PREVALENCE OF LEFT VENTRICULAR HYPERTROPHY BY ECHOCARDIOGRAPHY AND UTILITY OF ECG VOLTAGE CRITERIA FOR LEFT VENTRICULAR HYPERTROPHY AMONG AMBULATORY HYPERTENSIVE PATIENTS AT MBAGATHI HOSPITAL

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A dissertation submitted in partial fulfillment of the requirement for the award of the degree of Masters of medicine in Internal Medicine, university of Nairobi

DECLARATION

This dissertation is my original work and has not been published or submitted to any institution or university for award of any degree, diploma or fellowship.

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LIST OF ABBREVIATIONS

ACEs-Angiotensin converting enzyme inhibitors

ARBs-Angiotensin receptor blockers

AHA-American heart association

ACCF-American College of Cardiology Foundation

BSA-Body surface area

BMI-Body mass index

COPD-Chronic obstructive air-way disease

ECG-Electrocardiograph

ECHO-Echocardiography

HRS-Heart rhythmic society

HIV-Human immunodeficiency virus

IVS-Intraventricular septum

LVH-Left ventricular hypertrophy

LVID- Left ventricular internal diameter

LVM-Left ventricular mass

LV-Left ventricle

KNH-Kenyatta National Hospital

MOPC-Medical outpatient clinic

SPSS- Statistical Package for the Social Science

PWT- Posterior wall thickness

PI – Principal investigator

ABSTRACT

Left ventricular hypertrophy (LVH) is structural change and a physiological adaptation due to increased workload on the left ventricular myocardium. It is often a complication of hypertension and an independent risk factor for cardiovascular events. Echocardiography is the gold standard for assessment of LVH, however, in low resource setting it is not readily available and ECG can supplement the echocardiography in such setting. AHA/ACCF/HRS Recommendations for the standardization and interpretation of the electrocardiogram recommends testing of the available ECG criteria to identify criteria with high diagnostic yield.

Objective: To determine the prevalence of LVH by echocardiography and utility of the commonly used ECG criteria for LVH using echocardiography as the gold standard among ambulatory hypertensive participants at the medical outpatient clinic Mbagathi hospital

Methods: It was a cross sectional hospital outpatient based study done at Mbagathi hospital year 2016/2017. Participants with file diagnosis of hypertension were subjected to echocardiography and electrocardiography to asses left ventricular hypertrophy.

Results: A hundred and four (104) hypertensive patients with a mean age of 54.7 years were studied. Majority (72.1%) were females. The prevalence of echocardiography determined LVH was 61.5%. Majority of the patients had severe LVH at 48.4%. Cornell's voltage criterion had the highest sensitivity at 46.9% and specificity of 72.5% followed by Sokow-Lyon criterion with a sensitivity of 18.8% and specificity of 87.5%. Gubner-Ungerleider voltage criterion had the lowest sensitivity of 9.4% and specificity of 100%. R wave in AVL criterion had sensitivity of 12.5% and specificity of100%. Combination of ECG criteria improved sensitivity. A combination of all the four ECG criteria or Combination of the two most sensitive criteria demonstrated similar sensitivity and specificity at 53.1% and 67.5% respectively. Low specificity of 40% in male was observed with the Cornell's voltage criterion and a very low specificity in males at 30% was observed with combination of ECG criteria. Receiver operator curve demonstrated largest area under the curve for combination of ECG criteria at 0.603.

Conclusion – The prevalence of echocardiography determined LVH in hypertensive patients was high in this population. ECG criteria for LVH had generally low sensitivity and high specificity but combination of ECG criteria improved the sensitivity for ECG determined LVH.

1.0 BACKGROUND

Hypertension is the most common risk factor for cardiovascular diseases(1). In the year 2000, there were 80 million adults living with hypertension in Sub-Saharan Africa and projections based on current epidemiological data suggest that this figure will rise to 150 million by 2025(2).According to WHO 2013 cardiovascular morbidity accounts for 17 million deaths per year, approximately 1/3 of the total and hypertension is responsible for 45% death due to heart diseases and 51% of death due to stroke(3). In one study done in Kenya, Prevalence of hypertension in Nairobi at Kibera was found to be significantly high at 22.8(4).

Left ventricular hypertrophy is an anatomic enlargement and thickening of the left. LVH in hypertension is a structural change and a physiological adaptation of the left ventricular myocardium as a result of increased workload on the left ventricular chamber(5). Left ventricular hypertrophy is classified as eccentric or concentric hypertrophy. Concentric hypertrophy result from steady state of Pressure overload as occurs in a state of longstanding hypertension or aortic stenosis. It is characterized by increased ratio of wall thickness to chamber dimension. Eccentric hypertrophy result from longstanding state of volume overload as occurs aortic or mitral regurgitation. It is characterized by increased ratio of chamber dimension to wall thickness(6).

Left ventricular hypertrophy is of clinical importance because LVH is an evidence of target organ damage, an independent risk factor of cardiovascular and cerebrovascular events and very important factor in risk stratification of hypertensive patients(7). Accurate and prompt detection of LVH is therefore important in order to apply preventive as well as reversal measures because recent studies have demonstrated reversal of left hypertrophy with various intervention(8).

There are various diagnostic modalities for detection of LVH. These include ECG, 2/3-D ECHO and MRI. Echocardiography has been the gold standard for the assessment of left ventricular hypertrophy in our setting however it cannot obviate the ECG because of feasibility factors. 2-D ECHO has recently been challenged by MRI and 3-D echocardiography(9,10). ECG can substitute ECHO in LVH assessment in setting where echocardiography is inaccessible. There are multiple ECG criteria for LVH with varying diagnostic yield. AHA/ACC/HRS recommends testing the available ECG criteria in different population of patients in order to identify ECG criteria with higher diagnostic yield(11).

2.0 LITERATURE REVIEW

Left ventricular mass is best measured at autopsy(12–14). It can also be measured through imaging i.e. echocardiography or MRI. Before imaging was available, ECG provided acceptable indirect methods of assessment. Originally ventricular mass at autopsy and the clinical features were the standard measures used to establish criteria for the ECG(11). Later chest radiograph was used as the standard. Currently 2-dimension echocardiography is used as the gold standard though it is being challenged by MRI and 3-dimension electrocardiography(11). The evolution of these new techniques compels the current cardiologist to evaluate the role of ECG in the diagnosis of LVH.

2.1 Left ventricular hypertrophy in hypertension

Left ventricular hypertrophy in hypertensive patients may be the earliest evidence of end organ damage and a signal to the clinicians to reevaluate treatment strategies in order to lower the risk of cardiovascular events(15,16). Patients with either eccentric or concentric hypertrophy may remain in compensatory phase for many years and others readily develop systolic or diastolic heart failure or both systolic and diastolic heart failure(7). Left ventricular hypertrophy is associated with increased risk of cardiovascular morbidity and mortality even after adjusting for factors know to increase cardiovascular events i.e. smoking and diabetes, obesity, hypertension and cigarette smoking(17,18). LVH is an important factor in the pathogenesis of ischemic heart disease, cardiac arrhythmias, congestive cardiac failure and sudden cardiac death(6,19).

Various studies have demonstrated regression of left ventricular hypertrophy with different interventions i.e. antihypertensive therapy and use of ACEI containing regimen(8,20). Optimal management of hypertensive patients according to most guidelines i.e. European society of hypertension & European society of cardiology are based on individual risk category. LVH is very important factor in risk stratification (15,16). Left ventricular hypertrophy in hypertensive patients, need to be detected and assessed promptly in order to prognosticate these patients, address modifiable risk factors like obesity, blood pressure and initiation of therapy that have been shown to reverse LVH like ACE inhibitors(8).Meta-analysis of clinical trials have shown that regression of LVH results in decreased risk of cardiovascular events(21).

2.2 Echocardiography

It is non-invasive diagnostic modality which provides information on morphology of the heart, function and hemodynamics. Discovery of piezoelectricity in 1880 was important in evolution of echocardiography (22). All echocardiographic measurements of left ventricular mass irrespective of the mode applied i.e. M mode, 2D or 3D, involves subtraction of LV-cavity volume from LV-epicardium volume to get the LV muscle volume (shell). This is then multiplied by myocardial density to get LV mass(23). ASE recommended formulas for LV mass are based on modeling the LV as an ellipse, cylinder, truncated polyhedrons and cone. These formulas assume that LV geometry has not been distorted and may be inaccurate in abnormally shaped ventricles(23). 2D and M mode imaging can be used in calculation of LV mass. When ultrasound beam is properly positioned and ventricle shape is not distorted, M mode has a better endocardial border definition due to its higher resolution attributed to its higher frame. M mode technique is quick, simple for screening large population and subject to less measurement variability. 2-D technique depicts the actual ventricular shape and allows visualization of abnormal wall motion however it has poor images due to lower lateral resolution and frame rate. It is also time consuming with significant inter-observer variation and often not applicable in epidemiological studies.(23,24)

Echocardiographic left ventricular assessment is affected by a number of factors that include; body mass index, gender and height of the individual(25). It is therefore necessary to adjust for these factors. Adjustment of LV mass for body surface area would imply that obese patients will have a higher LV mass estimation. Height based adjustments accurately estimates LV mass(25,26). Different height based adjustments have been used. Height$^{2.7}$ derived from regression In M-mode, Intra observer variability up to 5% has been reported, while inter observer variability may reach model in normal samples from De Simone and coworkers offer an accurate estimation of LV mass(27). Zoccalli and colleagues found LVH indexed to height$^{2.7}$ to be a better predictor of cardiovascular risk than LVH indexed to BSA(26).

Inter observer and intra observer variability may result into varying LV mass measurements. In M-mode, Intra observer variability of up to 5% has been reported, while inter observer variability may reach 15%. Linear measurements of up to 5% may translate into differences in LV mass between 8% and 15%. Some trials retesting patients found differences of up to 30 gm between tests (28–30).

2.3 Electrocardiography

Diagnostic accuracy of electrocardiography for LVH is limited because of multiple ECG criteria with varying specificity and sensitivity as influenced by race, age, gender and body habitus(31,32). These ECG criteria have generally low sensitivity and high specificity as depicted from previous studies(5). In one study done in Nigeria, 3 ECG voltage criteria compared favorably well with echocardiography and were recommended as initial screening for LVH in that population(33). There are insufficient published studies to recommend superiority of either criterion over the other because of varying diagnostic yield in different populations of patients(11). AHA/ACCF/HRS recommended further studies on testing the available ECG criteria. They also recommended further studies on development and testing of ECG criteria for specific indications i.e. screening, prognosis and follow-up as well as adjustment of major ECG criteria for LVH in specific populations(11).

ECG criteria for LVH have continued to evolve over years. Previously ECG criteria were based on standard limbs(I and III) using clinical and autopsy data as the reference standard(34). Several other criteria were introduced after the discovery of the 12 lead ECG. Sokolow and Lyon proposed the first diagnostic criteria for left ventricular hypertrophy in 1949(35). The available ECG criteria are mainly based on;

1. Precordial lead voltage or Limb lead voltage
2. Combination of limb and precordial voltage
3. Combination of voltage & non-voltage measures
4. Combined criteria with left anterior fascicular block and bundle-branch block

The most commonly used ECG criteria are based on QRS voltages. This is because they are easy to employ as opposed to the time dependent criteria. It takes long for an electrical impulse to traverse a hypertrophied muscle and the amplitude of the electrical impulse is often increased due to increased muscle mass. This is evidenced by a widened QRS that is of greater amplitude. Widening is usually observed as initial delay in inscription of the QRS. Time to reach peak R wave is delayed, this is referred to as intrisicoid deflection(36). LVH changes are often associated with other ECG abnormalities which include; Left arterial abnormality, left axis deviation and T wave/ST segment abnormalities(36)

ECG criteria for LVH have mostly been elaborated and calibrated in the white population. Their applicability to African individuals is yet to be demonstrated fully(37). The existence of several criteria for the diagnosis of LVH makes clinical application difficult. Sensitivity of some of these criteria are quite low, sometimes up to below 50%, however, specificity is higher in the range of 85%-90%. Sensitivity and specificity of each criterion varies significantly. Diagnostic accuracy will depend on the criteria applied. Published studies are insufficient to recommend superiority of either criterion over the other because of varying specificity and sensitivity with different population of patients. AHA/ACCF/HRS recommends further studies in different populations to test available ECG criteria(11).

2.3.1 Examples of Commonly Used ECG Criteria

1. Sokolow-Lyon criteria: S wave in V1 added to R wave in V5 or V6. If the sum is greater than 35 mm
2. Cornell criteria: R wave in aVL added to S wave in V3. If the sum is greater than 28 millimeters in males or greater than 20 mm in females
3. Gubner-Ungerleider voltage: R wave in lead I added to S wave in lead III greater than 25mm
4. R in aVL: R wave in lead aVL greater than 11mm
5. Minnesota RV5 or RV6 >26mm
6. Araoye code system SV2 + RV6 > 40mm in male >35mm in female translates to LVH
7. Framingham criteria;

    I. R aVL > 11mm
    II. R V4-6 > 25mm
    III. S V1-3 > 25 mm
    IV. S V1 or V2 + R V5 or V6 > 35mm
    V. R V5 or V6 > 35 mm
    VI. R I + S III > 25 mm

2.3.2 Voltage Criteria employed in The Study

The study focused on 4 ECG criteria. They included; Sokolow-Lyon, Cornell's sex specific, Gubner-Ungerleider and R wave in aVL criteria. They were all voltage criteria and hence easy to apply. They were arrived at after literature search from the previous studies, one being a meta-analysis of the commonly used voltage criteria in assessment of LVH(5,10,33,37–40). These ECG criteria were not adjusted for race, age and body habitus. The ECGs were conducted routinely to reflect the actual clinical practice.

2.3.3 Previous Studies on ECG Sensitivity and Specificity

In a study done from Seychelles, 334 African individuals were selected from the general population(37). Participants were subjected to 9 ECG criteria for LVH. Left ventricular hypertrophy was assessed with M-mode echocardiography.

The prevalence of LVH was 9.3%. 31 participants had LVH, 16 Men and 15 women. Sokolow-Lyon criterion had the highest sensitivity 61%. R_{AVL} voltage criterion had the highest specificity of 97%. At fixed specificity of 95% the sensitivity of these criteria ranged from 16% to 32%.

The conclusion was that diagnostic accuracy of classic ECG criteria in that given population from East Africa was poor(15).

A similar study was done on African American hypertensive patients visiting emergency department in a single tertiary care facility(38). Patients above 35 years of age with a systolic blood pressure of ≥140mmHg or diastolic blood pressure of ≥90mmHg (two readings taken on different occasion at least 1hour a part) were recruited. A total of 161 patients were enrolled. Interpretation of LVH on ECG was based on Cornell product, Minnesota Code 3.1/3.2 and Cornell voltage criteria for LVH. All the participants had an echocardiography.

- Of the 161 patients, 89(55.2%) had LVH by echocardiography
- The sensitivity of all the ECG voltage criteria fell below 29%.
- The specificity for Cornell voltage was 50%
- Both Cornell product and Minnesota code had specificity of 87.5%
- ECG voltage criteria for LVH were not recommended for routine screening of LVH(38).

A study done in west Nigeria looked at 4 commonly used ECG criteria among hypertensive patients using echocardiography as the gold standard(33). Ninety participants were recruited.

- The prevalence of LVH by echocardiography was 32.2%. The sensitivities and specificities of the ECG criteria were 58.62% and 60.66% for Sokolow-Lyon, 48.28% and 60.65% for Araoye code system, 51.72% and 73.77% for Cornell's, and 13.79% and 86.89% for Gubner-Ungerleider criteria respectively.
- In this study ECG criteria compared favorably with echocardiography and were recommended as the initial screening tool for LVH in this population of patients(33).

2.4 Studies on Prevalence of LVH

There are very few published studies on prevalence of LVH in hypertensive patients in our setting. In a systematic review of 21 studies involving 5,608 patients with hypertension, prevalence of LVH by echocardiography was 65% at secondary care setting(41). A study done in south west Ethiopia found a prevalence of LVH by echocardiography in 200 hypertensive on treatment to be 52% (42). A different study in south western Nigeria found prevalence LVH by ECHO at 32.2% in 90 hypertensive participants(33). A study on prevalence of cardiovascular risk factors and target organ damage among 93 hypertensive participants at KNH found prevalence of ECG LVH at 32.3%(43). A Study done at Kenyatta National Hospital on patients with chronic kidney disease not on dialysis found an ECG prevalence of LVH at 29.7%(44). Yonga GO et al found prevalence of ECG derived LVH at 31.7% among hypertensive patients at KNH(45). A different study at KNH found a prevalence of ECG LVH among hypertensive at 27.5%(46). Bukachi Fo determined the sensitivity of ECG in detecting LVH among hypertensive patients attending KNH using Romhilt and Estes point score criteria and echocardiography as the gold standard and found an increasing sensitivity with increasing severity of LVH(47).

Table 1.0: Romhilt and Estes point score criteria for LVH vs. Echocardiography

LVH	NORMAL	GROUP 1 HTN	GROUP HTN	GROUP 3 HTN
ECG prevalence	4(7.2%)	3(16.7%)	8(44.4%)	12(67.7%)
Echocardiography prevalence	12(22.2%)	7(38.9%)	16(88.9%)	14(77.8%)

3.0 STUDY JUSTIFICATION

LVH is an evidence of target organ damage and an independent risk factor for cardiovascular events. LVH in hypertensive patients is important in risk stratification. Treatment of hypertension is based on individual risk category in most guidelines. ESH/ESC 2013 guidelines (European society of hypertension & European society of cardiology) risk stratifies hypertensive patients with LVH as "high-risk". There is need to determine echocardiography determined prevalence of LVH in order to estimate the disease burden in our population, risk stratify, prognosticate, reevaluate our treatment strategies, plan and allocate resources appropriately.

Echocardiography is the gold standard for assessment of LVH. However, in low resource setting it is not readily available and affordable. ECG can supplement echocardiography in such set-up. ECG exhibits varying diagnostic yield for LVH because of existence of multiple ECG criteria with varying sensitivities and specificities. AHA/ACC/HRS 2009 recommends further studies on testing the available ECG criteria in different populations (sensitivities and specificities) in order to identify ECG criteria with higher diagnostic yield and optimize on them. We therefore needed to assess the utility of the commonly used ECG criteria using echocardiograpy as the gold standard in our population and recommend criteria with higher diagnostic yield.

3.1 Research questions

What is the prevalence of echocardiography determined LVH among hypertensive patients and what is the utility of ECG criteria in diagnosis of LVH among similar patients at the medical outpatient, clinic Mbagathi Hospital?

4.0 OBJECTIVES

4.1 Broad objective

To determine the prevalence of echocardiography determined LVH and utility of the commonly used ECG voltage criteria for LVH among hypertensive participants at the medical outpatient clinic, Mbagathi hospital

4.2 Specific objective

1. To determine the prevalence of echocardiography determined LVH in hypertensive patients attending MOPC Mbagathi hospital
2. To determine the sensitivity and specificity of the four ECG voltage criteria for LVH using echocardiography as the gold standard
    I. Sokolow Lyon: maximum R in V5 or V6 + S in V1 > 35mm
    II. Cornell's sex specific voltage: R in AVL + S in V3 >28mm in men />20mm in women
    III. Gubner-Ungerleider voltage: R I + S III > 25 mm
    IV. R in aVL > 11mm

5.0 METHODOLOGY

5.1 Study Design

It was a cross sectional hospital outpatient based study done at Mbagathi hospital year 2016/2017

5.2 Study Site

The study was carried out at Mbagathi hospital, medical outpatient clinic. The hospital is located alongside Mbagathi road, on the edge of Kibera slum in Langata district, Nairobi County. The medical outpatient clinic is a specialized clinic run by consultant physician with the assistance of medical officers. Patients in this clinic are mostly referred by the clinical officer running outpatient clinic. Some patients in this clinic are also referred from the ward or peripheral low level facilities. Majority of the patients have chronic condition predominantly hypertension. The clinic runs two days in a week; Tuesday and Friday.

5.3 Study Population

The study population was ambulatory hypertensive patients attending medical outpatient clinic at Mbagathi hospital

5.4 Case Definition

These were defined as ambulatory patients with file diagnosis of hypertension

5.5 Inclusion Criteria

I. Ambulatory patients above the age of 18 years with hypertension

III. Signed informed consent

5.6 Exclusion criteria

I. Hypertensive participants with file diagnosis of a structural heart disease or coincidental findings of structural heart disease during echocardiography study

III. Participants who declined to consent to participate in the study

5.7 Sample Size estimation

Two different formulas were used to cater for the two different objectives

1) Echocardiography determined prevalence of LVH

2) ECG sensitivity and specificity

Objective 1: Formula for estimating sample size of prevalence in a cross-sectional study design (Fisher et al, 1998): **Echocardiography determined prevalence of LVH**

$$n = \frac{Z^2 \times P\,(1-P)}{d^2}$$

n – Sample size

Z – 1.96 (95% confidence interval)

P – Estimated prevalence of LVH by echocardiography = 32.2% (Ogunlade et al, 2013)

d – Margin of error (precision error) = ±9 %

A minimum of 103 patients will be required to estimate prevalence of LVH within 9% margin of error.

Objective 2: Formula for estimating sample size in diagnostic studies :(Flahault et al, 2005)**:**
ECG sensitivity

$$\boldsymbol{n = \frac{z1-\beta\sqrt{\pi(1-\pi)} + z1-\alpha\sqrt{(\pi-\delta)(1-\pi+\delta)}}{\delta 2}}$$

Where:

- **n -** Required sample size
- $\boldsymbol{\pi}$ - % sensitivity of Gurbner-ungerleider ECG criteria = 13% (lowest sensitivity reported in a previous similar study)

- **δ** - Degree of precision (maximum distance within which the 95% lower confidence limit is required to fall) = 9%. This is estimated from 4%.
- **Z1-β** = normal for 80% power = 0.84
- **Z1-α** = standard normal for 95% confidence interval = 1.96

When substituted, sample size **(n)** required will be 82 patients

The minimum number of participants required for the first objective is 103 participants and the minimum participants required for the second objective is 82 participants

To satisfy the two objectives in this study the minimum sample size must be greater than 103 participants.

5.8 Sampling Method

Consecutive sampling was employed. This was done through perusing files of the patients that turned up for the clinic. All eligible participants were recruited.

5.9 Patients Recruitment

Recruitment was done by the PI at the medical outpatient clinic. Prospective study participants were identified by perusing the files for eligibility. Informed consent was obtained from the corresponding sampled patients and demographic characteristics recorded in the data collection profoma. The patients were then subjected to the procedure outlined below. Recruitment continued in the clinic days (Tuesday and Thursday) until adequate sample was achieved

6.0 Operational Definition

Structural heart disease: Congenital heart defect or acquired abnormalities of valves or heart wall

Left ventricular hypertrophy: left ventricular mass index of >44g/$m^{2.7}$ for female and >48g/$m^{2.7}$ for male a cut off associated with increased cardiovascular morbidity and mortality(48).

6.1 Procedures

6.1.1 Anthropometry

Weight was measured using standardized clinical scale balance machine and height using a stadiometer. Body weight was measured to the nearest 0.1kg and height to the nearest 0.5cm. BMI was calculated (weight (kg)/height (m^2) and categorized according to WHO physical status interpretation(49). This was done by trained research assistant, a registered nurse by profession.

6.1.2 Blood Pressure Measurements

Blood pressure measurements were done by trained research assistant (registered nurse). This was done after the patient had rested for 30 minutes using a mercury sphygmomanometer. Participants had three blood pressure readings with sphygmomanometer while seated. An average of the last two readings was calculated. AHA(American heart association) guidelines for blood pressure measurement were employed(50).

6.1.3 Echocardiography

Echocardiography was performed by one trained cardiac technologist. HP Sonosite (2000 Color Doppler ver. A.) a portable echocardiography with a transducer of operating frequency range of 4–7 Megahertz was used. Left ventricular hypertrophy was assessed using M-mode tracing. A standard echocardiogram was performed with focus on left ventricular measurements in accordance to ASE recommendation(51). The linear internal measurement of the left ventricle was done in the parasternal long axis view. The linear dimensions of the ventricular septum, left ventricular posterior wall and left ventricular internal dimension were measured at the end of diastole. Values were obtained perpendicular to the LV long axis and measured at or immediately below the level of the mitral valve leaflet tips. The electronic calipers were positioned on the interface between the myocardial wall and cavity and the interface between the wall and the pericardium

LV mass was calculated from the three measurements; intraventricular septum wall thickness, left ventricular internal dimension and posterior wall thickness using a calculator installed in the ECHO machine and employing the formula referenced below.

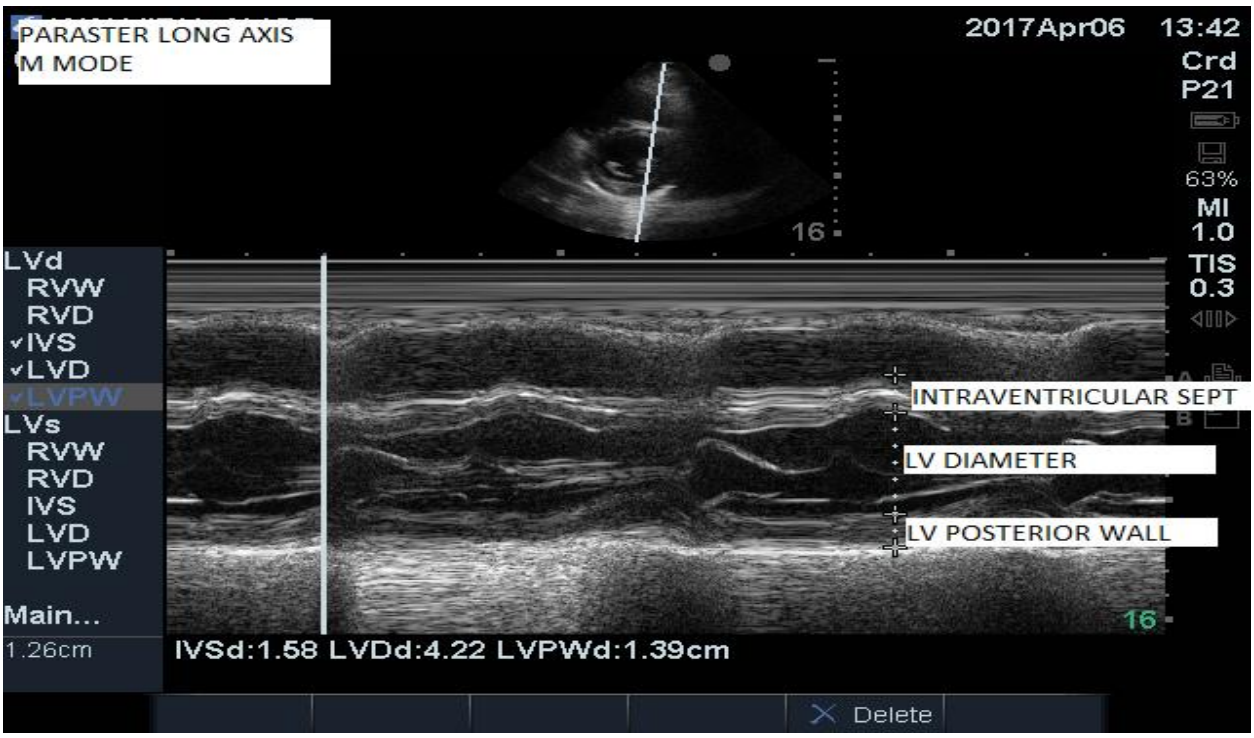
Cube formula employed in calculation of LV mass (in grams). LV mass=0.8*1.04⌈(IVS+LVID+PWT)^3-LVID^3⌋+0.6gm(52).

LV mass was indexed to height$^{2.7}$. Interpretation of LVH was based on ASE (American society of echocardiography) recommendations as highlighted in the table below.

Table 2.0: LV mass indexed to height$^{2.7}$, ASE recommendations(51)

	Normal	Mild LVH	Moderate LVH	Severe LVH
LV-mass Height$^{2.7}$ FEMALE (g/m$^{2.7}$)	18-44	45-51	52-58	>59
LV-mass Height$^{2.7}$ MALE (g/m$^{2.7}$)	20-48	49-55	56-63	>64

Fig 1.0: An echocardiogram of Parasternal Long axis



6.1.4 Electrocardiography

Electrocardiographic assessments were performed by the principal investigator. All the participants were subjected a standard 12-lead ECG recording with standardized portable automated ECG machine (MAC 1200 ST apparatus). The ECG machine settings were regulated at a speed and voltage regulation of 25mm/s and 1Mv/10mm respectively. ECG procedures were done according AHA/ACC/HRS recommendations(11). Two Copies of Electrocardiogram were printed for both the patient and the PI. Interpretation of the ECG-LVH was based on the four ECG criteria and the measurements recorded in data collection profoma. The interpretation of S wave or R waves was done to the nearest 0.1mv (1mm). Measurements were done with calipers and metal rulers. ECG measurements were verified by the cardiologist.

6.2 Quality Assurance

The ECG machine used had frequency in keeping with AHA guidelines

Performance and interpretation of ECG was done by the principal investigator. ECG recordings and measurements were verified by a cardiologist.

The cardiac sonographer was trained from an accredited u/s training program and had worked under the supervision of a cardiologist for a period greater than 5 years.

The cardiac sonographer was blinded to repeat at least two echocardiographs in every twenty echocardiographs performed in order to calculate intra observer variation.

Video report and images were verified by a cardiologist

6.3 Ethical Consideration

The study was undertaken after approval by the Department of Clinical Medicine and Therapeutics, KNH/UoN Research and Ethics Committee and Mbagathi hospital administration. Informed consent was obtained from the patient through writing and verbal explanation where needed. Participants had the right not to participate or discontinue in the course of the study. Confidentiality was maintained in the course of the study. Patients with ECG or echocardiography findings that necessitated immediate address were notified and referred appropriately. Copies of the report were issued to the patient to present to the clinician in the following clinic visit.

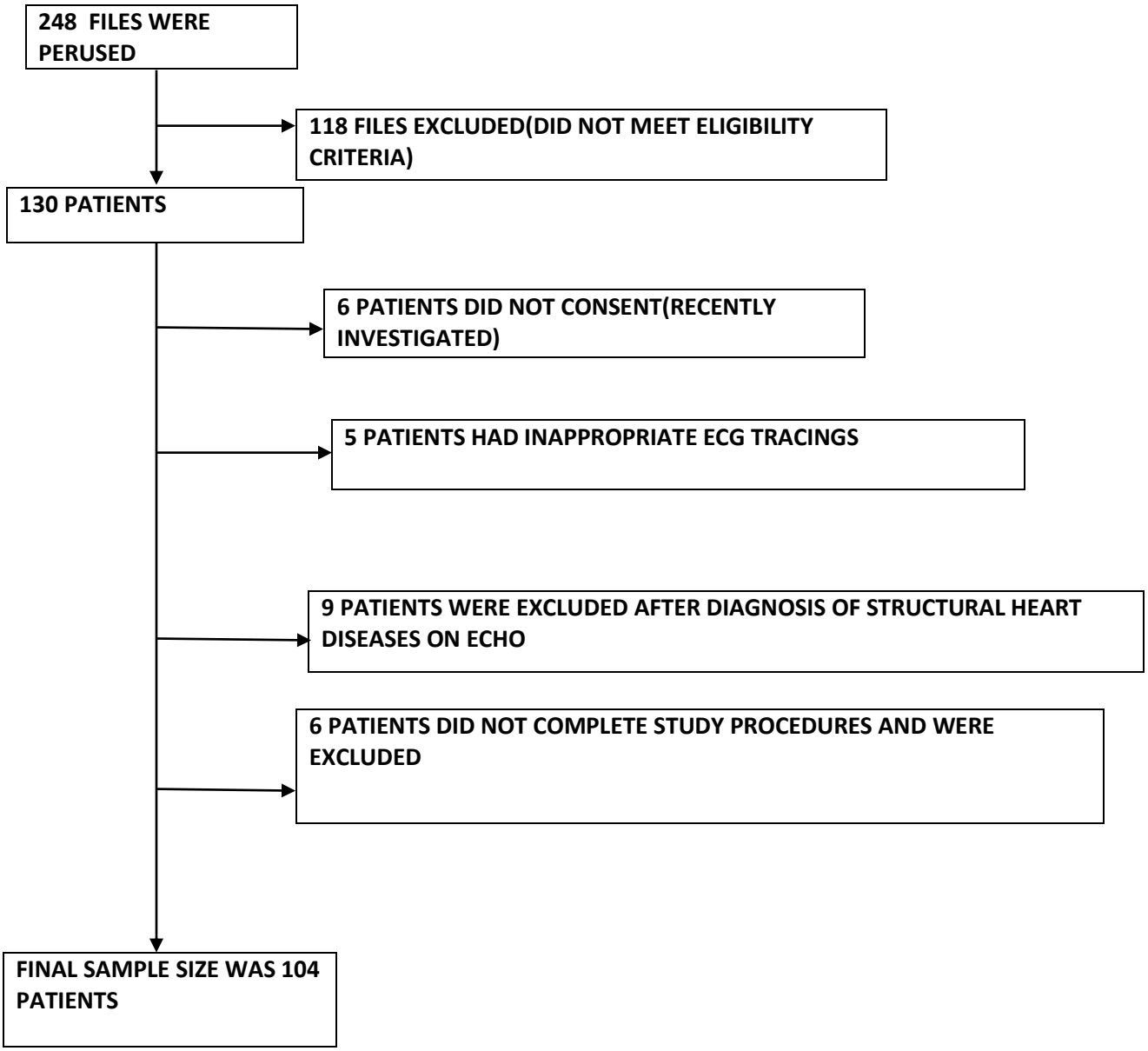
6.4 Data Management and analysis

Data was entered and managed in SPSS version 21.0. The study population was described using socio-demographic and clinical characteristics by summarizing categorical data into percentages and continuous data into means or medians. Prevalence of LVH by echocardiography was analyzed and presented as a percentage with 95% confidence interval. 2-by-2 tables were drawn for each ECG criterion using echocardiography as a gold standard to determine sensitivity and specificity of ECG in diagnosis of LVH. Receiver operator curve (true positive against false positive) was drawn for each ECG criteria in order to determine diagnostic accuracy of the test. All statistical tests were performed at 5% level of significance.

7.0 RESULTS

The study was carried out among ambulatory hypertensive patients at the medical outpatient clinic Mbagathi hospital from March 28th 2017 to May 9th 2017. A total of 248 patient files were screened and 118 files excluded. 104 patients were considered as the final sample size.

Fig 2.0: Flow chart



7.1 Demographic Characteristics

A hundred and four (104) hypertensive patients with a mean age (SD) of 54.7 (12.8) years were analyzed. Majority (72.1%) were females

Table 3.0: socio-demographic characteristics of patients included in the study

Frequency Table	**Frequency (%)(n=104)**
Mean age (SD)	54.7 (12.8)
Sex	
Male	29 (27.9)
Female	75 (72.1)
Marital status	
Married	72 (69.2)
Single	17 (16.3)
Widowed	11 (10.6)
Divorced	4 (3.8)
Level of education	
None	4 (3.8)
Primary	57 (54.8)
Secondary	36 (34.6)
Tertiary	7 (6.7)
Current status of employment	
Unemployed	36 (35.0)
Employed	17 (16.5)
Self employed	45 (43.7)
Retired	5 (4.9)

7.2 Clinical Characteristics

The patients studied had a mean weight (SD) of 74.9 (19) kg and a mean BMI (SD) of 28.1 (7.4) Kg/m^2. Majority of the patients 85.6% were on anti-hypertensive agent.

Table 4.0: Clinical Characteristics of the patients included in the study

Frequency Table	**Frequency (%)**
Weight in Kg	
Mean (SD)	74.9 (17.0)
Median (IQR)	74 (63-84)
Height in cm	
Median (IQR)	165 (157-174)
Mean (SD)	164.5 (13.6)
Mean height (SD) for male	170.6 (10.9)
Mean height (SD) female	162.1 (13.8)
Mean BMI (SD) (kg/m^2)	28.1 (7.4)
Category, n (%)	
<18.5 Underweight	8 (7.7)
18.5-24.9 Normal weight	27 (26.0)
25-29.9 Overweight	33 (31.7)
30-34.9 Obesity Class 1	21 (20.2)
35-39.9 Obesity Class 2	9 (8.7)
>=40 Obesity Class 3	6 (5.8)
Antihypertensive treatment	
On antihypertensive	90 (86.5)
Previously on antihypertensive	2 (1.9)
Not on antihypertensive	12 (11.5)
Blood pressure level	
Category, n (%)	
>140/90 mmHg	27 (26.0)
≤140/90 mmHg	77 (74.0)

7.3 Prevalence of LVH

Prevalence of echocardiography-LVH was 61.5%. Majority of the patients had severe LVH at 48.4%. Mean LV mass indexed declined after adjustment for height more especially among men.

Table 5.0: Summary of echocardiography findings of the study patients

Frequency Table	**Frequency (%)**
LVH by echocardiography	64 (61.5)
Rating of echocardiography LVH (n=64)	
Mild	18 (28.1)
Moderate	15 (23.4)
Severe	31 (48.4)
Mean measurements of LV mass in grams (SD)	
ALL	197.8 (55.4)
Male	224.6 (68.5)
Female	187.4 (45.8)
Mean LV mass index height 2.7($g/m^{2.7}$) (SD) ‘	56.0 (39.7)
Male	53.2 (15.4)
Female	57.1 (45.9)

7.5 Reproducibility of Echocardiograpy Results

Intra-observer agreement was tested by selecting 15 echocardiographs to be read by the same observer. Table 1.9 below shows there was 87% level of agreement between the 1st and the 2nd reading. The kappa statistic was at 0.7 indicating a substantial level of agreement which was statistically significant (p=0.006). *Level of agreement 13/15 (87%)

Table 6.0: Reproducibility of Echocardiography Results

	1st reading		**Total**	**Kappa value**	**P value**
	LVH	No LVH			
2nd reading				0.7	0.006
LVH	10	2	12		
No LVH	0	3	3		
Total	10	5	15		

7.4 ECG Sensitivity and Specificity

All ECG measurements and interpretation done by the PI were verified by a cardiologist at 100% level of agreement. Cornell's voltage criterion had the highest sensitivity at 46.9% but a low specificity in male at 40%. Gubner-Ungerleider and R wave in AVL criteria had the lowest sensitivity at 9.4% and 12.5% respectively but both were highly specific at 100%. Low specificity of 40% in male was observed with the Cornell's voltage criterion.

Table 7.0: Sensitivity and Specificity of various ECG criteria

ECG criteria	**n (%)**	**Gender variability**	**Sensitivity (95% CI)**	**Specificity (95% CI)**
Sokolow-Lyon voltage index	17 (16.3)	M&F	18.8 (10.1-30.5)	87.5 (73.2-95.8)
		Male	31.6 (12.6-56.6)	77.8 (40-97.2)
		Female	13.3 (5.1-26.8)	93.3 (77.9-99.2)
Cornell's voltage index	41 (39.4)	M&F	46.9 (34.3-59.8)	72.5 (56.1-85.4)
		Male	47.4 (24.5-71.1)	40 (12.2-73.7)
		Female	46.7 (31.7-62.1)	83.3 (65.3-94.4)
Gubner-Ungerleider voltage index	6 (5.8)	M&F	9.4 (3.5-19.3)	100 (91.2-100)
		Male	10.5 (1.3-33.1)	100(69.2-100)
		Female	8.9 (2.5-21.2)	100 (88.4-100)
R wave in aVL	8 (7.7)	M&F	12.5 (5.6-23.2)	100 (91.2-100)
		Male	10.5 (1.3-33.1)	100 (69.2-100)
		Female	13.3 (5.1-26.8)	100 (88.4-100)

7.4.5 Combined ECG Criteria

A combination of all the four ECG criteria or Combination of the two most sensitive criteria demonstrated similar sensitivity and specificity at 53.1% and 67.5% respectively. Combination of ECG criteria reduced sensitivity especially in males at 30%.

Table 8.0: Sensitivity and Specificity of Combined ECG Criteria of LVH in the study patients

ECG criteria	**n (%)**	**Gender variability**	**Sensitivity (95% CI)**	**Specificity (95% CI)**
Combination of 4 ECG criteria	47 (45.2)	M&F	53.1 (40.2-65.7)	67.5 (50.9-81.4)
		Male	63.2 (38.4-83.7)	30.0 (6.7-65.3)
		Female	48.9 (33.7-64.2)	80 (61.4-92.3)
Combination of Sokolow's & Cornell's	47 (45.2)	M&F	53.1 (40.2-65.7)	67.5 (50.9-81.4)
		Male	63.2 (38.4-83.7)	30 (6.7-65.3)
		Female	48.9 (33.7-64.2)	80 (61.4-92.3)

7.4.6 Sensitivity and Specificity according To Severity of LVH

ECG criteria demonstrated increasing sensitivity with increasing severity of LVH.

Table 9.0: Sensitivity and Specificity according To Severity of LVH in the study patients

ECG criteria	**Mild LVH**		**Moderate LVH**		**Severe LVH**	
	Sen	Spec	Sen	Spec	Sen	Spec
Sokolow-Lyon>35mm	10	87.5	13.3	87.5	32.3	87.5
Cornell's voltage index	33.3	72.5	46.7	87.5	54.8	87.5
Gubner-Ungerleider voltage: R I+S 111>25mm	-	-	-	-	19.4	100
R wave in AvL > 11mm	5.6	100	-	-	22.6	100
Combined criteria	33.3	67.5	53.3	67.5	64.5	67.5

7.6 Receiver operator characteristic Curve (ROC-Curve)

The receiver operator curves for all ECG criteria showing diagnostic accuracy of the tests. Combined ECG criteria had the largest area under the curve. However, all the ECG criteria had poor diagnostic accuracy since the area under the curve (AUC) fell below 0.7

Fig 3.0: ROC-Curve of the study patients

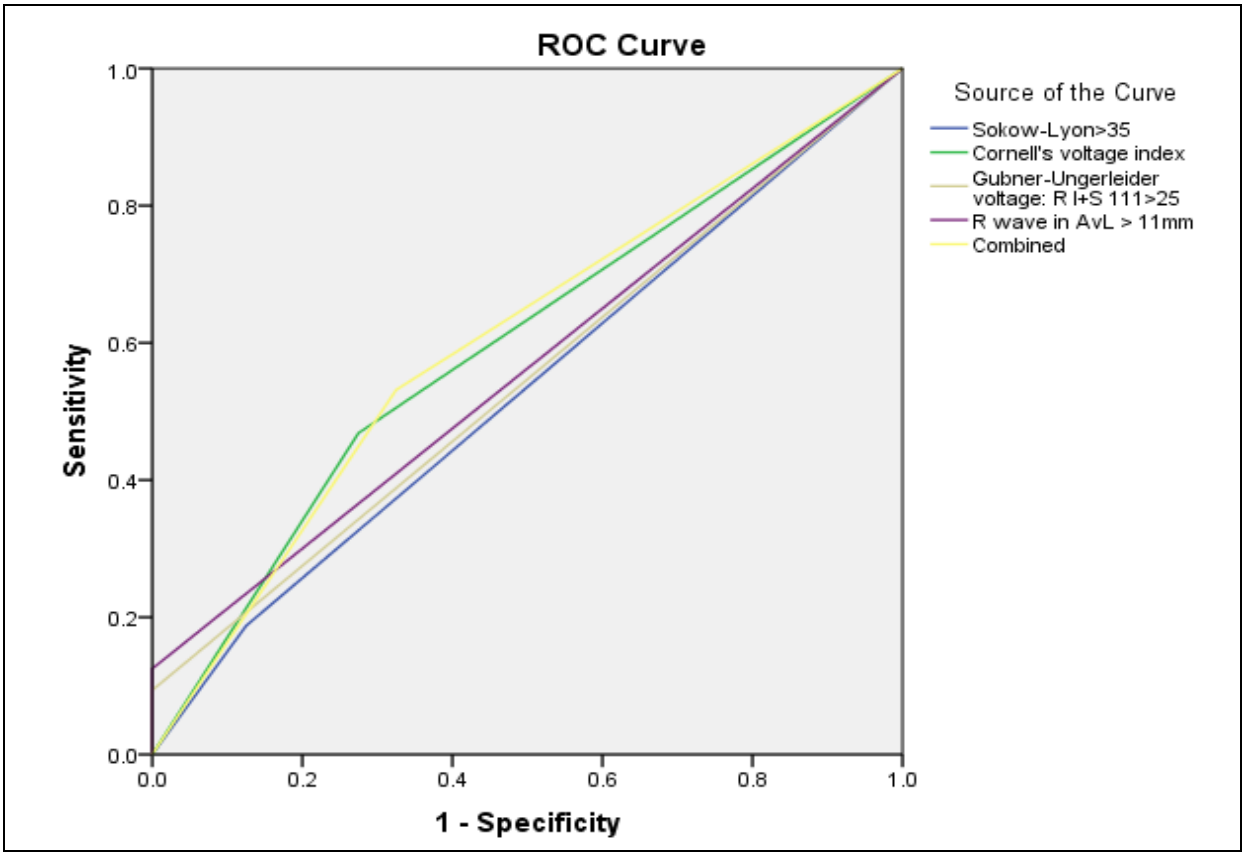


Table 10.0: interpretation of the ROC-Curve

Criteria	AUC	95% CI
Sokolow-Lyon	0.531	0.418-0.644
Cornell's voltage index	0.597	0.486-0.708
Sokolow-Lyon/ Cornell's voltage index combined	0.603	0.492-0.714
Gubner-Ungerleider voltage	0.547	0.435-0.659
R wave	0.563	0.452-0.714
All combined	0.603	0.492-0.714

8.0 DISCUSSION

This was a study done to determine the prevalence of echocardiography determined LVH and sensitivity and specificity of the commonly used ECG voltage criteria for LVH among hypertensive participants at the medical outpatient clinic, Mbagathi hospital. A hundred and four participants were analyzed. Echocardiography- LVH was diagnosed in 61.5% of the participants studied. Cornell's voltage criterion had the highest sensitivity at 46.9%. Combination of both Cornell's and Sokolow-Lyon or combination of all the four ECG criteria demonstrated similar sensitivity and specificity of 53.1% and 67.5% respectively. R wave in aVL and Gubner-Ungerleider voltage criteria showed the highest specificity at 100%. Majority of the study participants (72.1%) were females. This is probably due to poor health seeking behavior among males. Review of data from the medical outpatient clinic (Mbagathi hospital) visit in 2 months (April and May 2017) showed that a total of 281 hypertensive patients were seen at the medical outpatient clinic and 192(64.7%) were females.

8.1 Echocardiographic LVH

Left ventricular hypertrophy in hypertensive patients may be the earliest evidence of end organ damage(15,16). It is an important factor in the pathogenesis of ischemic heart disease, cardiac arrhythmias, congestive cardiac failure, and sudden cardiac death(19,20) and is associated with increased risk of cardiovascular morbidity and mortality(5,18). It is therefore prudent to promptly and accurately detect LVH in order to optimize therapies that have been shown to reduce cardiovascular events. Our study showed echocardiography determined prevalence of LVH at 61.5%. High prevalence of echocardiographic LVH among hypertensive participants have been reported in previous studies; Prevalence of echocardiography determined LVH in a hospital based cross sectional descriptive study done at three municipal hospitals of Dar es salaam region among 160 patients with hypertension was 71.88%(53). In a systematic review of 21 studies involving 5608 patients with arterial hypertension, echocardiographic LVH was 65% in secondary care setting This study involved Caucasians, black and white Americans, Japanese and afro-Caribbean. Africans were not involved in this study (41). A cross sectional descriptive study done in Cuba looked at echocardiographic LVH among 200 patients above the age of 18 year with essential hypertension and showed a prevalence of echocardiography determined LVH in essential hypertension at 67%(54).

There is limited data on echocardiography determined prevalence of LVH among hypertensive in our setting and studies done have showed lower prevalence of LVH because they were based on ECG which has lower sensitivity for LVH(11). A study on prevalence of cardiovascular risk factors and target organ damage among 93 hypertensive participants at KNH found prevalence of ECG LVH at 32.3%(43). Another study done at Kenyatta National Hospital on patients with chronic kidney disease not on dialysis found an ECG prevalence of LVH at 29.7%(44).

The high prevalence of LVH in hypertension is a red flag and probably highlights unexplained higher prevalence of cardiovascular morbidity and mortality in our setting as depicted by WHO 2013, that cardiovascular morbidity accounts for 17 million deaths per year. It also reflects sub optimal management of hypertensive patients which may be due to delay in diagnosis, poor control of blood pressure and inappropriate choice of antihypertensive. High prevalence of LVH in our setting predicts an accelerated cardiovascular morbidity and mortality if no interventions are put in place.

8.2 ECG Sensitivity and Specificity

ECG criteria had generally low sensitivity and high specificity for LVH from our study findings. Lower prevalence of ECG-LVH have been reported in and outside Africa as depicted in previous studies (33,38,40,55). The QRS amplitude produced by the electrical impulse traversing through the myocardial mass is influenced by several non-cardiac factors i.e. body habitus, age, sex and race(11) The multiple ECG criteria for LVH implies that there is no single ECG pattern that is predictive of left ventricular mass and that there is several unexplained association. The low sensitivity for ECG-LVH observed in this study impact negatively on actual clinical practice where ECG is the initial screening tool among hypertensive patients in our setting. It translates to missed diagnosis and sub-optimal management of hypertensive patients. It also predicts an explained cardiovascular morbidity like heart failure and arrhythmic heart diseases which could be preventable if LVH was accurately and promptly detected and the management of hypertension optimized. Accurate and prompt detection of LVH is therefore important in order to apply preventive as well as reversal measures because recent studies have demonstrated reversal of left hypertrophy with various intervention(8). Meta-analysis of clinical trials have shown that regression of LVH results in decreased risk of cardiovascular events(21).

Cornell's voltage criterion had the highest sensitivity at 46.9% and specificity of 72.5% followed by Sokolow-Lyon index, at sensitivity of 18.8% and specificity of 87.5%. Cornell's voltage was the only ECG criterion that was adjusted for gender. Several other studies have demonstrated that Cornell's voltage criterion outperform other ECG criteria. A study done in The New York Hospital-Cornell Medical Center, correlated ante-mortem ECG of 135 patients (ECG done not more than 10 days prior to the death of the patients) with the autopsy findings of their left ventricular mass and found that Cornell's voltage criteria significantly improved sensitivity at 42%, while maintaining high specificity at 96%(56). The Sensitivity of Sokolow-Lyon voltage criteria for LVH was 22%, but specificity was 100%(56). A study done among 182 black African populations in Cameroon looked at 6 classic ECG criteria using echocardiography as the gold standard and found Cornell's to be the most sensitive criteria at 37.2% followed by Sokolow-Lyon at 26.5% (40). Another study done among Korean patients, compared Cornell's and Sokolow-Lyon electrocardiographic Criteria for Left Ventricular Hypertrophy and found that Cornell-based criteria had better performance than Sokolow-Lyon criteria in both men and women(57).

Adjustment of ECG criteria for gender significantly improved ECG sensitivity for LVH as depicted from our study and studies depicted above. AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram recommends adjustment of ECG criteria in order to increase diagnostic yield(11). ECG is much more readily available in our setting than echocardiography. ECG is cheap and easy to use and therefore it is necessary to improve its utility through adjustment and proper choice of the criteria for better identification of patients with LVH who are at high risk of cardiovascular events.

Cornell's voltage criterion showed almost equal sensitivity for both male and female at 47.4% and 46.7% respectively, unlike Sokolow Lyon which had a higher sensitivity for male at 31.6% and lower sensitivity for female at 13.3%. This is because Sokolow Lyon is not adjusted for gender and does not take into consideration structural body difference attributable to gender. In one study, 4684 normal Partipants were enrolled and subjected to multiple ECG criteria. LVH

was found to be lower in female (1.5%) than males (2.9%) when an unadjusted criteria were used(18). The findings were attributed to lower voltage generated by female heart muscle probably because female myocardial mass is less than male by 25%(58). These findings suggest that ECG criteria for LVH should be adjusted to QRS amplitude of lower threshold in females. Sokolow Lyon is one of the most commonly used criterion and its poor sensitivity especially among female impact negatively on actual clinical practice. There is need to apply adjusted criteria in ECG-LVH assessment in order to minimize gender bias.

Low specificity for LVH in male was observed in the ECG criteria that were relatively sensitive for LVH; low specificity of 40% in male was observed with the Cornell's voltage criterion and a very low specificity in males at 30% was observed with combination of ECG criteria. A lower specificity among male was also observed with Sokolow Lyon at 77.2% than female at 93.3%. The explanation is that tall subject have generally large myocardial mass as it was with male participants in our study; the mean height for male was 170.6 cm and the mean LV mass for male was 224.6 gram versus mean height of 162.1 cm and mean LV mass of 187.4 grams in female participants. The increased myocardial mass was directly interpreted by the ECG as left ventricular hypertrophy but not so with echocardiography because of height based adjustments of LV mass. The height based adjustments (indexing) resulted into lower mean left ventricular mass index (LVMI) in males at 53.2 $g/m^{2.7}$ (mild LVH) than in females at 57.1 $g/m^{2.7}$ (moderate LVH). This is because males were generally taller. The conclusion was that tall subject may present with false ECG LVH due to an increased in LV mass that is not adjusted for height. This explains the low ECG specificity in males who were taller from our study findings.

Low specificity among tall subject (mostly male) demonstrated in our study was not consistent with previous studies and contradicts what is already known about ECG criteria, to be highly specific. The above findings were probably not comparable to previous studies because all the previous studies reviewed indexed the left ventricular mass to body surface area and not height. American Society of echocardiography denotes that it is still controversial on whether to use height, weight, or BSA as the indexing term (48). Previous studies depict that adjustment of LV mass for body surface area overestimates LVH in obese patients(25,26). Zoccalli and colleagues found LVH indexed to $height^{2.7}$ to be a better predictor of cardiovascular risk than LVH indexed

to BSA(26). Our study finding concluded that low specificity of ECG in diagnosis of LVH in tall subject may be due to increased myocardial mass and not necessarily LVH.
R-wave in aVL and Gubner-Ungerleider voltage criteria had the lowest sensitivity at 12.5% and 9.4% respectively but both maintained a very high specificity of 100%. Both criteria are derived from limb leads. Previous studies have demonstrated that limb lead voltage criteria performs poorly. The Cameroon study cited above(40), in which 6 ECG criteria were evaluated, found that the mentioned criteria had poor sensitivity but were highly specific (Gubner- 98.6% and R wave in AVL-97.1%)(40). The clinical correlate of an ECG with low voltage in the limb leads but normal precordial QRS amplitudes is unclear as observed in previous studies(59). Interpretation of LVH by either of the two ECG criteria may results into missed diagnosis and suboptimal management of hypertensive patients.

Combination of ECG criteria improved sensitivity. Combination of the 2 most sensitive ECG criteria was similar to combination of all the 4 ECG criteria in terms of sensitivity. Combination of Cornell's voltage and Sokolow-Lyon or combination of all the four criteria showed improved sensitivity at 53.1%. Combined ECG criteria had a higher sensitivity for severe LVH at 64.5%. Majority of the patients studied (48.4%) had severe LVH. The combination of the two most sensitive could identify all the LVH identified by all the 4 ECG criteria in this study. Findings from combination of ECG are consistent with Murphy et al who found that use of more than one ECG criteria significantly improved sensitivity(12). Our study findings are also supported by the Cameroon study discussed earlier(40) in which combination of ECG criteria improved sensitivity(40). Combination of at least 2 most sensitive criteria (Sokolow and Cornell's) are applicable and increases sensitivity but at the expense of specificity, however both sensitivity and specificity increase with increasing severity of LVH.

The receiver operator curve demonstrated that ECG was poor in delineating left ventricular hypertrophy as shown by poor diagnostic accuracy demonstrated by area under the curve (AUC) of <0.7. The largest area under the curve was recorded with combination of ECG criteria at 0.603(0.492-0.714). These findings were similar to those of Sohaib et al at who constructed ROC curve for 4 ECG criteria and found that they fell below AUC<0.7(60). Combination of ECG does not meet threshold of a good diagnostic test however in low resource set up where the

diseases prevalence is high (61.5%), ECG may be the only available test and combination of ECG criteria can be considered.

9.0 Conclusion

The prevalence of echocardiography determined LVH in hypertensive patients was high in this population. ECG criteria for LVH had generally low sensitivities and high specificities but combination of ECG criteria improved the sensitivity

10.0 Recommendations

- Echocardiographic screening for LVH among hypertensive patients with increased risk for cardiovascular events in order risk stratify and optimize management
- Combination of ECG criteria in diagnosis of LVH is recommended as initial screening tool among hypertensive in low resource set up where echocardiography is not readily available
- There is need to adjust the available ECG criteria for various factors i.e. gender and height in order to increase the diagnostic yield
- Further studies are recommended to assess utility of adjusted criteria in diagnosis of left ventricular hypertrophy

11.0 STUDY LIMITATIONS

- Majority of the study participants (72.1%) were females, this is probably due to poor healthy seeking behavior among men this would probably mean that the study findings are not generalizable.
- This was a hospital based study and the results obtained may not be generalized to other population.
- Participants with file diagnosis of hypertension were recruited however some study participants may have been wrongly labeled as hypertensive.

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APPENDIX I

Informed consent form

Informed consent on the study to establish ECHO determined prevalence of left ventricular (LVH) and utility of ECG voltage criteria for LVH among hypertensive patients on follow-up at medical outpatient clinic, Mbagathi hospital.

Introduction

I am Dr. James Ndiritu, a student in university of Nairobi pursuing a master's degree in Internal Medicine. I intend to conduct a study to determine the burden of hypertensive heart disease (left ventricular hypertrophy) and evaluate diagnostic modalities for these conditions among hypertensive patients attending Mbagathi hospital medical outpatient clinic.

Informed consent

This form contains details of risks and benefits involved in the study to enable you make an informed choice on whether to or not to participate in the study.

Purpose of the study

The purpose of this study is to evaluate diagnostic modalities (ECG & ECHO) used in evaluation of a complication associated with hypertension (left ventricular hypertrophy).

Procedures to be followed in the study

At the beginning we shall obtain an informed consent from you. If eligible we will record your demographic characteristics. We will then take your weight, height and blood pressure and perform an ECHO and an ECG studies on you. Copies of ECHO and ECG report will be filed in your file to be reviewed by your doctor in the next clinic visit. In case of coincidental ECG or ECHO finding that necessitate immediate action we shall contact you for further evaluation and management.

Risks and costs incurred

All the procedures are non-invasive and there is no pain expected however it will cost you time. The procedures will take approximately 30 minute to one hour after your review in the clinic.

Your rights as a participant

Participation in this study is voluntary. You have the right to accept or decline participating in the study now and in the course of the study. You also have the right to ask any question or seek clarification.

Assurance of confidentiality

The information we shall obtain from you will remain confidential. The information will only be availed to the principal investigator and the research assistant doing the statistical analysis. Both hard and soft copy will be held under lock and key. Soft copy will also be kept in password protected software.

Benefits to the participant

Participants will have the advantage of screening for complication of hypertension to the heart (left ventricular hypertrophy) at no cost. Copies of the result will be to the participant. The results will help prognosticate and recommend a new management plan.

Contacts

Participants are allowed to contact the principal investigator, institution or the department through the contact provided.

Institution:

Department of Clinical Medicine and Therapeutics, College of Health Sciences

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Ethical Approval:

Kenyatta National Hospital /University of Nairobi Ethics and Research committee,

P.O BOX 20723-00100, Nairobi

Tel 2726300/2716450 Ext 44102I

Consent

I have read the above information/the above information has been explained to me. I have had the opportunity to ask question about the study and any question that I asked have been answered to my satisfaction.

Print Name of Participant/ Next of kin……..

Signature / Left thumbprint of subject:……

Date:……

Investigator's statement:

I have explained to the patient about the study and he/she reports that he/she has understood

Signed: ..... Date: ……

APPENDIX 2

Fomu ya maelezo ya utafiti

Fomu ya maelezo ya utafiti wa kuchunguza ugojwa wa moyo kwa kutumia vyombo tofauti kwenye wagonjwa wa shinikizo la juu la damu.

Nina tarajia kufanya uchunguzi kuhusu maadhara ya ugojwa wa presha ya juu ya damu kwa moyo. Natarajia pia kufanya utafiti kuhusu vyombo vinavyo tumika kuangalia haya maadhara..

Lengo la utafiti

Ninafanya utafiti huu ili kudhibitisha kiasi ya watu walioadhilika na kutambua njia mwafaka kati ya zile zilizoko zinazoweza kutumika kutambua haya maadhaara mapema iwezekanavyo.

Utaratibu wa utafiti

Mara utakapo kubali kuhusika kwenye utafiti huu, utatia sahihi katika fomu ya ridhaa na matakwa ya utafiti. Kisha utaulizwa maswali na kupimwa ili kudhibitisha kwamba wastahili kuhusika katika utafiti huu. Baada ya kudhibitishwa utafanyiwa utafiti wa electrocardiography/echocardiography (ECG/ECHO).lengo la utafiti huu itakuwa kuchunguza matatizo ya moyo inayotokana na shinikizo la damu na chombo maalum cha kung'amua haya matatizo.

Manufaa ya utafiti huu

Utapata manufaa ya kuchunguzwa ugojwa ya moyo bila malipo. Vipimo utakazofanyiwa zitasaidia kwa kiasi kikuu katika matibabu ya ugojwa wa shinikizo la juu la damu

Hatari na gharama inayohusika

Hakuna pesa utahitajika kulipa kwa kufanyiwa utafiti huu, lakini itakugharimu wakati/saa ya kusubili isio zidi saa moja.

Haki zako

Kujiunga na utafiti huu ni kwa hiari yako. Hutabaguliwa kimatibabu ukikataa kujiunga na utafiti huu. Ukijiunga na utafiti huu una uhuru wa kutoka katika utafiti huu wakati wowote utakapo.

Una uhuru wa kuuliza maswali yoyote uliyo nayo kabla ya kutia sahihi fomu ya makubaliano. Maelezo yako yote yata wekwa pahali pa siri. Ni mtafiti mkuu na mwanatakwimu wake pekee ambao wataangalia maelezo yako.

Cheti cha ridhaa

Nimesoma, au nimesomewa maelezo yaliyopewa. Nimepata fursa ya kuuliza maswali kuhusu utafiti na maswali yote niliyouliza yamejibiwa vyema. Nina kubali kuhusika katika utafiti huu.

Jina la mhusika: ……

Sahihi/Alama ya kidole gumba cha kushoto: ……Tarehe: ……

Kauli ya mtafiti:

Miye, mtafiti mkuu, nimemweleza mhusika vilivyo kuhusu utafiti huu.

Sahihi: ..... Tarehe: ……..

Mawasiliano

Ukiwa na maswali yoyote ya ziada, unaweza kuwasiliana na wafuatao:

Taasisi: Idhaa ya matibabu ya watu wazima, Chuo cha sayansi ya afya, Chuo kikuu cha Nairobi S.L.P. 30197-00400, Nairobi.

Mtafiti mkuu: Dkt. James Ndiritu, S.L.P. 43529-0100, Nairobi. Idhaa ya matibabu ya watu wazima, Simu – 0721751301; nderituwgr40@gmail.com

Msimamizi mkuu: Prf. Elijah Ogola , Idhaa ya matibabu ya watu wazima, S.L.P 19676-00400 Nairobi, Simu - (0) 20 2710062, 2726502, 2725452/254 (0)722737944

Ridhaa: Kenyatta National Hospital /University of Nairobi Ethics and Research committee, S.L.P. 20723-00100, Nairobi. Tel 2726300/2716450 Ext 44102; uonknh_erc@uonbi.ac.ke

APPENDIX II1

Data Collection Profoma

1. Date……
2. Participant's initials……
3. Age……..
4. Sex……..
5. Marital status [ ] 1=married 2=single 3=widowed 4=divorced
6. Level of education [ ] 1=none 2=primary 3=secondary 4=tertiary
7. Current status of employment [ ] 1=employed 2=unemployed 3=self-employed 4=retired
8. Antihypertensive [ ] 1=on antihypertensive 2=not on antihypertensive 3=previous antihypertensive
9. Weight……
10. Height…….
11. BMI……Interpretation……
12. First blood pressure…….Second blood pressure…….Third blood pressure…….Average blood pressure (2 last BP)…….

Table 11.0: BMI classifications

BMI CLASSIFICATION	WEIGHT(Kg/M^2)
UNDERWEIGHT	<18.5
NORMAL	18.5-24.9
OVERWEIGHT	25-29.9
OBESITY (CLASS 1)	30-34.9
OBESITY (CLASS 2)	35-39.9
OBESITY (CLASS 3)	≥40

TABLE 12.0: ECG voltage criteria for LVH in Mill volts

ECG voltage criteria for LVH in Mill volts	Millimeters	Respond by a tick for LVH	Respond by cross if NO LVH
Sokolow-Lyon >35 mm			
MALE>28mm Cornell's voltage index FEMALE > 20mm			
Gubner-Ungerleider voltage: R I + S III > 25 mm			
R wave in AVL > 11mm			

TABLE 13.0: LVH by ECHO

LVH by ECHO	Measurements of LV mass in grams	LV mass indexed height2.7 (g/m2.7)	Mild LVH	Moderate LVH	Severe LVH	No LVH
MALE						
FEMALE						