% associated with</td>
<td>PTA</td>
</tr>
</tbody>
</table>
### 2.2 STUDY JUSTIFICATION

Most studies of diabetes and hearing have limited themselves to the peripheral auditory system. We undertook a cross sectional survey, investigating both the peripheral and central auditory pathways.

### 2.3 AIMS AND OBJECTIVES OF THE STUDY

**GENERAL OBJECTIVE**

To determine the prevalence of sensorineural hearing loss among patients with type 2 Diabetes Mellitus at the KNH.

**SPECIFIC OBJECTIVES**

1. To determine demographic and clinical characteristics of study subjects.
2. To determine pattern & degree of sensorineural hearing loss among diabetics.
3. To assess neural conductance along the auditory pathway.

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample Size</th>
<th>Findings</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toth (2001)</td>
<td>Case control</td>
<td>15/15</td>
<td>Lower amplitude of waves I,III,V</td>
<td>ABR</td>
</tr>
<tr>
<td>Durmus C (2004)</td>
<td>Case Control</td>
<td>43/43</td>
<td>Increased absolute latency</td>
<td>PTA/ABR</td>
</tr>
</tbody>
</table>
CHAPTER 3: STUDY METHODS

3.1 STUDY SITE AND POPULATION

The study site was the KNH Diabetic outpatient clinic located at clinic number 17 within the outpatient complex. The clinic is open on every weekday and in addition a consultant diabetic clinic is held on Friday. The screening hearing test was carried out at the KNH ENT outpatient clinic located at clinic number 34 within the outpatient complex. The ABR testing was carried out at the Nairobi audiology centre 1st floor Landmark plaza on Argwings Kodhek road approximately one kilometer from KNH. Currently KNH does not have a functional ABR machine. The Nairobi Audiology centre was chosen due its proximity to KNH and the availability of qualified audiologists.

The inclusion criteria were:

1. Patients diagnosed with type 2 diabetes mellitus at the Kenyatta National Hospital.
2. Patients between the ages of 18 and 55 years.
3. Patients who consent to participate in the study.

The exclusion criteria were:

1. Age greater than 55 years whose hearing loss may be complicated by presbycusis or less than 18 years as the vast majority of diabetic patients in this age group suffer from type 1 diabetes.
2. Diagnosed with congenital hearing loss
3. History of occupational noise exposure, middle ear disease, prior treatment with ototoxic medication and temporal bone trauma
4. Patients declining to participate in the study

3.2 STUDY DESIGN

This was a hospital based cross sectional survey.
3.3 SAMPLING

Simple random sampling was utilized until the desired sample size was reached.

The desired sample size as calculated using the formula\(^{51}\):

\[
\text{n} = \frac{u \sqrt{\pi (1 - \pi)} + v \sqrt{\pi_0 (1 - \pi_0)}}{(\pi - \pi_0)^2}
\]

Where:

- \( n \) = sample to be selected
- \( u \) = One-sided percentage point of the normal distribution corresponding to power of 80%, therefore 0.84
- \( v \) = Two-sided percentage point of the normal distribution corresponding to 95% level of significance, therefore 1.96
- \( \pi_0 \) = The proportion of hearing loss cases in the general population. Estimated to be 5.3% according to the World Health Organization\(^{52}\)
- \( \pi \) = The proportion hypothesized to be detected, given by 15%\(^{52}\)

The sample size obtained thus becomes 78 persons. Including a 5% increase in the sample to account for drop outs, we get a sample to be selected of 83 persons.

3.4 STUDY PROCEDURES

The principal researcher took participants bio data and a comprehensive history including duration of diabetes, co-morbidities, and medication use. The principal researcher also carried out a comprehensive otologic examination that included tuning fork tests and otoscopy to rule out middle ear disease.

Pure tone audiometry was done for each ear using a clinical audiometer AC 33 with supra aural earphones in a sound proof booth at the ENT department at the following frequencies: 250, 500, 1000, 2000, 4000, 6000 & 8000Hz. Pure tone audiometry was conducted by one trained audiologist to avoid inter-personal bias.

Participants were classified as having low/mid frequency hearing impairment if the average of the pure tone thresholds measured at 250, 500, 1000 & 2000 Hz in either ear exceeded 25dBHL. Participants were classified as having high frequency hearing impairment if the pure tone average measured at 4000, 6000 & 8000 Hz in either ear exceeds 25 dbHL.
ABR was recorded in a sound proof booth at the Nairobi Audiology center by a single trained audiologist. The Nairobi Audiology center is a private institution to which patients from KNH requiring ABR services are currently referred to. The Nairobi Audiology center is located on the 1st floor of Landmark Plaza along Argwings Kodhek road approximately one kilometer from KNH. Study participants were transported by the principal investigator to the site at no extra cost. ABR was recorded by placing active electrodes positioned at vertex and reference electrodes at each mastoid. A stimulus at a supra-threshold level of 80 dB was generated by using a 100 microsecond pulse. The equipment used for ABR was IHS – BERA. Two recordings were utilized.

Weight was measured using a SECA 799 electronic column scale that was calibrated daily, the scale has an attached measuring rod for measuring height, and this allowed both height and weight to be determined in one step.

Venous blood samples was collected by a trained phlebotomist and analysed at the KNH clinical chemistry laboratory number 16. Approximately 5 millilitres of blood was collected for analysis of glycosylated haemoglobin (HbA1c). Fasting blood glucose was analysed from a pin prick blood sample and measured in mmol/l using an Accu – Chek Aviva glucometer

3.5 DATA MANAGEMENT
Data was collected on questionnaires and entered into Microsoft Excel worksheets which were then be transferred to SPSS for analysis. All data was cleaned (including checks for completeness and consistency) before commencing analysis. All questionnaires and informed consent forms were stored securely in a lockable drawer in the University of Nairobi ENT department. Soft copy versions of the data were stored in a password protected laptop. The data was accessible only to the principal investigator

3.6 DATA ANALYSIS
The variables that were analysed were audiometry measures including right ear low frequency, right ear high frequency, left ear low frequency and left ear high frequency; gender; age; other
factors including anthropometric measures such as body mass index, waist circumference, glycosylated haemoglobin, fasting blood sugar and wave amplitude and inter-wave latencies. The outcome measures were the audiometry measures. Gender was the only binary variable. The continuous variables were converted to categorical variables for simplicity during univariate analysis. The dataset had no missing variables. All the data was used to conduct the analysis.

3.7 ETHICAL CONSIDERATIONS
The study was carried out after obtaining ethical approval from KNH – UON ethics and research committee (P704/11/2015 – appendix 4)

Results of the study will be published and made available to members of the medical fraternity
CHAPTER 4: RESULTS

a) Gender and Age characteristics

The sample had 44.9% (n=35) male participants and 55.1% (n=43) female participants. The study sample had a mean age of 43.9 years with a standard deviation of 8.3 and ranging from 22 to 55 years.

![Graph of Gender distribution in the study population](image)

**Figure 1: Graph of Gender distribution in the study population**

Prevalence Of Sensorineural Hearing impairment in the Study Population

The crude prevalence rate of hearing loss was found to be 39.7%. The WHO audiometric descriptor was used to assess the hearing level. Patients with slight sensorineural hearing loss accounted for most of the patients with hearing loss (90.3%). No patient had severe or profound hearing loss. Amongst the patients with hearing impairment, high frequency hearing loss was a lot more prevalent.
**Table 1:**

<table>
<thead>
<tr>
<th>Audiometry Outcome Measure</th>
<th>Audiometry Categories</th>
<th>Audiometry status frequency (Percentage)</th>
<th>Mean (Standard Deviation) in dbHL</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right low frequency</td>
<td>Normal Hearing</td>
<td>72 (92.31%)</td>
<td>15.47 (5.79)</td>
<td>5 – 30</td>
</tr>
<tr>
<td></td>
<td>Slight Hearing impairment</td>
<td>6 (7.69%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right high frequency</td>
<td>Normal Hearing</td>
<td>55 (70.51%)</td>
<td>19.95 (9.31)</td>
<td>5 – 50</td>
</tr>
<tr>
<td></td>
<td>Slight Hearing impairment</td>
<td>21 (26.92%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate hearing impairment</td>
<td>2 (2.56%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left low frequency</td>
<td>Normal Hearing</td>
<td>73 (93.59%)</td>
<td>16.12 (6.41)</td>
<td>5 – 38</td>
</tr>
<tr>
<td></td>
<td>Slight Hearing impairment</td>
<td>5 (6.41%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left high frequency</td>
<td>Normal Hearing</td>
<td>51 (65.38%)</td>
<td>20.29 (10.69)</td>
<td>5 – 56</td>
</tr>
<tr>
<td></td>
<td>Slight Hearing impairment</td>
<td>24 (30.77%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate hearing impairment</td>
<td>3 (3.85%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Symmetry of Hearing Loss**

A t-test was used to compare the means of audiometry outcome measures and thus assess the asymmetry of hearing loss in this sample. The Right high frequency mean was compared to the left high frequency mean while the right low frequency mean was compared to the left low frequency mean.

The t test results for the comparison between the right high frequency and left high frequency had a p-value of 0.6467, a mean difference of -0.35, and a 95% confidence interval of -2.17 to 1.48. The data showed that in the population, there was very little evidence against the
hypothesis that the right high frequency and left high frequency have different means. This therefore implies that the two means are equal thus symmetrical.

The t test results for the comparison between the right low frequency and left low frequency had a p-value of 0.8508, a mean difference of -0.64, and a 95% confidence interval of -1.86 to 0.58. The data showed that in the population, there was very little evidence against the hypothesis that the right low frequency and left low frequency have different means. This therefore implies that the two means are equal thus symmetrical.

ABR WAVE LATENCIES

The ABR latency values for the left and right ears are shown in the tables below. A t-test was further used to compare this values against the normative results. All the latency values yielded a p-value of 0.001 except interpeak latency values I-III and I-V. Therefore, there is very strong evidence against the hypothesis that the values in this sample are equal to the normative values. This therefore means that the results from this sample are not similar to normative results. However, in the case of interpeak latency I-III, there is very little evidence (p=0.865) against the hypothesis that the values in this sample are equal to the normative values while in the case of I-V (p=0.123) there is weak evidence against the hypothesis that the values in this sample are equal to the normative values.

**Table 2: Left and Right ear latency measures**

<table>
<thead>
<tr>
<th>Latency (msec)</th>
<th>I.</th>
<th>III.</th>
<th>V.</th>
<th>I-III</th>
<th>III-V</th>
<th>I-V</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Left Ear</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean(SD)</td>
<td>.67(.26)</td>
<td>2.87(.43)</td>
<td>4.64(.60)</td>
<td>2.20(.40)</td>
<td>1.77(.36)</td>
<td>3.97(.54)</td>
</tr>
<tr>
<td>Range</td>
<td>.20 – 1.73</td>
<td>1.67 – 3.73</td>
<td>2.8 – 5.47</td>
<td>1.13 – 2.8</td>
<td>.87 – 2.63</td>
<td>2.2 – 4.73</td>
</tr>
<tr>
<td><strong>Right Ear</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean(SD)</td>
<td>.67(.21)</td>
<td>2.88(.40)</td>
<td>4.61(.61)</td>
<td>2.21(.40)</td>
<td>1.73(.32)</td>
<td>3.93(.61)</td>
</tr>
<tr>
<td>Range</td>
<td>.27 – 1.27</td>
<td>1.60 – 3.47</td>
<td>2.67 – 5.47</td>
<td>1.0 – 2.87</td>
<td>.87 – 2.27</td>
<td>2.0 – 5.00</td>
</tr>
<tr>
<td>Comparison against the normative values*</td>
<td>1.54</td>
<td>3.70</td>
<td>5.60</td>
<td>2.20</td>
<td>1.84</td>
<td>4.04</td>
</tr>
</tbody>
</table>
RISK FACTORS

The anthropometric risk factor measures were body mass index, waist circumference, glycosylated haemoglobin, fasting blood sugar. The fasting blood sugar had a mean of 6.98 (standard deviation 2.02) and ranging from 2.2 to 14 mmol/l. The waist circumference ranged from 70 cm to 118 cm with a mean of 90.13 cm and standard deviation of 10.08 cm. The BMI and glycosylated haemoglobin are shown in table 3 below.

Table 3: The risk factors

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Categories</th>
<th>Frequency (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Mass Index</td>
<td>Underweight (&lt;18.0)</td>
<td>3 (3.85%)</td>
</tr>
<tr>
<td></td>
<td>Normal weight (18.1 – 24.9)</td>
<td>28 (35.90%)</td>
</tr>
<tr>
<td></td>
<td>Overweight (25.0 – 29.9)</td>
<td>30 (38.46%)</td>
</tr>
<tr>
<td></td>
<td>Obese (&gt;30)</td>
<td>17 (21.79%)</td>
</tr>
<tr>
<td>Waist Circumference</td>
<td>High risk men (&gt;120cm)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Low risk men (&lt;120cm)</td>
<td>35 (100%)</td>
</tr>
<tr>
<td></td>
<td>High risk women (&gt;88cm)</td>
<td>32 (71%)</td>
</tr>
<tr>
<td></td>
<td>Low risk women (&lt;88cm)</td>
<td>11 (25.58%)</td>
</tr>
<tr>
<td>Glycosylated haemoglobin</td>
<td>Good glycaemic control (&lt;7%)</td>
<td>43 (55.13%)</td>
</tr>
<tr>
<td></td>
<td>Poor glycaemic control (&gt;7%)</td>
<td>35 (44.87%)</td>
</tr>
<tr>
<td>Fasting blood sugar</td>
<td>Low (&lt;4 mmol/l)</td>
<td>1 (1.28%)</td>
</tr>
</tbody>
</table>

*p* reported by Schwartz, Pratt, and Schwartz (1990). Subjects: 20 subjects; 10 male, 10 female; age range of 19 to 36 years (mean age of 26 years); hearing threshold criteria not specified. Intensity level 80dB nHL; stimulus rate was not specified; repetitions, 2000 – 4000Hz. Acquisition-band pass filters.
Normal (4 – 7 mmol/l) & 45 (57.69%) \\
High (>7 mmol/l) & 32 (41.03%) \\

ASSOCIATIONS

Unadjusted odds ratios and chi-square tests were used to assess the association between hearing loss (outcome) and other independent variables (gender; comorbidities and treatments; other factors including anthropometric measures such as body mass index, glycosylated haemoglobin, and fasting blood sugar.)

Of the 78 patients in the study, 31 (39.7%) had hearing loss. There was strong evidence (p=0.002) of association between hearing loss and body mass index (OR presented in table 4 is stratum specific, pooled OR=0.33, 95% CI 0.02 – 4.95). There was weak evidence of association between hearing loss and hypertension (OR=2.45, 95% CI 0.94 – 6.44, p= 0.058). There was very little evidence of association between hearing loss and type of medication oral hypoglycaemics and insulin (OR=1.12, 95% CI 0.41 – 3.01, p= 0.736), sex (OR=1.22, 95% CI 0.28 – 3.06, p= 0.672), oral hypoglaecaemics only (OR=1.17, 95% CI 0.46 – 2.98, p= 0.736), Glycosylated haemoglobin (OR=1.27, 95% CI 0.51 – 3.17, p= 0.612) and fasting blood sugar (OR= 0.63, 95% CI 0.25 – 1.58, p=0.434). (Table 4)
### Table 4: Association of hearing loss with members' characteristics

<table>
<thead>
<tr>
<th>Categories</th>
<th>No, did not have hearing loss N=47</th>
<th>Yes, Had hearing loss N=31</th>
<th>Odds ratio of hearing loss (95% CI)</th>
<th>P-values</th>
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</thead>
<tbody>
<tr>
<td><strong>Comorbidities hypertension</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>27 (71.05%)</td>
<td>11 (28.95%)</td>
<td>1.00(Reference)</td>
<td>0.058</td>
</tr>
<tr>
<td>Yes</td>
<td>20 (50.00%)</td>
<td>20 (50.00%)</td>
<td>2.45(0.94, 6.44)</td>
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</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Male</td>
<td>22 (62.86%)</td>
<td>13 (37.14%)</td>
<td>1.00(Reference)</td>
<td>0.672</td>
</tr>
<tr>
<td>Female</td>
<td>25 (58.14%)</td>
<td>18 (41.86%)</td>
<td>1.22(0.48, 3.06)</td>
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</tr>
<tr>
<td><strong>Oral hypoglycaemics and Insulin</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>20 (62.50%)</td>
<td>12 (37.50%)</td>
<td>1.00(Reference)</td>
<td>0.736</td>
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<tr>
<td>Yes</td>
<td>27 (58.70%)</td>
<td>19 (41.30%)</td>
<td>1.12 (0.41, 3.01)</td>
<td></td>
</tr>
<tr>
<td><strong>Oral Hypoglaecaemics only</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>20 (62.50%)</td>
<td>12 (37.50%)</td>
<td>1.00(Reference)</td>
<td>0.736</td>
</tr>
<tr>
<td>Yes</td>
<td>27 (58.70%)</td>
<td>19 (41.30%)</td>
<td>1.17 (0.46, 2.98)</td>
<td></td>
</tr>
<tr>
<td><strong>Body Mass Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight (&lt; 18.0)</td>
<td>2 (66.67%)</td>
<td>1 (33.33%)</td>
<td>1.00(Reference)</td>
<td>0.002</td>
</tr>
<tr>
<td>Normal weight (18.1 – 24.9)</td>
<td>24 (85.71%)</td>
<td>4 (14.29%)</td>
<td>0.33(0.02, 4.59)</td>
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</tr>
<tr>
<td>Overweight (25.0 – 29.9)</td>
<td>11 (36.67%)</td>
<td>19 (63.33%)</td>
<td>3.45 (0.28, 42.62)</td>
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</tr>
<tr>
<td>Obese (&gt;30)</td>
<td>10 (58.82%)</td>
<td>7 (41.18%)</td>
<td>1.4 (0.11, 18.61)</td>
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</tr>
<tr>
<td><strong>Glycosylated haemoglobin</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good glycaemic control (&lt;7%)</td>
<td>27 (62.79%)</td>
<td>16 (37.21%)</td>
<td>1.00(Reference)</td>
<td>0.612</td>
</tr>
<tr>
<td>Poor glycaemic control</td>
<td>20 (57.14%)</td>
<td>15 (42.86%)</td>
<td>1.27 (0.51, 3.17)</td>
<td></td>
</tr>
</tbody>
</table>
### Chapte 5: Discussion

The prevalence rate of sensorineural hearing impairment among type 2 diabetics was found to be 39.7% which was slightly lower than what Akinpelu found in a systematic review in 2014 showing the prevalence ranging from 44% to 69.7% (32). However, the rate we found was higher than the prevalence of 21.6% found in a recent study in a tertiary health institution in Ogbomoso, Nigeria (53). A study by Mozzafari et al among diabetics less than 60 years found a 45% prevalence of sensorineural hearing loss (33).

It is interesting to note that the vast majority of patients with hearing loss (90.3%) had a mild hearing loss. The higher frequencies of 4 – 8 kHZ were the most affected and this was similar to the findings by Cullen and Cinnamond (8). This is important because most cases of mild hearing impairment may not produce sufficient clinical symptoms to warrant aggressive treatment. This implies that the possibility of having hearing loss impact the quality of life of type 2 diabetics is slight. However, these mild degrees of hearing loss may be easily worsened when superimposed upon by other conditions that affect the hearing organ.

The bilaterally symmetrical high frequency sensorineural hearing impairment is in keeping with histological findings in the inner ear of type 2 diabetics. A post mortem examination of 8 temporal bones of diabetics who had been known to have worse hearing as compared to age and sex matched controls revealed microangiopathy. Makashima and Tanaka found atrophy of spiral ganglia in the basal to middle turn of the cochlear (54)

We could not corroborate reports (7, 34) indicating that audiometric thresholds are correlated with poor glycaemic control. There was a strong association between hearing loss and BMI ( OR 0.33, 95% CI 0.02 – 4.95) and a slight association with co-morbid hypertension (OR=2.45, 95%)}
CI 0.94 – 6.44, P=0.058), cardiovascular disease and its risk factors have been linked to hearing impairment in the general population (37, 38).

**ABR WAVE LATENCIES**

The absolute wave latencies I, III, V were significantly shorter as compared to normative values as reported by Schwartz, Pratt and Schwartz (55) P value = 0.001. This is different from the reports of Durmus who found prolonged absolute latencies (48), and Gupta who found the latency of waves III & V were prolonged and wave I was equal in diabetics and control (50).

The interpeak latencies I – III, III – V, and I – V were similar when compared to normative values P values 0.865, 0.003, 0.123 respectively.

The shortened absolute latencies could be accounted for by the normative data set used from a Caucasian population and differing laboratory conditions. A study by Zakaria MN et al in Malaysia showed differences in the ABR wave latencies and amplitudes of ethnic Malay and Chinese when compared to Caucasian normative data sets (56).
CONCLUSION

The overall prevalence of sensorineural hearing impairment in type 2 diabetics was found to be 39.74%. Majority of the patients had mild hearing loss (90.3%) and was more prevalent in the higher frequencies (4 – 8 kHZ). These results are comparable to most studies.

The absolute wave latencies I, III & V were significantly shorter when compared to adult normative ABR data (P value = 0.001) and this differed from most other studies that found a prolongation of the latencies.

STUDY LIMITATIONS

It was not possible to completely rule out hearing loss from causes such as noise exposure and ototoxic medication especially as the feasibility of getting records of prior ototoxic medication usage was impossible.

The cost and added complexity of establishing a local normative data set for ABR latencies was a huddle this study could not surmount.

RECOMMENDATIONS

As the hearing loss associated with type 2 diabetes mellitus was shown to be mild, in a country such as Kenya where audiometry resources and qualified audiologists are scarce, the available evidence we have as of now doesn’t justify the added cost to advocate for routine hearing assessment in patients with type 2 diabetes mellitus.

A study should be done to establish normative ABR data amongst Kenyans for both adults and infants to be used by the various audiology facilities within the country.
## WORK PLAN

<table>
<thead>
<tr>
<th>PERIOD</th>
<th>ACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2015 – June 2015</td>
<td>Proposal writing</td>
</tr>
<tr>
<td>July 2015</td>
<td>Proposal presentation</td>
</tr>
<tr>
<td>January 2016</td>
<td>Ethical approval</td>
</tr>
<tr>
<td>February 2016 – April 2016</td>
<td>Data collection and analysis</td>
</tr>
<tr>
<td>May 2016</td>
<td>Report writing and submission</td>
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## BUDGET

<table>
<thead>
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<th>ITEM</th>
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</tr>
</thead>
<tbody>
<tr>
<td>ABR @ 5,000</td>
<td>400,000</td>
</tr>
<tr>
<td>PTA @ 700</td>
<td>56,000</td>
</tr>
<tr>
<td>STATIONARY</td>
<td>5,000</td>
</tr>
<tr>
<td>PRINTING &amp; BINDING</td>
<td>5,000</td>
</tr>
<tr>
<td>TRANSPORT</td>
<td>15,000</td>
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<tr>
<td>STATISTICIAN</td>
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<tr>
<td>DISSEMINATION OF RESULTS</td>
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</tr>
<tr>
<td>TOTAL</td>
<td>526,000</td>
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</table>
REFERENCES


15. Gratton MA, Schmiedt RA, Schulte BA. Age related decreases in endocochlear potential are associated with vascular abnormalities in the stria vascularis. *Hear Res* 1996;102: 181-190


29. WHO report of the informal working group on prevention of deafness and Hearing impairment programme planning. Geneva 1991


APPENDIX

APPENDIX 1: CONSENT INFORMATION DOCUMENT

TITLE: Prevalence and pattern of sensorineural hearing impairment among patients with type 2 diabetes mellitus at the Kenyatta National Hospital.

INTRODUCTION: My name is Dr. Neville Okwiri; I am pursuing a degree of Masters of Medicine in Ear, Nose, Throat, Head & Neck surgery at the University of Nairobi.

I would like to seek your permission to participate in the study as titled above. Kindly read the information provided. You are free to discuss this with family and friends and I am willing to answer any questions raised.

OBJECTIVES OF THE STUDY: TO determine the prevalence and pattern of sensorineural hearing impairment among patients with type 2 diabetes mellitus at the Kenyatta National hospital.

HOW YOU WILL PARTICIPATE: Your role in this study, should you agree to participate will be as follows. We will ask you questions and review your medical records seeking to know when the condition was diagnosed and current treatment. A comprehensive otologic examination will be carried out. A blood and urine sample will be obtained, as part of the comprehensive care of diabetics these are routine tests that are done at KNH even if one wasn’t participating in the study. Minimal pain and discomfort will be experienced at the time of drawing the sample.

You will undergo a screening hearing test at the KNH ENT audiology unit and a specialized auditory brainstem response testing at Nairobi audiology centre located one kilometer from KNH. We will bear the cost of testing and transportation. Similar findings from all participants will be used for analysis.

BENEFITS: You may not accrue direct benefit by participating in this study, but your participation will greatly contribute to our better understanding of the effects that diabetes has on hearing.

RISKS: Participation in this study is expected to have no risk. Your choosing or declining to participate in this study will NOT have any impact on the quality of care that you will receive.

VOLUNTARISM: Participation in this study is voluntary.
RIGHTS OF STUDY PARTICIPANTS: You are at liberty to decline participation or withdraw from the study at any point.

COMPENSATION: No monetary or material compensation will be offered to study participants.

CONFIDENTIALITY: Strict confidentiality will be maintained at all times. Your name and test results will not be linked and no single test result will be reported on its own but as a summation of all the results.

If you understand everything said and are willing to participate kindly sign the consent form provided.

If you have any questions or need further clarifications about the study contact the principal investigator, Dr. Neville Okwiri on phone number 0733-954411.

If you have any questions on your rights as a participant contact the Kenyatta National Hospital Ethics and Research Committee (KNH-ERC) by calling 2726300 Ext. 44355.
KIAMBATISHO 1: FOMU YA MAELEZO KUHUSU IDHINI YA MGONJWA

KICHWA: Idadi na ruwaza ya upungufu wa kusikia miongoni mwa wagonjwa na kisukari aina 2 katika hospitali kuu ya Kenyatta.

KIINGILIO: Jina langu ni Daktari Neville Okwiri mwanafunzi wa Shahada ya Uzamili wa upasua jiwa masikio, mapua na koo.

Ningependa kuchukua idhini au ruhusa kwako kushiriki katika utafiti. Tafadhali soma maelezo yafuatayo, ukihitaji kushauriana na jamaa na familia unauhuru wa kufanya hivyo na niko tayari kujibu maswali yoyote.

LENGO LA UTAFITI: Kutathmini ida di na sababu zinazo changia kwa upungufu wa kusikia miongoni mwa wagonjwa na kisukari aina 2 katika hospitali kuu ya Kenyatta.


FAIDA: Habari itakayotokea na utafiti huu peingine haitakufaidi binafsi lakini itatupa maarifa ambayo itaboresha matibabu wa ugonjwa hii siku zijazo.

ATHARI: Hakuna hatari yoyote itakayo jiri kwa kushiriki au kutoshiriki.

HIARI: kushiriki katika utafiti huu ni kwa hiari yako.

HAKI: Uko uhuru kutoshiriki au kujiondoa kwa utafiti huu wakati wowote ule.

FIDIA: Hakuna pesa au chochote kile kitapewa kwa washiriki wa utafiti huu

USIRI: usiri utahakikishwa wakati wote.

Kama umeridhika na maelezo, na uko tayari kushiriki, tafadhali weka sahihi yako kwenye fomu ya idhini.

Ikiwa una swali ama ungetaka kupata maelezo zaidi kuhusu utafiti huu, wasiliana na mtafiti mkuu Daktari Neville Okwiri kupitia nambari ya simu 0733-954411 au KNH-ERC kupitia nambari ya simu 2726300 Ext. 44355.
APPENDIX 2: CONSENT FORM

STUDY NUMBER ____________________

I Mr. / Mrs. / Miss ______________________ hereby agree to enroll myself into this study as explained to me by Dr. Neville Okwiri.

My signature is confirmation that I have understood the nature of the study and that whatever information I give will remain confidential.

I also confirm that no monetary or material gains have been promised or given to me for participating in the study.

Signed ___________________________ Date ___________________________

Signature of principal investigator ___________________________

Date ___________________________

KIAMBATISHO 2: KIBALI CHA UTAFITI

NAMBARI YA UTAFITI __________________________

Mimi Bi / Bwana ___________________________ nimekubali kushiriki katika utafiti huu baada ya kuelezwa na daktari Neville OKwiri.

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

Pia nathibitisha ya kwamba sijapewa au kuahadiwa pesa au chochote kile, kushiriki kwenye utafiti huu. Sahihi_______________ tarehe_______________
Appendix 3: study proforma

STUDY NUMBER ____________

1. BIODATA

   Age ___________

   Sex   M______ F ________

2. CLINICAL

   • Duration of illness ____________________

   • Type of medication

<table>
<thead>
<tr>
<th>Diet modification ONLY</th>
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<tbody>
<tr>
<td>Oral hypoglycaemics ONLY</td>
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</tr>
<tr>
<td>Insulin ONLY</td>
<td></td>
</tr>
<tr>
<td>Oral hypoglycaemics &amp; Insulin</td>
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   • Co – morbidities

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<tbody>
<tr>
<td>Hypertension</td>
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<tr>
<td>Chronic kidney disease</td>
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</tr>
<tr>
<td>Stroke</td>
<td></td>
</tr>
<tr>
<td>Heart disease</td>
<td></td>
</tr>
<tr>
<td>Foot ulcer/ amputation</td>
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</table>

3. CLINICAL EXAMINATION
• Tuning fork tests: Rhinne’s left ________ Rhinne’s right ________ Weber ________

• PTA findings: Degree of Hearing loss (WHO audiometric descriptor\textsuperscript{27})

<table>
<thead>
<tr>
<th>Degree of Hearing Loss</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Normal (&lt;25dbHL)</td>
<td></td>
</tr>
<tr>
<td>Slight (25 – 40dbHL)</td>
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</tr>
<tr>
<td>Moderate (41-60 dbHL)</td>
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</tr>
<tr>
<td>Severe (61 – 80 dbHL)</td>
<td></td>
</tr>
<tr>
<td>Profound (&gt;81 dbHL)</td>
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</tbody>
</table>

• Anthropometric measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
</tr>
<tr>
<td>Waist circumference</td>
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</table>

4. LABORATORY MEASURES

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<tr>
<th>Test</th>
<th>Measurement</th>
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<tr>
<td>Fasting blood sugar</td>
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</tr>
<tr>
<td>HbA1c</td>
<td></td>
</tr>
<tr>
<td>Urinalysis</td>
<td></td>
</tr>
<tr>
<td>Serum creatinine</td>
<td></td>
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<td>EGFR</td>
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5. AUDITORY BRAINSTEM RESPONSE

<table>
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<tr>
<th>Wave</th>
<th>Intensity (in dB)</th>
<th>Latency (msec)</th>
<th>morphology</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>V</td>
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<td></td>
<td></td>
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<tr>
<td>I - III</td>
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</tr>
<tr>
<td>I - V</td>
<td></td>
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</tr>
</tbody>
</table>
Appendix 4: Ethical approval

Revised research proposal: Prevalence and Pattern of Sensorineural Hearing Impairment among Patients with Type 2 Diabetes Mellitus at the Kenyatta National Hospital (PT04/11/2015)

This is to inform you that the KNH-UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above proposal. The approval period is from 15th February 2016 – 14th February 2017.

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) 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).
f) Clearance for export of biological specimens must be obtained from KNH-UoN ERC for each batch of shipment.
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 Deputy Director, CS, KNH
     The Chair, KNH-UoN ERC
     The Assistant Director, Health Information, KNH
     The Dean, School of Medicine, UoN
     The Chair, Dept. of Surgery, UoN
     Supervisors: Prof. Isaac Macharia, Dr. Catherine Irungu