FACTORS ASSOCIATED WITH LEFT VENTRICULAR HYPERTROPHY AMONG PATIENTS UNDERGOING HEMODIALYSIS AT KENYATTA NATIONAL

HOSPITAL

RUTH WANJIKU NDEGWA H56/34853/2019

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DECLARATION

I hereby declare that this thesis is my original work and has never been presented for a degree in any other college or university. Anyone with intentions of reproducing it should obtain a written permission from the author or The University of Nairobi.

Ruth Wanjiku Ndegwa

H56/34853/2019

Department of Nursing Sciences

The University of Nairobi

Signature.

Date. 29/11/2021

SUPERVISORS CERTIFICATE OF APPROVAL

SUPERVISORS CERTIFICATE OF APPROVAL

This thesis has been submitted with my own approval as the University of Nairobi supervisor.

Dr. Dorcas Maina

PhD, MScN&BScN

Department of Nursing Sciences

University of Nairobi

Signature:

Date: 29/11/2021

Dr. Omuga M.B.ChB (UoN); M.Med (Obs/Gynae) Department of Nursing Sciences University of Nairobi Signature:

Date: 29 [1] 2021

DEDICATION

I dedicate this work to my husband John, my children and my parents for their support, compassion and encouragement throughout my study period.

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LIST OF ABBREVIATIONS

BMI	-	Body Mass Index
CKD	-	Chronic Kidney Disease
ECG	-	Electro-cardiograph
ESRD	-	End-stage renal disease
eGFR	-	Estimated glomerular filtration rate
KNH	-	Kenyatta National Hospital
SCD	-	Sudden Cardiac Death
WHO	-	World Health Organization

DEFINITION OF OPERATIONAL TERMS

Left Ventricular Hypertrophy: increase in left ventricular mass characterized by increased inter-ventricular septal or posterior left wall thickness wall >1.2cm in male and >1.1cm in female and/or increased left ventricular cavity.

Sudden Cardiac Death: natural death from cardiac causes characterized by a sudden loss of consciousness within 1 hour of onset of symptoms with/without previous history of cardiac disease.

ABSTRACT

Study Background: Cardio-vascular disease (CVD) remains a major health threat among patients with ESRD more so those on dialysis with the rate of cardiovascular disease in those patients being 10-20 times higher than in patients without kidney disease. The cardiorenal syndrome has greatly contributed to this effect with the Left Ventricular Hypertrophy being classified under type 4 cardiorenal syndrome. Left Ventricular Hypertrophy among patients undergoing hemodialysis is highly prevalent at 70% followed by coronary artery disease whose prevalence is at 40% among the cardiovascular complications affecting this group. The presence of LVH is a strong predictor of future cardiovascular events and therefore identifying the factors associated with its occurrence is critical in establishing the various management strategies of LVH.

Aim of the study: To determine the factors associated with left ventricular hypertrophy among patients undergoing hemodialysis at Kenyatta National Hospital.

Methodology: A descriptive cross-sectional study design was carried out to assess what factors were associated with the occurrence of LVH in this population. An interviewer-administered questionnaire was used to obtain data from 70 participants who participated in the study. Echocardiography investigations were done on each participant to determine the presence of LVH. Data was analyzed using SPSS including descriptive and inferential analysis. Presentation of data was done using tables and narration. Ethical considerations were adhered to during data collection as well as covid-19 protocols to ensure the protection of the participants, principal researcher, and research assistants.

Results: Based on the results of the baseline characteristics from the 70 participants who were included in the analysis of data, the mean age was 46.46 years which was within a range that spanned from 18 years to 87 years. Majority (61.4%) of the participants were male. The prevalence of Left Ventricular Hypertrophy among patients undergoing hemodialysis at the renal unit was at 70%. Hypertension $x^2 = 4.091$, df= 1 and p-value = 0.043 had a statistically significant association with LVH and had a high likelihood (OR=2.433) of hypertensive participants having LVH. The presence of hypertensive heart disease from ECHO had a statistical significant association with LVH $x^2 = 48$, df= 1 and p-value = 0.000 and had a high likelihood (OR=177.784) of patient with hypertensive heart disease having LVH. A patient with an elevated pulse rate had also a high likelihood (OR=1.073) of having LVH. A higher BMI and an extended duration of hemodialysis treatment showed a lower likelihood of being associated with LVH. There was no association between gender, alcohol intake and cigarette smoking with the presence of LVH.

Conclusion: The prevalence of left ventricular hypertrophy among patients who are undergoing hemodialysis is high (70%) and has been greatly associated to the presence of hypertension and hypertensive heart disease. This indicates that these patients are at risk of various cardiovascular complications as LVH is an independent risk factor of cardiovascular complications. A higher pulse rate was noted to increase the likelihood of the presence of LVH in a patient.

Recommendation: Routine screening of cardiovascular diseases should be done so that there's prevention and early identification of any cardiovascular conditions such as LVH among patients undergoing hemodialysis such as by the routine use of Echocardiography investigation. More follow up of hypertensive patients to ensure that their blood pressures are well controlled.

CHAPTER ONE

1.1 Introduction

This chapter entailed an introduction to the study problem. It contained, the definition of terms classification of left ventricular hypertrophy, the background of the research problem and problem statement. The chapter also contains the study justification, significance of the study, the research objectives and questions.

1.2 Background

Left ventricular hypertrophy is defined as an increase in the left ventricular mass which could be characterized by increased wall thickness or/and an increase in the size of the chamber (Bornstein et al., 2021). It is classified as an independent predictor of cardiovascular diseases such as sudden cardiac arrest and heart failure (Okwuosa et al., 2015). It is known as the best indicator of target organ damage caused by various factors (Bacharova et al., 2014) and based on the cause, it's a signal that a clinician can use to plan the next course of action.

Among patients with end-stage renal disease and especially those on dialysis, cardio-vascular disease (CVD) remains a major health threat with the rate of cardiovascular disease in those patients being 10-20 times higher than in patients without kidney disease (Aoki &Ikari, 2017). The risk of death due to cardiovascular complications rises as kidney function worsens (Webster et al., 2017). Cardiovascular complications such as atrial fibrillation, sudden cardiac death, heart failure and acute coronary syndromes among patients undergoing hemodialysis are the leading cause of mortality (Mavrakanas & Charytan, 2016). Sudden cardiac death (SCD) accounts for the majority, 61%, of mortality due to cardiac complications among patients

undergoing hemodialysis (Goldstein et al., 2014). Arrhythmias such as ventricular arrhythmias (Shenasa&Shenasa, 2017) that occur due to the presence of factors like left ventricular hypertrophy, diastolic dysfunction or functional mitral regurgitation are known risk factors for SCD.

Cardiovascular changes such as Left Ventricular Hypertrophy and atherosclerosis occur among patients with CKD (Tong et al., 2016) and usually result in cardiovascular complications. These changes could be either functional or/and structural cardiovascular changes (Wanner et al., 2016). This has been attributed to the cardio renal syndrome which depicts an interrelationship between the renal and cardiovascular system whereby in case of dysfunction of one system, it induces dysfunction in the other organ (Chirakarnjanakorn et al., 2017) .Left Ventricular Hypertrophy is classified under type 4 cardio renal syndrome (Rangaswami et al., 2019) whose trigger is factors associated with CKD. Various mechanisms such as oxidative stress, neuro-hormones, inflammatory stress and metabolic derangements have been associated with the occurrence of the cardio renal syndrome (Savira et al., 2020).

The prevalence of LVH is high among patients with CKD Han et al., (2020) and as the kidney function worsens, the prevalence rises (Cozzolino et al., 2018). Mechanisms responsible for LVH are combined volume and pressure overload that results in the increased intercellular matrix and the hypertrophy of the cardiomyocyte (McCullough et al., 2016). Due to the increased cardiac work, hypertrophy of the left ventricle occurs as an adaptive mechanism (Chirakarnjanakorn et al., 2017) and in the end predisposes the heart to myocardial ischemia due to the reduced coronary blood flow reserve.

The presence of LVH has been associated with various factors (Sharif et al., 2019) such as BMI, hypertension, minerals disorder and hemoglobin. Uremic toxins have also been identified to be

strongly associated with the development of LVH (Lim et al., 2021). Hypertension is the major cause of LVH Wanner et al., (2016) as it causes fluid overload that affects how the myocardial functions. In assessing the role of obesity in the occurrence of LVH, obesity influences LVH by increasing the left ventricular volume hence body surface area is a factor in determining left ventricular mass index(*Approaches to Echocardiographic Assessment of Left Ventricular Mass*, n.d.).Left ventricular hypertrophy has been noted to be present early in CKD even before decline in the GFR however (Amoako et al., 2017) noted that for patients undergoing maintenance hemodialysis, prevalence of LVH is higher at 58.3 as compared to pre-dialysis where the prevalence was 43.3%.

The various available modalities for determining LVH are important in making a diagnosis or determining the severity of the disease Kubo and Kitaoka, (2017) with the echocardiogram being used to determine the severity. Electrocardiogram and echocardiogram are commonly used to diagnose LVH (W et al., 2019) but for accurate measurement of the left ventricular mass, echocardiogram and MRI are used (Bornstein et al., 2021). When using ECG to diagnose LVH, several criteria are available differing in sensitivity and specificity, however, Peguero-Lo Presti has been noted to be better in the diagnosis of LVH than Cornell and Sokolow-Lyon which was previously very popular (Noubiap et al., 2020). Peguero-Lo Presti criteria determines LVH by getting the sum of the S wave in lead 4 with the deepest S wave in any lead (SD+SV4) (Yu et al., 2021).Values of (SD+SV4) that are greater or equal to 2.8 in males or greater or equal to 2.3 for females are considered confirmatory for the presence of LVH (Patted et al., 2018). A 2D echocardiography is used to determine LVH whereby according to the American Society of Echocardiography left ventricle mass is estimated using cavity dimensions and wall thickness and the values being in females >88 g/m² and in males, it's >102 g/m².

1.3 Statement of the problem

Cardiovascular diseases remain to be the leading cause of mortality among hemodialysis patients, accounting for more than half of the mortalities (Ahmadmehrabi& Tang, 2018) .Unpublished data in Kenyan mortality among patients with the end-stage renal disease show that cardiovascular complications were the leading cause of mortality in 2020. Among the various risk factors for CVD in patients undergoing maintenance hemodialysis, hypertension is highly prevalent ranging between 70-80% of those patients (Bucharles et al., 2019). Sudden cardiac death is among the various cardiovascular complications occurring in patients undergoing hemodialysis and it occurs in about 60% of hemodialysis patients (Allon, 2013). Sudden cardiac death usually occurs secondary to being predisposed to an underlying condition (de Albuquerque Suassuna et al., 2018) such as LVH that interferes with the electrical conductivity of the heart and other mechanical functions.

The prevalence of left ventricular hypertrophy has been a consistent finding among patients with chronic kidney disease (Oliveira E Silva et al., 2019) and its presence predicts a poor prognosis among those patients. McCullough et al., (2016)noted the prevalence of LVH in patients who were commencing dialysis to be at 75%. In contrast, among patients undergoing maintenance hemodialysis Hagembe, (2018)found that the most predominant lesions were left ventricular hypertrophy (58%) followed by systolic dysfunction (25%).Various risk factors have been associated with LVH, Amoako et al., (2017) which are high diastolic blood pressure, increased BMI, increased pulse pressure and being male. In addition, (Sheikh, 2003) noted that the presence of LVH was associated with the degree of kidney dysfunction and anemia among patients with renal insufficiency.

Various strategies are being used in the prevention of cardiovascular risk factors among patients with CKD; maintaining blood pressure below 130/80mmHg, use of specific antihypertensive medications, lifestyle modification such as cessation of smoking and physical exercises to maintain body weight at the acceptable range (Dave et al., 2019). Among patients undergoing dialysis, specific strategies are being used in some countries to reduce the occurrence of cardiovascular complications (Makar & Pun, 2017) which include; doing more dialysis sessions to reduce the rapid ultrafiltration, lowering dialysate temperature and minimizing the use of low potassium dialysate. The recommendation made by (Hagembe, 2018) was on the need for routine screening of patients undergoing hemodialysis for cardiovascular diseases which would aid in early detection and prevention of LVH. Good control of factors associated with the occurrence of LVH can help reduce morbidity and mortality associated with left ventricular hypertrophy (Zanib et al., 2020).

Routine screening of patients undergoing hemodialysis of any cardiovascular disease is faced by patient's financial challenges. This usually results in a delay in early detection of cardiovascular complications and this predisposes them to poor prognosis. Prompt diagnosis of cardiovascular diseases has been accompanied by good clinical outcomes such as reduced incidences of sudden cardiac death due to regression of LVH. Routine screening aids in reducing the mortality rates related to cardiovascular complications as interventions are usually made early. This study will aid in providing data that can be used for evidence-based decision making in the development of various strategies for minimizing cardiovascular complications such as sudden cardiac death that is usually linked to LVH.

This study will therefore seek to fill a literature gap that exists on the prevalence and risk factors of left ventricular hypertrophy among patients undergoing hemodialysis at the renal unit KNH.

This will be relevant when addressing the various measures that need to be established to reduce incidences of SCD.

1.4 Justification of the Study

The increased morbidity and mortality associated with cardiovascular diseases among patients with end-stage renal disease is a worrying trend that impacts the quality of life among these patients. Among patients undergoing renal replacement therapy, left ventricular hypertrophy is highly prevalent at 70% followed by coronary artery disease whose prevalence is at 40% among the cardiovascular complications affecting this group (Cozzolino et al., 2018). The presence of left ventricular hypertrophy among patients undergoing hemodialysis plays a major role in the pathophysiology of cardiovascular events such as sudden cardiac death (Makar & Pun, 2017).Several factors have been identified to be associated with the presence of LVH (Sharif et al., 2019) amongst them being hypertension, hemoglobin levels and BMI.

As a potent indicator of cardiovascular events among patients undergoing hemodialysis, it was important to identify the prevalence of LVH as well as various factors associated with its occurrence. This will be vital in the plan of the various management strategies for patients noted to have LVH. (S. Ali et al., 2019) suggested that some strategies that could be used in the prevention of LVH would be the use of certain specific antihypertensive medication to maintain blood pressure below 130/80 mmHg and also aid in the regression of LVH.

This study will seek to determine the current prevalence of LVH and the factors associated with its occurrence among patients undergoing hemodialysis at KNH. The local data available does not show a current view of the prevalence and the associated factors of LVH in this population. This data will therefore aid in evidence-based decision making on the various strategies to use in the prevention of LVH as well as in regression of LVH. In addition, the availability of that data could be used to advocate for routine screening of hemodialysis patients of left ventricular hypertrophy that could aid in early prevention and detection. Based also on the findings of this study, it laid a basis for exploration of other factors that could be associated with LVH or other cardiovascular complications among patients undergoing hemodialysis.

1.5 Significance of the Study

The study was conducted in KNH, which is a referral facility that handles patients referred from various parts of the country. Therefore the findings were generalized to the hemodialysis population in Kenya.

1.6 Research Questions

- 1. What was the prevalence of left ventricular hypertrophy among hemodialysis patients in the KNH renal unit?
- 2. What was the association between BMI and left ventricular hypertrophy among patients undergoing hemodialysis at the renal unit in KNH?
- 3. What was the association between patients' dialysis ages and the occurrence of LVH among patients undergoing hemodialysis at the renal unit in KNH?
- 4. What was the association between hypertension and LVH among patients undergoing hemodialysis at the renal unit in KNH?

1.7 Research Objectives

1.7.1 Broad Objective

To determine the factors associated with left ventricular hypertrophy among patients undergoing hemodialysis at KNH.

1.7.2 Specific Objectives

- 1. To determine the prevalence of left ventricular hypertrophy among patients undergoing hemodialysis at the renal unit in KNH.
- 2. To describe how BMI was associated with left ventricular hypertrophy among patients undergoing hemodialysis at the renal unit in KNH.
- 3. To assess how the duration in which a patient had been on hemodialysis was associated with LVH among patients undergoing hemodialysis at the renal unit in KNH.
- 4. To assess how hypertension was associated with LVH among patients undergoing hemodialysis at the renal unit in KNH.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter contains overview of the end-stage kidney disease, the prevalence of left ventricular hypertrophy among patients undergoing hemodialysis, the association between hypertension and LVH, the association between body mass index and LVH, the influence of the duration of hemodialysis and occurrence of LVH and conceptual framework.

The search engines used to conduct the literature review are Pub-med, Research gate and Google scholar. The key search terms were "end-stage renal disease AND epidemiology", "cardiovascular diseases AND patients undergoing hemodialysis", "left ventricular hypertrophy AND prevalence AND patients undergoing hemodialysis, "left ventricular hypertrophy AND pathophysiology", "left ventricular factors AND risk factors".

2.2 Overview of End-Stage kidney Disease

The end-stage kidney disease remains to be a global concern with the number of those requiring RRT being estimated to be between 4.902 and 7.083 million (Zhang et al., 2019). This increased the number of patients seeking the various forms of renal replacement therapy and the number is expected to raise more by 2030 (Elshahat et al., 2020).Differences that exist in the burden of kidney disease between developed and developing countries have been attributed to the different cultural, political and socioeconomic factors (Crews et al., 2019). A key challenge in the care of patients with ESRD in the developing world remains to be affordability with low economic capabilities among the patients occasioned by poor health policies in the African countries (Bello et al., 2019). The health insurance that is provided by few countries does not cover all treatment modalities and there is rationing to the treatment covered (Arogundade et al., 2020).

Most African countries lack proper renal registries and thus data on ESRD and CKD is not readily available(GBD Chronic Kidney Disease Collaboration, 2020). The global mortality rates due to CKD has been on an increase with rates increasing from 41.5% to 46.5% between 1990 and 2017 (GBD Chronic Kidney Disease Collaboration, 2020). The global burden of disease in 2015 estimated that 18 million deaths that had occurred then were due to cardiovascular diseases that were related with reduced glomerular filtration rates. Infections and advanced age have also been associated with high mortality rates in this population (Ajiro et al., 2007).

Cardiovascular diseases are the most common complications among ESRD patients and the leading cause of death among this population with the mortality rates being 20 times more than the general population (Cozzolino et al., 2018). Three etiologies are responsible for the high prevalence of CVD among patients with ESRD: traditional risk factors, patients genetic factors and factors associated with dialysis therapy and uremic syndrome (Ronco et al., 2006). Traditional risk factors include dyslipidemia, high, hypertension, being male, cigarette smoking and diabetes (Vallianou et al., 2019). Hypertension accounts for the highest risk factors for CVD in CKD with the prevalence ranging between 50% - 60% (Tonelli et al., 2016). The cardio renal syndrome accounts for the cardiovascular complications in this population (Yogasundaram et al., 2019) which then predisposes the patient to a poor prognosis. Type 4 cardio renal syndrome is characterized by LVH and heart failure that occur in CKD (Rangaswami et al., 2019).

2.3 Prevalence of Left Ventricular Hypertrophy among Patients undergoing hemodialysis

Left ventricular hypertrophy provides a significant prediction of cardiovascular morbidity and mortality among patients undergoing hemodialysis (McCullough et al., 2016). Left ventricular

hypertrophy is present in each stage of CKD and its prevalence increases with the advancement of CKD such that at the time of commencing dialysis it's at 75% (Cozzolino et al., 2018). A comparison between the prevalence of LVMI peritoneal dialysis patients and HD patients, among hemodialysis patients was noted to be higher at 68.8% than among patients undergoing PD which was at 45.2% (Tian et al., 2008).Similarly, among the various cardiovascular risk factors assessed LVH had the highest prevalence of 47% in patients with renal insufficiency (Sheikh, 2003).

Underlying LVH among patients undergoing hemodialysis treatment has been greatly associated with events of sudden cardiac death. Sudden death is said to account for approximately 60% of cardiac-related deaths in hemodialysis patients (Allon, 2013). Arrhythmias that are experienced by patients undergoing hemodialysis with an underlying LVH occur in a different way than the general population and are associated with the hemodialysis procedure and often lead to sudden death (Makar & Pun, 2017). In an attempt to understand those factors that are associated with hemodialysis procedure and can be modified to decrease incidences of sudden cardiac death there was controversy on the effect of rapid ultrafiltration rates and electrolyte components of the dialysate (Rhee et al., 2018).

Left ventricular hypertrophy among patients undergoing hemodialysis is a result of the adaptation of the cardiovascular system due to increased work to the heart (Wanner et al., 2016). The increased work has been associated with the combination of both volume and pressure overload which in turn cause the cardiomyocytes to hypertrophy and the intracellular matrix to increase (McCullough et al., 2016). Pressure overload causes hemodynamic overload to the heart that results in changes of the cardiomyocytes and the chamber of the left ventricle in an attempt to stabilize the stress-induced (Frohlich&Susic, 2012). On the other hand, volume overload

associated with increased intracavity volume causes an increase in the afterload that result in eccentric LVH (Carabello, 2012). Hypertension which is associated with hemodynamic overload does cause organ damage in the body with the earliest effect being on the left ventricle causing left ventricular hypertrophy (Yildiz et al., 2020). Besides the hemodynamic factors, non-hemodynamic factors also play a major role in the occurrence of LVH (Nadruz, 2015) they are: neuro-hormonal, genetic, ethnic, environmental and gender factors. Despite being associated with LVH, It remains unclear if preload and afterload are independent predictors of LVMI (Kim et al., 2015).

The pathophysiology of LVH is in two categories; physiological and pathological (Oláh et al., 2016). Both are associated with an increase in left ventricular mass which is either characterized by enlarged left ventricle cavity due to volumetric burden or increased wall thickness associated with excess hemodynamic pressure (Nadruz, 2015). Physiological LVH is an acute significant compensatory mechanism of the heart that enables the left ventricle to maintain its normal cardiac function and regresses upon withdrawal of the cause whereas in pathological LVH there is maladaptation and abnormal functioning of the heart (Lazzeroni et al., 2016). There are two types of LVH based on relative wall thickness and left ventricular mass index; eccentric and concentric hypertrophy (Nubé et al., 2018) with the eccentric LVH being the most common among patients on maintenance hemodialysis. Eccentric LVH refers to an increase in relative wall thickness and left wall mass index which is equal to or less than 0.42 while concentric LVH has an increased relative wall thickness of more than 0.42 (Bornstein et al., 2021).

The presence of LVH in patients with CKD predicts that those patients may experience cardiovascular complications in the future (Nakagawa &Hasebe, 2018). Particularly, LVH diagnosed using ECG is a risk factor for sudden cardiac death (Porthan et al., 2019). This is

because LVH is often accompanied by fatal arrhythmias that are due to disruption of myocardial electrical pathways associated with a combination of increased interstitial fibrosis, enlargement of cardiomyocyte and increased interstitial space between cardiomyocyte (Charytan, 2014) which results in SCD. Furthermore, LVH due to pressure overload can also result in mechanical dysfunction of the heart characterized by left ventricular failure which results in reduced functioning of the systolic and diastolic left ventricle hence progresses to heart failure (Norton et al., 2002).

Left ventricular hypertrophy is the most common cause of cardiac arrhythmias and heart failure (Orihuela-Rodríguez et al., 2017) caused mainly by increases in preload or afterload resulting in the Induction of apoptosis and buildup of extracellular matrix causing fibrosis. Myocardium changes that occur in LVH influence the way electrical impulses are triggered hence creating a catalyst for the occurrence of arrhythmias that are detected on the ECG with an abnormal QRS complex being noted (Bacharova, 2019). Arrhythmic mitral valve prolapse has been associated with SCD (Basso et al., 2019) whose origin is due to the generation of ventricular fibrillation arising from LVH, fibrosis and Purkinje fibers that causes the release of immature ventricular beats. The mechanism associated with the occurrence of heart failure have been electrical dysfunction characterized by early repolarization and delayed end of repolarization of an action potential due to stretching from hypertrophy of myocardial tissue (Alvarez et al., 2019).

Echocardiography and 12 lead ECG are used to determine the diagnosis of LVH (Okin et al., 2017) and they provide a prediction of cardiovascular morbidity and mortality. Left ventricular mass is usually the key finding in LVH diagnosis and is accompanied by changes in impulse generation and maintenance whereby changes in depolarization and repolarization are manifested on the ECG by alteration of QRS and T waves (Bacharova& Estes, 2017). On the other hand,

Jian et al., (2020) echocardiography can be used to measure the severity of LVH as increased thickness of the left ventricular wall is usually associated with LVH. Echo was previously considered the gold standard for LVH detection due to its high specificity and sensitivity though its use is restricted by the cost implication to carry out a test (Zhang et al., 2019). In the most recent times, Magnetic resonance imaging is considered the gold standard for LVH detection (Rautaharju&Soliman, 2014).

Echocardiography determines the left ventricular mass index in which LVH is defined as LVMI greater than 95g/m in women and 115g/m in men which is following the American Society of Echocardiography (Bornstein et al., 2021). Moreover, (Cuspidi et al., 2020) Echo can give a detailed assessment of the heart condition as well as differentiate between eccentric and concentric LVH. Left ventricular hypertrophy detected using an echo predicts an increased risk of heart failure complication in those patients (Almahmoud et al., 2015).

Several risk factors have been associated with the occurrence of LVH (Vigan et al., 2018) noted the prevalence of LVH was at 54.6% and was associated with obesity, pre-dialysis hypertension and cardiomegaly. Similar findings were noted where hypertension and high body mass index were among the factors that were associated with the presence of LVH (Zanib et al., 2020). In addition to that (Amoako et al., 2017) being male is also associated with increased incidence of LVH. Other risk factors also associated with the occurrence of LVH are diabetes, patient's age, history of cardiovascular diseases and anemia (Nitta et al., 2019). Obesity alone is not a risk factor for LVH (Sciacqua et al., 2020) but when related to metabolic dysfunctions it causes the development of LVH. Genetics factors for instance in Fabry disease cause unexplained LVH among women above 40 years and men above 30 years (Hagège et al., 2019).

2.4. The association between hypertension and LVH

The prevalence of hypertension among patients undergoing hemodialysis is at 80% and is a known major risk factor for developing CVD in that population(Shaman et al., 2020). In the general population, (Kjeldsen, 2018) hypertensive heart diseases such as diastolic dysfunction, left atrial and left ventricular hypertrophy among others are commonly caused by hypertension. Among patients with CKD hypertensive disease also causes an increased risk of developing coronary artery disease and left ventricular hypertrophy (Cozzolino et al., 2018b). A similar occurrence is among patients undergoing maintenance hemodialysis(Zanib et al., 2020) as hypertension is a major risk factor for the occurrence of LVH that is highly prevalent in this population. Hypertension causes damage to organs with the main target being the left ventricle where it causes concentric and eccentric LV hypertrophy (Yildiz et al., 2020).

Hypertension causes hypertensive heart disease that is characterized by neurohormonal changes, LVH, dysfunctional diastolic and increased left atria that all give rise to arrhythmias that predisposes one to SCD (Shenasa&Shenasa, 2017) . There is also an increased likelihood of ventricular fibrillation and/or ventricular tachycardia that is caused by hypertensive LVH which also increase the occurrence of SCD (Koracevic et al., 2021). Hypertension is a major determinant for the changes that occur in the left ventricle as it causes hemodynamic overload which causes left ventricular hypertrophy (Oktay et al., 2016). Several mechanisms have been related to the development of heart failure in hypertension (Slivnick&Lampert, 2019) among them being chronic pressure overload causing fibrosis and LVH that result in dysfunctions of the diastole and increased left-sided filling pressure. In addition, (Sorrentino, 2019) noted that decreased ejection fraction and ischemic heart diseases in hypertensive heart disease usually cause degeneration of the heart that progress to heart failure. Another effect associated with LVH

in hypertension is stroke that impairs cognitive function and is known to persist even after underlying hypertension has been treated (Restrepo et al., 2018).

Stabilization of blood pressure is one of the strategies being used to cause regression of LVH however debate is still ongoing on the most appropriate pharmacological therapy (Soliman&Prineas, 2017). Concerning monitoring of blood pressure, interdialytic hypertension among patients undergoing hemodialysis had been associated with mortality related to cardiovascular events (Bucharles et al., 2019). However (Kim et al., 2015), found controversial information that higher diastolic and systolic pulse pressures were associated with increased LVMI regardless of the timing the blood pressures were taken during a dialysis session. (Merchant et al., 2015) in their study also concluded that post dialysis and pre-dialysis blood pressure monitoring could be adopted while monitoring hypertension in hemodialysis patients but emphasized that using interdialytic blood pressure was important.

2.5. The association between Body Mass Index and LVH

Obesity is a great threat to people in the general population (Roth et al., 2020) as it predisposes them to CKD while still increasing the risks of patients with CKD progressing to ESRD. Among patients with CKD, (Ladhani et al., 2017) obesity is an independent risk factor for the occurrence of CVD and death. In relation to LVH, a higher BMI increases the likelihood of the development of eccentric hypertrophy among young people (Heiskanen et al., 2021) and efforts aimed at controlling body weight in this population are associated with reduction of LVH incidences.

Malnutrition is highly prevalent among hemodialysis patients with incidences ranging between 18-75% (Günalay et al., 2018). Patients undergoing hemodialysis have lower BMI values when compared to people of the general population with similar features. This is due to the high prevalence of protein-energy wasting among patients in this population (Sabatino et al., 2017).

Metabolic acidosis is among the various causes of protein-energy wasting as a lot of muscle protein is broken down to a large extent (Zha&Qian, 2017) hence resulting in protein catabolism and malnutrition. Protein-energy wasting usually results in fluid overload and pulmonary edema that causes an increased risk of cardiovascular diseases (Yuenyongchaiwat et al., 2020). Hypervolemia is a known independent risk factor for LVH which is associated with many cardiovascular complications (Unver et al., 2015).

The lowered BMI has a great impact on the increased mortality rate (Kalantar-Zadeh et al., 2003). The effectiveness of a low protein diet has been quite controversial in how it slows the progression of CKD (Yan et al., 2018). However, concerning LVH among patients undergoing hemodialysis, a high BMI was associated with the occurrence of LVH (Zanib et al., 2020). Among patients undergoing maintenance hemodialysis, the frequency of LVH was noted to be at 54.6% and obesity was one of the risk factors that was associated with this occurrence (Vigan et al., 2018). In contrast, obesity has been linked with a good prognosis in heart failure as it is said to have a protective effect due to the adipose tissue that enables the body to overcome catabolic metabolism by acting as an energy reservoir (Cescau et al., 2017). Severe obesity causes hemodynamic changes such as increased cardiac output that results in changes in the heart structure and function characterized by left ventricular diastolic dysfunction and LVH (Lavie et al., 2018). The changes of the heart's structure then predispose the patient to heart failure (Alpert et al., 2016).

2.6. The influence of the duration of hemodialysis and occurrence of LVH

The health-related quality of life among patients undergoing hemodialysis is worse compared to people in the general population of similar age (Zazzeroni et al., 2017) and is associated with

increased complications and comorbidity. Decreased quality of life is usually characterized by reduced physical activity, sleep disorders and poor mental health (Kraus et al., 2016). Patients undergoing hemodialysis are usually vulnerable and have increased mortality rates resulting from immune deficiency and cardiovascular complications (Klinger &Madziarska, 2019). Cardiovascular disease is the highest leading cause of death among patients with ESRD (Ahmadmehrabi & Tang, 2018) and especially those undergoing hemodialysis.

The most commonly observed cardiovascular complications are LVH, coronary artery calcification and cardiac valve calcification (Kitamura et al., 2017) and were noted to be present in most patients commencing hemodialysis treatment. Left ventricular hypertrophy is an important indicator of cardiovascular morbidity and mortality and results in enlargement of the cardiomyocyte (McCullough et al., 2016) and its prevalence in new dialysis patients is at 75%. However, among patients on chronic hemodialysis, (Vigan et al., 2018) noted the prevalence of LVH to be at 54.6%. Several mechanisms are associated with increased cardiovascular complication among patients undergoing hemodialysis have been associated with stress to the cardiovascular system and a risk of organ damage.

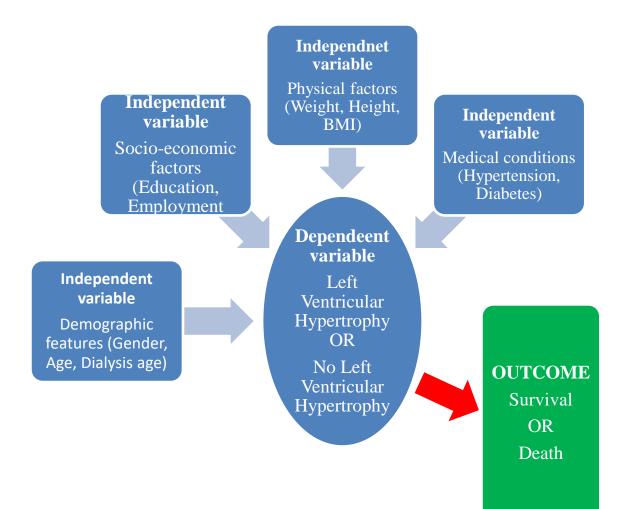
2.7 Literature gap that this research will seek to address

Following the comprehensive literature review above, it was established that indeed left ventricular hypertrophy is highly prevalent among patients undergoing hemodialysis. The high prevalence had been greatly attributed to various factors some of which are modifiable while a few are not. It was noted that hypertension, body mass index and duration in which a patient has been on dialysis were among the various factors that are associated with the occurrence of left ventricular hypertrophy in this population. Some of the factors though had not been clearly determined if they independent or dependently influence the presence or absence of LVH. The numbers of studies that had been reviewed in this literature review that deal with LVH were 59 worldwide and among them 3 are from Africa and 2 are from Kenya. The two studies from Kenya had been done in two different geographical locations and both look at cardiovascular conditions in general that affect patients undergoing hemodialysis. They therefore did not give conclusive information about specific cardiovascular complications such as LVH and the factors associated with its occurrence. This study was specifically seeking to explore the prevalence of Left Ventricular Hypertrophy and the factors associated with its occurrence which had not been done at the renal unit KNH. The data that generated filled a literature gap about the prevalence of LVH and factors associated with its occurrence.

2.8 Conceptual Frameworks

Figure 1: Conceptual framework

The conceptual framework shows a relationship of the independent variables (hypertension, BMI, socio economic factors and duration in which a patient has been on hemodialysis) with the dependent variable (presence or absence of left ventricular hypertrophy). The relationship lead to an outcome which can either be survival or death due to the cardiovascular complications associated with presence of LVH.



CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study Design

This was a cross-sectional study design which was carried out on the patients undergoing maintenance hemodialysis at the KNH. The study was seeking to assess the prevalence of LVH and establish the factors were associated with its occurrence among that population. Quantitative data was collected from the study participants to identify their predialysis blood pressure levels, their body mass index, to find out those participants who were hypertensive and the type of antihypertensive medications they were taking, the duration in which they had been on maintenance hemodialysis and those who had left ventricular hypertrophy. A cross-sectional design was adopted as it was inexpensive, saved on time and allowed the assessment of many independent variables at that time.

3.2 Study Area

The study was carried out at the renal unit and cardiology department in Kenyatta National Hospital. It is the oldest and largest public referral hospital in Kenya. It was founded in the 1901 during the colonialism era when it was referred to as the Native Civil hospital, then in 1952 it was renamed after England's king to King George VI. After the country gained its independence, it was renamed after the first president of Kenya to Kenyatta National Hospital. It is a teaching hospital for the University of Nairobi, Kenya medical and training College-Nairobi and many others. It offers specialized care to patients from all parts of the country, east and central Africa. Among the various specialized units, there are the renal unit, intensive care units, accident and emergency, cardiology and obstetric units. It has a bed capacity of over 2000 beds and is served by over 6000 medical and non-medical staff.

The study site for this research was the renal unit and cardiology department of Kenyatta National Hospital. The renal unit in KNH is the oldest renal unit in Kenya and it offers all types of renal replacement therapies which include hemodialysis, peritoneal dialysis and kidney transplant. The most commonly used form of renal replacement therapy is hemodialysis. It serves the largest number of patients in the country in need of any of the available renal replacement therapies. The staff attending to the patients are of diverse specialties, all trained to offer quality services to all the patients with kidney failure. The renal unit has three sections, which are the hemodialysis section, peritoneal dialysis section and the kidney transplant section. This study was carried out in the hemodialysis section which has a capacity of 26 beds and serves approximately 130 total numbers of patients per week. In a day the unit serves approximately 50 patients. Most patients have 2 sessions of dialysis weekly while a few have 3 sessions in a week. The hemodialysis services are offered from 5am in the morning until around 11pm in the evening with each session lasting a maximum of 4 hours. The patient served at the renal unit could either be inpatient (admitted in the hospital) or outpatient (coming from home).

Cardiology department serves all patients at the Kenyatta National Hospital (both inpatients and outpatients). It is usually accessible from Monday to Friday from 8am to 4.30pm. All investigations related to the cardiovascular system are offered here and this includes Electrocardiography investigations, echocardiography, cardiac catheterization and other investigations. The staff offering services in this department are of diverse qualifications, all trained to offer all the services available in the department

3.3 Study Population

The study population was all patients undergoing hemodialysis patients at the renal unit KNH.

3.4 Inclusion Criteria

- 1. All patients undergoing maintenance hemodialysis who are not critically ill and who consent to participate in the study.
- 2. All patients undergoing maintenance hemodialysis at KNH with results for Echocardiography done within the last three months.

3.5 Exclusion Criteria

- 1. Patients with acute kidney injury who are not at risk of left ventricular hypertrophy.
- 2. Patients who decline to give consent for participating in the study.
- 3. Patients who are critically ill or mentally ill who are not able to offer informed consent.

3.6 Sample Size Calculation and Sampling Technique

The sample size was determined by the commonly used precision-based sample size formula for small populations developed by Fisher and Cochran ("(No Title)," n.d.). This was because the sample size was small (below 1000) and the prevalence of the outcome (LVH) as well as the factors associated with its occurrence was not known.

The formula is as below:.

$$n = \frac{z^2 \times p \times q \times N}{E^2 \times (N-1) + z^2 \times p \times q} = \frac{z^2 p q N}{E^2 (N-1) + z^2 p q}$$

Where,

n =The desired sample size

z =Standard normal deviation at 1.96

N = The population size; the total number of patients undergoing dialysis in KNH renal unit: 130

p = The proportion in the target population that was estimated to have characteristics being studied (LVH). In this study, the proportion in the target population was 58% derived from a previous similar study done in Eldoret, Kenya(Hagembe, 2018)

q = 1 - p Was the estimated population proportion of patients without LVH. In this study it was assumed that p = 0.58, and q = 0.42 just to make sure that the dominance of attributes of interest was not biased; and

e = The degree of precision at 0.05 or 5%

Therefore, using fisher's formula to calculate the sample size of a population less than 10000:

$$n = \frac{z^2 p q N}{E^2 (N-1) + z^2 p q}$$

= 97

The minimum sample size required were 97 patients receiving hemodialysis in KNH renal unit.

3.7 Sampling Method

A census method was used in selection of participants for the study. All the participants were given an equal chance to participate in the study but those who did not consent were exempted. This included selecting those who already had their echocardiography investigations done within the past three months and those who did not have and echocardiography investigations were done.

3.8 Study Instruments

An interviewer-administered questionnaire was used to obtain the participants demographic and medical information.

Physical examination of the participants was done by the researcher and documented. This entailed the examination finding such as their pre dialysis blood pressure, height and postdialysis weight. The pre-dialysis blood pressure measurements were taken using an automated blood pressure monitor (Mindray type of a machine). The post dialysis weight was measured by having the participant step on the weighing machine (TTM) barefooted while having light clothes on to obtain accurate data. Height was measured by having the participant step on the floor barefooted then the height of the participant taken in centimeters.

Participants BMI was also be calculated by dividing the obtained weight by height in meters squared.

Electrocardiography and Echocardiograph were used to assess the left ventricular hypertrophy. A resting 12 lead electrocardiography machine (MAC 2000) was used to do the ECG imaging studies and it gave us the computerized interpretations if a participant had LVH or not. A 2D Echocardiogram machine (Philip iE33 ultrasound machine) was used to also determine the presence of LVH where the qualified sonographer positioned the probe appropriately to attain long parasternal view, apical 4 views, short axis view and the subcostal view. The views enabled the sonographer to get the left ventricular mass index and if the dimensions were greater than 95g/m² in women and 115g/m² for men one was considered to be having left ventricular hypertrophy.

3.9 Pre-Testing

Pre-testing of the questionnaire tool was done at the renal unit in Kenyatta National Hospital. The questionnaire was administered to 9 patients (10% of the sample size) visiting KNH and there were no errors that were identified hence the questionnaire was adapted for the study. The results of the pre-testing were not included in the study. The echocardiography machines were pre-tested on patients who had already been diagnosed with LVH to confirm they measured a true value of what they needed to measure based on the left ventricular mass index dimensions.

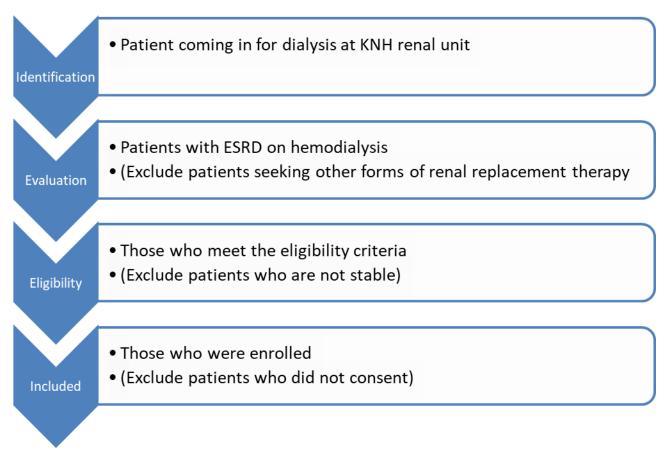
3.10 Data Collection and Management

3.10.1 Data Collection

First step involved identifying the patients who were undergoing maintenance hemodialysis and had undergone electrocardiography and echocardiography investigations in the last three months where the information was obtained at the cardiology department. These patients were then followed up at the renal unit and using the daily register they were checked to see which day they came for their dialysis session. Once identified, the patient was informed about the study, they were also informed about the participant information and an informed consent was obtained. Anthropometrics measurements, blood pressure and other vital signs measurements were taken. During the dialysis session, the participants were taken through the interviewer administered questionnaire and relevant information obtained. Finally, the electrocardiogram and echocardiogram findings from their medical records was obtained and filled in the questionnaire. Patients who came for hemodialysis were screened by the principal investigator if they were not critically ill. The PI or research assistant then informed them about the study, its potential benefits and its importance. Informed consent was then sought and those who consented and met the eligibility criteria were enrolled in the study. Anthropometric measurements, pre-dialysis blood pressure and other vital signs measurements was taken and recorded before the patients underwent the hemodialysis. During dialysis, they were engaged in an interviewer administered questionnaire by the principal investigator and the research assistant and the data collection tool was filled. Once the dialysis was over, the patient's weight and other vital signs were taken and recorded. We also ensured that the participants got all the care they were supposed to get for that

day. Patients were allowed to rest for an hour before commencing the imaging studies. They were later escorted to the cardiology department where the echocardiography procedures were done. The procedures were done as per the procedure outlines in the appendices. A standard 2D echocardiography (Philips iE33 ultrasound machine) with both color and spectral Doppler were used to acquire apical views, parasternal long-axis views, parasternal short-axis views, Suprasternal and subcostal views. Those views assessed the left ventricular end diastolic dimension, intraventricular septal thickness at end- diastole and left ventricle posterior wall thickness at end diastole. These dimensions were taken to get the left ventricular mass index for each participant whereby in women values that exceeded 95g/m² and in men values greater than 115g/m² indicated that one had left ventricular hypertrophy. Moreover the type of left ventricular hypertrophy was also specified based on the relative wall thickness dimensions such that if they are equal or less than 0.42 one is said to have eccentric LVH and if more than 0.42 one has concentric LVH. The sonographer was able to identify other heart conditions such as types of left ventricular systolic or diastolic dysfunctions and many others using the 2D echocardiography machine.

Figure 2: Recruitment strategy



3.10.2 Data Management

Checking of data was done by the principal investigator to ensure the questionnaires were complete and that the information that had been captured was accurate.

The questionnaires were coded in preparation of analysis.

Safety precautions were taken for the protection of the data such as locking the questionnaires in a safe cupboard as they awaited analysis, and after analysis the data in soft copy form was stored in a password protected laptop that is only accessed by the principal investigator.

The consent forms and questionnaires will be safely stored for five years; after which they will be destroyed

3.11 Data Analysis

Data analysis was done using SPSS version 26 which included both descriptive and inferential analysis.

Absolute values were used for age, alcohol taking and cigarette smoking and the duration in which one had been on hemodialysis.

Categorical data was analyzed using frequencies and percentages and was presented in charts.

Continuous data was tested for normality using the Shapiro-Wilk test and analyzed using mean

(SD) and median (IQR).

All comparisons were performed at a 0.05 significance level.

The prevalence of left ventricular hypertrophy among patients undergoing dialysis in the KNH renal unit was calculated as a proportion of the total sample size investigated in the study. This was done using the formula as shown:

$$\% prevalence = \frac{\text{Number of patients with left ventricular hypertrophy}}{\text{The total number of patients included in the study who were undergoing hemodialysis}}*100$$

A Pearson chi-square or Fisher's exact tests was used to test for associations between categorical independent variables in the study such as gender, alcohol, smoking, Body mass index group, and hypertension and the dependent variable left ventricular hypertrophy. An independent samples t-test was used to compare continuous independent variables such as age, pulse rate, respiration rate, temperature, SPO2% and duration of dialysis with the dependent variable left ventricular hypertrophy.

In multivariate analysis, a binary logistic regression analysis was conducted to determine independent predictors of left ventricular hypertrophy among patients receiving hemodialysis at the KNH renal unit. The odds ratio was calculated to explain the likelihood of the independent variable influencing the dependent variable.

3.12 Ethical Consideration

Ethical approval was received from Kenyatta National Hospital/University of Nairobi (KNH/UoN) Ethics and Research Committee with the approval Ref: KNH-ERC/A/375. Permission was also sought from the KNH administration then upon approval I also sought permission at the renal unit and cardiology before the commencement of data collection. Participants were taken through what the study entails and its purpose and informed consent will be sought. Confidentiality of the participants, their privacy and was observed during the data collection and handling of the collected data. Patients who were noted to have LVH or any other abnormality were referred to a nephrologist for further review and management with the informed consent of the participant.

3.13 COVID 19 precautions during data collection

During data collection, COVID 19 guidelines as per the KNH-UON Ethics and Review committee available in the appendix 6 were observed to ensure there was no room for transmitting the infection between participants and the researcher or research assistant. Data collection was done in a spacious room in the renal unit which has good lighting and aeration. All the participants were requested to wash their hands and put on their masks before data collection was done. The principal researcher as well as the research assistant ensured that they washed their hands before handling any participants as well as put on their masks. Hand sanitizer was also availed to be used in the room during data collection. Social distancing was highly observed between participants, the research assistant and the principal researcher. All participants were encouraged to report in case they felt they were experiencing COVID 19 like symptoms.

3.14 Minimizing Errors and Bias

A standardized questionnaire for all respondents was used to increase the consistency of the information collected and thus enhanced its reliability. The questionnaire was adopted from previous research work to enhance its reliability and validity.

The echocardiography investigations were carried out using the same machine by one study dedicated sonographer who works at the cardiology department, Kenyatta National Hospital. The images were archived in an external hard disk and were reviewed later by the PI and the study dedicated sonographer.

3.15 Dissemination

The report copies of this study were presented to the department of nursing services at University of Nairobi, KNH/UON ethics review committee, renal unit at KNH and the University of Nairobi library for deposited in the repository. Participant's information was not shared during dissemination of the findings to ensure confidentiality and privacy was highly observed. A manuscript for the study was written for publication in peer reviewed journals. They shall also be presented in scientific conferences.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter the findings and results that relate to the factors associated with left ventricular hypertrophy among patients undergoing hemodialysis at Kenyatta National Hospital are presented. A presentation of the socio demographic data has been done followed by a presentation of the results regarding the prevalence of left ventricular hypertrophy among patients undergoing hemodialysis at the renal unit in KNH. A presentation of the analysis showing the relationship between various factors (BMI; duration in which a patient had been on hemodialysis and hypertension) and occurrence of Left Ventricular Hypertrophy among patients undergoing hemodialysis at the renal unit in KNH has been done.

The target population was 97 patients receiving hemodialysis in KNH renal unit. 80 participants were accessed for the study; however, only 70 patients consented and took part in the study which represents 87.5% response rate.

Data from the 70 (n=70) interviewer -administered questionnaires was analyzed using the Statistical Package for Social Science (SPSS) version 26. Data was entered, cleaned and screened to ensure there were no errors or missing data. The results are presented in narration and tables.

Shapiro wilk test of normal distribution for continuous variable was performed to check whether the continuous data was normally distributed. The significant level (Alpha) was set at 0.05. The Age of patients undergoing hemodialysis, Pre-dialysis systolic pressure, pre dialysis diastolic pressure, pulse rate of the patients, weight of the patient were normally distributed with a P value > than the set Alpha value of 0.05 while the respiration rate, temperature, pulse oxygen concentration, height of the patient, Body Mass Index (BMI), patients duration on dialysis in months and left ventricle ejection fraction were not normally distributed with a P value < than the set Alpha value of 0.05.

4.2 Social-demographic characteristics

The participants ages ranged from 18 to 87 years with a mean age of 46.46 years (SD=14.74). Majority of the participants were male at 45 (61.4%) while 27 (38.6%) were females. On the occupation status; 36 (51.4%) of the participants were unemployed with only 34 (48.6%) having a source of livelihood either being employed or self-employed. Majority of the participants at 68 (97.1%) did not take alcohol nor smoke as shown in table 1.

Socio-demographic characteristics (<i>n</i> =70)					
Variable	Frequency (n)	Percentage (%)			
Gender					
Male	45	61.4			
Female	27	38.6			
Totals	70	100			
Employment status					
Un-employed	36	51.4			
Employed	34	48.6			
Totals	70	100			
Alcohol in-take & Smoking					
Yes	2	2.9			
No	68	97.1			
Totals	70	100			

Table 1: Participants socio-demographic characteristics

Mean	Median	Standard deviation	Mode	Minimum	Maximum	Range
46.46	45.5	14.75	36	18	87	69

Age (Years)

4.3 Prevalence of left ventricular hypertrophy among patients undergoing hemodialysis

The first objective sought to find out the prevalence of Left Ventricular Hypertrophy among patients undergoing hemodialysis at the renal unit.

The prevalence of Left Ventricular Hypertrophy (concentric) among patients undergoing dialysis in the KNH renal unit was calculated as a proportion of the total sample size investigated in the study. This was done using the formula as shown:

% prevalence = $\frac{\text{Number of patients with left ventricular hypertrophy}}{\text{The total number of patients included in the study}}*100$

% prevalence = $\frac{49}{70}$ * 100 = 70%

4.4 Participants vital signs, anthropometric measures and dialysis duration/frequency characteristics

The pre dialysis systolic and pre dialysis diastolic median result for the participants was (145.5/92 mm/hg). The median pulse rate and respiratory rate was 83 and 19 respectively. The temperature ranges was noted to be 36.9- 35.7 degree Celsius whereas the median pulse oxygen concentration was noted to be 97 amongst the participants. The median BMI for the participants was 22.02 (Kgs/M²), a majority of the patients had BMI within 12.3- 34.47 ranges. Further the

average duration for patient on dialysis was 18.51 months and all the patients were undergoing 2

dialysis sessions in a week.

Table 2: Participants vital signs, anthropometric measures and dialysis duration characteristics

	Mean	Median	Standard deviation	Mode	Minimum	Maximum	Range
Vital signs chara	cteristics	(n=70)					
Pre-dialysis systolic blood pressure	150.39	145.5	29.99	137	88	236	148
(mmHg) Pre-dialysis diastolic blood pressure (mmHg)	91.77	92	19.31	72	48	140	92
	86.6	83	13.17	73	54	120	66
Respiration rate (Breadths/min)	19.03	19	2.03	18	16	26	10
Temperature (Degree Celsius)	36.4	36.4	0.21	36.4	35.7	36.9	1.2
Pulse Oxygen saturation (%)	95.57	97	3.85	97	72	99	27

Participants vital signs, anthropometric measures and dialysis duration characteristics

Anthropometric measures characteristics (n=70)

Weight (Kgs)	62.47	62	10.16	51	41.6	87.7	46
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Height (Centimete	ers)	165.6	164	12.82	164	86	186	100
Body Index Kgs/M2	Mass (BMI)	22.03	22.02	3.7	22.02	12.3	34.47	22.17
Patient duration on dialysis (n=70)								
Duration dialysis months	on in	18.51	11	20.99	1	1	84	83

4.5 Participants comorbidities characteristics and medication used

Majority of the patients 66 (94.3%) were hypertensive and all used anti-hypertensive. All the hypertensive participants used more than one anti-hypertensive. The main anti-hypertensive used were calcium channel blocker 57(31.5%), vasodilators 45(24.9%), beta blockers 42(23.2%) and diuretics 20(11%) as anti-hypertensive drugs. The remaining 17(9.4%) used angiotensin receptor blockers, Alpha 2 agonists and angiotensin converting enzyme I as anti-hypertensive. A minority of the participants were diabetic 11(15.7%) and used the following anti-diabetics; 7 (58.3%) were on insulin injectable, 4(33.3%) oral anti-diabetics and only 1(8.3%) were using both insulin injectable and oral anti-diabetics. Slightly more than half of the participants 38(54.3%) were on other medications such as haemopoietin 44.2%, anticoagulants 11.5%, iron supplements and proton pump inhibitors at 9.6% each.

-			
		Frequency (n)	Percentage (%)
Hypertensive participants (<i>n</i> =70)	Hypertensive	66	94.3
participants $(n-70)$	Non- hypertensive	4	5.4
	Totals	70	100
Diabetic participants	Diabetic	11	15.7
(<i>n</i> =70)	Non-diabetic	59	84.3
	Totals	70	100
Type of anti- hypertensive used	Calcium channel blocker	57	31.5
(<i>n</i> =181)	Vasodilators	45	24.9
	Beta blockers	42	23.2
	Diuretics	20	11
	Angiotensin receptor blocker	9	5
	Alpha 2 agonist	7	3.9
	Angiotensin converting enzyme I	1	0.6
	Totals	181	100
used by the	Hematopoietin	23	44.2
participants (<i>n</i> =52)	Anti-coagulant	6	11.5

Table 3: Comorbidities characteristics and medication used by participants

Comorbidity Characteristics and medication used by participants (*n*=70)

 Iron supplements	5	9.6
Proton pump inhibitor	5	9.6
Xanthine oxidase inhibitor, corticosteroids, acetaminophen, phosphate binder, ant- retroviral	13	25
Totals	52	100

4.6 Participants Electrocardiograph (ECG) and Echocardiogram (ECHO) findings

All the participants involved in the study had echocardiogram done with only 13 (18.6%) having electrocardiograph findings. 10 (14.3%) of the electrocardiogram results had abnormal findings that included ST and T wave abnormalities 7 (10%) and prolonged QT wave 4 (5.7%). Electrocardiograph results showed only 2(2.9%) of the participants had LVH. The major heart conditions identified from echocardiogram were Tricuspid regurgitation 57 (20%), Pulmonary artery hypertension 52(81.4%), pulmonary artery hypertension 52 (74.3%), Hypertensive heart disease 50 (71.4%) and Left Ventricular Hypertrophy 49 (70%). Other heart functions that were identified included Tricuspid Regurgitation 37 (52.9%) and Pleural effusion 21(30.0%). The table 4 highlights the various heart condition identified from echocardiogram and electrocardiogram.

Table 4: Distribution of heart conditions identified from ECG and ECHO findings	

I DOTTO M

Distribution of heart conditions identified from Electrocardiograph (ECG) and							
Echocardiograph (ECHO)							
Heart condition					Frequency	Percentage	
					(n)	(%)	
ECG Findings (<i>n</i> =70)	ST	and	Т	wave			
abnormalities							
	Present (%)			7	10		

	Absent (%)	63	90
	Total	70	100
	Prolonged QT		
	Present (%)	4	5.7
	Absent (%)	66	94.3
	Total	70	100
	1 st Degree AV block		
	Present (%)	2	2.9
	Absent (%)	68	97.1
	Total	70	100
	Left Vent	ricular	
	Hypertrophy (Concen		
	Present	2	2.9
	Absent	68	97.1
	Total	70	100
ECHO Findings (n=70)	Tricuspid regurgitation	n	
	Present	57	81.4
	Absent	13	18.6
	Total	70	100
	Pulmonary	Artery	
	Hypertension		
	Present (%)	52	74.3
	Absent (%)	18	25.7
	Total	70	100
	Hypertensive heart di	sease	
	Present (%)	50	71.4
	Absent (%)	20	28.6
	Total	70	100
		ricular	
	Hypertrophy (Concen		
	Present (%)	49	70
	Absent (%)	21	30
	Total	70	100
	Mitral regurgitation		
	Present	37	52.9
	Absent	33	47.1
	Total	70	100
	Pleural effusion		
	Present	21	30
	Absent	49	70
	Total	70	100

Aortic regurgitation		
Present	19	27.1
Absent	51	72.9
Total	70	100
Type I Left Ventr Diastolic Dysfunction	icular	
Present (%)	18	25.7
Absent (%)	52	74.3
Total	70	100
Type II Left Ventr Diastolic Dysfunction	icular	
Present $(\%)$	10	14.3
Absent (%)	60	85.7
Total	70	100

A cross tabulation to assess the predictability of identifying abnormal findings from electrocardiogram and echocardiogram was done that showed electrocardiogram only observed 10 cases of abnormal heart function while the echocardiogram done on the same patients showed 65 cases of abnormal heart function. 65 (92.86%) of all participants in the study had abnormal findings.

Table 5: Cross tabulation	of ECG and ECHO) in identifying abnorn	al heart conditions

ECG findings in the last 3 months * Participants with ECHO investigation in the last 3 months Cross-tabulation								
			Participants investigation months	with ECHO in the last 3	_			
			Normal	Abnormal				
			ECHO	ECHO				
			findings	findings	Total			
ECG findings in the	Normal ECG finding	gs	1	2	3			
last 3 months	Abnormal E findings	CG	0	10	10			
	No ECG findings		4	53	57			
Total			5	65	70			

4.7 Association between Hypertension, BMI, duration of patients on hemodialysis and other independent factors and the dependent variable (presence/absence of LVH)

4.7.1 Chi-square for associations between presence/absence of hypertension, presence of other cardiac conditions

A Pearson chi-square or Fisher's exact tests was used to test for associations between categorical independent variables in the study such as gender, presence/absence of hypertension, presence of other cardiac conditions and the dependent variable left ventricular hypertrophy among participants undergoing hemodialysis in the renal unit in Kenyatta National Hospital.

There was a statistical significance identified between the presence of hypertension reporting a chi square value $x^2 = 4.091$, df= 1 and p-value = 0.043, presence of hypertensive heart disease from ECHO reporting a chi square value $x^2 = 48$, df= 1 and p-value = 0.000 and the presence of other heart conditions reporting a chi square value $x^2 = 7.313$, df= 1 and p-value = 0.007 and the occurrence of LVH where p< set significance of 0.05. There was no statistical significance between gender of the participants which reported a chi square value $x^2 = 0.03$, df= 1 and p-value = 0.957 > set significance of 0.05 and the occupation of the participants which reported a chi square value $x^2 = 2.789$, df= 1 and p-value = 0.095 > set significance of 0.05 and the occurrence of LVH. More so, the chance that gender would lead to LVH was low based on the likelihood ratios which was at $G^2 = 0.003 < 1$. Participants who had hypertensive heart disease from echocardiogram had a likelihood ration $G^2 = 49.82 > 17.254$ which showed a high likelihood of getting LVH.

Parameters	Left Ve	ntricular		Chi-	Df	Likelihood	Sig.	Phi	n
	Hypertr	ophy		square		Ratio	p-	Cramers	
	(LVH)			(x^2)			value	V	
	LVH	No	Totals						
	(%)	LVH							
		(%)							
Gender				.03 ^a	1	.003	.957	.006	70
Male	30	13	43						
	(69.8%)	(30.2%)							
Female	19	8	27						
	(70.4%)	(29.6%)							
Hypertensive				4.091 ^a	1	3.677	.043	.242	70
participants									
Hypertensive	48	18	66						
	(72.7%)	(27.3%)							
Non-	1 (25%)	3 (75%)	4						
hypertensive									
Diabetic				2.717 ^a	1	3.257	.099	.197	70
participants									
Diabetic	10	1	11						
	(90.9%)	(9.1%)							
Non- diabetic	39	20	59						
	(66.1%)	(33.9%)							
Hypertensive				48 ^a	1	49.821	.000	.828	70
heart disease									
Present	47	3 (6%)	50						
	(94%)								
Absent	2 (10)	18	20						

 Table 6: Pearson Chi-Square showing Association between categorical independent
 variables and the dependent variable (presence/absence

		(90%)							
Other heart				7.313 ^a	1	7.544	.007	.323	70
conditions									
Present	49	18	67						
	(73.1%)	(26.9%)							
Absent	0 (0%)	3	3						
		(100%)							

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 5

4.7.2 Independent sample t-test comparing BMI, duration on dialysis and other continuous variables

An independent samples t-test was used to compare continuous independent variables such as BMI, pulse rate, respiration rate, temperature, SPO2% and duration of dialysis with the dependent variable left ventricular hypertrophy.

Based on the independent t-test results of Table 11; the p-values of the Levene's Test for Equality of Variances were all >0.05. This implies that the variability in the participant's age, pre dialysis systolic and diastolic pressure, pulse rate, respiration rate, temperature, SPO2%, BMI and duration of patient on dialysis in months and LVH are more or less similar. The participants' pre-dialysis systolic blood pressure p- 0.014, pulse rate p-0.044 and BMI p-0.038 had a statistical association with presence of LVH. Nonetheless, the p-values representing the t-test for Equality of Means for pre dialysis diastolic pressure p- 0.452, respiration rate p- 0.741, temperature p- 0.284, SPO2% p- 0.947, and duration of patient on dialysis in months p- 0.688 were all >0.05; indicating that they are had no statistical association with LVH.

				J~-~					
				Lev	ene's				
				Tes	t for				
				Equ	ality				
				(of				
				Vari	ances	t	-test for E	Equality of	Means
						Sig. (2-	Mean Differen	Std. Error cDifferend	95% Confidence Interval of the Difference
		Mean	SD	F	Sig. t	df taile	d)	e	Lower Upper
Age (Years) of participar undergoing hemodialysis	ntsLVH present No LVH	46.87 76 45.48	622	3.452	2.068.362	68.718	1.40136	3.86969	-6.320 9.12320
Pre dialysis systolic pressu	rol VH	156 1	30.15						
of the participants	present	150.1	30.13		432.2.53	68 014	19 0544	27 53287	4.0228 34.08603
	No LVH	137.0	25.58		. 1022.00	00.011	1910011	27.33207	102203 1000003
Pre dialysis diastolic pressu	reLVH	92.91	20.32						
of the participants	present			2.140	0.148.757	68.452	3.82313	5.05230	-6.259 13.90483
	No LVH	89.10	16.86						
Pulse rate (beat/min) of the		81.53	12.78						
participants	present			.009	.924-2.1	68.044	-6.89790	5 3.35706	-13.5919905
	No LVH	88.43	13.09						
1	te LVH hepresent	19.08	2.110						

Table 7: Independent sample t-test for continuous variables and presence of LVH

respiration rate, Spo2%, BMI and duration on dialysis

Independent sample t-test for participants age, pre-dialysis systolic and diastolic blood pressure, pulse rate,

participants	No LVH	18.90	1.868	.428	.515.33	2 68.741	.17687	.53254	8858 1.23953
Pulse oxygen concentrati of the participants	onLVH present No LVH	95.59 95.52		.190	.66 .06	8 68.947	.06803	1.01167	-1.951 2.08679
	No LVH								
Body Mass Index (BMI) the participants	ofLVH present	22.63	3.201				1 00 401	0.4201	112662.05525
	No LVH	20.63	4.453		5.1312.1	2 68.038	1.99401	.94281	.112663.87537
Duration on dialysis months for the participants	inLVH present	19.22	23.24		5.090.43	1 68.668	2.36735	5.48700	-8.582 13.31648
	No LVH	16.86	14.42						
	No LVH	60.14	11.68						

4.7.3 Multivariate Analysis: binary regression analysis to determine independent predictors of LVH

In multivariate analysis, a binary logistic regression analysis was conducted to determine independent predictors of left ventricular hypertrophy among patients receiving hemodialysis at the KNH renal unit. The odds ratio was calculated to explain the likelihood of the independent variable influencing the dependent variable.

The binary logistic regression analysis was performed to assess how a number of factors affect the likelihood of participants having LVH. The model contained various independent variables (presence/absence of hypertension, duration on hemodialysis, BMI, pre-dialysis systolic blood pressure, pulse rate, presence of other heart diseases such as presence of hypertensive heart disease from echocardiogram) and their relationship with presence/absence of LVH.; however only one variable was found to be statistically significant; presence of hypertensive heart disease on ECHO. The full model containing these predictors was statistically significant as shown by the Hosmer- lemeshow goodness of fit test with a chi-square value of 11.832 with a significance of 0.159 at a degree of freedom of 8.

Table 8: Hosmer and lemeshow goodness of fit test

Hosmer and Lemeshow Test for the binary logistic regression analysis of (BMI, duration on dialysis, presence of hypertension and various variables and presence of

LVH

Step	Chi-square	Df	Sig.
1	11.832	8	.159

Based on the model summary (Table 9), the influence of presence/absence of hypertension, duration on hemodialysis, BMI, pre-dialysis systolic blood pressure, pulse rate, presence of other heart diseases such as presence of hypertensive heart disease from echocardiogram on Left Ventricle Hypertrophy (LVH) ranges from 55.2% to 78.2% based on the Cox & Snell R square and the Nagelkerke R Square. This is a significant result because, the binary logistic regression model often offers lowered results of the model summary as compared to the multiple regression results.

Table 9: Model Summary for the binary logistic regression analysis

Model Summary for the binary logistic regression analysis of (BMI, duration on dialysis, presence of hypertension and various variables and presence of LVH

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.374 ^a	.552	.782
a. Estimatio	on terminated at iteration	number 20 because may	kimum iterations has been
reached.			

From the classification Table 10 the percentage of cases that can actually and accurately be classified as having LVH is 95.9%. This implies that the LVH found in patients is statistically valid and could be viewed as truly the actual case. It also possesses the sensitivity of the cases that are classified as having no LVH which is at 85.7%. The 95.9% highlights that the study accessed the positive predictive value of the LVH presence in patients.

Table 10: Classification of LVH table

Classification Table^a

Classification Table					
			Predicted		
			Presence (Concentric	Н	
			LVH		
			(Concentric)	Percentage
Observed			present	No LVH	Correct
Step 1 Presence of	LVHLVH	(Concentric	:)47	2	95.9
(Concentric)	present				
	No LV	Н	3	18	85.7
Overall Percenta	age				92.9

a. The cut value is .500

Hypertensive heart disease on echocardiogram had a statistical significant effect on the presence of LVH (p=.000). Presence/absence of hypertension, BMI and duration of patient on dialysis in months did not have the statistical significance on presence of LVH. However, presence of hypertension (OR= 2.433), pre-dialysis diastolic pressure (OR= 1.025), elevated pulse rate (OR= 1.073), presence of hypertensive heart disease on echocardiogram (OR=177.784), and presence of other cardiac conditions on echocardiogram, apart from LVH (OR=172027088.316) created a higher likelihood for the presence of LVH.

Participants with a higher BMI (OR= 0.961) and extended duration of dialysis (OR= 0.969) created a lower likelihood for the presence of LVH.

conditions) on LVH								
								C.I. for
					p-value	Likelihood	EX	P(B)
					(Sig.)	ratio		
Characteristic	B	S.E.	Wald	df		(Exp(B))	Lower	Upper
Pre dialysis systolic pressure of the participants	e025	.030	.728	1	.394	.975	.919	1.034
Pre dialysis diastolic pressure of the participants	f.025	.040	.374	1	.541	1.025	.947	1.109
Pulse rate (beat/min) of the participants	e.071	.044	2.543	1	.111	1.073	.984	1.170
Body Mass Index (BMI) of the participants	e040	.153	.069	1	.793	.961	.712	1.297
Duration on dialysis in months for the participants	031	.042	.558	1	.455	.969	.893	1.052
Hypertensive participants Presence of hypertension (r)	.889	2.652	.112	1	.737	2.433	.013	440.161
Hypertensive heart disease Participants with hypertensive heart disease on ECHO (r)	5.181 t	1.350	14.721	1	.000*	177.784	12.605	2507.44
		22719.70	.000	1	.999	172027088.32	2.000	
conditions on ECHO (r)		22719.70	.000	1	.999	.000		

Table 11: Binary Logistics Results of Variables (BMI, duration on hemodialysis, hypertension and other heart conditions) on LVH

Binary Logistics Results of Variables (BMI, duration on hemodialysis, hypertension and other heart conditions) on LVH

Note *: Predictors with a significant P-value. "r": Reference category, df: Degree of freedom, p: P-value, B: Regression coefficients.

CHAPTER FIVE: DISCUSSION OF FINDINGS, CONCLUSIONS AND

RECOMMENDATIONS

5.1 Introduction

This study sought to assess the factors associated with left ventricular hypertrophy among patients undergoing hemodialysis at Kenyatta National Hospital. This chapter includes discussion of the findings, recommendation and conclusion made of the study.

5.2 Discussion of the Findings

5.2.1 The prevalence of left ventricular hypertrophy among patients undergoing hemodialysis at Kenyatta National Hospital

In this study, assessment of the prevalence of left ventricular hypertrophy was one of the objectives. From the findings, the prevalence of left ventricular hypertrophy among patients undergoing hemodialysis at the renal unit was more than half (70%). This findings correlated with (Cozzolino et al., 2018a) who also found the prevalence of LVH (70%) which was the same as for our study findings. Being a known independent risk factor for cardiovascular complications, the high prevalence from the findings of this study raised concern. This implies that the patients who are undergoing hemodialysis and have LVH are predisposed to high risk of getting sudden cardiac death and ventricular arrhythmias as the left ventricular hypertrophy interferes with electrical conductivity and mechanical functions of the heart(de Albuquerque Suassuna et al., 2018). Left ventricular hypertrophy is also a known trigger of the development of diastolic dysfunction (Slivnick & Lampert, 2019b) and this could be associated with the occurrence of both type one and type two left ventricular diastolic dysfunction that was noted in this study.

Presence of Left ventricular hypertrophy among patients undergoing hemodialysis is caused by the combination of mechanisms such as fluid and pressure overload (McCullough et al., 2016). Among our study population the high prevalence of LVH can be attributed to hypertension which was highly prevalent at 94.3% and fluid overload as all the participants were only doing two sessions of hemodialysis in a week. The two hemodialysis sessions in a week results to inadequate hemodialysis as the KIDIQO guidelines recommended that to achieve hemodialysis adequacy patients needed a minimum of three sessions per week.

The findings of this study can be compared to (Hagembe, 2018) who found the prevalence of LVH to be lower at 58% compared to the findings of this study. The findings can be interpreted to mean that despite both studies having some similar patient's characteristics, the patients from this study were still having more factors that influenced the occurrence of LVH. Some of the factors that contributed to the higher prevalence of LVH from this study were the presence of hypertension, presence of hypertensive heart disease and an elevated pulse rate which had a high likelihood of the causing LVH.

5.2.2. The association between Hypertension and Left Ventricular Hypertrophy

The findings of the study showed that almost all (94.3%) were hypertensive and all of them were on various types of antihypertensive medications. However despite being on the various antihypertensive medications, the pre-dialysis blood pressure measurements showed that half of them at the time of data collection had high blood pressure measurements. This was an indication of poorly uncontrolled hypertension and could be related to a number of factors associated with the patient or factors related to the antihypertensive therapy. (Visanuyothin et al., 2018) also added that poorly controlled hypertension was associated with resistant hypertension or inadequate use of antihypertensives. Hypertensive participants were noted to have a higher likelihood of left ventricular hypertrophy being present. This was particularly among those patients with an elevated diastolic blood pressure. The high likelihood could be attributed to the left ventricle being the primary end organ to get damaged by hypertension (Yildiz et al., 2020). Therefore strategies aimed at maintaining the blood pressure within the normal range could help in the prevention of occurrence of LVH. The risk of cardiovascular complications is said to be raised in long standing hypertension in the presence of other factors such as obesity or chronic kidney disease (Calhoun et al., 2008). From the findings of this study, the number of participants with hypertensive heart disease was slightly higher than those who had LVH. Furthermore, those participants with hypertensive heart disease had the highest likelihood of having LVH. This echoed (Kjeldsen, 2018) that hypertension has also been associated with the occurrence of other cardiovascular conditions such as hypertensive heart disease. This depicts that the effects of hypertension on the heart of the affected persons are detrimental especially when the blood pressure is not well controlled.

Strategies are being employed in the control of blood pressure in attempt to mitigate the end organ damage that is brought about by hypertension for instance by maintaining the systolic blood pressure <120 mmhg (Bourdillon & Vasan, 2020). However, when compared to our study findings the mean systolic blood pressure was higher than the upper limit in a normal range. This could therefore explain the presence of end organ damage on the heart that was seen. Despite there not being a conclusive evidence as to which choice of antihypertensive regimen is effective in regression of LVH (Soliman & Prineas, 2017), patients should be followed up and the antihypertensive therapy revised until normal blood pressures are achieved. This will be paramount in ensuring prevention of cardiovascular complications that could arise from the damage caused by long standing effects of hypertension.

5.2.3 The association between BMI with the presence of LVH

The participant's weight and height measurements were also taken and were used to estimate the participant's body mass index. From the findings, majority of the participants had a body mass index that was within the normal range which indicated that they were neither overweight nor underweight. This findings contrasted with (Sabatino et al., 2017) who had shown that majority of the patients undergoing hemodialysis have a lower BMI due to the high prevalence of protein energy wasting. This could indicate that though our study participants were prone to protein energy wasting, they were able to withstand its effects and maintain good nutrition that enabled them maintain their normal weight. However, a few were noted to have body mass index that was below the normal range while others were above the normal range.

A higher BMI that was noted from our study participants had a lower likelihood of having LVH. This dis-agreed with (Heiskanen et al., 2021) who had stated that a higher BMI increased the likelihood of LVH occurring. The findings could also be supported by (Cescau et al., 2017) that though obesity is said to cause cardiovascular complications it also does provide a protective effect to the heart by enabling the body by acting as an energy reservoir. Despite a few of our study participants being noted to have a lower BMI, the study findings did not establish any likelihood of the lower BMI with the occurrence of LVH. This could not therefore concur with (Yuenyongchaiwat et al., 2020) that a lowered BMI would result in fluid overload due to protein energy wasting that would eventually result to development of LVH.

5.2.4 The association between duration of hemodialysis and left ventricular hypertrophy

The findings of our study showed that an extended duration of hemodialysis created a lower likelihood of participants having left ventricular hypertrophy. Left ventricular hypertrophy was noted to be present in some of the participants who had the lowest duration of dialysis and the prevalence was seen to increase with the longer the duration in which one had been on hemodialysis. This echoed (Cozzolino et al., 2018a) that LVH could be in every stage of CKD and its prevalence increases as the kidney function worsens. Several mechanisms are said to be responsible for the increased cardiovascular complication with a longer duration of hemodialysis (Canaud et al., 2019) among them is rapid ultrafiltration during intermittent dialysis which have been associated with stress to the cardiovascular system and causes risk of organ .damage.

5.3 Conclusion

The prevalence of left ventricular hypertrophy among patients who are undergoing hemodialysis is high (70%) and has been greatly associated with the presence of hypertension and hypertensive heart disease. LVH was attributed to the uncontrolled hypertension in the hypertensive patients which was thought to be predisposing them to end organ damage. Despite all of the hypertensive patients being on various antihypertensive regimens, majority still presented with high blood pressure readings. A higher pulse rate was noted to increase the likelihood of the presence of LVH in a patient. Both a higher BMI and an extended duration in which one was on hemodialysis were noted not to have an association with the occurrence of LVH. LVH is an independent risk factor of cardiovascular complications and these patients are at risk of getting cardiovascular complications

5.4 Recommendations

- 1. More follow up of hypertensive patients to ensure that their blood pressures are well controlled.
- 2. Routine screening of patients undergoing hemodialysis for early detection and prevention of cardiovascular diseases such as left ventricular hypertrophy.

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APPENDIX I: BUDGET

	ITEM	QUANTITY	UNIT	TOTAL COST
			COST @ In	In Kshs.
			Kshs.	
1.	Printing and binding of proposals	8	400	3,200
2.	Stationery (pens, counter books)	1	1,000	1,000
3.	Internet bundles per month	4	2,000	8,000
4.	Ethical clearance fee	1	2,000	2,000
5.	Printing of questionnaires	105	30	3,150
6.	Research assistant for 30 days duration	1	30,000	30,000
7.	Echo-cardiograph	40	3,000	120,000
8.	Data analysis	1	30,000	30,000
9.	Printing and binding of thesis	5	600	3,000
10.	Publication to a peer reviewed journal	1	10,000	10,000
	TOTAL			210,350

Year 2021	Janua	Febru	Marc	April	May	June	July	Augus	September-
Activity	ry	ary	h					t	November
Problem									
identification									
Proposal									
writing									
Proposal									
defense and									
consent from									
ERC									
Data									
collection									
Data cleaning									
& entry									
Data analysis									
Report writing									
and									
presentation									
Compilation									
of final report									
&									
dissemination									

APPENDIX II: TIME FRAME

APPENDIX III: PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY; ENGLISH VERSION

Title: Factor associated with left ventricular hypertrophy among patients undergoing hemodialysis at Kenyatta National Hospital.

Investigator: Ruth Ndegwa Role: Principal investigator Contacts: 0713189416

Introduction

My name is Ruth Wanjiku Ndegwa, a student at the University of Nairobi, Nairobi County, Kenya and pursuing a Master's degree in Renal Nursing. As part of my course work, I will be carrying out a study to investigate the prevalence and the risk factors of left ventricular hypertrophy among patients undergoing hemodialysis at the renal unit KNH, Kenya.

Purpose of study

The purpose of this study is to identify the prevalence and risk factors of LVH among patients undergoing hemodialysis, renal unit KNH. The findings of this study will help policy makers and the management identifies strategies to promote routine screening for prevention and early detection of LVH. This will contribute to reduced mortality among patients undergoing hemodialysis that are due to cardiovascular diseases.

Study procedures

The study will use a self-administered questionnaire where the participants will be required to fill the questionnaire. Measurement of Blood pressure height and weight will be done. We shall perform ECG one hour after hemodialysis and participants with abnormal ECG will be done an Echo. Training has been done for the research assistants and adequate information will be provided to you (research participant) to ensure that you understand your role in the study and alleviate any suspicions on the use of data collected.

Role of the participant

If you are willing to participate in the study, you will be required to give a written consent on the form provided. You will then go ahead and fill the given questionnaire, which has instructions on how to do it. We will be taking your measurement for blood pressure, weight, ECG and Echo if you haven't done one in the last 4 months. It will take about 15 minutes for you to complete this questionnaire and a further 30 minutes to take an ECG and Echo for the eligible participants.

Voluntariness of participation and Benefits

Participation is voluntary and there shall be no monetary benefits involved. Study findings will be made available to the management of renal unit KNH and the entire management so as to raise awareness of the prevalence of LVH and also for decision making purposes during policy making. You reserve the right to withdraw from the study at any point without any form of victimization

Potential Risks

There are neither risks nor harm anticipated on the participants when filling this selfadministered questionnaire as the study aims to use honest personal experiences of the participants which will be self-reported in anonymity of the actual information giver to protect their right to anonymity in the study. Study materials inclusive of ECG and Echo papers will be stored safely and will only be accessible to authorized study personnel.

Confidentiality and Anonymity

To maintain confidentiality and anonymity, your name or any other information that may identify you will not be required. However, you shall be assigned a code number which shall be used in the report.

Investigator's statement

This study seeks to find information from individual patients on the prevalence and risk factors of left ventricular hypertrophy among patients undergoing hemodialysis at the renal unit KNH. Thank you so much for your time and devotion in answering this questionnaire and building a strong foundation in studies on the prevalence and risk factors of left ventricular hypertrophy among patients undergoing hemodialysis.

In case of any clarification contact the following;

Principal researcher:

 Ruth Wanjiku Ndegwa
 Email: muthyndegwa@gmail.com Mobile:0713189416

 Supervisors:
 Dr. DorcasMaina,

 Dr. DorcasMaina,
 Senior Lecturer, School of Nursing Sciences, University of Nairobi, Kenya

 University of Nairobi
 Dr. Omuga

 Senior Lecturer, School of Nursing Sciences, University of Nairobi, Kenya
 University of Nairobi

 Dr. Omuga
 Senior Lecturer, School of Nursing Sciences, University of Nairobi, Kenya

 University of Nairobi
 The secretariat:
 Kenyatta National Hospital /University of Nairobi Ethics and research

 Committee (254-020)2726300-9 extension no. 44102/44355.Email: uonknh erc@uonbi.ac.ke
 Senior Lecture (254-020)2726300-9

APPENDIX IV: CONSENT FORM

I understand that my participation is voluntary without an	y monetary compensation, and I may
withdraw my consent and stop participating at any point w	ithout any penalty. The purpose of the
study and method to be applied has been explained to me.	
I hereby freely consent to take part in the study.	
	Date:
Participant's signature	
	Date:
Researcher's signature	

APPENDIX V: PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY; SWAHILI VERSION

Kichwa: Sababu inayohusishwa na hypertrophy ya ventrikali ya kushoto kati ya wagonjwa wanaofanyiwa uchunguzi wa hemodialysis katika Hospitali ya Kitaifa ya Kenyatta.

Mpelelezi: Ruth NdegwaWajibuwa: MchunguziMkuuMawasiliano: 0713189416

Utangulizi

Jina langu ni Ruth Wanjiku Ndegwa, mwanafunzi katika Chuo Kikuu cha Nairobi, Kaunti ya Nairobi, Kenya na anafanya digrii ya Uzamili katika Uuguzi wa Uharia. Kama sehemu ya kozi yangu ya kazi, nitakuwa nikifanya utafiti kuchunguza kuenea na sababu za hatari ya hypertrophy ya kushoto ya ventrikali kati ya wagonjwa wanaofanyiwa uchunguzi wa hemodialysis katika kitengo cha figo KNH, Kenya.

Kusudi la kusoma

Madhumuni ya utafiti huu ni kutambua kuenea na sababu za hatari za LVH kati ya wagonjwa wanaofanyiwa uchunguzi wa hemodialysis, kitengo cha figo KNH. Matokeo ya utafiti huu yatasaidia watunga sera na usimamizi kutambua mikakati ya kukuza uchunguzi wa kawaida wa kuzuia na kugundua mapema ya LVH. Hii itachangia kupunguza vifo kati ya wagonjwa wanaofanyiwa uchunguzi wa hemodialysis ambao ni kwa sababu ya magonjwa ya moyo na mishipa.

Taratibu za kusoma

Utafiti utatumia dodoso linalosimamiwa kibinafsi ambapo washiriki watahitajika kujaza dodoso. Upimaji wa urefu wa shinikizo la damu na uzito utafanyika. Tutafanya ECG saa moja baada ya hemodialysis na washiriki walio na ECG isiyo ya kawaida watafanywa Echo.

Mafunzo yamefanywa kwa wasaidizi wa utafiti na habari za kutosha zitapewa wewe (mshiriki wa utafiti) kuhakikisha kuwa unaelewa jukumu lako katika utafiti na kupunguza tuhuma zozote juu ya utumiaji wa data iliyokusanywa.

Wajibu wa mshiriki

Ikiwa uko tayari kushiriki katika utafiti, utahitajika kutoa idhini ya maandishi kwenye fomu iliyotolewa. Kisha utaendelea kujaza dodoso lililopewa, ambalo lina maagizo ya jinsi ya kuifanya. Tutachukua kipimo chako kwa shinikizo la damu, uzito, ECG na Echo ikiwa haujafanya moja katika miezi 4 iliyopita. Itachukua kama dakika 15 kukamilisha dodoso hili na dakika 30 zaidi kuchukua ECG na Echo kwa washiriki wanaostahiki.

Kujitolea kushiriki na Faida

Kushiriki ni kwa hiari na hakutakuwa na faida yoyote ya kifedha inayohusika. Matokeo ya utafiti yatapatikana kwa usimamizi wa kitengo cha figo KNH na menejimenti nzima ili kuongeza uelewa wa kuenea kwa LVH na pia kwa malengo ya kufanya uamuzi wakati wa utengenezaji wa sera. Una haki ya kujiondoa kwenye utafiti wakati wowote bila aina yoyote ya unyanyasaji

Hatari zinazowezekana

Hakuna hatari wala madhara yanayotarajiwa kwa washiriki wakati wa kujaza dodoso hili linalojisimamia kwani utafiti unakusudia kutumia uzoefu wa kibinafsi wa washiriki ambao utaripotiwa kibinafsi bila kujulikana kwa mtoaji wa habari halisi kulinda haki yao ya kutokujulikana katika kusoma. Vifaa vya kujifunzia pamoja na karatasi za ECG na Echo zitahifadhiwa salama na zitaweza kupatikana tu kwa wafanyikazi walioidhinishwa wa utafiti.

Usiri na Kutokujulikana

Kudumisha usiri na kutokujulikana, jina lako au habari nyingine yoyote inayoweza kukutambulisha haitahitajika. Walakini, utapewa nambari ya nambari ambayo itatumika katika ripoti hiyo.

Kauli ya mchunguzi

Utafiti huu unatafuta kupata habari kutoka kwa wagonjwa binafsi juu ya kuenea na sababu za hatari ya hypertrophy ya ventrikali ya kushoto kati ya wagonjwa wanaofanyiwa uchunguzi wa hemodialysis kwenye kitengo cha figo KNH.

Asante sana kwa muda wako na kujitolea kwako kujibu dodoso hili na kujenga msingi thabiti katika masomo juu ya kuenea na sababu za hatari ya hypertrophy ya ventrikali ya kushoto kati ya wagonjwa wanaofanyiwa hemodialysis.

Ikiwa kuna ufafanuzi wowote wasiliana na yafuatayo;

Mtafiti mkuu:

Ruth Wanjiku Ndegwa Barua pepe: ruthyndegwa@gmail.com Simu: 0713189416

Wasimamizi:

Dk. DorcasMaina,

Mhadhiri Mwandamizi, Shule ya Sayansi ya Uuguzi, Chuo Kikuu cha Nairobi, Kenya

Chuo Kikuu cha Nairobi

Dk Omuga

Mhadhiri Mwandamizi, Shule ya Sayansi ya Uuguzi, Chuo Kikuu cha Nairobi, Kenya

Chuo Kikuu cha Nairobi

Sekretarieti: Hospitali ya Kitaifa ya Kenyatta / Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi (254-020) 2726300-9 ugani Na. 44102/44355.**Barua pepe:** uonknh_erc@uonbi.ac.ke

APPENDIX VI: CONSENT FORM; KISWAHILI VERSION

Fomuyaidhini

Ninaelewa kuwa ushiriki wangu ni wa hiari bila fidia yoyote ya pesa, na ninaweza kuondoa
idhini yangu na kuacha kushiriki wakati wowote bila adhabu yoyote. Madhumuni ya utafiti na
njia ya kutumiwa nimeelezewa.

Ninakubali kwa hiari kushiriki katika utafiti.	
	Tarehe:
Saini ya mshiriki	
	Tarehe:
Saini ya mtafiti	

APPENDIX VII: QUESTIONNAIRE

Introduction

1. Information obtained with this questionnaire is for study purposes only. It will be used to better understand the prevalence of LVH among patients undergoing dialysis and the risk factors for the same. This will help policy makers and dialysis units to help prevent the occurrence of LVH and improve outcomes for patients undergoing dialysis. Your response will be held in total confidence and information gathered will only be used for research purposes.

2. Do not write your name on the questionnaire.

3. The questionnaire has ... questions. Please complete all questions.

4. *Tick* (✓) *as applicable*

Study Code Date

Demographic Data

1.	Age	
2.	Gender: a).Male b). Female	
3.	Occupation	
4.	Do you take alcohol? a). Yes	b). No
5.	Do you smoke? a). Yes	b). No
6.	Vital Signs	
	Pre-dialysis Blood pressure:	
	Pulse rate:	
	Respiration rate:	
	Temperature:	
	SPO2%:	

	DIVIT
--	-------

- 8. How long in months have you been on dialysis?
- 9. How many sessions of dialysis do you receive per week?

a). Once..... b). Twice..... c). Thrice..... d). Daily.....

Co-morbidities

10. Are you a known hypertensive? a). Yes..... b). No.....

If yes, are you on any anti-hypertensive? a). Yes..... b). No.....

Tick whichever applies to you

- i. Diuretics
- ii. Beta blocker
- iii. ACE I
- iv. Other (Specify).....

11. Are you a known diabetic? a). Yes.....b). No.....

If yes, are you on any anti-diabetic? a). Yes.....b). No.....

Tick whichever applies to you

- i. Orals
- ii. Insulin

12. Are you on any other medications? a). Yes..... b). No.....

If yes, which ones.....

.....

- 13. ECG findings in the last three months
- 14. Echo findings in the last three months

APPENDIX VIII: KNH-UoN ERC GUIDELINES ON COVID- 19

KENYATTA

Tel: 726300-9

Fax: 725272

Telegrams:

Nairobi

HOSPITAL (KNH)

P O BOX 20723 Code 00202

NATIONAL

MEDSUP,



UNIVERSITY OF NAIROBI (U0N) COLLEGE OF HEALTH

SCIENCES

P O BOX 19676 Code 00202 Telegrams: varsity (254-020) 2726300 Ext 44355

Ext Facebook:

KNH-UoN ERC

ttps://www.facebook.com/uonknh.erc

Website: http://www.erc.uonbi.ac.ke

Email: uonknh erc@uonbi.ac.ke

Twitter: @UONKNH_ERC

KNH-UON ERC- GUIDELINES ON CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC

Introduction Given the highly infectious nature of SARS-Cov-2 and the rapidly changing circumstances around COVID-19 containment, mitigation and management strategies in Kenya, the priority for all study activities should be to uphold public health obligations, and continue care of the research participants while guaranteeing the safety for the participants, the research team, and the general public. This is the obligation of the Principal Investigator (PI) working together with the other members of the research team. The scenario calls for a need to revise

standards related to research interactions with human research participants with a strong push towards interacting **remotely**.

General considerations

1. Adherence to COVID-19 related public health directives: Researchers should remain aware of, and abide by all applicable COVID-19 related public health directives, policies and recommendations as issued by the World Health Organization, Ministry of Health or other Kenyan government agencies on what to do in case they encounter participants reporting possible COVID-19 exposure or symptoms during a study visit or those particularly vulnerable to COVID-19 disease.

2. Public Health and Clinical Activities: Actions taken for public health or clinical purposes as part of the COVID-19 prevention, control or management are not considered research procedures and therefore do not require KNH-UoN ERC approval before being implemented. For example, mandatory clinical screening procedures in health facilities as directed by Ministry of Health or other designated public health authorities for purposes of identifying, monitoring, assessing/investigating or managing the COVID-19 outbreak, and sharing of such screening results with the participants and public health authorities does not require ERC approval.

3. Research changes made to mitigate risk of COVID 19 disease transmission: - Researchers will need to implement changes to previously approved research to mitigate risk of COVID-19 disease pandemic.

4. Essential research visits or procedures: -

i. A study procedure or visit is deemed essential if it is required to ensure participants' health, safety, or wellbeing. Such procedures include administration of certain types of study

interventions, safety evaluations and management of serious adverse events or laboratory tests to monitor possible adverse effects of drugs.

ii. The determination of what constitutes essential study visit or procedure shall be made in line with the current public health guidance regarding the COVID-19 pandemic in Kenya.

iii. Research visits should continue remotely as much as possible. In the absence of feasible remote options for essential visits or procedures, face-to-face interactions may continue **but investigators must** adhere to current public health guidelines to reduce COVID-19 exposure to research participants and staff.

iv. The PI shall be responsible for providing this service in the safest way possible, based on good clinical practice and optimal social distancing. The following guidance should be considered:

a) Immediately before the face-to-face visit, the participants should be remotely screened for symptoms of respiratory illness and other key defining symptoms of COVID-19 disease such as fever, cough, and shortness of breath or difficulty in breathing as well as possible recent exposure to individuals with COVID-19 disease. Participants with possible exposure or symptoms suggestive of a respiratory disease should not be invited for face-to-face visits/procedures until COVID-19 has been ruled out. Such participants should be immediately referred to the Ministry of Health for further diagnostic procedures and possible isolation, as necessary.

b) All research staff who conduct face-to-face visits or procedures with participants should, on a daily basis, be screened for COVID-19 exposure and symptoms including daily temperature checks. Only staffs who are symptom-free with no history of exposure to COVID-19 should take part in face-to-face interactions.

c) At the site of the face-to-face visits/procedures, appropriate infection prevention control measures should be ensured as follows:

i. Temperature checks for all participants and other individuals arriving at the research site using a non-contact thermometer should be taken.

ii. Hand-washing station and hand sanitizers for all to use should be availed.

iii. Avail 3-ply face masks for participants and research staff to use during the face-to-face interactions

iv. Physical distancing of minimum 1.5 metres in the waiting room and procedure rooms should be maintained. v. Staff should use appropriate personal protective equipment as recommended in the MOH infection prevention and control (IPC) guidelines when conducting close-contact or invasive procedures and handling bio-specimens.

vi. Staff should be trained on appropriate cleaning and infection control procedures necessary to mitigate COVID-19 spread at study site.

5. Contingency Planning:

a. Each research study team should have a contingency plan in place to continually assess the effect of any disruptions arising from the research protocol changes which might impact on the safety of their research participants.

b. All approved studies that require face-to-face interactions must submit an amendment to the KNH-UoN ERC indicating measures taken to minimize COVID-19 exposure to research participants, staff and the community.

c. Study visits and procedures should be conducted remotely through phone-based or internetbased methods using KNH-UoN ERC approved tools that define when, how, where, why and by whom each online process will be carried out.

Responsibilities of Principal Investigator

1. KNH-UoN ERC -approved studies where study procedures such as consenting and data collection are to be conducted remotely can continue and submit a notification in case of changes with regards to adherence to MOH COVID- 19 guidelines.

2. KNH-UoN ERC approved studies that had indicated in their protocols that they would conduct in-person study visits or procedures should submit an amendment to request the change from in-person to remote visits/procedures as necessary.

3. Research requiring on going in-person visits/procedures /interactions with participants should submit an amendment / modification to KNH-UoN ERC indicating the measures that shall be taken to minimize risk of COVID-19 exposure to participants and staff. KNH-UoN ERC approval is required before effecting the changes.

4. If there is need to modify the schedule of study procedures to accommodate COVID-19 related measures, this should be done through an amendment application to KNH-UoN ERC.

5. Participants should promptly be informed of cancellations of study visits and reasons why, and assured that they would be contacted if the visits are rescheduled. The cancellations and rescheduling of visits should be submitted to ERC as notifications.

6. If a study has been or needs to be temporarily paused to fulfil COVID-19 related containment measures, the following should be considered:

a. If temporarily halting research activities has or will have no effect on the safety or welfare of participants, this should be reported as a notification to ERC.

b. If temporarily halting research activities could result in increased risk of harm or affect the welfare of participants, the researcher must submit a protocol amendment for ERC review and approval.

c. For a study that had temporarily halted research activities and noted increased risk of harm / negative effect on the welfare of participants, the researcher must complete a protocol violation report and submit a detailed declaration of the risk /harm suffered including any mitigation on the same

d. The researcher should clearly indicate the short- and long-term effect(s) that the pausing of research activities could have on research participants

The EKG procedure

1. The subject will be asked to remove any jewelry or other objects that may interfere with the procedure.

2. She/he will be asked to remove clothing from the waist up. The technician will ensure the subjects privacy by covering you with a sheet or gown and exposing only the necessary skin.

3. He/she will lie flat on a table or bed for the procedure. It will be important for the subject to lie still and not talk during the procedure, so as not to interfere with the tracing.

4. If the subject's chest, arms, or legs are very hairy, the technician may shave or clip small patches of hair, as needed, so that the electrodes will stick closely to the skin.

5. Electrodes will be attached to the subject's chest, arms, and legs.

6. The lead wires will be attached to the skin electrodes.

7. Once the leads are attached, the PI will type in the identification information about the subject into the machine's computer.

8. The ECG will then be started. It will take only a short time for the tracing to be completed.

9. Once the tracing is completed, the technician will disconnect the leads and remove the skin electrodes.

10. The EKG findings will be interpreted by the PI and confirmed by a study dedicated cardiologist.

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Doppler Echocardiography technique

- 1. Doppler Echocardiography
- \Box Machine –
- Probe-
- □ Approach
- Triage
- -Explain the procedure
- -Exposure of the upper body and cover with gown
- Position the patient in Left lateral position
- Apply gel on the probe
- Positioning of the probe in appropriate windows:
- I. PLAX (Long parasternal axis of the RV Inflow)
- II. Apical 4 window
- III. SAX (Short Axis LV/AOV- RV Outflow tract)
- IV. Subcostal- IVC

Echocardiography Findings:

Part A.

ECHO Number:	
Previous ECHO Report:	
. Brief clinical history	
	••••

PART B

M-Mode Measurements:

RV:	LVIDD:	LVIDS:	LA:	IVS:
LVPW:	AO:	FS:	HR:	SV:
ESV:	EDV:			
Conclusion:				
Additional Commer	nts:			

ECHO Reported by:.....Date:....

APPENDIX IX: KNH/U0N ETHICS AND RESEARCH COMMITTEE APPROVAL



UNIVERSITY OF NAIROBI FACULTY OF HEALTH SCIENCES P 0 B0X 19676 Code 00202 Telegrams: varsity Tel:(254-020) 2726300 Ext 44355

Ref: KNH-ERC/A/375

Ruth Wanjiku Ndegwa Reg. No.H56/34853/2019 Dept. of Nursing Sciences Faculty of Health Sciences University of Nairobi

Dear Ruth



Facebook: https://www.facebook.com/uonknh.erc Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC



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

18th October, 2021

RESEARCH PROPOSAL: FACTORS ASSOCIATED WITH LEFT VENTRICULAR HYPERTROPHY AMONG PATIENTS UNDERGOING HEMODIALYSIS AT KENYATTA NATIONAL HOSPITAL (P374/05/2021)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above research proposal. The approval period is 18th October 2021 – 17th October 2022.

This approval is subject to compliance with the following requirements:

- i. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- ii. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- iii. 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.
- iv. 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.
- v. Clearance for export of biological specimens must be obtained from KNH- UoNERC for each batch of shipment.
- vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (<u>Attach</u> a comprehensive progress report to support the renewal).
- vii. 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.

Protect to discover

APPENDIX X: KNH STUDY REGISTRATION CERTIFICATE

	101 CONTRACTOR (01
	KNH/R&P/FORM/01
KENYATTA NATIONAL HOSPITAL P.O. Box 20723-00202 Nairobi	Tel.: 2726300/2726450/2726565 Research & Programs: Ext. 44705 Fax: 2725272 Email: <u>knhresearch@gmail.com</u>
Study Registrati	ion, Certificate
1. Name of the Principal Investigator/Researcher RUTH WANTIKU NDEGWA	
2. Email address: Ruthyndegwall gmit	
3. Contact person (if different from PI)	
4. Email address:	
***************************************	Renal Unit
7. Endorsed by KNH Head of Department where stud	y will be conducted.
	ire 07694 Date 19/18/21
(Please attach copy of ERC approval) 9. I <u>Roth Nodequica</u> findings to the Department where the study will Research. Signature	commit to submit a report of my study be conducted and to the Department of Medical
10. Study Registration number (Dept/Number/Year)	1202 1 181 / 1807
(To be completed by Medical Research Department	1 4 00 00 P
11. Research and Program Stamp All studies conducted at Kenyatta National Hospital m Research and investigators <u>must commit</u> to share resu	I 9 OCT 2021 ≥ ust be registered with the Department of Medical (Swith the hospital Con 20723 - 00 ²⁰ Control Con

APPENDIX XI: PLAGIARISM CHECK

