

**HYPERTENSION AS A RISK FACTOR OF HEARING LOSS IN PATIENTS  
ATTENDING THE HYPERTENSIVE CLINIC AT THE KENYATTA NATIONAL  
HOSPITAL**

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**A thesis submitted as partial fulfillment of the requirements by the University of  
Nairobi, for the award of the degree of Masters of Medicine in Otorhinolaryngology,  
Head and Neck Surgery.**

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## DECLARATION

I declare that this thesis is my original work and has not been presented for the award of a degree at any other university.

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## TABLE OF CONTENTS

<b>DECLARATION</b> .....	<b>ii</b>
<b>ACKNOWLEDGEMENT</b> .....	<b>iii</b>
<b>TABLE OF CONTENTS</b> .....	<b>iv</b>
<b>LIST OF TABLES AND FIGURES</b> .....	<b>vi</b>
<b>ABBREVIATIONS</b> .....	<b>vii</b>
<b>ABSTRACT</b> .....	<b>viii</b>
1.0 Introduction .....	1
2.0 Background .....	2
2.1 Anatomy and physiology of the auditory system.....	2
2.2 Blood supply of inner ear.....	3
2.3 Hearing loss.....	6
2.4 Hypertension .....	8
2.5 Hypertension and hearing loss .....	9
3.0 Literature review .....	11
4. Justification .....	14
5. Research question.....	14
6.0 Objectives.....	15
6.1 Broad objective.....	15
6.2 Specific objectives .....	15
7.0 Methodology .....	16
7.1 Study design .....	16
7.2 Study area.....	16
7.3 Study population.....	16

7.4 Inclusion criteria .....	16
7.5 Exclusion criteria .....	16
7.6 Sample size.....	17
7.7 Sampling Procedure.....	18
7.8 Quality control.....	19
7.9 Study limitations.....	19
7.10 Data management and analysis .....	20
7.11 Ethical consideration.....	21
8.0 Results.....	22
9.0 Discussion .....	29
10.0 Conclusion.....	31
11.0 Recommendation .....	32
<b>REFERENCES .....</b>	<b>33</b>
<b>APPENDICES .....</b>	<b>39</b>
Appendix 1: General Patient Information.....	39
Appendix 2: Consent Form.....	42
Appendix 3: Questionnaire .....	44
Appendix 4: KNH-UON ERC Letter .....	46

## LIST OF TABLES AND FIGURES

### FIGURES

Figure 1:Anatomy of the auditory system. ....	3
Figure 2: Blood supply to the inner ear. ....	5
Figure 3: Pie chart showing degree of hearing loss distribution among cases .....	25
Figure 4: showing degree of hearing loss distribution among controls.....	25
Figure 5: Duration of treatment and number of patients with hearing loss .....	27

### TABLES

Table 1: WHO grading of hearing impairment.....	7
Table 2: WHO/ISH grading of blood pressure .....	8
Table 3: Gender distribution of patients .....	22
Table 4: Age distribution of patients .....	22
Table 5. Duration of treatment.....	23
Table 6: History of tinnitus.....	23
Table 7: Blood pressure findings .....	24
Table 8: patients with hearing loss in both cases and controls .....	25
Table 9: pattern of hearing loss.....	26
Table 10: Grade of hypertension and hearing loss.....	27
Table 11: Pearson correlation between age and hearing loss .....	28

## ABBREVIATIONS

ABR	Auditory Brainstem Response
AICA	Anterior Inferior Cerebellar Artery
BP	Blood Pressure
CHL	Conductive Hearing Loss
CN	Cranial Nerve
dB	Decibel
DBP	Diastolic Blood Pressure
DHL	Disabling Hearing Loss
DpOAE	Distortion product Otoacoustic Emission
ENT	Ear, Nose and Throat
HELLP	Hemolysis, Elevated Liver enzymes, Low Platelet count
HZ	Hertz
ISH	International Society of Hypertension
JNC	Joint National Committee
KNH	Kenyatta National Hospital
MHL	Mixed Hearing Loss
mmHg	Millimeters of Mercury
MOPC	Medical Outpatient Clinic
OHC	Outer Hair Cells
PTA	Pure Tone Audiometry
SBP	Systolic Blood Pressure
SNHL	Sensorineural Hearing Loss
UON	University of Nairobi
WHO	World Health Organization

## ABSTRACT

**Background:** Hearing loss is the most frequent sensory deficit in the human population with World Health organization estimating 360 million people in the world to have disabling hearing loss of which 328 million (91%) are adults. Hypertension whose prevalence in developing countries is increasing, has been associated with sensorineural hearing loss in recent studies. Hypertension causes sensorineural hearing loss by microcirculatory insufficiency in the cochlear. Primary prevention, delaying onset of hypertension and consistent control of high blood pressure can significantly decrease the burden of hearing loss in patients.

**Study objective:** To determine the association between hearing loss and hypertension in patients on treatment for hypertension at the Kenyatta National Hospital.

**Methods:** Case control study with 51 hypertensive patients aged 45 to 64 years on treatment at KNH MOPC as cases and 51 non-hypertensive patients aged 45 to 64 years attending dental outpatient clinic as controls. A detailed history, physical examination, blood pressure measurement and otoscopy was done by the primary investigator. Pure tone audiometry (PTA) was conducted by a qualified audiologist in the ENT clinic.

**Results:** Thirteen out of fifty one hypertensive patients (25.5%) and seven out of fifty one non-hypertensive patients (13.7%) had hearing loss. Four out of twenty two (18.2%) patients with grade 1 hypertension and three out of eleven (27.3%) with grade 2 hypertension had hearing loss. Among the hypertensive patients 29.0% who had been treated for 5 years or less had hearing loss while 33.3% who had hypertension for more than 10 years had hearing loss. Ten out of the 13 (76.9%) hypertensive patients had mild hearing loss. Twenty (39.2%) of the hypertensive patients had tinnitus.

**Conclusion:** This study has shown that hypertension is a risk factor for hearing loss as demonstrated by the higher prevalence and raised hearing threshold levels by pure tone audiometry in all frequencies in the hypertensive patients. However, it is not statistically significant.



## **1.0 INTRODUCTION**

Hearing loss is any degree of impairment of the ability to comprehend sound. It is partial or total inability to hear sound in either one or both ears. Hearing loss is the most frequent sensory deficit in the human population with WHO (1) estimating 360 million people in the world to have disabling hearing loss of which 328 million (91%) are adults. Fifty percent of the causes are avoidable by prevention or early treatment. Hypertension is one of the causative factors.

Hypertension is defined as systolic blood pressure equal to or more than 140mmHg and diastolic blood pressure equal to or more than 90 mmHg taken at least in three different settings 6 hours apart. The prevalence of hypertension in developing countries is increasing rapidly despite it being a preventable disease in a significant number of cases (2).

A study by Chen et al (3) and Marchiori et al (4) has shown that the duration and complications of hypertension accelerate and worsen hearing loss. Hypertension causes sensorineural hearing loss by microcirculatory insufficiency. This may occur due to vascular occlusion caused by emboli or vasospasm. Increased blood pressure may cause microangiopathy and micro hemorrhage in the cochlea vessels. This will lead to increase in blood viscosity (5) and a decrease in tissue oxygenation (6, 7). Primary prevention, delaying onset of hypertension and consistent control of high blood pressure can significantly decrease the burden of hearing loss in patients.

## **2.0 BACKGROUND**

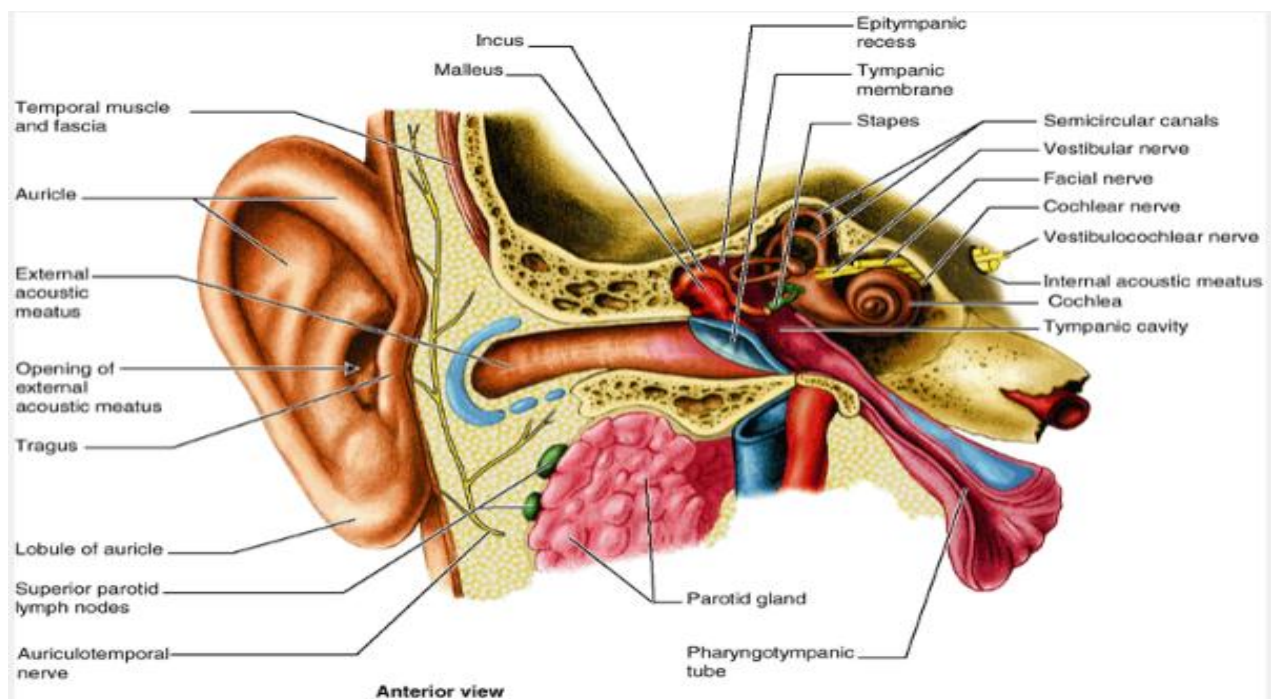
### **2.1 Anatomy and physiology of the auditory system**

The ear is made up of outer, middle and inner ear. The inner ear is made up of auditory (cochlear) part and vestibular apparatus. The vestibular apparatus consists of the saccule, the utricle and the three semicircular canals. The outer and middle ear is responsible for transmission of sound waves from air to the inner ear. In the cochlear the sound waves are converted into electrical impulses sent along the nerve to the brain.

The auditory part of inner ear is made up of the cochlear which in turn has 3 chambers; the scala media, tympani and vestibule. The scala media houses the organ of Corti which has outer and inner hair cells. The outer hair cells (OHC) are in three rows and are 20,000 in number. The tips of the hair cells are in contact with the tectorial membrane. They constitute 5-10% of afferent neurons while majority of the efferent neurons from cranial nerve 8, auditory part terminate on them. The outer hair cells are responsible for hearing depending on their stimulation by the sound wave. Inner hair cells (IHC) form one row, are 3,500 in each cochlear and constitute 90-95% of afferent neurons. They are the primary sensory cells for hearing and receive a minority of the efferent innervation. The inner ear also has an autonomic nerve supply. The autonomic fibers are mostly adrenergic sympathetic nerve fibers and innervate blood vessels. They also contact hair cells.

The stria vascularis is an important structure located between the perilymphatic and the endolymphatic space along the cochlear wall. The stria vascularis as shall be seen later can be adversely affected by hypertension. It has a rich blood supply. It is supported by the spiral ligament, to which the basilar membrane is attached. Stria vascularis maintains the ionic concentration of the endolymph which is important for normal functioning of the organ of Corti and cochlear. Consequently, in a compromised integrity of stria vascularis such as seen

in hypertension, the ionic composition of endolymph will be adversely changed further undermining its function. The IHC are the primary sensory cells that generate action potentials in the auditory nerve. But, if the OHC are not functioning normally even with intact IHC, a louder sound is required to cause impulse transmission. This malfunction of the OHC can cause a hearing loss of up to 40-50dB, and tends to compromise ability to understand speech in a noisy background.



Moore, Keith L: Clinically Oriented Anatomy, 5th Edition, pg 1023

**Figure 1: Anatomy of the auditory system.**

## 2.2 Blood supply of inner ear

The vascular supply to the cochlea is complex. The arterial supply to the cochlea is the labyrinthine artery. It originates in the anterior inferior cerebellar artery (AICA) and follows the eighth cranial nerve in the internal auditory meatus, where it gives off the anterior vestibular artery to the vestibular apparatus. In the internal auditory meatus the labyrinthine

artery branches to form the vestibular-cochlear artery that supplies parts of the cochlear (8). The other branch is the spiral modiolar artery that serves as a collateral blood supply to the cochlear (9). The labyrinthine artery is an end-artery with little or no collateral blood supply to the cochlear (10). The labyrinthine artery that runs in the internal auditory meatus is not a single artery but several smaller arterioles, almost like an arterial plexus. Such a series of parallel small caliber arteries attenuate rapid changes in blood flow and thus contribute to providing a smooth blood supply to the cochlear and the vestibular system. The small diameter arteries in connection with a distal reservoir function as a low-pass filter that attenuates fast changes in blood flow. Pulsation of the blood flow in the cochlear could excite hair cells, which would result in constantly hearing ones own pulses.

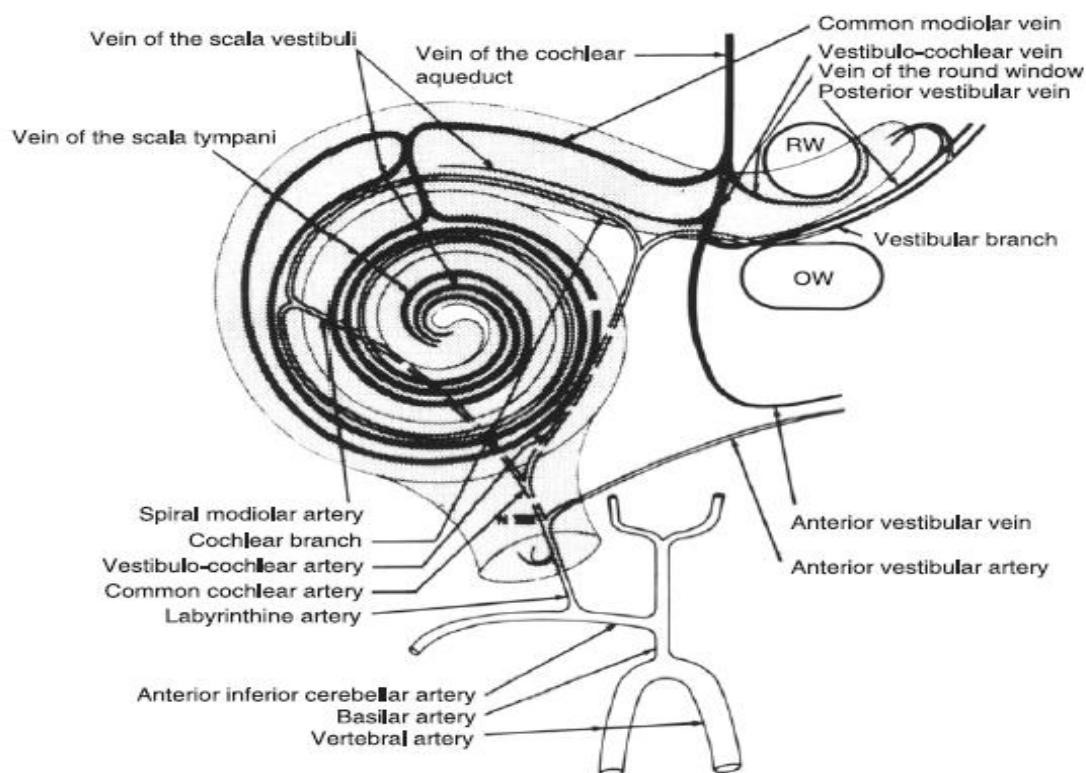
In order for the cochlear to function properly, the blood supply to the cochlear must be kept within relatively narrow limits and arterial pulsation must be kept low (11). Autoregulation of cerebral blood flow is an important mechanism for maintaining constant perfusion of the brain, independent of fluctuations in systemic blood pressure. In the brain, autoregulation is maintained by controlling the width of arterioles. Similar regulation of cochlear blood flow is unknown. The labyrinthine artery consists of many small arterioles, which could be the anatomical basis for such an autoregulation. However, cochlear blood flow is affected by catecholamines such as epinephrine and that contradicts autoregulation. A study by Carrasco (6) on cochlear microcirculation, effect of adrenergic agonists on arteriole diameter, the findings were consistent with arteriolar constriction in response to  $\alpha$ -adrenergic stimulation. The presence of  $\alpha_1$  and  $\alpha_2$  receptors was established, with a predominance of  $\alpha_2$  receptors in the cochlear.

Sensorineural hearing loss (SNHL) can occur during disorders where plasma viscosity is altered, for example in leukemia, polycythemia or sickle cell disease (5), pathology of the

cochlear or interruption of the blood supply to the cochlear. Normal function of the cochlear depends on correct blood supply. Variation in perfusion caused by vascular occlusion via atherosclerosis which occurs in hypertension, diabetes and hypercholesterolemia, sudden rise or cessation of blood supply or wild fluctuation as occurs in hypertension, may therefore give rise to abnormal function of the cochlear (11).

Thrombosis which can occur in cardiovascular disease or bleeding of the labyrinthine artery or surgical injury to the artery results in deafness on that ear. Bleeding into the subarachnoid space can produce both auditory and vestibular symptoms. This has been postulated to be due to the leakage of blood products into the inner ear.

A study done by Bachor et al (8) on the vascular variations in the temporal bone showed a possible link between vascular variations and function disturbance in the inner ear.



Moller, Hearing-anatomy, physiology and disorders of the auditory system 2nd ed.pg 17

**Figure 2: Blood supply to the inner ear.**

### **2.3 Hearing loss**

Hearing loss is any degree of impairment of the ability to comprehend sound. It is either a partial or total inability to hear affecting one or both ears. Hearing loss is the most frequent sensory deficit in the human population. In adults, disabling hearing loss refers to the inability to hear 40dB or more in the better ear (1). Hearing loss is divided into 3, sensorineural (SNHL), conductive (CHL) and mixed (MHL). Conductive hearing loss is reversible in most cases while SNHL tends to be irreversible hence a lot is emphasized on prevention. Ninety one percent of disabling hearing loss occurs in adults with half being preventable (1). In adults hearing loss due to aging occurs from the third decade and men are affected more than women. Hearing loss may be worse in elderly patients who have other parallel advancing age pathologies including hypertension. Any degree of hearing loss will affect communication and this will lead to a reduced quality of life. It has psychosocial effects, like low self-esteem, isolation, depression and irritability.

The degree of hearing impairment, as graded by WHO is shown in the table below,

**Table 1: WHO grading of hearing impairment**

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

**Table From: ©WHO 2015**

Grades 2, 3 and 4 are classified as disabling hearing impairment. The audiometric ISO values are averages of values at 500Hz,1000Hz,2000Hz &4000 Hz.

The management of SNHL depends on the degree of impairment. Grade 1 to 3 can be managed by hearing aids while grade 4 plus the other candidates who don't benefit from hearing aids over six months need cochlear implant. Aural rehabilitation, lip reading, sign language and assistive listening devices are other management options.

## 2.4 Hypertension

Hypertension is defined as systolic blood pressure more than or equal to 140 mmHg and or diastolic blood pressure more than or equal to 90 mmHg, readings taken at least in three different settings or use of prescribed antihypertensive medication (12). WHO/ISH divides it into three grades, as shown below (13);

**Table 2: WHO/ISH grading of blood pressure**

Blood pressure	Grade 1	Grade 2	Grade 3
SBP mmHg	140-159	160-179	≥180
DBP mmHg	90-99	100-109	≥110

Hypertension is a leading cause of cardiovascular disease worldwide (14). The burden of disease in the world caused by hypertension was 4.5% in 2000 (15) and increased to 7% in 2010 (16). This puts hypertension as a significant cause of morbidity and mortality. Hypertension is now the most common cardiovascular problem in Africa, and it is estimated that more than 20 million people are affected (17). In Kenya, studies have shown a prevalence ranging between 6.4% to 50.1% in different populations and age groups (2, 18-20). This prevalence is of public health concern as hypertension is associated with many complications with hearing loss being one of them.

Management is by lifestyle modification and medication (21) to lower and maintain blood pressure less than 140/90mmHg. According to JNC 7 data up to 67% have uncontrolled BP hence at risk of complications (21). Medications used to treat hypertension are calcium



channel blockers, beta-blockers, angiotensin receptor blockers, diuretics and angiotensin-converting enzyme inhibitors among others. These are used either singly or in combination.

With proper public awareness, most causes of hypertension are preventable. For those who already have the disease proper control can significantly reduce complications (22-25), including hearing loss. Agrawal recommended that efficient treatment for diabetes mellitus and high blood pressure may delay hearing loss onset (26).

## **2.5 Hypertension and hearing loss**

All living cells in the human body depend on a proper supply of oxygen and nutrients in order to maintain their function. The supply depends on the functional and structural integrity of the heart and blood vessels. Hypertension facilitates structural changes in the heart and blood vessels (27). Uncontrolled blood pressure can result in generalized arteriosclerosis. The inner ear vessels are also affected. Tachibana (28) showed that acute hypertension leads to leakage of a macromolecule in the temporal bone. In chronic hypertensive states, stria vascularis cells may be damaged if some substances leak into its extracellular space (29). With a reduced cochlear blood flow in a rabbit model, distortion product OAEs were reduced (30) and this may create irreversible damage to cochlear integrity.

Chronic hypertension potentiates noise induced cochlear damage histologically and thus decrease in cochlear function (31). High pressure in the vascular system may cause inner ear hemorrhage, which may cause progressive or sudden hearing loss (27). Systemic arterial hypertension has been shown to cause retinal vascular changes and has been significantly correlated with hearing loss (32). It may also cause ionic changes in the hair cells and high action potential thresholds thus causing hearing loss (33).

Fang (34) found out that the vessel changes in patients with age related hearing loss might be accelerated by atherosclerosis and hypertension. The vessel changes result from endothelial dysfunction which predisposes to the development of a pro-thrombotic state. The endothelium malfunction results in development of adhesion molecules, endothelial progenitor cells and pro-inflammatory vascular conditions which lead to distortion of the ear microcirculation impairing cochlear functions (35). Preeclampsia, a vascular disorder in pregnancy characterized by proteinuria and hypertension, is thought to affect cochlear microcirculation through vasospasm, endothelial dysfunction and ischaemia (36). Bakhshae et al (37) has shown a positive correlation between preeclampsia and hearing loss using TEOAES.

The organ of Corti hugely depends on the spiral artery for oxygenation (38,

39). Patients undergoing cochlear implants may get a worsening of hearing if the spiral artery is injured during the procedure.

### **3.0 LITERATURE REVIEW**

Hearing loss has multi-factorial causation and hypertension is one of the preventable risk factors. Studies outside Africa have shown a link between hypertension and hearing loss with prevalence ranging from 7.3% to 59.2%. The studies have also shown an association between duration & severity (grade) of hypertension and the prevalence and degree of hearing loss. The data on prevalence, patterns of hearing loss, degree of hearing loss in relation to hypertension is scanty in sub-Saharan Africa. The audiological tests used to assess hearing loss are PTA, ABR and OAE. Saurabh Agarwal et al (40) in 2013 did a case controlled study on the effects of hypertension on hearing. The study conducted in India had 150 cases and 124 controls both genders aged between 45-64 years with males comprising 65.8%. Hearing was assessed by measuring pure tone threshold at 250 - 8,000 Hz. They found that the p value calculated by Pearson's correlation method was less than 0.001 showing a significant association between hypertension and increase in hearing thresholds. In the study, there was a mild hearing loss in 18 % of patients without hypertension, 36.7 % of patients with grade 1 hypertension, grade 2 hypertension had 40.4% while they were 54.2% of the patients with grade 3 hypertension. Grade 3 hypertensive patients had a longer duration of hypertension, a mean of 9 years while those with grade 1 had a mean duration of 3.7 years. The results thus showed that duration and severity of hypertension increase risk of hearing loss.

Marchiori et al (4) in 2004 did a non-paired case-control study on hypertension as a factor associated with hearing loss. The study was conducted in South Brazil and had 154 cases with hearing loss and 154 controls without hearing loss, both genders, aged 45 to 64 years. Women predominated with 57.8% in cases and 77.3% in controls. Pure tone audiometry was used for hearing assessment. Seventy two (46.8%) of the cases, had hypertension and hearing loss while 108 (70.1%) without hearing loss (controls) did not have hypertension. The degree of

hearing loss was mild in 62% of the cases. They concluded that hypertension was significantly associated with hearing loss.

In 2014 in Mumbai, Harish Chander Goel et al (41), conducted a prospective age and sex matched study on the effect of systemic hypertension on inner ear functions. The study had 50 cases with hypertension and 50 controls without hypertension age and sex matched. They found that hearing threshold levels by PTA were raised in all frequencies along with impaired vestibular functions (10%) in hypertensive patients and correlated with the degree of hypertensive retinopathy changes. All cases with moderate SNHL had grade II retinopathy while 68% of the cases had hearing loss. Hypertension is postulated to cause inner ear vascular disorders and to impair its function in a similar way as of hypertensive retinopathy. Distortion product Otoacoustic emissions (DpOAE) were not evident in the octaves from 2 to 5 KHz in 22% of patients suffering from hypertension as opposed to 8% of controls.

Chen YL and Ding YP (3) in 1997 did a Prospective case-control study on relationship between hypertension and hearing disorders of the elderly. The study was conducted in Shandong province, China. It included 50 subjects with hypertension (cases) and 50 subjects without hypertension (controls) all males aged between 55 and 89 years. Pure tone audiometry and ABR was done. The hearing thresholds by PTA increased with age more in the hypertensive patients. ABR showed prolonged absolute latencies of wave V and inter peak latency of wave I-V and III-V. The duration and complications of hypertension also had influence on hearing impairment.

Altuntas EE et al (42) in 2012 did a prospective, case-control study to compare the ratio of hearing loss evaluated with transient evoked otoacoustic emission (TEOAEs) testing in normal and hypertensive pregnant women during the first week after delivery in Cumhuriyet university hospital, Turkey. Cases included 96 women with gestational hypertension,

preeclampsia, eclampsia or HELLP (hemolysis, elevated liver enzymes, low platelet count) syndrome, while the controls included age-matched 107 women with normal pregnancy. Preeclampsia is a vascular disorder which affects microcirculation and would be expected to cause cochlear dysfunction. Hearing loss demonstrated using TEOAE during the first postpartum week was detected in seven (7.3%) women in the hypertensive pregnancy group and in three (2.8%) women without hypertension. Both TEOAEs and PTA results were not statistically significantly different in the cases and controls. However hearing loss detected using TEOAEs was significant in the HELLP syndrome group.

Sogebi (43) did a prospective, comparative, hospital-based study in Nigeria using PTA to assess hearing. He had 76 subjects with SNHL and 51 controls without SNHL age and sex matched. Age ranged between 45-94 years and males were 59.8%. Logistic regression analysis revealed that hypertension, with odds ratio (OR) =7.5 and P=0.010, had significantly increased odds of developing SNHL. The other risk factors included family history of hearing loss (OR= 26.3), head injury (OR=56.8), noise exposure (OR=17.3), ototoxic drugs (OR=6.3) and cigarette smoking (OR=19.2). The extreme of age may have had an influence on the results as the prevalence of hearing impairment is higher after 65 years.

Hutchison et al (44) in a cross sectional study conducted in United States of America with 101 participants aged between 10-78 years examined the correlation between cardiovascular health (including hypertension) and hearing function. Hearing assessment was done by PTA and DpOAEs. They found that the lower the cardiovascular fitness and the higher the age, the worse the PTA at high frequencies (2 & 4 KHz). OAEs were better for the cardiovascular fit subjects but not statistically significant.

In 2007 Mondelli & Lopes (45) did a retrospective review using pure tone audiometry, auditory anamneses and tympanogram to assess hearing loss. The study conducted in Brazil

comprised of 392 patients with hearing loss aged between 45-60 years. They found that 232 (111 males and 121 females) had hypertension and hearing loss (59.2%). Moderate SNHL was at 56.7% and tinnitus at 43.7%.

#### **4.0 JUSTIFICATION**

Hearing loss has been associated with hypertension. Hypertension is becoming a public health concern in the developing countries and Kenya is not an exception. The prevalence of hypertension is increasing in Kenya despite its link with risk factors that can be avoided. Hearing loss is approaching epidemic levels for those in the middle age cohort and above. Hearing disability reduces productivity & quality of life, impedes health care access and increases medical expenses. Studies in the developed countries on the association between hypertension and hearing loss have been conducted but such data is missing in our set up. Therefore, this study will help to get local data on whether hypertension is a risk factor for hearing loss and if so, the patterns of hearing loss. The data will help in giving emphasis on the prevention of hearing loss in hypertensive patients by ensuring proper blood pressure control and rehabilitation for those already affected. The data will help in improving quality of care of these patients by linking them to otorhinolaryngologists and audiologists.

#### **5.0 RESEARCH QUESTION**

What is the association between hearing loss and hypertension in patients on treatment for hypertension at the KNH.

## **6.0 OBJECTIVES**

### **6.1 Broad objective**

To determine the association between hearing loss and hypertension in patients with hypertension being treated at the KNH.

### **6.2 Specific objectives**

To determine the proportion of patients with hearing loss in hypertensive patients on treatment at the KNH.

To determine the proportion of patients with hearing loss in non-hypertensive patients on treatment at the KNH.

To determine the patterns of hearing loss in the hypertensive and non- hypertensive patients on treatment at the KNH.

To determine the association between the grade of hypertension and hearing loss in hypertensive and non-hypertensive patients on treatment at the KNH.

## **7.0 METHODOLOGY**

### **7.1 Study design**

This is a case control study.

### **7.2 Study area**

The hypertension medical outpatient clinic (MOPC), the dental outpatient clinic and the ear nose and throat (ENT) clinic at the KNH.

### **7.3 Study population**

The study sample comprised of hypertensive patients, aged 45 to 64 years on treatment at hypertension clinic at the KNH as cases and non- hypertensive patients attending the dental outpatient clinic at the KNH as controls. The rationale for including patients aged 45 to 64 years is that, this is the cohort (middle aged) commonly used in hypertension studies which aim to check for outcome; morbidity and mortality in hypertensive patients. It also reduced the effect of presbycusis on the study outcome. The rationale for the controls was that most of the patients attending dental outpatient clinic were less likely to have other co morbidities which fall under exclusion criteria (e.g head injury, renal disease etc).

### **7.4 Inclusion criteria**

Hypertensive patients aged 45 to 64 years on treatment at MOPC at the KNH and non-hypertensive patients aged 45 to 64 years attending dental outpatient clinic at the KNH who gave a written consent.

### **7.5 Exclusion criteria**

Patients with pre-existing hearing loss before hypertension, diabetes mellitus, congenital hearing loss, head injury, temporal bone trauma, meningitis, confirmed childhood hearing



loss, ototoxic hearing loss (aminoglycosides, quinine, salicylates, cisplatin, diuretics), Noise induced hearing loss, kidney disease and known retroviral disease. Known hypertensive patients were also excluded from the controls. Noise induced hearing loss was determined through history (noise exposure in a work place or residence requiring speaking with a raised voice for at least 3 months) and late exclusion after PTA (characteristic pattern). It is almost always bilateral sensorineural hearing loss with notching of the audiogram at 3000, 4000, 6000Hz and recovery at 8000Hz. The greatest loss is at around 4000Hz which forms acoustic (boilers) notch.

## 7.6 Sample size

A study done by Saurabh Agarwal (40) showed 43.8% hearing loss in hypertensive patients and 18 % hearing loss in non hypertensive patients. Using Fleiss, statistical methods for rates and proportions, formulars 3.18 and 3.19 (46,47),

$$n = \left(\frac{r+1}{r}\right) \frac{(\bar{p})(1-\bar{p})(Z_{\beta} + Z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

n= Sample size

$Z_{\beta}$ = one sided percentage point of the normal distribution corresponding to power of 80%, therefore  $Z_{\beta}=0.84$

$Z_{\alpha}$  = two sided percentage point of the normal distribution corresponding to 95% level of significance (0.05), therefore  $Z_{\alpha}=1.96$

r=1 (equal number of cases and controls)

$p_1$ = the proportion of hearing loss in the control group,  $p_1=18\%$

$p_2$  = the proportion of hearing loss in hypertensive group,  $p_2=43.8\%$

$$\bar{P} = \frac{P_1 + P_2}{2}$$

$$n = \left( \frac{1+1}{1} \right) \left( \frac{(0.309)(1-0.309)(0.84+1.96)}{(0.18-0.438)^2} \right)^2$$

The sample size of the cases and controls was 51 in each arm. Therefore, the total sample size was 102.

### **7.7 Sampling Procedure**

Convenient sampling technique was used to recruit patients, starting with cases and then controls. Patients attending hypertension medical outpatient clinic and on treatment for hypertension were recruited into the study. The patients who fulfilled the inclusion criteria and gave an informed written consent to be involved in the study were picked by the principal researcher.

Using the preformed questionnaire, history was taken and recorded by the principal researcher. Physical examination was done by the principal researcher. Indirect blood pressure was measured using a proper cuff and Omron M3 automatic BP monitor by the principal researcher. Ear (otoscopy), nose and throat examination was done. Ear wax was found in a few patients and removed prior to tuning fork test (TFT) and pure tone audiogram (PTA). Tuning fork tests were done using 512Hz Karl Storz stainless steel tuning fork. History, physical examination, BP measurement, otoscopy and tuning fork test were conducted and recorded by the principal researcher at the MOPC during routine clinic days. Patients were then sent to the KNH ENT clinic for pure tone audiometry (PTA) which was performed by a specific appointed qualified audiologist using an Interacoustics® clinical audiometer AC 33. This was done in a sound proof booth using a pure tone. Air conduction was done from 250

HZ to 8,000HZ and bone conduction from 500-4,000HZ. Pure tone average was calculated using 500-4,000 HZ values. All the findings were recorded in the questionnaire by the principal researcher. A total of 51 hypertensive patients were included in the study.

Controls were then picked from patients attending the KNH dental outpatient clinic, matching them for age (within 3 years) and sex. The same procedure as above was followed. Consent, history taking, physical examination, BP measurement, otoscopy and tuning fork test were performed by the principal researcher at the dental outpatient clinic. The patients were then sent to the KNH ENT clinic where a pure tone audiometry was conducted by the same qualified audiologist as for cases. The procedures were conducted during routine clinic visits after patients had been attended to by the primary clinician.

### **7.8 Quality control**

Patient selection, history taking and examination was done by the principal researcher to prevent inter observer bias.

Pure tone audiometry was done by a specific appointed qualified audiologist. The same audiometer was used for all the 102 patients.

The questionnaire had been pre-tested before use and appropriate adjustments made.

### **7.9 Study limitations**

The duration of treatment and hence hypertension was presumed to have started at the time the diagnosis of elevated blood pressure was made. However, it is known that hypertension may have started several years before diagnosis & treatment since it is insidious and asymptomatic for some patients. Therefore, the duration may be underestimated for some patients.

Grading of hypertension was made based on the measurements obtained during the time of study; however, it is known that blood pressure measurements can fluctuate within a given period of time. Blood pressure can fluctuate temporarily due to stress, activity, missing a dose of the medication, anxiety (white coat hypertension) etc. The difference is however not exaggerated due to the physiological homeostatic balance.

Eighteen hypertensive patients had a normal blood pressure since they were on medication.

### **7.10 Data management and analysis**

Data was collected using the formulated checklists, checked for completeness and entered into a password-protected data entry platform. The entered data was assessed for completeness, accuracy and consistency before analysis was commenced. Data analysis was carried out using IBM statistics® Version 21.

Exploratory data analysis was carried out to describe the study population. Categorical variables like gender were summarized using frequency tables. Continuous variables like age were summarized using measures of central tendency and dispersion such as mean, median and standard deviation.

In order to determine associations between the outcome and independent variables such as gender and age, Pearson's correlation was done. The patterns of hearing loss (low, mid and high frequencies) were calculated using mean and standard deviation. The degree of hearing loss in relation to grade of hypertension was calculated. In each analysis, confidence intervals and p values have been used to demonstrate the magnitude of the association.

Results were presented using tables and figures.

### **7.11 Ethical consideration**

The study was carried out after the approval by the KNH/UON ethics and research committee (P615/09/2015) and after obtaining authority from the KNH management. Only those who gave informed consent were recruited in the study. Confidentiality was maintained at all times. Raw data was stored under lock and key, while database was protected with password to prevent access by an unauthorized people. Use of coded data was done to ensure maximum confidentiality. At the end of the study raw data was destroyed by paper shredding of all hard copies and soft copy data was deleted from all storage devices including computers, flash discs and hard disks. Results will be published in journals and presented in medical conferences. Results may also be published in print or electronic media where applicable. The study population will be the first to benefit from any positive findings from the study. There was no monetary gain by the researcher and no conflict of interest. The patients had the right to withdraw from the research at any time without victimization and none incurred extra financial costs.

## 8.0 RESULTS

### Demographic characteristics of patients.

The sample size was a total of 102 patients i.e 51 cases and 51 controls. The male to female ratio for both the cases and controls was 1:3.4 with 13 males (25.5%) and 38 females (74.5%) included in the study.

The mean age for cases was 54.14 years with a standard deviation of 5.74 and 55.75 years for the controls with a standard deviation of 6.12. The age ranged from 45 to 64 years for both cases and controls.

**Table 3: Gender distribution of patients**

		Arm					
		Case		Control		Total	
		N	%	n	%	n	%
Gender	Female	38	74.5	38	74.5	76	74.5
	Male	13	25.5	13	25.5	26	25.5

**Table 4: Age distribution of patients**

Age	Control	Case	Total
Mean	54.14	55.75	54.94
Median	54.00	57.00	55.00
Minimum	45.00	45.00	45.00
Maximum	64.00	64.00	64.00
Standard Deviation	5.74	6.12	5.96
<i>p-value</i>		0.174	

### Duration of treatment for hypertensive patients

The mean duration of treatment was 5.75 years with the shortest treatment time being 3 months and the longest duration 20 years with a standard deviation of 5.02. The median was 3 years. This did not apply for controls. Thirty one of the patients (60.8%) had been treated for five years or less, 14 patients for 6-10 years while 6 patients (11.8%) were on treatment for more than ten years.

**Table 5. Duration of treatment**

<b>Duration of treatment for hypertension</b>			
	<b>Case</b>	<b>Control</b>	<b>Total</b>
Mean	5.75	.	5.75
Median	3.00	.	3.00
Minimum	.25	.	.25
Maximum	20.00	.	20.00
Standard Deviation	5.02	.	5.02
<i>p-value</i>		-	

### History of tinnitus

Twenty hypertensive patients (39.2%) had tinnitus with only two (3.9%) of the controls having tinnitus ( $p$ -value  $<0.0001$ ), this was statistically significant. In 15 patients tinnitus was in both ears, right ear in one and left ear in four. Seventeen of the patients with tinnitus in the cases were female while 3 were male. Five of the hypertensive patients with tinnitus had normal Bp, nine had BP grade 1 while 6 had BP grade 2. Five of the 20 patients (25%) with tinnitus also had hearing loss.

**Table 6: History of tinnitus**

		<b>Arm</b>						<b>p-value</b>
		<b>Case</b>		<b>Control</b>		<b>Total</b>		
		<b>N</b>	<b>%</b>	<b>n</b>	<b>%</b>	<b>N</b>	<b>%</b>	
<b>Tinnitus</b>	<b>No</b>	31	60.8	49	96.1	80	78.4	$<0.0001$
	<b>Yes</b>	20	39.2	2	3.9	22	21.6	

### Physical Examination: Blood pressure measurement.

The mean blood pressure was 146/85 mmHg for cases and 125/79 for the controls with a p-value of <0.0001, it was statistically different.

Among the patients with hypertension 18 out of 51 (35.3%) had well controlled BP, 22 (43.1%) had grade 1 hypertension and the other 11(21.6%) had grade 2 hypertension with the highest systolic reading at 178mmHg and diastolic reading at 104 mmHg.

**Table 7: Blood pressure findings**

		Arm						p-value
		Case		Control		Total		
		N	%	N	%	N	%	
BP grade	Normal	18	35.3	51	100.0	69	67.6	<0.0001
	Grade 1	22	43.1	0	.0	22	21.6	
	Grade 2	11	21.6	0	.0	11	10.8	
	Grade 3	0	.0	0	.0	0	.0	

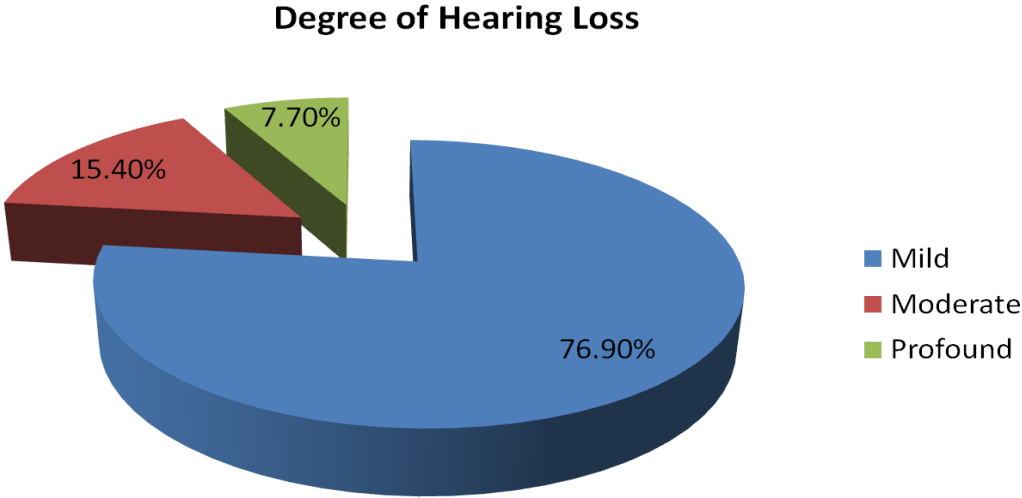
### Pure tone audiogram

Among the hypertensive patients, 13 out of 51 (25.5%) had hearing loss with 5 having bilateral hearing loss and 8 unilateral hearing loss giving a total of 18 individual ears out of 102 (17.65%). Ten out of the 13 patients (76.9%) had mild hearing loss, 2 (15.4%) had moderate hearing loss, with 1 having profound hearing loss. Seven (13.7%) of the controls had hearing loss. Four had bilateral hearing loss, hence 11 individual ears (10.8%). Six of the 7 (85.7%) non-hypertensive patients had mild hearing loss while 1 had severe SNHL.

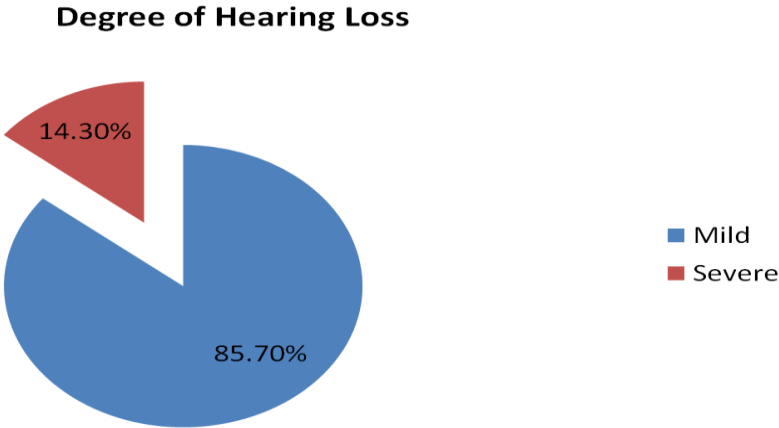


**Table 8: patients with hearing loss in both cases and controls**

		Arm				p-value
		Case		Control		
		n	%	N	%	
Hearing loss defined by above 25 decibels	Hearing loss	13	25.5	7	13.7	0.135
	No hearing loss	38	74.5	44	86.3	



**Figure 3: Pie chart showing degree of hearing loss distribution among cases**



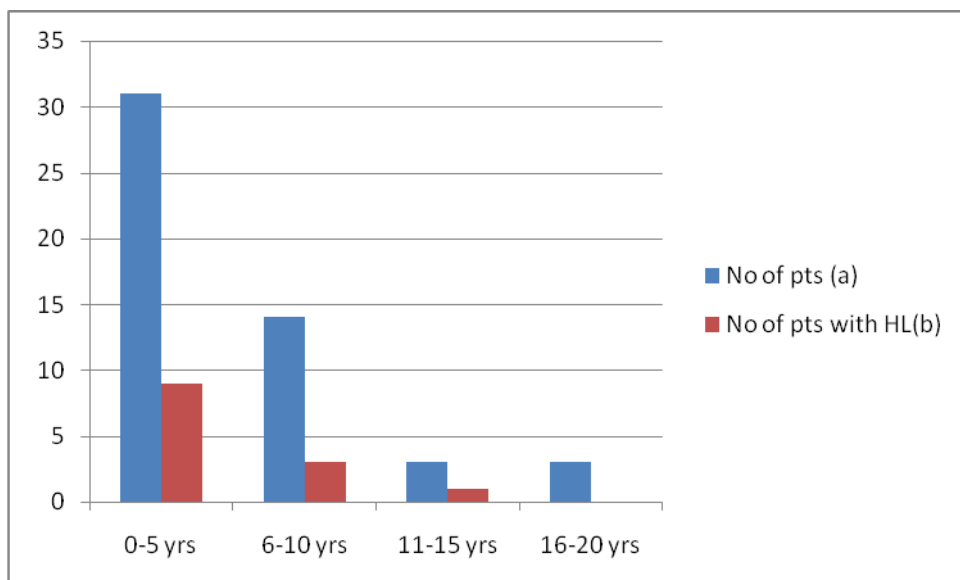
**Figure 4: showing degree of hearing loss distribution among controls**

### Pattern of hearing loss

The configuration of hearing loss was divided into low, mid and high frequency hearing loss. For the low frequency the mean was 20.3 dB on the right ear and 17.6 dB on the left for cases. The low frequency for the controls was 17.1 dB on the right ear and 15.7 dB on the left. There was an increase in the mid and high frequency with the right ear having 26 dB and the left ear 23.3 dB in the cases. The right ear had 24.9 dB and the left 23.2 dB in the control arm. The P-values ranged from 0.222-0.912 and were not statistically significant.

**Table 9: pattern of hearing loss**

		Arm			p-value
		Case	Control	Total	
PTA Right Ear 250-500	Mean	20.3	17.1	18.7	0.222
	Standard Deviation	15.8	9.6	13.1	
PTA Left Ear 250-500	Mean	17.6	15.7	16.6	0.251
	Standard Deviation	9.2	7.5	8.4	
PTA Right Ear 1000-2000	Mean	18.2	15.5	16.9	0.324
	Standard Deviation	17.2	9.7	14.0	
PTA Left Ear 1000-2000	Mean	15.2	14.6	14.9	0.748
	Standard Deviation	10.9	7.2	9.2	
PTA Right Ear 4000-8000	Mean	26.0	23.8	24.9	0.489
	Standard Deviation	18.7	12.8	16.0	
PTA Left Ear 4000-8000	Mean	23.3	23.0	23.2	0.912
	Standard Deviation	15.7	10.7	13.4	



**Figure 5: Duration of treatment and number of patients with hearing loss**

Nine (29%) of the patients treated for  $\leq 5$  years had hearing loss while 1 out of the 3 (33.3%) patients treated for 11-15 years had hearing loss.

**Table 10: Grade of hypertension and hearing loss**

		BP grade								p-value
		Normal		Grade 1		Grade 2		Grade 3		
		N	%	N	%	N	%	N	%	
Hearing loss defined by above 25 decibels	Hearing loss	6	33.3	4	18.2	3	27.3	0	.0	0.543
	No hearing loss	12	66.7	18	81.8	8	72.7	0	.0	

Four (18.2%) of patients with grade 1 and 3 (27.3%) of patients with grade 2 hypertension had hearing loss. This was not statistically significant (p value=0.543).

**Table 11: Pearson correlation between age and hearing loss**

a. Arm = Case

		Age	PTA Right Ear	PTA Left Ear
Age	Pearson Correlation	1	.078	.289*
	Sig. (2-tailed)		.587	.040
	N		51	51
PTA Right Ear	Pearson Correlation		1	.473**
	Sig. (2-tailed)			.000
	N			51
PTA Left Ear	Pearson Correlation			1
	Sig. (2-tailed)			
	N			51

\*. Correlation is significant at the 0.05 level (2-tailed).

\*\*. Correlation is significant at the 0.01 level (2-tailed).

a. Arm = Control

		Age	PTA Right Ear	PTA Left Ear
Age	Pearson Correlation	1	.206	.612**
	Sig. (2-tailed)		.146	.000
	N		51	51
PTA Right Ear	Pearson Correlation		1	.465**
	Sig. (2-tailed)			.001
	N			51
PTA Left Ear	Pearson Correlation			1
	Sig. (2-tailed)			
	N			51

\*\*. Correlation is significant at the 0.01 level (2-tailed).

## 9.0 DISCUSSION

Hearing loss which has multifactorial causation is currently a public health concern. Several studies in developed countries have been conducted to find out whether hypertension is one of the risk factors. The results have been contradictory with some showing positive correlation (4,40,45,48) while others have shown no association between hearing loss and hypertension (42,44). With that in mind this study was conducted to ascertain whether hypertension is a risk factor for hearing loss in our set up where such data is not available.

This hospital based case control study recruited 38 female patients (74.5%) who were hypertensive and on treatment as cases & 38 non-hypertensive as controls. Thirteen hypertensive males (25.5%) were picked as cases and 13 non hypertensive as controls. The cases and controls were gender and age matched within 3 years. The age (p-value=0.174) and gender (p-value=1) differences were not statistically significant. However the studies by Chen et al (3) with 100% and Agarwal et al (40) with 65.8% had high numbers of male subjects. This may account for some differences in the results as males are more predisposed to hearing loss as shown by Pearson et al (49) and Dubno et al (50). Some studies have also used older populations (3, 43). The prevalence of hearing loss is known to increase with aging (50) hence this may account for the difference in results with this studies.

The mean duration of treatment was 5.78 years with the longest treatment period been 20 years. This compared to the study by Agarwal et al (40) with a mean ranging from 3.73 years for grade 1, 5.46 years for grade 2 and 9.05 years for grade three. In our study, the duration of treatment had a slight influence on hearing loss with 29% of those in the 0-5 years category and 33.3% in the 11-15years having hearing loss but it was not statistically significant. This was not in keeping with Agarwal et al (40) who showed a strong correlation between duration of hypertension and hearing loss. The group with a mean duration of 3.7 years had 36.7%

hearing loss while the group with a mean of 9 years had hearing loss in 54.2%. The longer duration of hypertension is postulated to increase the risk of ischemic damage to the cochlea through vascular changes (48).

Twenty of the hypertensive patients (39.2%) had tinnitus while only two of the controls had tinnitus. This was statistically significant with a p-value  $\leq 0.0001$ . This is slightly lower than in Mondelli et al (45) study where 43.7% of the hypertensive patients had tinnitus. Hypertension as a risk factor for tinnitus has been demonstrated in other studies (51,52, 53). This is due to its effect as a high output state (pulsatile tinnitus), effects of antihypertensive medication or in relation to hearing loss. There was also a correlation between tinnitus and hearing loss as 5 of the 20 cases (25%) with tinnitus had hearing loss while the 2 (100%) in control arm had hearing loss.

The mean blood pressure for cases was 146/85mmHg and for controls was 125/79mmHg. Hypertension has been associated with hearing loss (4,48) which is thought to occur due to microcirculatory insufficiency with prevalence ranging between 7.3% to 59.2%. In our study patients with hypertension were at higher risk of hearing loss 25.5% as compared to controls (13.7%). However this was not statistically significant at a p value of 0.135. The low prevalence may be explained by the fact that in our study we recruited both the well controlled hypertensives (35.3%) and the uncontrolled hypertensives. The mean blood pressure was also relatively low. The percentage of hypertensive patients on treatment with well controlled BP is similar to the results of JNC7 (21). Our findings are similar to other studies (42,44) which have shown a weak link between high blood pressure and hearing loss. Its postulated that the autoregulatory mechanisms of inner ear may be able to buffer it from effects of systemic vascular disorders. The grade of hypertension was also found not to have a major influence on hearing loss (p-value=0.543) . The grade of hypertension was one of this

study's limitation given the fact that blood pressure fluctuates and this could account for this findings.

The pure tone audiometry thresholds were increased in all the frequencies slightly more for cases (hypertensives) as compared to the controls which indicates a possible effect of high blood pressure on hearing loss. The p values ranged from 0.184 to 0.879 and were statistically not significant. The increase in PTA thresholds is similar to other studies (3,41,54).

The pattern of hearing loss demonstrated a mild sloping configuration with all frequencies affected more in the hypertensive patients than in the controls. Hypertensive micro angiopathy has been postulated to affect cochlear microcirculation in all turns hence why all the frequencies are affected. This was similar to other research (55, 56) findings. Some other studies found that low and mid frequencies were more affected Marchiori et al (4). The explanation for that was that the cochlea apex was more affected during ischemic episodes. This is questionable since the inner ear has possible micro circulation autoregulation and vascular anastomosis.

## **10.0 CONCLUSION**

This case controlled study has shown some link between hearing loss and hypertension as demonstrated by the higher prevalence and the raised hearing threshold levels by pure tone audiometry in all frequencies in hypertensive patients. However it is not statistically significant to make a conclusion of causation and effect. Tinnitus was more common in the hypertensive patients than the controls.

## **11.0 RECOMMENDATION**

A prospective cohort study with a long duration of follow up of hypertensive patients after a base line PTA at diagnosis may give a more reliable information in our set up on the association between hypertension and hearing loss.



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## Appendices

### APPENDIX 1: GENERAL PATIENT INFORMATION

#### 1. Introduction

I am a senior house officer in ENT-Head & Neck Surgery department. I am requesting for your consent to participate in a study on hypertension as a risk factor of hearing loss in patients attending the hypertensive clinic at the Kenyatta National Hospital.

#### 2. How you will participate

1. I will ask you questions regarding your past medical history and the current complaints.
2. I will carry out a complete Ear, Nose, Throat, Head and Neck examination.
3. There will be no monetary benefits for participating in the study and it will be purely on a voluntary basis.
4. You will incur no extra financial costs and the confidentiality will be maintained at all times.
5. You will reserve the right to withdraw from the study at any time without any penalty.
6. You will be informed about investigations and importance of the results.

#### 3. How will participation affect you?

The study does not affect you negatively in any way because:

1. All the information you give will be confidential.
2. The conclusions drawn from the study shall be useful to improve the current management of hypertension and hearing loss.

#### 4. Are there any hidden dangers in your participation or non-participation?

1. None whatsoever.
2. Objecting to any part or whole of this study will not affect the quality of care you will receive.





**5. What do we do with the information we get.**

The information we get will help us in the long run in managing the condition better.

Like all scientific information we will seek to share our findings with other people undertaking similar studies.

Therefore we may publish our findings in scientific journals or present them in scientific meetings.

**6. Are you satisfied with the information given?**

If you are satisfied with our explanation and you are willing to participate, then please sign the consent form below.

**KIAMBATISHO 1: FOMU YA MAELEZO KUHUSU IDHINI YA MGONJWA**

**1. Kitangulizi**

Mimi ni daktari ninaye endelea na masomo ya juu kwa kitengo cha upasuaji wa masikio, mapua, koo, kichwa na shingo katika Chuo kikuu cha Nairobi. Ningependa kuomba idhini yako ya kushiriki katika utafiti wenye lengo la kujua uhusiano kati ya shinikizo la juu la damu na kiwango cha kusikia kwa wanaotibiwa shinikizo la juu la damu katika Hospitali Kuu ya Kenyatta.

**2. Jinsi ya Kushiriki**

1. Nitakuuliza maswali kuhusu historia ya hali yako ya afya na matibabu uliyopata mbeleni pamoja na malalamiko ya sasa.

2. Nitafanya uchunguzi wa kikamilifu wa masikio, pua na koo.

3. Utafiti huu utafanywa kwa hiari ya mgongjwa na hakutakuwepo na faida ya fedha au fidia kwa kushiriki.

4. Hakutakuwa na malipo yoyote ya ziada au gharama utakayohitajika kulipa na siri za mgonjwa zitaendelezwa wakati wote.

5. Una haki ya kujiondoa kutoka kwa utafiti huu wakati wowote bila adhabu yoyote.

6. Utapewa taarifa au habari kuhusu uchunguzi utakaofanywa na umuhimu wa matokeo.



**3. Jinsi gani kushiriki kwako kunaweza kuleta madhara.**

Utafiti hautakudhuru kwa njia yoyote kwa vile:

1. Taarifa yote kuhusu mgonjwa itakuwa ni ya siri.
2. Utambulisho hautatangazwa.
3. Baada ya kuhitimisha utafiti huu maarifa itakayo patikana itakuwa na manufaa na inaweza kusaidia kuboresha matibabu ya ugonjwa huu.

**4. Je, kuna hatari ya kushiriki au kutoshiriki?**

1. Hakuna hatari yoyote itakayo jiri kwa kushiriki au kutoshiriki.
2. Kujiondoa wakati wowote au kupinga sehemu ya utafiti hakutaathiri matibabu au ubora wa huduma ya afya utakayopokea.

**5. Je tutafanyia nini matokeo ya utafiti huu?**

Habari itakayotokea na utafiti huu pengine haitakufaidi binafsi lakini itatupa maarifa ambayo itaboresha matibabu ya ugonjwa huu siku zijazo.

Kuna uwezekano wa kuchapishwa kwa matokeo ya utafiti huu katika majarida ya kisayansi au kuwekwa katika mikutano ya kisayansi.

**5. Je umeridhika**

Ukiridhika na maelezo yangu na uko tayari kushiriki, tafadhali weka sahihi yako kwenye fomu ya idhini.



**APPENDIX 2: CONSENT FORM**

Patient number: .....

Consent by patient:

I.....of.....do hereby give consent to be included in this study on hypertension as a risk factor of hearing loss in patients attending the hypertensive clinic at the Kenyatta National Hospital .

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

Date.....Signed.....

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

Date.....Signed.....

Contacts: Principal researcher. Dr. Stephen M. Ndambuki. Resident in ENT, Head and Neck surgery, University of Nairobi. Telephone contact: +254 721 794760. Email address: [stmand1@yahoo.com](mailto:stmand1@yahoo.com)

Supervisors: Prof H.O. Oburra, Professor ENT-Head & Neck surgery, University of Nairobi.

Dr Simon M. Makau, Consultant ENT Head & Neck Surgery, Kenyatta National Hospital.

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.

**Kiambatisho 2: Kukubali Kwa mgonjwa**

Namba ya hospitali.....

Mimi.....kutoka.....ninakubali kushirikishwa katika utafiti huu wenye lengo la kujua uhusiano kati ya shinikizo la juu la damu na kiwango cha kusikia kwa wanaotibiwa shinikizo la juu la damu katika Hospitali Kuu ya Kenyatta.

Nimeelezwa na daktari.....

Tarehe:.....Sahihi.....



Mimi daktari..... nahakikisha ya kwamba nimeelezea mgonjwa juu ya utafiti huu.

Tarehe..... Sahihi .....

Mawasiliano: Mtafiti mkuu. Daktari Stephen M. Ndambuki. Mwanafunzi masomo ya juu katika kitengo cha upasuaji wa masikio, pua, koo, kichwa na shingo, Chuo kikuu cha Nairobi.

Nambari ya simu: +254 721 794760. Barua pepe: [stmandl@yahoo.com](mailto:stmandl@yahoo.com)

Wasimamizi: Prof H.O. Oburra, Profesa kitengo cha upasuaji wa masikio, pua, koo, kichwa na shingo, Chuo kikuu cha Nairobi.

Daktari Simon M. Makau, Mshauri upasuaji wa masikio, pua, koo, kichwa na shingo.

Hospitali Kuu ya Kenyatta.

Ikiwa una swali ama ungetaka kupata maelezo zaidi kuhusu utafiti huu, wasiliana na KNH/UON-ERC kupitia nambari ya simu 2726300 ugani 44355.



**Appendix 3: Questionnaire**

Study number .....Date.....

**Section A**

Patient biodata

Age.....Gender .....



**Section B**

History

1. Duration of treatment.....
2. Medication for hypertension .....
3. Tinnitus .....Yes/No. Right Ear, Left Ear, Both.
4. Hearing loss ..... Yes/No. Right Ear, Left Ear, Both, If yes....Sudden /slowly progressive
5. Ear pain.....Yes/No Right Ear, Left Ear, Both
6. Dizziness..... Yes /No

**Section C**

Examination

1. Blood pressure.....mmHg Grade I, II, III
2. Otoscopy. Right Ear.....Normal... Wax .....Wax Removal Yes/No Other.....  
Left Ear.....Normal... Wax.....Wax Removal Yes/ No Other.....
3. Tuning fork test  
Right Ear- Rinne's test..... Positive / Negative.  
Left Ear - Rinne's test..... Positive / Negative  
Weber .....Central.....Lateralize to .....Right Ear.....Left Ear...

4. Pure tone audiogram. Number.....Date.....

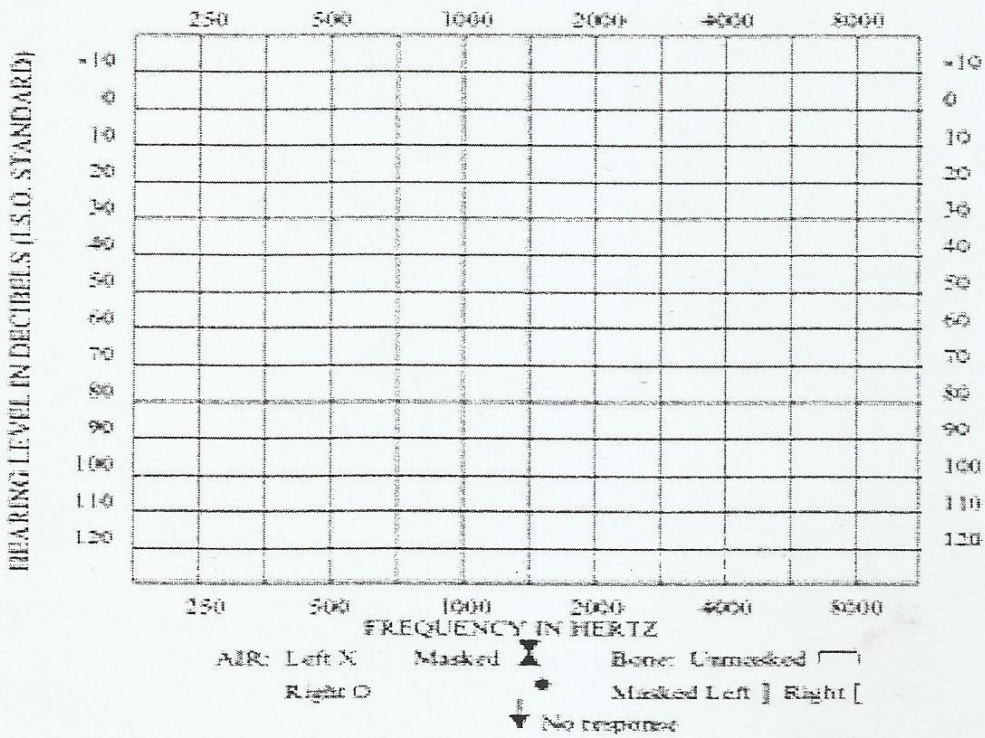
Report .....

Right ear.....

Left ear.....

Performed by.....

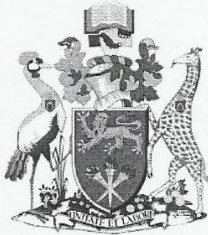
### PURE TONE AUDIOGRAM



<http://audiometry.sydneyinstitute.wikispaces.net>



## Appendix 4: KNH-UON ERC Letter



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



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

**KNH-UON ERC**  
Email: [uonknh\\_erc@uonbi.ac.ke](mailto: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](https://twitter.com/UONKNH_ERC)

Ref: KNH-ERC/A/152

9<sup>th</sup> May, 2016

Dr. Stephen M. Ndambuki  
H58/69986/2011  
Dept. of Surgery  
School of Medicine  
College of Health Sciences  
University of Nairobi

Dear Dr. Ndambuki

**REVISED RESEARCH PROPOSAL: HYPETENSION AS A RISK FACTOR OF HEARING LOSS IN PATIENTS ATTENDING THE HYPERTENSIVE CLINIC AT THE KENYATTA NATIONAL HOSPITAL P615/09/2015)**

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 9<sup>th</sup> May 2016 – 8<sup>th</sup> May 2017.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
- 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.
- 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.
- 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*).
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- 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>

Protect to discover

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 Assistant Director, Health Information, KNH  
          The Chair, KNH- UoN ERC  
          The Dean, School of Medicine, UoN  
          The Chair, Dept. of Surgery, UoN  
          Supervisors: Prof. H.O. Oburra, Dr. Simon M. Makau

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