Prevalence and Factors Associated with Electrocardiographic Abnormalities among Heart Failure Patients at Kampala International University Teaching Hospital, Ishaka, Uganda

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Declaration

I Dr. Yves Tibamwenda Bafwa, hereby declare that the work I have presented in this dissertation titled: "Prevalence and factors associated with electrocardiographic abnormalities among heart failure patients at Kampala International University-Teaching Hospital, Ishaka, Uganda" is my original work and idea, and has not been previously submitted by me or anyone else, for any degree or diploma award at this or any other institution.

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Approval

This research dissertation titled "Prevalence and factors associated with electrocardiographic abnormalities among heart failure patients at Kampala International University-Teaching Hospital, Ishaka, Uganda" has been developed under our supervision and we hereby approve this work to be forwarded to the next level for consideration.

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Dedication

I dedicate this dissertation to my parents Jean-Louis Bamuhiga and Thereza Kiza Dive; my parents in law Jean-Baudouin Lokengama and Elisabeth Kwambele. To my wife Rachel Lokengama Kwambele; and to my children Marie-Ange Rehema Bafwa, Amanda Tibasaga Bafwa, Elisabeth-Dacruz Kansime Bafwa and Thereza Lokengama Bafwa. I also dedicate it to my brothers Tresor Asimwe, David Alemi and my sister Joyce Bakho with her husband Vicky Katsuva. I would never have made it far without your love, guidance, encouragement and financial support.

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List of Acronyms and Abbreviations

AF	Atrial fibrillation
ACEIs	Angiotensin II converting enzymes inhibitors
BB	Beta-blockers
BMI	Body mass index
BP	Blood Pressure
CAD	Coronary artery disease
CI	Confidence Interval
COPD	Chronic obstructive pulmonary disease
DM	Diabetes Mellitus
ECG	Electrocardiogram (Electrocardiography)
ESC	European Society of Cardiology
HF	Heart Failure
HR	Hazard ratio
IHD	Ischemic Heart Disease
KIU-TH	Kampala International University-Teaching Hospital
LAE	Left Atrium Enlargement
LBBB	Left bundle branch block
LMICs	Low- and Middle-Income Countries
LVEF	Left Ventricular Ejection Fraction
LVH	Left Ventricular Hypertrophy
MI	Myocardial Infarcts
MOH	Ministry of Health
NYHA	New-York Heart Association
RAE	Right Atrium Enlargement
RBBB	Right bundle branch block
SD	Standard Deviation
UK	United Kingdom
USA	United States of America
WPWS	Wolff-Parkinson-White Syndrome

Operational Definitions

Associated factors: These are factors such as socio-demographic characteristics (i.e. age, sex and level of education); behavioral factors (i.e. smoking and alcohol use) and medical factors (i.e. duration of heart failure, medication, NYHA and comorbidities which included, but not limited to, diabetes mellitus, hypertension, chronic obstructive pulmonary disease and obesity) that influence ECG findings.

Electrocardiographic abnormalities: ECG abnormalities refer to any deviation from the normal findings (see Appendix A) which can be either minor abnormalities (where the ECG shows one or more of the following: first and second degree Atrio-Ventricular block (AV-block), Left Ventricular Hypertrophy (LVH) without ST-abnormalities, left atrial enlargement, atrial premature beat, ventricular premature beat, right atrium enlargement and non-specific ST-abnormality) or major abnormalities (where the ECG shows one or more of the following: Q-QS wave abnormalities, LVH with ST-abnormalities, Wolff-Parkinson-White syndrome, bundle branch block or intraventricular block, atrial fibrillation or atrial flutter, major ST-T changes and Third degree AV-block).

Heart Failure: In this study the diagnosis of heart failure was made based on the Framingham criteria (Appendix B). A patient was diagnosed to have heart failure if he/she has two major criteria (i.e. paroxysmal nocturnal dyspnea or orthopnea, neck vein distension, cardiomegaly, basal crepitations, S3 gallop, clinical acute pulmonary edema or pulmonary edema on chest X-ray, hepatojugular reflux, weight loss of 4.5 kg in 5 days in response to treatment and central venous pressure greater than 16 cm water) or one major criterion plus two minor criteria (the minor criteria were accepted only if they were not attributed to other medical conditions (i.e. tachycardia (rate $\geq$ 120 bpm), exertional dyspnea, nocturnal cough, hepatomegaly, pleural effusion, bilateral ankle edema and a decrease in vital capacity by one third the maximal value recorded).

Abstract

Background: The prevalence of cardiovascular diseases is increasing rapidly in Sub-Saharan Africa. A multicenter prospective cohort study of 1,006 patients with acute heart failure in a Sub-Saharan Africa Survey showed that 814 patients had ECGs readings among which 97.7% had abnormalities. There is paucity of data on ECG abnormalities among heart failure patients in many developing countries, Uganda inclusive.

Methods: A cross sectional study was conducted at KIU-TH between January and March 2020 which recruited 122 heart failure patients. Questionnaires were administered to respondents to obtain factors associated with ECG abnormalities. A 12-lead ECG machine was used to obtain ECG findings. Data were analyzed using bivariate and multivariate logistic regression analyses to establish the association between each independent variable and the ECG abnormalities.

Results: The mean age of study respondents was 62.4 ± 20 years and 54.9% of the respondents were females. The prevalence of ECG abnormalities among heart failure patients was 86.1 % (95% CI: 78.6-91.2). The main ECG abnormalities were left ventricular hypertrophy (29.5%), left bundle branch block (12.4%) and right bundle branch block (11.4%). The factors associated with ECG abnormalities were age ≥ 50 years (aOR = 23.1, 95% CI: 1.81 – 294.33, p= 0.016), smoking (aOR = 23.6, 95% CI: 1.19 – 465.86, p= 0.038), hypertension (aOR = 11.9, 95% CI: 1.05 – 135.65, p= 0.046) and being in NYHA functional class III and IV (aOR = 168.7, 95 % CI: 6.85 – 4155.5, p=0.002).

Conclusion: The prevalence of abnormal ECG among heart failure patients was very high. Respondents aged above 50 years, smokers, hypertensive and those staged in NYHA functional class III and IV were at high risk of having abnormal ECG. It is recommended that ECG test should be included as a routine test in the management of heart failure patients at KIU-TH, regular refresher training in ECG should be organized for clinicians. Routine health education on the dangers of alcohol misuse and smoking to the heart and other organs, should be encouraged at triage centres of all health facilities by the Ministry of Health in Uganda.

Chapter One

Introduction

1.1 Background

1.1.1 Historical Background

With more than 100 years of development, the history of electrocardiograph (ECG) has been complicated and unorganized (Yang et al., 2015). Galvani in 1781, observed while dissecting a frog, that electric stimulation of frog nerves could cause muscle contraction, which he called "animal electricity". This discovery revealed the biological basis of electrophysiology. Later, the first ECG of a human being was recorded in 1869 with a siphon instrument by Muirhead in London (Yang et al., 2015). With the introduction of chest x-ray in 1895 by Roentgen and the electrocardiograph (electrocardiogram) in 1902 by Einthoven who was inspired by the work of Waller, objective information about the structure and function of the heart was provided. Electrocardiography has played an important role in the diagnosis of heart diseases (AlGhatrif & Lindsay, 2012).

In the first half of the 20th century, the electrocardiograph no longer employed a string galvanometer to record the potential difference between the extremities resulting from the electrical activity of the heart (Yang et al., 2015). In 1930, Wolff, Parkinson, and White reported on 11 young patients with paroxysms of tachycardia, or atrial fibrillation (AF) that had a functional bundle branch block and an abnormally short PR interval on ECG. It was subsequently described as Wolff-Parkinson-White syndrome or pre-excitation syndrome (Yang et al., 2015). Later, in 1966, Dessertenne first described "torsades de pointes" and in 1967, the ECG characteristics of sick sinus syndrome were first proposed by Lown. However earlier in 1957, Norman Holter invented the dynamic ECG, also named Holter ECG, a portable device which enables the continuous monitoring of various electrical activities of heart for more than 24 hours (Yang et al., 2015).

The progression of physics led to the invention of the 12-lead electrocardiogram as it is now known. The ECG (called, the electrokardiogram (EKG) in German language), measures how the electrical activity of the heart changes over time as action potential is propagated through the heart during a cardiac cycle. It shows electrical differences across the heart when depolarization and repolarization of the atrial and ventricular cells occur (Dupre, Vincent &

Laizzo, 2005) (The normal ECG tracing is described in Appendix A). Heart failure is associated with widespread electrophysiological remodelling of the cardiac conduction system, resulting in electrocardiographic (ECG) abnormalities such as reduced RR variability, prolongation of the QRS and PR intervals, and atrial fibrillation (Nikolaidou, Ghosh & Clark, 2016).

Vinit and Jayesh (2016) in India conducted a retrospective study among 400 heart failure patients and found that the main ECG abnormalities among them included left ventricular hypertrophy (LVH) (42.9%), left axis deviation (39.8%), left bundle branch block (LBBB) (19.4%), and left atrial enlargement (25.8%). Arrhythmias included: ventricular extrasystoles (11.8%), atrial fibrillation (9.1%), complete heart block (5.7%) and ventricular tachycardia (3.9%). They reported a prevalence of ECG abnormalities of 92% among patients with heart failure, and normal ECG in 8% of the patients.

Gouda, Brown, Brian, Finlay and Justin (2016) in Canada studied patients with heart failure and reported the prevalence of LBBB to be between 8% and 31%, right bundle branch block (RBBB) ranged from 7% to 14%, while AF ranged from 22% to 37%. Each ECG abnormality has variable effects on mortality. They reported the prevalence of ECG abnormality among heart failure patients to be 92.5%. In the Korean Heart Failure Registry, the prevalence of first-degree heart block was 10% among patients presenting with acute heart failure and 26% of the patients had a previous history of heart failure (Nikolaidou et al., 2016). In Sub-Sahara Africa; Owusu, Boakye and Appiah (2014) from a retrospective study done in Ghana, reported a prevalence of 93% of ECG abnormalities among heart failure patients, while in a cross-sectional study conducted in Nigeria by Karaye and Sani (2008), 98.2% of a total of 113 patients with heart failure studied had abnormal ECGs.

1.1.2 Theoretical Background

A theory is a system of ideas intended to explain a phenomenon. Theory in medical education is the participation in scientific dialogue around different explanations of phenomena with a specific lens through which the inquiry was conducted rather than emphasizing an imperative of proof from the biomedical view (Laksov, Dornan & Teunissen, 2017).

This study was guided by the Lead Theory developed by Horacek in 1989. The Lead Theory describes the relationship between electrical sources in the heart and the potential differences they generate on the surface of the body in the electrocardiographic leads (Macfarlane et al., 2010). Two components can be considered separately in this relationship: the active cardiac

electric sources which are disturbed in and restricted to the heart region, and the passive aggregate of electrically conductive extracardiac tissues of the body which provide an electrical load of cardiac sources and makes the external measurement of cardiac activity possible (Macfarlane et al., 2010). Other theories have been developed such as the Einthoven's classical Lead Theory in 1903, which postulates that the human body is part of an infinite, homogeneous conductor in which the electrical sources of the heart are represented by a single, time-varying current dipole fixed at the center of an equilateral triangle in the frontal plane, with apices corresponding to the functional positions on measurement sites in the limbs. Also, Burger and van Milaan developed in 1946 a more precise Lead Theory referred to as the "volume-conductor theory". This includes an assumption that the human body is a three dimensional, bounded, irregularly shaped and an homogeneous volume conductor that relies on a fixed dipole hypothesis under which the potentials anywhere on the surface of the body can be derived by projecting a heart vector in three-dimensional space (Tomasic & Trobec, 2013).

Studies demonstrates that some factors (sociodemographic, behavioral, environmental and medical) can produced changes in the normal electrical activity of the heart and produce electrocardiographic changes. The conduction disorders may occur because of problems directly associated with the electrical "wiring", the sinoatrial node, the atrioventricular node or the ventricular conducting system. It may also be due to influences on the conducting system from outside the heart (electrolyte imbalance, abnormal hormone levels mainly from the thyroid and medication or drug ingestions) (Antzelevitch & Burashnikov, 2011). The Lead Theory was chosen for this study because, it helps in understanding the occurrence of abnormalities in the electrical activity of the hearts of patients with heart failure with different socio-demographics, behavioral factors and medical factors.

1.1.3 Conceptual Background

In this study, the indicators of the ECG abnormalities among heart failure patients are categorized as the independent variables which include socio-demographic factors, behavioral factors and medical factors of heart failure patients. Electrocardiographic abnormalities are the dependent variables. According to the European Society of Cardiology, heart failure is a clinical syndrome characterized by typical symptoms such as breathlessness, ankle swelling and fatigue. The indicators of heart failure are related to the presence of clinical features like peripheral edema, elevated jugular venous pressure and pulmonary crackles, caused by a structural and/or functional cardiac abnormality that cause reduced cardiac output and/ or

elevated intracardiac pressures at rest or during stress (Ponikowski et al., 2016). In this study heart failure is defined as presence of two major criteria (i.e. paroxysmal nocturnal dyspnea or orthopnea, neck vein distension, cardiomegaly, basal crepitations, S3 gallop, clinical acute pulmonary edema or pulmonary edema on chest x-ray, hepatojugular reflux, weight loss of 4.5 kg in 5 days in response to treatment and central venous pressure greater than 16 cm water) or one major criterion plus two minor criteria. The minor criteria were accepted only if they were not attributed to other medical conditions (i.e. tachycardia, exertional dyspnea, nocturnal cough, hepatomegaly, pleural effusion, bilateral ankle edema and a decrease in vital capacity by one third the maximal value recorded) from the Framingham criteria.

Socio-demographic factors are group related characteristics defined by social and demographic characteristics which include age, race, ethnicity, religion, language, education level, occupation and wealth (Bacharova et al., 2015). In this study, the socio-demographic characteristics of patients and their behavioral factors included age, gender, level of education, smoking and history of alcohol use. According to Valderas, Starfield, Sibbald, Salisbury and Roland (2009), several definitions of comorbidities have been suggested based on different conceptualizations of a single core concept: the presence of more than one distinct medical condition in an individual. Although always used as a person-level construct, four major types of distinctions are made: the nature of the health condition, the relative importance of the co-occurring conditions, the chronology of presentation of the conditions and the expanded conceptualizations. In this study comorbidities is defined as the presence of other medical conditions apart from heart failure. Such conditions include, but not limited to, diabetes mellitus, hypertension, chronic obstructive pulmonary disease, coronary artery diseases and obesity.

Other medical factors in this study are duration of heart failure, medications being used and the NYHA classification of the heart failure patients. The duration of heart failure was categorized into heart failure less than a year and heart failure more than a year. Medications being used by patients referred to current medications and they were determined from previous medical notes of patients. The NYHA classification was determined during the physical examination conducted during the data collection. Auer et al. (2012), found that both major and minor ECG abnormalities were associated with underlying conditions such as smoking, diabetes mellitus, increased blood pressure, increased total and high-density lipoprotein cholesterol.

The criteria for minor ECG abnormalities include the presence of first and second degree AV-block, Left Ventricular Hypertrophy (LVH) without ST-abnormalities, left atrial enlargement, atrial premature beat, ventricular premature beat and non-specific ST-abnormality while for major abnormalities they include Q-QS wave abnormalities, LVH with ST-abnormalities, Wolff-Parkinson-White syndrome, bundle branch block or intraventricular block, atrial fibrillation or atrial flutter, major ST-T changes and Third degree AV-block (Auer et al., 2012). The indicators of ECG abnormalities were related to the presence of irregular rhythm, tachycardia or bradycardia, history of syncope, chest pain and shortness of breath which can be seen in heart failure patient. These indicators were correlated to the ECG abnormalities described above. In this study, ECG abnormalities and their classifications were based on the description of Auer et al. (2012).

1.1.4 Contextual Background

The burden of non-communicable diseases (NCDs) is rising fast in Low-Income Countries (Uganda inclusive) and they will be the leading cause of death by 2030. Cardiovascular diseases, including heart failure, contribute up to 30% of deaths from NCDs and most patients with heart failure in Africa present with advanced disease (Namukwaya, Grant, Downing, Leng & Murray, 2017). According to the Ministry of Health of Uganda (2012), NCDs particularly cardiovascular diseases, diabetes, cancers, as well as chronic obstructive pulmonary diseases are becoming increasingly important causes of morbidity and mortality in the Ugandan population. NCDs were estimated to account for 33% of all deaths in Uganda and 10% of them were due to cardiovascular diseases (WHO, 2018). The prevalence of cardiovascular diseases is increasing rapidly in Sub-Saharan Africa. The current prevalence in many developing countries, particularly in urban areas, is already as high as that seen in developed countries (Cappuccio & Miller, 2016). A multicenter prospective cohort study of 1,006 patients with acute heart failure in a Sub-Saharan Africa Survey showed that 814 patients had ECGs readings among which 97.7% showed abnormalities (Dzudie et al., 2014).

A study done at Uganda Heart Institute on cardiac arrhythmias and underlying cardiac conditions in patients attending the Heart Clinic revealed that a total number of 95 patients had one or more arrhythmias with a prevalence of 37.1%. The most common arrhythmias were those of sinus origin (atrial fibrillation) followed by conduction blocks (Buenza, 2001). No study on heart failure and electrocardiographic abnormalities has been done at Kampala International University Teaching Hospital (Ishaka) despite being one of the main Referral and

Teaching Hospitals in Western Uganda; therefore this study focused on the prevalence and the factors associated with ECG abnormalities among heart failure patients at Kampala International University Teaching Hospital in Uganda.

1.2 Statement of the Problem

The normal human heart undergoes cycles of depolarization and repolarization as it contracts to pump oxygenated blood to the body and relaxes to receive deoxygenated blood from the body. The electrical changes that occur during depolarization and repolarization are recordable on the body surface as electrocardiogram (ECG). A heart that is unable to adequately satisfy the blood supply demands of the body is describes as a heart in failure. The electrical activities of a heart in failure produce abnormal ECGs.

The abnormal ECGs generated by a heart in failure are influenced by sociodemographic and behavioral factors, medical factors and the comorbidities present in patients. High prevalence of ECG abnormalities among heart failure patients has been reported (97.7%) in 9 sub-Saharan African countries (Dzudie et al., 2014). The reported abnormalities include, but not limited to LVH, RBBB, LBBB, complete heart block and arrhythmias.

The prevalence and the associated factors varies among different populations. Globally, human communities are not homogenous. Data on the prevalence, ECG pattern and factors associated with ECG abnormalities among heart failure patients who receive clinical care at KIU-TH are useful in guiding their management. In view of the fact that all communities are not homogenous and data on ECG abnormalities among heart failure patients are yet to be documented and published in this community, there is need to determine the prevalence, the ECG pattern and factors associated with ECG abnormalities among heart failure patients who received clinical care at KIU-TH.

1.3 Study objectives

1.3.1 General objective

The main objective of this study was to determine the prevalence and factors associated with electrocardiographic abnormalities among heart failure patients at Kampala International University-Teaching Hospital, Ishaka, Uganda.

1.3.2 Specific objectives

1. To determine the prevalence of ECG abnormalities among heart failure patients at KIU-TH.
2. To determine the ECG pattern among heart failure patients at KIU-TH.
3. To establish the relationship between patient factors and ECG abnormalities among heart failure patients at KIU-TH.

1.4 Research questions

1. What is the prevalence of ECG abnormalities among heart failure patients at KIU-TH?
2. What is the ECG pattern among heart failure patients at KIU-TH?
3. What is the relationship between patient factors and ECG abnormalities among heart failure patients at KIU-TH?

1.5 Justification for the study

The ECG is a very helpful investigation in the management of patients with heart failure. It is useful for diagnosing the etiology and aggravating factors of heart failure, especially in acute exacerbation states (Vinit & Jayesh, 2016). Electrocardiography services are not offered in the routine care of patients with heart failure in many Sub-Sahara Africa countries because of its limited availability and high cost (Batte et al., 2016). Uganda is not spared from this situation. The knowledge of the pattern and prevalence of ECG abnormalities among heart failure patients can guide the formulation of appropriate recommendations that will improve the clinical management of heart failure patients through early diagnosis of cardiac abnormalities. This in turn can lead to a reduction in the overall morbidity and mortality due to heart failure. This study was therefore designed to help establish the prevalence of ECG abnormalities, the ECG pattern and factors associated with those abnormalities among heart failure patients at Kampala International University Teaching Hospital.

1.6 Significance of the study

The study was of benefit to the following:

1.6.1 Respondents

During the study, heart failure patients benefited from cost-free electrocardiography. The ECG findings were used to appropriately guide their management through correct diagnosis of etiology, early detection of complications, institution of appropriate medications and prevention of further complications.

1.6.2 Community

The resultant proper management of patients with heart failure from ECG findings reduced manpower loss due to hospitalization of decompensated heart failure. In addition, their caregivers had time to participate in useful economic ventures rather than staying to nurse their hospitalized relatives. These benefitted the community through reduction of morbidity and mortality related to heart failure and reduced loss of human capital.

1.6.3 Clinicians

The study drew attention of clinicians to the practical use of ECG in management of heart failure patients through prompt detection of etiology, aggravating factors and appropriate medical care. This study also stimulated clinicians to use electrocardiogram as a routine tool in the management of heart failure patients.

1.6.4 Contribution to science

This study described the burden of ECG abnormalities in terms of prevalence and established the factors associated with these abnormalities at KIU-TH. The research findings serve as a benchmark for future studies on the use of ECG in clinical practice. The findings are also expected to stimulate further research relevant to the reduction of morbidity and mortality related to heart failure. The findings also added to the pool of existing knowledge on the role of ECG in management heart failure patients.

1.6.5 Healthcare training institutions

The findings of this research are hoped to have created more awareness on the use of ECG and lead to further emphasis on ECG training in healthcare training institutions. This will stimulate devotion of more time for healthcare trainees to be trained in proper use and interpretation of ECG findings in their existing curricular.

1.6.6 Contribution to policy

The findings from this research will help in the formulation of policies which will help to reduce the burden related to late diagnosis of complications of heart failure and possibly stimulate more doctors to consider specializing in cardiology. It is also expected that the findings will inform policy makers in healthcare training institutions to ensure that ample time is created for ECG training to promote proper use and interpretation of ECG in their existing curricular.

1.6.7 Researcher

This research improved the knowledge of the researcher on ECG use in clinical practice. The study serves as partial fulfillment of requirements for the award of the degree of Master of Medicine in Internal Medicine of Kampala International University, Uganda.

1.7 Scope of study

1.7.1 Content scope

This study focused on patients who received care at the Internal Medicine Department (Medical Out-Patients Department, Medical Ward and Private Ward) of KIU-TH, with a confirmed diagnosis of heart failure based on the operational definitions. This study focused on the prevalence of ECG abnormalities, types of ECG abnormalities and factors associated with abnormal ECGs among HF patients. Structured investigator-administered questionnaires were used to gather information.

1.7.2 Geographical scope

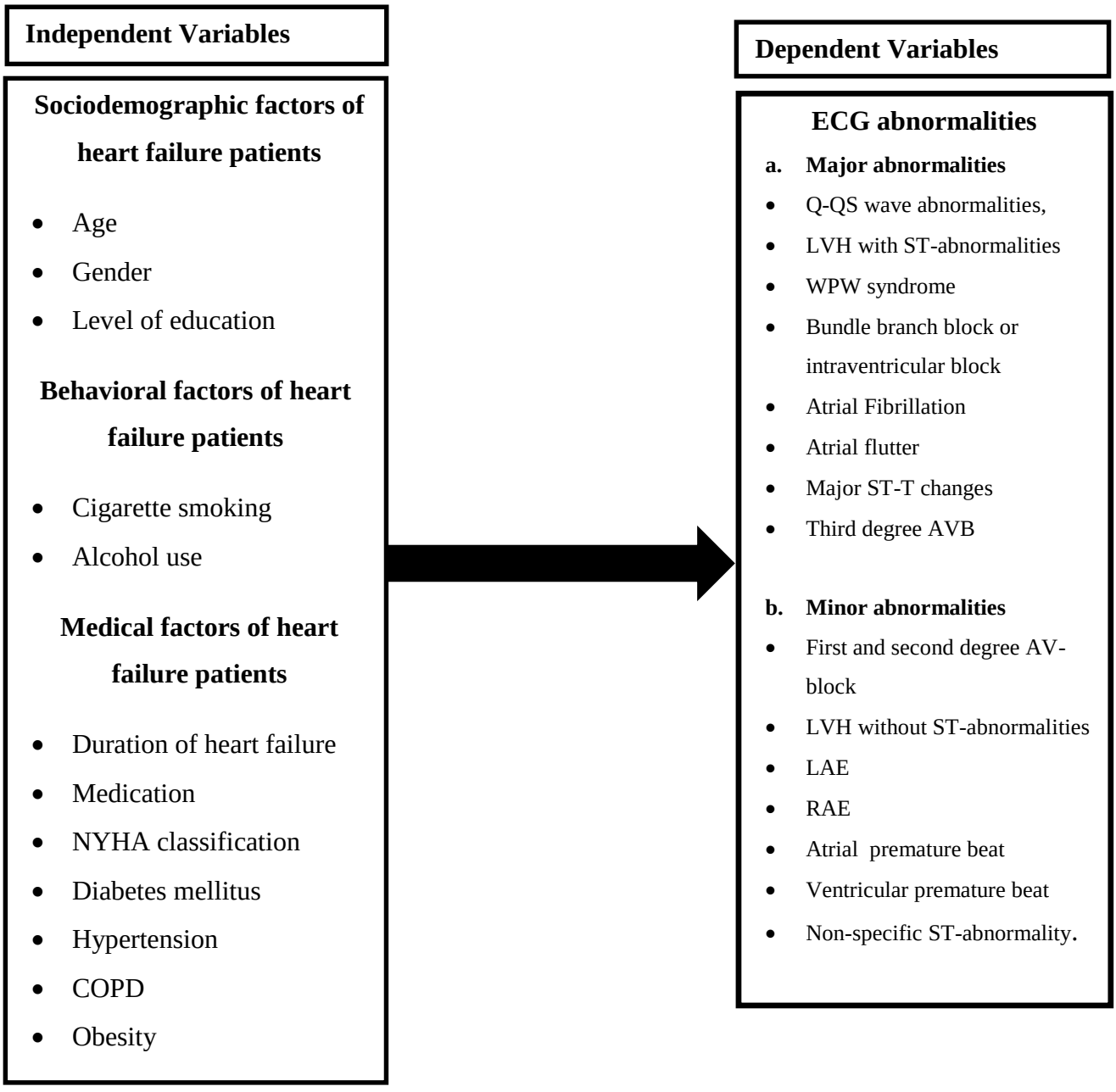
The study was conducted at KIU-TH which serves clients from the areas of Bushenyi, Sheema, Rubirizi, Mitooma and other neighboring districts in western Uganda. Kampala International University Teaching Hospital is located in Ishaka town. Ishaka is a municipality in Bushenyi District (Appendix C) and is found in Igara County, Bushenyi District, approximately 62 kilometers (39 miles) West of Mbarara Town in western Uganda. Some patients come from other parts of Uganda, Democratic Republic of Congo, Rwanda and Tanzania. In addition, the institution serves staff members and their families from other countries within and outside the African continent.

1.7.3 Time scope

The study was conducted over a period of three months, from January to March 2020. On average, the Internal Medicine Department received approximately 50 heart failure patients monthly. Therefore, a period of three months was adequate to obtain the desired sample size for this study.

1.8 Conceptual framework

Figure 1: Conceptual framework



1.8.1 Explanation of conceptual framework

The conceptual framework (figure 1) depicts the model used while studying electrocardiographic abnormalities, the ECG pattern and the associated factors among heart failure patients. The independent variables on the left side influence the dependent variables on the right in an integrated manner. The sociodemographic variables such age, gender and level of education can interdependently induce ECG abnormalities. Ageing can directly affect the normal function of heart and other organ. However, gender alone does not influence the change on the cardiac activity as shown in the previous literature, but when gender is associated with ageing the change in the electrical activities of the heart occurs. Level of education has been known to influence people's risk of developing cardiovascular disease. Lower level of education in heart failure patients is associated with high levels of anxiety, limited physical functioning and an increased risk of hospitalization (Barbareschi, Sanderman, Leegte, Van Veldhuisen & Jaarsma, 2011; Ponikowski et al., 2016).

The behavioral variables can independently influence the occurrence of ECG abnormalities among HF patients. Exposure to nicotine and carbon monoxide induced arteriosclerotic changed of coronary artery which can lead to coronary artery diseases and impaired the electrical activities of the heart. Alcohol consumption causes ECG changes (Venkatesh, 2011). Evidence reveals that chronic consumption of alcohol can impaired the contractile forces of heart. The medical factors can induce ECG abnormalities independently or in an integrated manner. Chronic Heart failure (recurrence decompensation or NYHA class III and IV) patients may have ECG abnormalities compared to patients with onset HF. ECG abnormalities are among the side-effect of some HF medications such as beta blockers, digoxin, etc. The commonest comorbidities found in previous literature has showed that hypertension, diabetes mellitus, COPD and obesity are independently associated with ECG abnormalities.

Macroangiopathies are the complication of hypertension and DM. When they involved the coronary artery they induced CAD and ECG abnormalities can occur. Chronic Obstructive Pulmonary Disease caused right heart failure with pulmonary hypertension and the commonest ECG abnormalities associated with COPD is right bundle branch block. Obesity can induce alterations in cardiac morphology and various ECG abnormalities can be observed.

Chapter Two

Literature Review

2.0 Introduction

This chapter discusses the relevant literature related to the prevalence of ECG abnormalities, the ECG pattern and factors associated with ECG abnormalities among heart failure patients. It particularly focuses on the proportion, factors and comorbidities associated with ECG abnormalities among heart failure patients. These are considered as the pillars of the study. The literature review is guided by the objectives of the study and ended with a conclusion.

2.1 Prevalence of ECG Abnormalities among Heart Failure Patients

Daniel (2009) defines prevalence as a statistical concept referring to the number of cases (new and old) of a disease that are present in a particular population at a given time.

In Canada, Gouda et al. (2016) did a cohort study to describe the ECG findings in patients with acute heart failure and to determine the features that are related to clinical outcomes after adjustment for other key variables. Using a Cox's proportional hazards model they found that among 816 patients with acute heart failure 82.5% had abnormal ECGs and only 17.5% of them had normal ECGs. Baris et al. (2015) in Switzerland conducted a prospective cohort study in 2,915 respondents aged 70 to 79 years without preexisting heart failure and used the Cox models to make the association between ECG abnormalities and incident heart failure. They found a prevalence of ECG abnormalities of 34.3%.

In a study conducted among older adults population in United States of America by Auer et al. (2012) which aimed to determine wheter baseline ECG abnormalities or development of new and persitent ECG abnormalities are associated with increased coronary heart disease. Using cox proportional hazards regression models, they found that 13% of the study respondents had minor ECG abnormalities and 23% had major abnormalities. Vinit and Jayesh (2016) in India did a retrospective study where 400 patients were randomnly selected in the study and the analysis was done using the measure of central tendency (mean) and the measure of spread (standard deviation), the result showed a prevalence of 92% of ECG abnormalities among patients with heart failure and 8% of those patients had normal ECG readings.

A Survey in Sub-Sahara Africa on Heart Failure, a multicenter prospective cohort study of 1006 acute heart failure patients, where regression models were used to relate baseline ECG

findings to all-cause mortality and readmission during a 6-month follow-up period revealed that 97.7% had abnormal ECGs (Dzudie et al., 2014). Another cross-sectional study was conducted in Nigeria by Karaye and Sani (2008) which aimed to determine and compare the ECG abnormalities among heart failure patients presenting with preserved left ventricle ejection fraction and those with reduced left ventricle ejection fraction. They found that 98.2% of the respondents had abnormal ECGs. A cross-sectional study conducted among HF patients in Kumasi (Ghana) showed that the ECGs were abnormal in 93% of respondents (Owusu et al., 2014). Buenza (2001) in Uganda carried out a cross sectional descriptive study to determine the prevalence and type of cardiac arrhythmias and the type of underlying cardiac conditions among patients attending the Uganda Heart Institute. The respondents were enrolled consecutively and the results revealed that the prevalence of arrhythmias among heart failure patients was 37.1%.

The above studies showed a high prevalence of ECG abnormalities and most of them were multicenter and the populations involved in the study mainly had acute heart failure. This current study focused on the prevalence of ECG abnormalities in a finite population based on a hospital setting and it involved both patients with acute and chronic heart failure. However, the above literature raise contextual and methodological gaps. Contextually, most of the studies were carried out in heart institute where there is proper follow-up of heart failure patients (e.g. Buenza 2001; Karaye & Sani 2008; Dzudie et al. 2014; Gouda et al. 2016 and Vinit & Jayesh 2016). At methodological level, in some of the studies the respondents were selected randomly such as Vinit and Jayesh (2016) and the inclusion criteria in all the above literature focused only on patients with acute heart failure. In addition, none of them was conducted in Western Uganda and the only which was conducted in Uganda focused only on arrhythmias among heart failure patients. To address the above gaps, this study was conducted in Ishaka (Western-Uganda), to determine the prevalence of heart failure patients (both acute and chronic) with abnormal ECG, the pattern of the ECG and factors associated with the abnormalities.

2.2 ECG pattern among heart failure patients

Heart failure can have multiple and diverse presentations on ECG from normal to abnormal ECG pattern. Karaya and Sani (2008) found that the ECG in HF patients was almost always abnormal, and most of those patients had at least three abnormalities. The diagnosis of the normal ECG is made by excluding any recognized abnormality as described in appendix A.

ECG abnormalities can be defined by using the traditional Minnesota code criteria or the Novacode ECG classification system which provides a comprehensive hierarchical set of criteria for ECG abnormalities and for clinically significant serial ECG changes. The Novacode classification is used to grade Q wave and ischemic abnormalities in order to achieve stable classification of myocardial infarctions by minimizing false classification due to clinically insignificant ECG variations (Rautaharju et al., 1998). The Minnesota code is a classification system for the electrocardiogram that utilizes a defined set of measurement rules to assign specific numerical codes according to severity of the ECG findings. In order to be able to provide a complete diagnostic result with the Minnesota code, it is required to have a 12-lead ECG and the corresponding various parameters of the ECG, approximately 55 parameters for each lead which can pose significant problems in practice and that constitute the weakness of the Minnesota code (Sram & Takacs, 2015).

In this study the classification according to Auer et al. (2012) was used. They classify abnormalities as follow: criteria for minor ECG abnormalities include the presence of first and second degree AV-block, Left Ventricular Hypertrophy (LVH) without ST-abnormalities, left atrial enlargement, atrial premature beat, ventricular premature beat and non-specific ST-abnormality while major abnormalities include Q-QS wave abnormalities, LVH with ST-abnormalities, Wolff-Parkinson-White syndrome, bundle branch block or intraventricular block, atrial fibrillation or atrial flutter, major ST-T changes and Third degree AV-block.

According to Vinit and Jayesh (2016) in India, the main ECG abnormalities were left ventricular hypertrophy (42.9%), left axis deviation (39.8%), left bundle branch block (19.4%), and left atrial enlargement (25.80%). They found that arrhythmias included ventricular extrasystoles (11.8%), atrial fibrillation (9.1%), complete heart block (5.7), and ventricular tachycardia (3.9%). Studies involving chronic HF patients identified that a widened QRS, left bundle branch block (LBBB), a prolonged PR interval and an increased heart rate were all associated with poorer long-term outcomes. Also, ECGs with any abnormality were found to be associated with poorer outcomes (Gouda et al., 2016). Karaye and Sani (2008) found in their study that left ventricular hypertrophy was the commonest ECG abnormality in 77.5% of heart failure patients with reduced Left Ventricular Ejection Fraction (LVEF) and 50% of patients with preserved LVEF. The most common arrhythmia was atrial fibrillation which was found among 14.1% of patients with reduced LVEF and 9.1% with preserved LVEF. In Ghana,

Owusu et al. (2014) found in their study that the main ECG abnormalities were LVH (43.7%), left axis deviation (39.6%), LBBB (19.2%) and left atria enlargement (25.6%).

Dzudie et al. (2014), in the Sub-Saharan Africa Survey of Heart Failure found that the commonst ECG abnormalities were LVH (30.6%), atrial fibrillation (23.6%), Non-Specific ST-T changes (23.7%), LBBB (8.1%) and RBBB (5.0%). They also found that the wideness of the QRS, QT duration, RBBB and Ischemic changes were not associated with increased ventricular rate, death or absence of sinus rhythm, the presence of sinus rhythm was associated with low risk of complications. The commonest ECG abnormalities found in an observational retrospective study conducted by Santos et al. (2018) which aimed to analyze the prevalence of self-reported comorbidities and electrocardiographic abnormalities according to age and sex among Brazilian primary care patients were nonspecific ventricular repolarization abnormalities and complete LBBB. Their findings also revealed that atrial fibrillation and flutter, premature beats, intraventricular blocks, complete RBBB and left ventricular hypertrophy were more frequent among men.

Almost all the above studies found similar types of ECG abnormalities. This could be due to the anatomy and physiology of the heart which are the same for all human being and when the heart is failing the consequences are the same despite the origin of the patient. The conceptual gap emerged from Santos et al. (2018) research where they focused their study on ECG abnormalities according to age and sex. This study, focused on ECG pattern among other socio-demographic factors, behavioral factors and medical factors among heart failure patients.

2.3 Relationship between patient factors and ECG Abnormalities among heart failure patients

Factors associated with ECG abnormalities are factors in individuals that contribute to abnormalities of ECG. For this study, these factors were subdivided into sociodemographic, behavioral and medical factors. Bacharova et al. (2015) defines socio-demographic factors as group related characteristics defined by social and demographic characteristics which include age, race, ethnicity, religion, language, education level, occupation and wealth. Behavioral factors are stemming from human behavior, they might be due to personality, the situation, or are a reaction to the environment. According to Valderas et al. (2009), medical factors are defined as the patient's condition, prognosis, relationship with the treatment team and recommended type of treatment. Socio-demographic, behavioral variables and medical factors

(e.g. medication, duration of heart failure, obesity, diabetes mellitus, hypertriglyceridemia and hypertension) can be associated with ECG abnormalities (Auer et al., 2012).

2.3.1 Age

The prevalence of electrocardiographic abnormalities varies with age (Santos, Ribeiro, Andrade & Marcolino, 2018). Previous studies showed increased prevalence of ECG abnormalities among ageing heart failure patients. A population-based study of 2,192 white and black adults aged 70 to 79 years without known cardiovascular disease were conducted in United States of America by Auer et al. (2012) to determine whether baseline ECG abnormalities or development of new and persistent ECG abnormalities were associated with increased coronary heart disease and they used Cox proportional hazards regression models for data anlysisis. They found that the mean age of study respondents with ECG abnormalities was 73.5 (±2.8) years. Clark et al. (2008) in United Kingdom conducted a cohort study of patients with confirmed diagnosis of left ventricular systolic dysfunction. The study aim was to describe the prevalence and incidence of LBBB in a representative sample of ambulatory patients with chronic heart failure, together with an analysis of predictors of the development of LBBB and its association with prognosis. They found that the mean age was 70.5 (±10.4) and the age older than 72.2 years was more associated with ECG abnormalities with an HR of 1.05, 95% CI, 1.04-1.07, $p<0.0001$.

Baris et al. (2015) in Switzerland found that the mean age of patients with abnormal ECG was 73.6 years. Another study by Gouda et al. (2016) revealed that the median age was 77 years compared to Dzudie et al. (2014) who found a mean age of 52.0 (±18.4) years among HF patients with abnormal ECG. Bussink et al. (2012) in Denmark published a cohort study which followed 18,441 respondents free from previous myocardial infarction, chronic heart failure and LBBB with the aim of describing the prevalence of right bundle branch block and incomplete RBBB in the general population, to determine risk factors and to establish the prognostic implications of incidentally found RBBB and incomplete RBBB. The results showed a prevalence of 2.3% of RBBB and it was associated with increased age. Santos et al. (2018) got the mean age of 51 (±19) years among patients with ECG abnormalities. In Moroccan center-based study conducted by Bouquata et al. (2015) which aimed to determine the in-hospital outcome of congestive heart failure patients with LBBB versus those without, they found that the mean age of HF patients with LBBB was 62.27 (±7.26) years. In Nigeria,

Karaye and Sani (2008) found that the mean age was 42.82 (±18.31) years among HF patients with ECG abnormalities.

Ageing can directely affect the normal function of the heart and other organs. That can explain the high prevalence of ECG abnormalities among older patients. The above literature raises contextual and conceptual gaps. Contextually, all the studies were carried out in developed countries where life expectancy is higher compared to developing countries. At conceptual level, most of the studies focused on one type of ECG abnormalities like bundle branch block (e.g. Clark, Goode & Cleland 2008; Bussink et al 2012). Also, the population involved in some of the studies were not HF patients (e.g. Auer et al 2012; Bussink et al 2012). These gaps prompted focusing this study on determining factors associated with ECG abnormalities among HF patients in our context, with particular interest on age factor.

2.3.2 Gender

The prevalence of electrocardiographic abnormalities varies with sex (Santos et al., 2018). Auer et al. (2012) during their study which aimed to determine whether baseline ECG abnormalities or development of new and persistent ECG abnormalities were associated with increased coronary heart disease found that 55% of respondents were women. Gouda et al. (2016) during their cohort study which aimed to describe the ECG findings in patients with acute heart failure and to determine the features that were related to clinical outcomes after adjustment for other key variables found that male gender was predominat and represented 53% of the study respondents. Bussink et al. (2012) in Denmark in their cohort study found that the prevalence of RBBB was higher in men than in women. In their study, Clark et al. (2008) found that the male gender was prevalent among patients with LBBB and it represnted 74% of the study respondents.

A prospective observational study was conducted by Bouquata et al. (2015) in Morocco to determine the in-hospital outcome of congestive HF patients with LBBB versus those without. The results showed that the male gender was dominant and represented 82.7% of HF patients with abnormal ECG. Dzudie et al. (2014) found during their sub-saharan survey that the female gender was predominant, being 51% of the study respondents. In Nigeria, Karayi and Sani (2008) found that 64.3% of study respondents with ECG abnormalities were females.

Gender does not influence the change on the cardiac activity as shown by some studies above where women were more prevalent than men depending on the type of abnormality. The above literature raises similar gaps like for age. These gaps prompted focusing this study on

determining factors (especially gender) associated with the ECG abnormalities among HF patients in our context.

2.3.3 Level of education

According to the European Society of Cardiology, education level has been known to influence the risk of developing cardiovascular disease. Researchers looked at 6,318 older adults in three Atlanta-based hospitals who underwent a procedure to diagnose and assess problems in coronary arteries and each participant was asked about his/her highest level of education. They found that those with lower educational attainment appeared to have a higher risk of heart attack, dying from a cardiovascular event and overall death (Ponikowski et al., 2016).

Lower education in heart failure patients is associated with high levels of anxiety, limited physical functioning and an increased risk of hospitalization (Barbareschi et al., 2011). The same authors found during their randomized controlled trial which aimed to examine whether educational level is related to longitudinal differences in quality of life in HF patients that 32% of the patients had very low level of education, 24% had low level of education and those patients with low level of education had the worst physical and functional conditions. However, they found also that highly educated patients improve more than the other patients in functional limitations related to emotional problems over time.

2.3.4 Smoking and ECG abnormalities

Auer et al. (2012), reported that ECG abnormalities were associated with smoking among HF patients. Gouda et al. (2016) who conducted their study in Canada among heart failure patients found that ECG abnormalities were associated with smoking. They found that 12.3% of HF patients with abnormal ECG were smokers. In Brazil, Santos et al. (2018) found that smoking was associated with ECG abnormalities. Bouquata et al. (2015) in a Moroccan center-based study found that smoking was associated with LBBB and 54.5% of study respondents were smokers. In sub-Sahara Africa, Dzudie et al. (2014) found that 8.7% of HF patients with ECG abnormalities were smokers.

Exposure to nicotine and carbon monoxide induce arteriosclerotic changes in coronary artery which can lead to coronary artery diseases and impaired electrical activities of the heart. This in turn led to electrocardiographic abnormalities. The above literature showed that smoking is associated with ECG abnormalities. The contextual gap is that most of those studies were conducted outside Uganda except for Dzudie et al. (2014). In view if the fact that all

communities are not homogenous, this study focused on determining the factors associated with ECG abnormalities among HF patients in our context, with particular interest on smoking.

2.3.5 Alcohol and ECG abnormalities

Alcohol consumption causes ECG changes (Venkatesh, 2011). Evidence reveals that chronic consumption of alcohol can impair the contractile forces of the heart and may contribute to the occurrence of alcoholic cardiomyopathy which can progress to congestive heart failure. Results also showed that chronic alcohol consumption in the absence of heart disease may alter ECG (Almaz, Andualem, Amare & Tadessie, 2017). The cross-sectional study of Almaz et al. (2017) which aimed to study the effect of alcohol on ECG in Ethiopia showed that the prevalence of alcohol consumption was 25.3% and there was a significant statistical association between alcohol consumption and ECG alteration.

Raheja et al. (2018) conducted a Systematic Review and Meta-Analysis (PRISMA) guidelines to highlight best evidence regarding ECG changes associated with acute alcohol intoxication. They found that 63.8% respondents had P-wave prolongation, 56% had QTc prolongation, 13.5% developed T-wave abnormalities, 7% had QRS complex prolongation and 2.12% had ST segment depression. The contextual gap is that all these studies on ECG changes with acute or chronic alcohol intoxication were conducted outside Uganda. This study therefore focused on the association between use of alcohol and ECG abnormalities among HF patients in Ishaka, Uganda.

2.3.6 Duration of heart failure and ECG abnormalities

The European Society of Cardiology (ESC) defines acute HF as a rapid onset or worsening of symptoms and/or signs of HF and chronic HF or congestive HF as where the underlying cardiac dysfunction persists and the patients remain at risk of recurrent decompensation (Ponikowski et al., 2016). Previous studies on ECG abnormalities among HF patients focused on either they were in acute HF (Dzudie et al. (2014) in sub-Sahara Africa; Gouda et al. (2016) in Canada) or they were in chronic HF (Clark et al. (2008) in UK). Sadaka, Aboelela, Arab and Nawar (2013) conducted a cross-sectional study in Egypt which aimed to determine whether ECG gives prognostic and diagnostic values among patients with HF. They found that low ECG voltage is a marker of the severity of HF and is a risk factor for adverse outcomes in patients with systolic HF at 1 year. They also found that the mean duration of HF among respondents with abnormal ECG was 3.48 ± 2.72 years and the duration range from 3 months to 11 years.

Conceptual and contextual gaps emerged from the above literature. At the conceptual level, Dzudie et al. (2014) and Gouda et al. (2016) studied patients with only acute HF and Clark et al. (2008) focused only on chronic HF patients. Sadaka et al. (2013) studied the duration of HF among study respondent but the study was done outside Uganda. Contextually, most of the above literature were conducted outside Uganda. The study conducted in Uganda by Dzudie et al. (2014) selected only patients with acute HF. This focused on the association between the duration of HF and ECG abnormalities among HF patients in Ishaka, Uganda.

2.3.7 Medication

The study of Gouda et al. (2016) among HF patients in Canada did not show a statistically significant difference between patients who were on medication and those who were not. Many respondents with ECG abnormalities were on the following medications: angiotensin II receptor blocker 15.8%, beta-blockers 68%, angiotensine-converting enzyme inhibitors 48.7%, digoxin 11.3%, and diuretics 91%. In UK, Clark et al. (2008) found that 73.7 % of chronic heart failure with LBBB were on loop diuretic and there was a statistically significant association between LBBB and the use of loop diuretic ($p< 0.0001$). They found also that 77.9 % of respondents were on ACEIs/ARBs regimen and 54.0% were on betablockers. The research conducted by Bouquata et al. (2015) in Morocco among HF patients with LBBB showed that 66.4% of study respondents were on betablockers, 65.5% on ACEIs, 58.2 % of them were on lasix, and 11.8% on ARBs. The above findings may be coincidental, not direct relationship. This study considered the association between ECG abnormalities and use of medications, but not as causal or direct effects.

2.3.8 NYHA classification

The study of Clark et al. (2008) showed that the presence of LBBB was associated with an adverse outcome among HF patients in stage III and IV of the NYHA classification with an Hazard Ratio respectively of 2.72 (95% CI, 1.84-4.06, $P<0.0001$) and 4.03 (95% CI, 2.13-7.63, $p<0.0001$). Contextual and conceptual gaps emerged from the above literature. Contextually, the above study was conducted in UK and up to now it is the only study in our knowlegde which described and classified HF patients with abnormal ECG using the NYHA classification. In this study HF patients were classified using the NYHA classification at enrollement and the association between the NYHA classification and ECG abnormalities was studied.

2.3.9 Comorbidities Associated with ECG Abnormalities

The study of Auer et al. (2012), showed that ECG abnormalities were associated with underlying medical conditions such as diabetes mellitus (DM), hypertension, increase total and high-density lipoprotein cholesterol. A study conducted by Gouda et al. (2016) among HF patients Canada showed that ECG abnormalities were asscociated with comorbidities; Hypertension was present in 75.5% of patients, DM in 36.2% of patients, previous coronary artery disease in 53.3% and atrial fibrillation in 54.0% of patients. In UK, Clark et al. (2008) found that the most common commorbidities among respondents with LBBB were hypertension (35.5%), diabetes mellitus (19.5%) and COPD (10.6%). Bussink et al. (2012) found that RBBB was associated with increased rsik of myocardial infarction but was not associated with atrial fibrillation or Chronic Obstructive Pulmonary Diseases (COPD).

The study conducted in Brazil by Santos et al. (2018) revealed that hypertension was the most frequent comorbidity among patients with ECG abnormalities, followed by family history of coronary artery disease and diabetes mellitus. In Morocco, Bouquata et al. (2015) reported that the comorbidities among HF patients with LBBB were hypertension (40.9%), diabetes mellitus (40%), dyslipidemia (29.1%) and obesity (28.2%). The sub-Saharan Africa survey of heart failure showed that hypertension was associated with ECG abnormalities among heart failure patients (55.8% of respondents). It shows also that other common comorbidities were diabetes mellitus (10.5%), HIV (8.8%) and hyperlipidemia (8.6%).

In LMICs, the burden of cardiovascular disease is greater because of larger population sizes and widespread exposure to increasing levels of risk factors such as unhealthy diet, physical inactivity, obesity, tobacco use, DM, elevated blood pressure and abnormal blood lipids (WHO, 2011). The above studies revealed a sample gap; most respondents in the study conducted by Auer et al. (2012) were selected from the general population without any underlying history of HF or any known comorbidities. In our context, patients with acute and chronic heart failure were included in the study.

2.4 Conclusion

The previous studies discussed above showed the prevalence, ECG pattern and factors associated with ECG abnormalities among HF patients. In Uganda few studies have been conducted on ECG abnormalities among HF patients. Most of the studies discussed in this literature review showed that the prevalence of ECG abnormalities is high and many modifiable

factors are associated with those abnormalities. Therefore, when used in conjunction with other clinical variables, the ECG may be a useful tool in long-term risk stratification of patients.

Chapter Three

Methodology

3.0 Introduction

This chapter presents a detailed description of the research design, study population, sample size determination, sampling techniques, research instruments and methods used for data collection, entry, editing and analysis that enabled the research objectives to be met. Ethical considerations and study limitations are also discussed below.

3.1 Study Design

Research design is the "overall plan or strategy for conducting the research" (Oso & Onen, 2009). Survey design was adopted for this study. Here, samples of the target population were chosen for study, analysis and discovery of occurrences as they were. Survey design is suitable for this type of research that involves a special population of only people diagnosed to have heart failure. It is also ideal in this situation where factors including cost, rapid data collection and ability to understand a population from a part of it were considered. This study was conducted among heart failure patients at Kampala International University-Teaching Hospital, Ishaka, using descriptive cross-sectional hospital-based survey approach that employed quantitative data collection method. The main outcome included ECG abnormalities among heart failure patients receiving care at KIU-TH.

3.2 Study Site

The study was conducted at Kampala International University Teaching Hospital (KIU-TH) Ishaka, in the Department of Internal Medicine (In- and Out-Patients Department, Private and Semi-Private Wards and Accident and Emergency Department). The Medical Out-Patient Department (MOPD) is accessible to patients daily from Monday to Friday. Patients with heart failure are seen at MOPD or Accident and Emergency Department. When there is need for admission, they are admitted into Medical Ward, Private Ward or Semi-Private Ward. Heart failure patients can access the 12-lead ECG, chest X-Ray and other laboratory and radiological investigations within the hospital.

3.3 Study Area

This study was conducted at Kampala International University Teaching Hospital, Ishaka. The hospital serves clients mainly from Bushenyi, Sheema, Rubirizi and Mitooma Districts. Others

served include clients from neighboring Districts in western Uganda and people from outside Uganda. Kampala International University Teaching Hospital (KIU-TH) is located in Ishaka town. Ishaka is in Igara County, Bushenyi District, approximately 62 kilometers (39 miles) west of Mbarara Town in western Uganda.

3.4 Study Population

3.4.1 Target Population

The target population for this study were adult heart failure (HF) patients in Western Uganda. Adult HF patients are in different stages of the disease and live in different communities. Some HF patients are either undiagnosed or misdiagnosed at different places where people seek healthcare. The population of HF patients in this community is therefore very scattered and infinite.

3.4.2 Accessible Population

The accessible population used in this study consisted of adults who were correctly diagnosed to have HF using the Framingham's criteria. These patients received care at different healthcare facilities in the community.

3.4.3 Sample Population

The sample of the accessible population chosen for this study consisted of adult HF patients who received medical care at KIU-TH during the duration of the study and met the inclusion criteria for the study. This sample was chosen because clients report to KIU-TH for health care and the hospital has the medical staff members who can appropriately diagnose HF. In addition, facility for determining ECG and other necessary clinical investigations were readily available.

3.5 Selection Criteria

3.5.1 Inclusion Criteria

Criteria for being included in the study were being diagnosed to have HF, age of 12 years and above, attending clinical care at KIU-TH, Ishaka and giving written consent to participate in the study during the study period.

3.5.2 Exclusion Criteria

All patients were excluded from participation in the study if they had any overt mental disorders or were unable to withstand the interview, did not consent to participate or changed their mind

during the study. Respondents with known allergy to the gel used in the ECG procedure were excluded from the study.

3.6 Sample Size Determination

Sample size was calculated using a formula for single population proportion with correction for finite population (Daniel, 2009).

That is:

n = N*X / (X + N – 1) (Equation 1)

Where:

N= population size, estimated at 160 HF patients attending the Internal Medicine Department (Both MOPD, Inpatients Department and Private ward) at KIU-TH from January 2019 to March 2019 (Unpublished data).

X = $Z_{\alpha/2}^2$ *p*(1-p) / MOE^2,

$\mathbf{Z_{\alpha/2}}$ = critical value of the Normal distribution at α/2 for α of 0.05= 1.96,

p= proportion of ECG abnormalities among HF patients in Uganda (Mulago, Kampala): 37.1% (Buenza, 2001).

MOE= margin of error considered at 5%,

X = (1.96^2 x 0.371 x 0.629)/ 0.05^2 = 358

Substituting, n = 160*358 / (358 +160-1) = 111

To cater for attrition, an additional 10% was added to the sample size which gave a sample size of 122 heart failure patients.

3.7 Sampling Techniques

This study employed cluster, purposive and convenience sampling techniques. Cluster sampling was used to categorize places where adult HF patients are usually seen in groups. These places are healthcare units; hence each healthcare unit in Bushenyi District was categorized as cluster. The study focused on adult patients with HF. Adult HF patients receive healthcare from different healthcare facilities and each healthcare facility that provide such care in Bushenyi District was considered as a cluster where adult HF patients could readily be

seen. Cluster sampling technique divides a population into relatively smaller groups (clusters) and some of the clusters randomly selected as the sample. All members of the chosen cluster are studied. It is used to select groups rather than individual members where a sampling frame cannot be constructed. The technique was chosen because it saves time and money, and it is suitable if a sampling frame cannot be obtained. In this study, a sampling frame is not obtainable because not all adult HF patients attend healthcare facilities and some who attend are misdiagnosed by healthcare workers.

Purposive sampling technique was adopted for selecting the cluster sample. In purposive sampling, one consciously chose who to include in the sample. KIU-TH was chosen as the cluster for this study because it is the only tertiary healthcare facility in Bushenyi District. In addition, it provides services to HF patients who visit on their own volition and those who are referred from other lower healthcare units. KIU-TH has sufficient human resource for health and facilities for proper diagnosis of HF. This study focused on gathering information from HF patients only. Purposive sampling technique selects "typical" and useful cases only, it saves time and money. These factors guided the adoption of purposive sampling for selection of KIU-TH as a good cluster for this study.

The convenience sampling technique was adopted for selecting individual respondents in the chosen cluster. Convenience sampling technique consist of selecting, on first come first served basis, those who happen to be available. This sampling technique is used for pilot or exploratory studies and in infinite populations when it is not possible to determine the sampling frame. It collects data at the spur of the moment without rigidity of procedure. It takes advantage of those who happen to be there at the moment of unexpected events. Hence, the convenience sampling technique was chosen for this study where respondents were consecutively enrolled until the desired sample size was attained. Respondents were enrolled into the study as they were diagnosed at the hospital entry points (MOPD, Accident and Emergency Department). Those who were admitted, but missed at the entry points, were enrolled from the Medical, Private and Semi-Private Wards. Every patient who met the selection criteria was eligible to participate.

3.8 Data collection

3.8.1 Data Collection Instruments

a. Questionnaire

The study used questionnaires as the main tool for data collection (Appendices D & E). The choice of questionnaire as the main data collection tool was guided by the study objectives. The main aim of the study was to determine the clinical characteristics and factors associated with ECG abnormalities among HF patients. A questionnaire is a collection of items to which a respondent is expected to react to (Oso & Onen, 2009). It is used for collection of many information over a short period of time and it is suitable for studying large literate populations in limited time and where the required information can easily be described in writing. The questions contained in the questionnaire focused on study objectives that explored sociodemographic factors (age and gender); behavioral factors (smoking and alcohol use); medical factors (type of heart failure, medication and NYHA classification at enrollment) and comorbidities (Hypertension, diabetes mellitus, COPD and obesity) among adult HF patients.

b. Standard Weight scale

Electronic weighing scale with high precision strain gauge sensor system (Clikon model) was used for measuring the weight of each respondent. The weight was measured to the nearest 100 grams with each respondent not wearing heavy cloths and standing bare-footed on the weighing scale in an upright position. Electronic weighing scale with high precision strain gauge sensor system was used in order to obtain accurate weight measurements by completely eliminating errors that could arise from use of manual weighing scales. Such errors may arise from observer position and variability in gauge strain with repeated use over time.

c. Standard Height pole

Portable standard height pole mounted vertically against a wall was used for height measurement. Each respondent's height was measured with the respondent standing upright, backing the height pole and his/her buttocks touching the height pole/wall. Care was taken to ensure that the lateral angles of the respondent's eyes were at the same level with the middle of the pinna. The height was read off with the horizontal piece directly touching the vertex of each respondent's head. The portable standard height pole was chosen because it gives better results than other crude locally used methods. Its results are comparable with results generated from anywhere with similar tool.

d. Sphygmomanometer

Manual sphygmomanometer with appropriate cuff sizes wrapped around the arms for each patient was used for the measurement of respondents blood pressure.

e. Stethoscope

Stethoscope 3 M Littmann ® Classic II SE was used for the cardiovascular examination during data collection.

f. Pulse Oximeter

The blood oxygen saturation and the pulse rate of each respondent were taken by using a fingertip pulse oximeter model MP-1000C with a measurement range of 77% to 99%. It has the advantages of small size, low power consumption, easy operation and being easy to carry (https://tp-wireless.com/a/chanpinfangan/healthcare/2020/06113/548, consulted on 27/06/2020).

g. ECG Machine

The "DRE/True ECG Plus machine" was used as for determining the ECG in each respondent. It is an excellent cost-effective portable ECG machine with an internal storage upgrade up to 200 ECGs, card reader, SD card and a flash drive. The machine has automatic measurement and interpretation for adults and pediatrics (https://www.dremed.com/dre-true-ecgl-singnle-channel-ecgekg/id/1974, consulted on 7/12/2019).

3.8.2 Study procedures

Quantitative data were collected from 122 adult HF patients who received healthcare services at KIU-TH from January to March 2020 using pre-tested questionnaires. The data sets were collected by the principal investigator and four trained research assistants. The research assistants were trained on how to use the data collection tool and recruit prospective respondents to ensure that all eligible adult HF patients who received healthcare at KIU-TH during the study period were given equal opportunity to participate in the study. The procedure for recruiting respondents into the study is depicted in Figure 2.

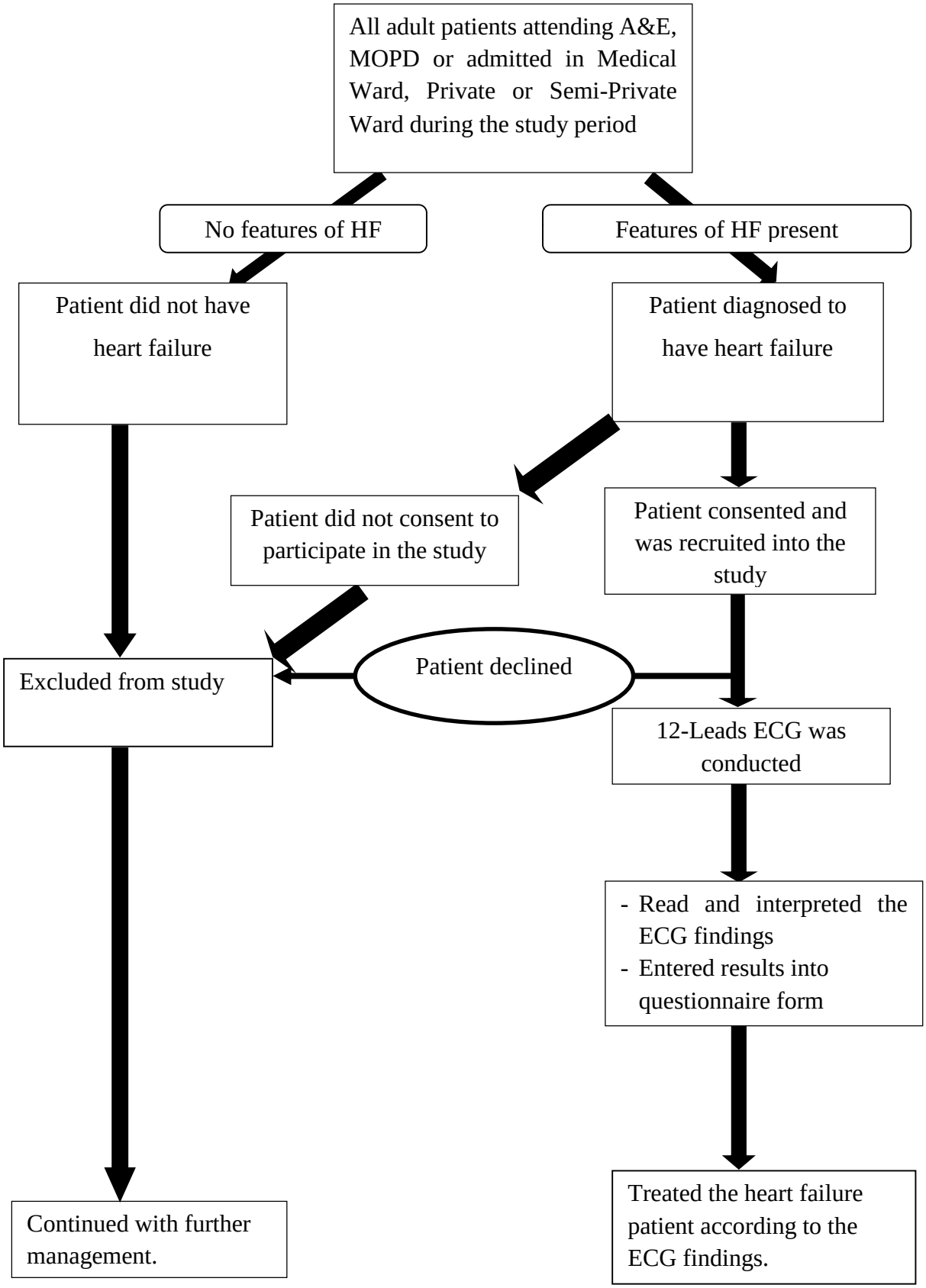


Figure 2: Patients flow chart showing sampling procedure and data collection

Each assistant was responsible for one study area described in the study site. The Framingham criteria for the diagnosis of HF were posted at each study area from where the respondents were recruited. All eligible respondents were given information about the study by the investigator/s in local language (Runyakole) or English. They were asked for clarifications about the different aspects of the study. After all aspects of the study were explained to the prospective respondents, those who consented to participate in the study were requested to give written consent and then enrolled into the study.

After obtaining consent, each respondent was interviewed by an investigator who administered the questionnaire in English or Runyakole according to the preference of the respondent in a face-to-face interview which allowed for clarification. Each respondent benefited from a full general examination, followed by ECG procedure which was conducted after the patient was properly prepared by an investigator at the ECG room, using a "DRE/True ECG Plus machine". The ECG procedure was done according to the Standard Operating Procedures (Appendix A). The ECG findings were printed and interpreted by the principal investigator. The supervisors of the study further verified the ECG findings.

3.9 Quality Control

Validity and reliability of the data collection instruments

Inclusion and exclusion criteria were strictly adhered to questionnaire. Pre-testing of the questionnaire was conducted among five adult HF patients at Ishaka-Adventist Hospital and the outcomes guided the adjustment of some questions. That contributed towards improvement of both validity and reliability of the final questionnaire used for this study. Validity was further strengthened by content and context experts who reviewed the instrument and confirmed that each construct was correctly measured. Experts in the field rated each items on the questionnaire on the scale of relevance: very relevant (4), quite relevant (3), somewhat relevant (2) and not relevant (1). Validity was determined using Content Validity Index (CVI).

CVI = items rated ≥ 3 by both judges/Total number of items in the questionnaire (equation 2).

The questions rated three and above were 42 out of 51; hence CVI = 42/51 = 0.8235 = 82%.

The data collectors ensured that the questionnaires were filled correctly by allowing enough time for the filling-in of questions. The questionnaires were in both English and local language for ease of communication. With the help of translators, unfamiliar technical terms were

explained to the respondents consistently. The ECG was done according to the SOP and the interpretation was done by the principal investigator. The supervisors verified interpretation of each ECG finding and final confirmation of the ECG findings was done by the cardiologist to ensure reliability.

3.10 Data processing, Analysis and Interpretation

Data from completed questionnaires were arranged, summarized and entered into the Microsoft Excel version 2010 and then exported to STATA version 14.2 for analysis. The baseline characteristics of respondents were analyzed using means for continuous variables with normal distribution and proportions for categorical variables.

Objective 1: The prevalence of ECG abnormalities among heart failure patients at KIU-TH was calculated as a ratio of number abnormal ECGs among HF patients at KIU-TH during the study period over the number of all heart failure patients seen at KIU-TH during the study period. It was expressed as a percentage with its corresponding 95% confidence interval. The prevalence was presented using a figure.

Objective 2: To determine the ECG pattern among HF patients at KIU-TH, ECG pattern was summarized as frequencies and percentages at a confidence interval of 95% and results were presented using table.

Objective 3: To assess the relation between patient factors (socio-demographic, behavioral and medical factors) and ECG abnormalities among HF patients at KIU-TH. ECG abnormalities among HF patients were the dependent variable (DV). Each component of the DV was coded "0= No and 1= Yes". The patient factors as presented in the conceptual framework were used as independent variables in the analysis. In Bivariate analysis, based on both Chi-square test and logistic regression, repeated analysis comparing each independent variable with electrocardiographic abnormalities was done. Crude odd ratio (cOR) with their corresponding 95% CI and p-values were reported. A variable was considered significant if it had a p-value < 0.05. All factors with a p-value < 0.05 or with a borderline p-value <0.1 and those which were biologically plausible with ECG abnormalities were considered in the multivariate analysis which was performed to control confounding. Assumptions for use of multiple logistic regression for example the absence of multi-collinearity among the independent variables, was exposed.

A manual backward stepwise selection method was used in establishing the final multivariate analysis model with factors that had an independent significant association with ECG abnormalities. In this method the variables that lose their meaningful association with ECG abnormalities after controlling for the effect of other variables in the model were excluded. The factors in the final multivariate model were then reported with their adjusted odd ratios and 95% CI and their respective p-values. A variable was considered significant in this analysis if it had a p-value < 0.05.

3.11Study limitations and delimitations

In this study, cardiac echography as one of the diagnostic tools used in HF patients was not used because it was not available at KIU-TH. To overcome this limitation the diagnosis of heart failure was made using Framingham criteria. Other limitations such as refusal to complete interview by eligible respondents, poorly completed questionnaires, unreadable or blurred ECG tracing were overcome by cancelling the questionnaires which were not properly completed and by repeating the ECGs that were unreadable.

3.12 Ethical considerations

3.12.1 Institutional Consent

Ethical approval was sought from the Research Ethics Committee (REC) of Kampala International University, Western Campus (Nr UG-REC-023/201937) (Appendix F). Permission to execute the study was sought from the Executive Director of Kampala International University Teaching Hospital, Ishaka (Appendix G).

3.12.2 Informed consent and respect for respondents

Voluntary recruitment was done and an informed consent was signed by each respondent. Informed consent from each respondent or from the guardian in the case of patients aged below 18 years was obtained after fully explaining the details of the study to them in English and local languages (Appendices H & I). Assent was also sought from minors after their legally authorized guardians or parents had consented (Appendices J & K). Respondents were free to withdraw from the study at any time without coercion or compromise of care they were entitled to.

3.12.3 Privacy and confidentiality

Identification of respondents was done by means of numerical codes to ensure anonymity and confidentiality. Details of respondents were kept under lock and key for privacy and confidentiality purposes throughout the course of research. There were no disclosure of information of respondents to the public without their consent.

3.12.4 Risks and benefits

Study respondents did not undergo any pain during ECG procedures. Physical examination did not induce pain or any form of harm. However any case of skin allergic reaction to gel used where the electrodes were placed was reported. The respondents benefited from a free of charge electrocardiography which helped to adjust their management.

3.12.5 Protection of the rights/integrity and well-being of the respondents

Respect of the rights of respondents and fair treatment was strictly adhered to, thus minimizing harm and discomfort to them.

3.12.6 Involvement of the community

The procedures involved in this study were not against the local community beliefs, traditions and culture. All respondents were given equal opportunity to participate in the study. Priority was not given in terms of tribe, interest group, social status, race or religion.

3.12.7 Incentives and reimbursement

No monetary or any other form of incentives were offered to respondents apart from the cost-free ECG procedure.

3.13 Dissemination

Internally the research paper will be disseminated as follows: copy to research supervisors, post graduate studies and research department and the university library. The results of this study will also be presented at scientific conferences. Externally the research paper will be submitted for publication in reputable publishing organization.

Chapter Four

Data Presentation, Analysis and Interpretation

4.0 Introduction

This study determined the prevalence of ECG abnormalities, the ECG pattern and factors associated with ECG abnormalities among HF patients at KIU-TH, Ishaka. This was in light of the fact that routine ECG monitoring is not done in many healthcare facilities (KIU-TH inclusive) and ECG is needed for early detection and prevention of complications and reduction of associated morbidity and mortality in cardiac diseases. The data collected were analyzed using Stata Version 14.2. This chapter presents the results of the data obtained, analyses and interpretations. Overall, 135 heart failure patients attended the study site during the study period. Among these, 122 (90.4%) completed the interview. Among the thirteen that could not complete the interview, seven were severely ill, two were referred to Uganda Heart Institute (UHI) and four declined to complete the interview.

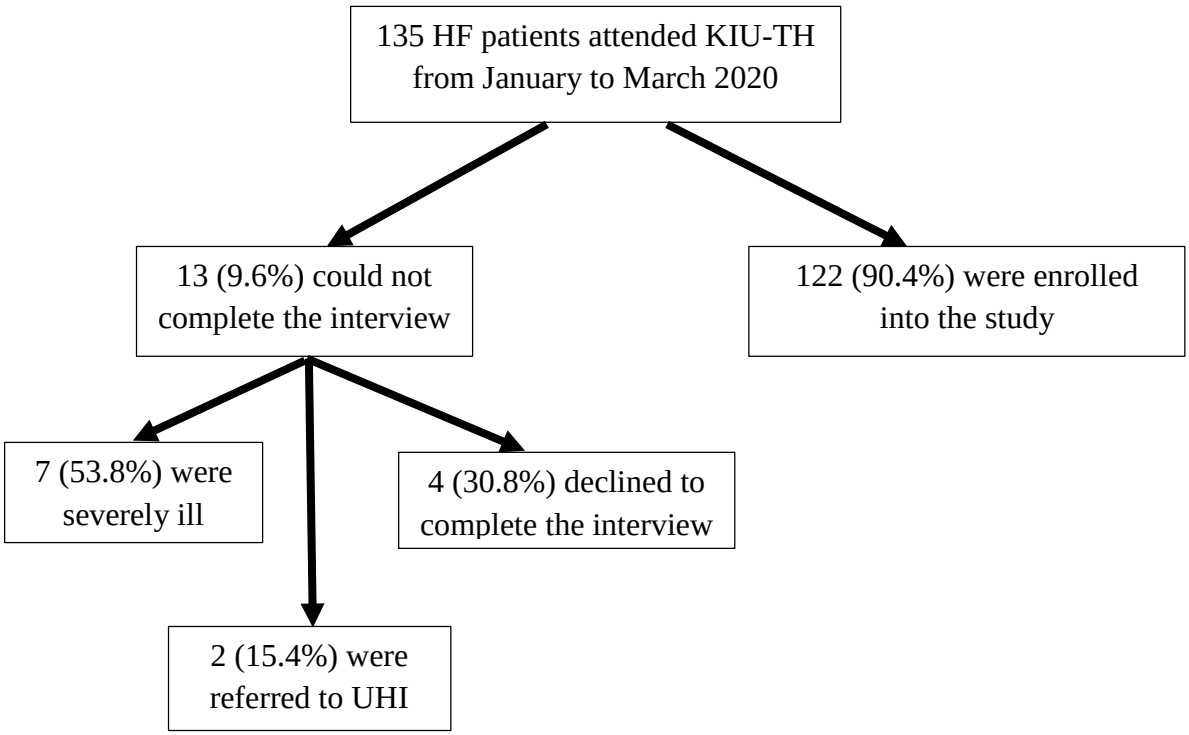


Figure 3. Profile of Study Respondents

4.1 Baseline Characteristics of Study Respondents

Table 1. Baseline Characteristics of Study Respondents (N = 122)

Variable	N = 122
Sociodemographic characteristics	
Female, n (%)	67 (54.9)
Age, mean (SD)	62.4 (±20)
Age categories (years), n (%)	
< 20	6 (4.9)
20-29	3 (2.5)
30-39	6 (4.9)
40-49	16 (13.1)
50-59	19 (15.6)
60-69	18 (14.7)
70-79	25 (20.5)
≥ 80	29 (23.8)
Greater Bushenyi, n (%)	107 (87.7)
Peasant farmer, n (%)	54 (44.3)
No formal education, n (%)	63 (51.7)
Behavioral characteristics	
Smoking history, n (%)	44 (36.1)
Alcohol use history, n (%)	
Never	85 (69.7)
Not harmful alcohol use	15 (12.3)
Hazardous drinking	22 (18.0)
Medical characteristics	
Duration of heart failure, n (%)	
< 1 year	67 (54.9)
> 1 year	55 (45.1)
Medication: ARBs / ACEIs, n (%)	56 (45.9)
Hypertension, n (%)	60 (49.2)
BMI, Mean (SD)	23.3 (±5.2)
BMI categories, n (%)	
Underweight	24 (19.7)
Normal	53 (43.4)
Overweight	28 (23.0)
Obesity	17 (13.9)
NYHA functional class, n (%)	
NYHA I-II	38 (31.1)
NYHA III-IV	84 (68.9)

The mean age of the respondents was 62.4 ± 20 years. Table 1 shows that the majority 67 (54.9%) of the respondents were females. The majority 107 (87.7%) were from great Bushenyi, 63 (51.6%) of them had no formal education; 44 (36.1%) were smokers and 37 (30.3 %) had history of alcohol use. About half of them were hypertensive 60 (49.2%) and 55 (45.1%) had a duration of HF of more than a year. The angiotensin receptor blockers or angiotensin converting enzyme inhibitors were the base of medication (45.9%). The majority 84 (68.9%) of respondents were decompensated and staged in NYHA class III and IV at enrollment while 45 (36.9%) of respondents were obese or overweight.

4.2 Prevalence of Electrocardiographic Abnormalities among Heart Failure patients at KIU-TH

The first objective of this study was to determine the prevalence of ECG abnormalities among HF patients at KIU-TH, Ishaka. To achieve this objective, cost free ECG was done for each respondent. The findings were interpreted by the principal investigator and confirmed by the study supervisors. The data obtained were analyzed under study question one "what is the prevalence of ECG abnormalities among HF patients at KIU-TH, Ishaka?" The results are presented in Figure 4.

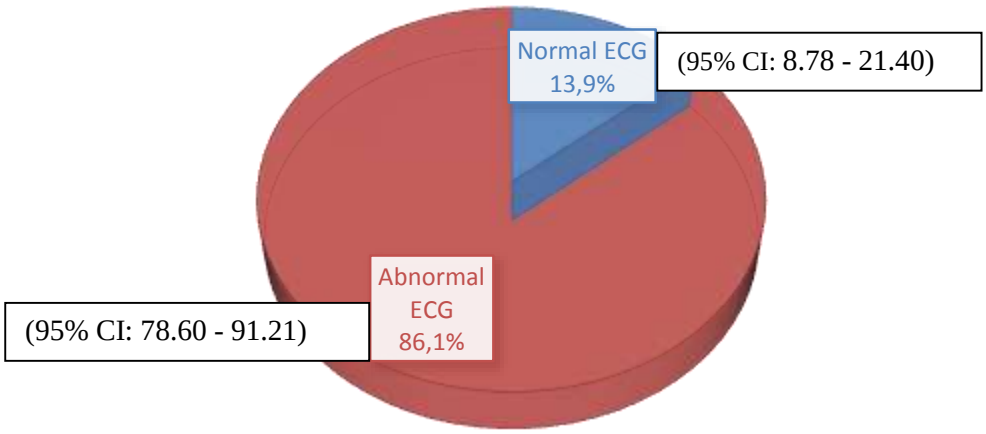


Figure 4. Prevalence of ECG Abnormalities among Study Respondents

The results show that the prevalence of ECG abnormalities among heart failure patients was 86.1% (95% CI 78.60 - 91.21). This shows that the majority 105 (86.1%) of HF patients that received healthcare at KIU-TH during the study period had abnormal ECGs.

4.3 Electrocardiographic Pattern of Heart Failure Patients at KIU-TH

The second objective of this study was to determine the ECG pattern of HF patients at KIU-TH, Ishaka. To achieve this objective, a cost free ECG was done for each respondent. The ECG findings were interpreted by the principal investigator and reviewed for confirmation the supervisors of the study. The data obtained were analyzed under the question "what is the ECG pattern among heart failure patients at KIU-TH, Ishaka?" The results are presented in Table 2.

Table 2. ECG Pattern of Heart Failure Patients at KIU-TH

ECG pattern	**N =122** **n (%)**
Normal ECG findings	17 (13.9)
Abnormal ECG findings	105 (86.1)
Major abnormalities only (n = 66)	
LVH with ST abnormalities	16 (15.2)
Left Bundle Branch Block	13 (12.4)
Right Bundle Branch Block	12 (11.4)
Other arrhythmia (SVT, VT, VP)	9 (8.6)
Atrial fibrillation	7 (6.7)
Isolated ischemic abnormalities	7 (6.7)
Third degree AV-Block	1 (0.9)
Q wave myocardial ischemia	1 (0.9)
Minor abnormalities only (n = 30)	
LVH without ST abnormalities	9 (8.6)
First and second degree AV-Block	6 (5.7)
Atrial premature beat	5 (4.8)
Right atrium enlargement	4 (3.8)
Non-specific ST-abnormalities	4 (3.8)
Ventricular premature beat	2 (1.9)
Major and minor abnormalities (n = 9)	
LVH with ST abnormalities + Left atrial enlargement	4 (3.8)
Atrial fibrillation + atrial premature beat	3 (2.9)
LVH with ST abnormalities + ventricular premature beat	2 (1.9)

SVT = Supra-Ventricular Tachycardia, VT = Ventricular Tachycardia, VP = Ventricular Preexcitation.

Table 2 describes the ECG pattern among HF patients. The majority 105 (83.1%) of study respondents had abnormal ECG and 17 (13.9%) had normal ECG findings. Nine (8.6%) respondents had both major and minor abnormalities, 66 (62.8%) respondents had only major abnormalities and 30 (28.6%) of them had only minor abnormalities. The main abnormalities found in the study were LVH with or without ST changes (23.8%), LBBB (12.4%) and RBBB (11.4%).

4.4 Factors Associated with ECG Abnormalities among Heart Failure patients at KIU-TH

The third objective of this study was to determine the relationship between patient factors (sociodemographic, behavioral and medical) and ECG abnormalities among HF patients at KIU-TH, Ishaka. To achieve this objective, patient factors were gathered during data collection and physical exam and a cost free ECG was done for each respondent. The data obtained were analyzed under the question "what is the relationship between patient factors and ECG abnormalities among HF patients at KIU-TH, Ishaka?" The results are presented in Tables 3 and 4.

4.4.1 Association between Sociodemographic, Behavioral, Medical Factors and ECG Abnormalities among Heart Failure Patients at KIU-TH, Ishaka

To test the association between sociodemographic, behavioral and medical factors of HF patients and ECG abnormalities, bivariate analysis (Crude Odds Ratio) and multivariate analysis (adjusted Odds Ratio) were done. Odd ratio is the most commonly used and suitable measure of association in cross-sectional studies. In cross-sectional studies, the odds ratio is also referred to as the prevalence odds ratio when prevalent cases are included. The results of the analyses are shown in Tables 3 and 4.

Table 3. Factors Associated with ECG Abnormalities among Heart Failure Patients at KIU-TH, Ishaka.

Variables	Abnormal Electrocardiogram			
	No	Yes		
	n (%)	n (%)	cOR (95% CI)	P-value
Female gender	9 (13.4)	58 (86.6)	1.1 (0.39 - 3.06)	0.860
Age (years) ≥ 50	7 (7.7)	84 (92.3)	5.7 (1.94 - 16.79)	**0.001**
Highest education level				0.398
No formal education	10 (15.9)	53 (84.1)	2.1 (0.36 – 12.49)	-
Primary	4 (12.5)	28 (87.5)	2.8 (0.40 – 19.60)	-
Secondary	1 (5.0)	19 (95.0)	7.6 (0.57 – 101.79)	-
Tertiary	2 (28.6)	5 (71.4)	1.0	-
Smoking	2 (4.6)	42 (95.4)	5.0 (1.09 – 23.00)	**0.015**
Alcohol (Hazardous drinking)	4 (18.2)	18 (81.8)	0.7 (0.21 – 2.56)	0.575
Duration of heart failure > 1 year	8 (14.5)	47 (85.5)	1.7 (0.44 – 6.41)	0.464
Medications				
Digoxin	1 (16.7)	5 (83.3)	0.8 (0.09 – 7.30)	0.846
Beta blockers	3 (16.7)	15 (83.3)	0.8 (0.20 – 3.03)	0.722
ARBs / ACEIs	4 (7.1)	52 (92.9)	3.2 (0.98 – 10.4)	**0.040**
Diuretics alone	7 (11.9)	52 (88.1)	1.4 (0.50 – 3.96)	0.521
Statins	2 (10.5)	17 (89.5)	1.4 (0.30 – 6.92)	0.630
Aspirin/Clopidogrel	4 (9.1)	40 (90.9)	2.0 (0.61 – 6.56)	0.232
Hypertension	3 (5.0)	57 (95.0)	5.5 (1.50 - 20.43)	**0.003**
COPD	1 (10.0)	9 (90.0)	1.5 (0.18 - 12.66)	0.696
Diabetes mellitus	4 (17.4)	19 (82.6)	0.7 (0.21 - 2.45)	0.603
HIV	1 (20.0)	4 (80.0)	0.6 (0.07 - 6.04)	0.703
BMI				0.143
Normal	9 (11.7)	68 (88.3)	1.0	-
Overweight	7 (25.0)	21 (75.0)	0.4 (0.13 – 1.20)	-
Obesity	1 (5.9)	16 (94.1)	2.1 (0.25 – 17.94)	
NYHA functional class				**< 0.001**
NYHA I-II	13 (34.2)	25 (65.8)	1.0	-
NYHA III-IV	4 (4.8)	80 (95.2)	10.4 (3.11 - 34.78)	-

P value is significant at < 0.05, cOR= crude Odds Ratio.

The results of bivariate analysis of sociodemographic, behavioral and medical characteristics of heart failure patients are shown in Table 3. Heart failure patients aged ≥ 50 years had about 6 times risk of having ECG abnormalities compared to those who were less than 50 years (cOR = 5.7, 95% CI: 1.94 - 16.79, p = 0.001). Respondents who were smokers were five times more likely to have abnormalities of ECG compared to those who had never smoked (cOR= 5.0, 95% CI: 1.09 – 23.00, p = 0.015). Heart failure patients on ARBS or ACEIs were three times at risk of developing ECG abnormalities compared to those on other medications (cOR = 3.2, 95% CI: 0.98-10.4, p = 0.040). Hypertensive respondents were five and half times more likely to have ECG abnormalities compared to those without hypertension (cOR = 5.5, 95% CI: 1.50 - 20.43, p = 0.003**)**. Respondents who were in NYHA functional classes III and IV were ten times more likely to have ECG abnormalities compared to those in class I and II (cOR=10.4, 95% CI: 3.11 - 34.78, p < 0.001).

4.4.2 Multivariate Analysis of Factors Associated with ECG Abnormalities

Table 4. Multivariate Logistic Regression Analysis of Factors Associated with Electrocardiographic Abnormalities among Heart Failure Patients

Variables	aOR (95% CI)	P-value
Female gender	0.7 (0.10 – 5.58)	0.786
Age ≥ 50 years	23.1 (1.81 - 294.33)	**0.016**
Smoking	23.6 (1.19 – 465.86)	**0.038**
Non-Hazardous alcohol use	2.3 (0.17 – 32.75)	0.525
Hazardous alcohol use	0.05 (0.00 – 1.05)	0.054
ARBS/ACEIs	3.9 (0.48 – 31.92)	0.200
Hypertension	11.9 (1.05 – 135.65)	**0.046**
Diabetes Mellitus	1.5 (0.14 – 15.92)	0.745
COPD	0.05 (0.00 – 3.55)	0.173
Overweight	0.7 (0.06 – 8.32)	0.795
Obesity	0.6 (0.02 – 18.16)	0.808
NYHA III-IV	168.7 (6.85 – 4155.5)	**0.002**

P value is significant at < 0.05, aOR= adjusted Odds Ratio.

In the multivariate analysis, the factors that were independently associated with ECG abnormalities among HF patients were age ≥ 50 years, smoking, hypertension and NYHA class III and IV. Age ≥ 50 years was 22.8 times associated with ECG abnormalities among HF patients (aOR = 23.1, 95% CI: 1.81 - 294.33, p= 0.016). Smoking was significantly associated statistically with ECG abnormalities among HF patients (aOR = 23.6, 95% CI: 1.19 – 465.86, p= 0.038). Respondents with hypertension as comorbidity were about 12 times more likely to have abnormal ECG compared to those without hypertension (aOR = 11.9, 95% CI: 1.05 – 135.65, p = 0.046) while those who were staged in NYHA class III and IV at enrollment had 165 times more risk of having abnormal ECG than those in NYHA class I and II (aOR = 168.7, 95% CI: 6.85 – 4155.5, p = 0.002).

Chapter Five

Discussion, Conclusions and Recommendations

5.0 Introduction

The purpose of this study was to determine the prevalence, the ECG pattern and factors associated with ECG abnormalities among HF patients at KIU-TH, Ishaka. This chapter presents the discussion of the results, followed by the conclusions according to the objectives of the study and some recommendations.

5.1 Discussion

5.1.1 Prevalence of ECG Abnormalities among Heart Failure Patients

The prevalence of ECG abnormalities in this study was 86.1%. This is higher compared to Baris et al. in 2015 in Switzerland who found that 34.3% of study respondents had ECG abnormalities. The current prevalence is also higher than the 36% of ECG abnormalities reported by Auer et al. (2012) in United States and with the prevalence reported by Buenza (2001) in Uganda who got 37.1% of ECG abnormalities. The disparities with the three studies above could be because Auer et al. and Baris et al. conducted community based-studies among populations without preexisting heart failure, while Buenza conducted his study among heart failure patients but the proportion reported was that of arrhythmias only, leaving out other ECG abnormalities.

In India, Vinit and Jayesh in 2016 from their study reported a prevalence of 92% of ECG abnormalities among patients with either acute or chronic heart failure. Dzudie et al. in 2014 in their Sub-Sahara survey reported a prevalence of electrocardiographic abnormalities of 97.7% among acute heart failure patients. Also, higher prevalence was reported by Karaye and Sani in 2008 in Nigeria from a cross-sectional study which involved both patients of acute and chronic HF. They reported a prevalence of 98.2% of ECG abnormalities. A study conducted in Kumasi (Ghana) showed that the prevalence of ECG abnormalities among HF patients was 93% (Owusu, 2014). These prevalences are higher than that reported in the current study. The discrepancy could be because the current study involved both patients with acute heart failure and those with chronic heart failure compared to the study conducted by Dzudie et al. (2014) that covered only patients with acute HF. Karaye and Sani, and Vinit and Jayesh studies involved all HF patients (acute and chronic) but the difference with the current study is that

they conducted theirs in heart clinics and respondents had been followed up for heart failure for a long period.

The prevalence of ECG abnormalities among HF patients in this study is similar to the study conducted by Gouda et al. in 2016 in Canada which showed a prevalence of 82.5% of ECG abnormalities among heart failure patients. This similarity could be explained because Gouda et al. used the first available ECG in the admission of the HF patients, the same way like in this study. Subtle ECG changes may occur as a patient improves or deteriorates and this may alter the relationship between an ECG and outcomes. A last ECG before death may also identify ECG changes unrelated to the initial presentation in a patient such as terminal arrhythmias or while advanced medical therapy is instituted.

5.1.2 Electrocardiographic Pattern among Heart Failure Patients

The main ECG abnormalities found during the study were LVH with or without ST changes (29.5%), LBBB (12.4%) and RBBB (11.4%). Nine (8.6%) respondents had both major and minor abnormalities, 66 (62.8%) respondents had only major abnormalities and 30 (28.6%) of them had only minor abnormalities. The pattern of ECG abnormalities found in this current study are similar to the study of Vinit and Jayesh in 2016 in India for who the main ECG abnormalities were LVH (42.9%), LBBB (19.4%), left atrial enlargement (25.8%) and atrial fibrillation (9.1%). Dzudie et al. in Sub-Sahara in 2014 found that the commonest pattern of the ECG abnormalities were RBBB and Ischemic changes; and Santos et al. (2018) in Brazil during their observational retrospective study reported that complete Left Bundle Branch Block was the commonest electrocardiographic abnormality. In Ghana, Owusu et al. (2014) found in their study that the main ECG abnormalities were LVH (43.7%), left axis deviation (39.6%), LBBB (19.2%) and left atria enlargement (25.6%). These similarities could be explained by the anatomy and the physiology of the heart which are the same for all human being and when the heart is failing, the consequences are the same despite the origin of the patient. Karaye and Sani during their study in 2008 however got different pattern of ECG abnormalities compared to the current study. They got a high prevalence of left ventricular hypertrophy in 77.5% of cases compared to 29.5% in this study. The discrepancy could be related to differences in the criteria used for defining ECG abnormalities. In addition, 78% of their respondents were hypertensives compared to 49.2% in this study. Thus, the presence of higher percentage of LVH can be attributed to higher percentage of hypertensives in the population studied by Karaye and Sani.

5.1.3 Relationship between Patients Factors and ECG Abnormalities among Heart Failure Patients

Upon adjusting for confounders in the multivariate analysis, factors that were independently associated with ECG abnormalities among HF patients were age equal or more than 50 years, smoking, hypertension and NYHA class III and IV.

a. Age

The mean age of the respondents was 62.4 ± 20 years. Age ≥ 50 years was 23.1 times associated with ECG abnormalities among HF patients (aOR = 23.1, 95% CI: 1.81 – 294.33, p= 0.016). These results are similar to those reported by Auer et al. (2012), Clark et al. (2008), Dzudie et al. (2014) and Gouda et al. (2016). Auer et al. in 2012 during their population-based study conducted in United States found that the mean age of patient with electrocardiographic abnormalities was 73.5 (2.8) years and there was a statistically significant relationship between age and ECG abnormalities (p=0.01). Clark et al., during their cohort study in 2008 conducted in United Kingdom found that the age above 72.2 years was associated with electrocardiographic abnormalities with an HR of 1.05 (95% CI: 1.04-1.07, p<0.0001). Gouda et al. (2016) in Canada found that the median age of HF patients with abnormal ECG was 77 years and a significant relationship between age and ECG abnormalities (p=0.022). Dzudie et al. in Sub-Sahara found that the mean age of heart failure patients with abnormal ECG was 52.0 years. Other authors also found that age above fifty years was associated with ECG abnormalities such as Bouquata et al. (2015) in Morocco who got a mean age of 62.27 (±7.26) among HF patients with LBBB. In Brazil, Santos et al. (2018) got that the mean age of respondents with abnormal ECG was 51 (±19) years. The reasons for similarities could be explained by the fact that ageing can directly affect the normal function of the heart and other organs; hence the high prevalence of abnormal ECG among patients above 50 years. In Nigeria, Karaye and Sani (2008) got different findings concerning the age of HF patients with abnormal ECG. They found that the mean age was 42.82 (±18.31). This difference can be explained by the young age of the population in Nigeria compared to the population of Ishaka (with a mean age of 62.4 years (± 20) where this study was conducted.

b. Smoking

The findings of the current study showed that 44 (36.1%) respondents were smokers and smoking was significantly associated with ECG abnormalities (aOR = 23.6, 95% CI: 1.19 –

465.86, p= 0.038). This result is similar to that reported in Brazil by Santos et al. (2018) who found that smoking was significantly associated with electrocardiographic abnormalities (p<0.001). Auer et al. (2012) reported that ECG abnormalities were associated with smoking for both HF patients with minor and major ECG abnormalities respectively seen in 12.3% of HF patients with minor ECG abnormalities and 8.3% of those with major abnormalities with a global p value=0.036. In Morocco, Bouquata et al. (2015) also got that smoking was statistically associated with LBBB (p=0.05) and 54.5% of study respondents were smokers; and in the sub-Sahara Africa survey on heart failure, Dzudie et al. (2014) found that 8.7% of HF patients with ECG abnormalities were smokers. This similarity based mainly on the statistical significance (p value) found in the current study and those of the above authors could be explained by the fact that exposure to nicotine and carbon monoxide induce arteriosclerotic changes in coronary artery which in turn lead to coronary artery diseases and impaired electrical activities of the heart which will reflect as electrocardiographic abnormalities.

c. New-York Heart Association classification

The medical factors associated with ECG abnormalities among HF patients were hypertension and respondents who were staged in NYHA functional class III and IV. The majority 84 (68.9%) of respondents were decompensated and staged in NYHA class III and IV at enrollment II (aOR = 168.7, 95% CI: 6.85 – 4155.5, p = 0.002). Clark et al. (2008) found that the presence of left bundle branch block was significantly associated with an adverse outcome among heart failure in stage III and IV of the NYHA classification with an OR of 4.03 (95% CI : 2.13-7.63, p<0.0001). This relationship between NYHA class III and IV with ECG abnormalities can be explained by the fact that patients in stage III and IV of the NYHA classification are in decompensation and the heart electrical conduction could be impaired especially the bundle branches. Hence there was no difference between findings in this study and others.

d. Hypertension

About half of respondents were hypertensive 60 (49.2%) and hypertension was the only comorbidity which was significantly associated with ECG abnormalities among HF patients statistically (aOR = 11.9, 95% CI: 1.05 – 135.65, p = 0.046). Heart failure patients who are hypertensives are about twelve times more likely to have ECG abnormalities compared to HF patients without ECG abnormalities. Auer et al. (2012), found that ECG abnormalities were statistically associated with increase blood pressure (p<0.001). A study conducted by Gouda et

al. (2016) showed that ECG abnormalities were asscociated with comorbidities and hypertension was present in 75.5% of patients. In UK, Clark et al. (2008) during their study found that the most common commorbidities among respondents with LBBB were hypertension with 35.5% of study respondents. An observational retrospective study conducted in Brazil by Santos et al. (2018) revealed that hypertension was the most frequent comorbidity among patients with ECG abnormalities ($p<0.001$) and in Morocco, Bouquata et al. (2015) got that the most comorbidity among HF patients with LBBB was hypertension (40.9%). The sub-Saharan Africa survey of heart failure showed that hypertension was associated with ECG abnormalities among heart failure patients (55.8% of respondents). The relationship between hypertension and ECG abnormalities can be explained by the fact that hypertension is one of the known cause of heart failure and the change in lifestyle does not involved only population of the Western countries but also the population in the South as seen in the current study.

5.2 Conclusions

The findings of this study showed that the prevalence of ECG abnormalities among heart failure patients was very high at KIU-TH and ECG abnormalities were most common among heart failure patients in NYHA functional classes III and IV. Left ventricular hypertrophy, left bundle branch block and right bundle branch block were the most common abnormalities among study respondents. Patient factors associated with ECG abnormalities included age equal or above 50 years, smoking, hypertension and NYHA functional class III and IV.

5.3 Recommendations

Due to the high prevalence of ECG abnormalities, ECG test should be included as a routine test in the management of heart failure patients at KIU-TH by the Department of Internal Medicine to promote better patient overall care. Also, regular refresher training on heart failure diagnosis and management should be organized for clinicians to promote early diagnosis of HF and ECG abnormalities. These can prevent recurrent decompensations. At the National level, routine health education, including the dangers of smoking to the heart and other organs, should be encouraged at triage centres of all health facilities by the Ministry of Health in Uganda.

5.4 Strengths and Weakness of the Study

5.4.1 Strengths

Our study was conducted in a rural setting hospital which is delivering service to a large part of the South-West part of the country and the study had established the prevalence of ECG abnormalities among HF patients which will help the direction of the hospital to create a special clinic for heart failure patients with the necessary equipment for diagnosis and follow up.

5.4.2 Weakness

In this study, cardiac echography was not used for the diagnosis of heart failure which could help to classify the phenotype of heart failure patients.

5.5 Areas for Further Research

Further research needs to be done to establish the etiology and the phenotype of heart failure patients and their outcomes related to their management in Western-Uganda. Another study needs to be conducted to describe the association between the electrolytes imbalances and electrocardiographic changes.

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Appendices

Appendix A: SOP Electrocardiogram

Standard Operating Procedures
Clinical and Translational Research Center

Purpose

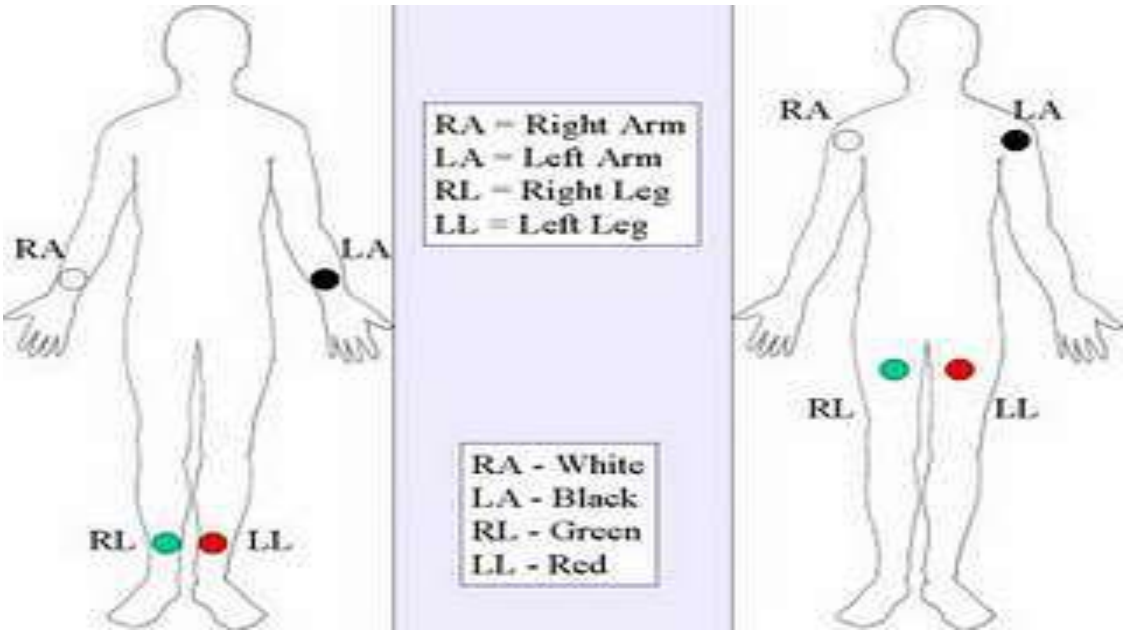
A 12-lead electrocardiogram (ECG) is a non-invasive procedure that is used to ascertain information about the electrophysiology of the heart. The purpose of this SOP is to ensure that all clinical staff uses the same procedure to obtain a standard 12-lead ECG to ensure consistency and accuracy of the ECG tracing. It is the responsibility of the Principal Investigator to analyze, interpret, and arrange appropriate follow-up for all abnormalities found.

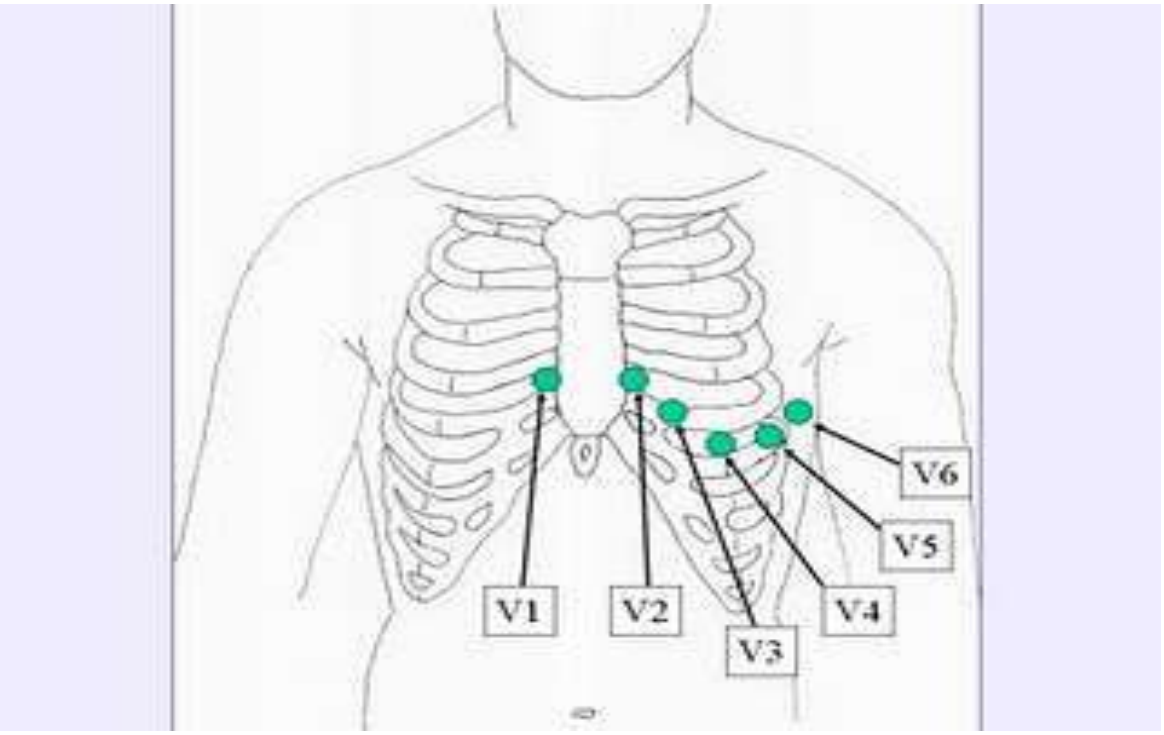
Procedure

1. The investigator or authorized personnel is responsible for ensuring that a 12-lead ECG is required by the study protocol and also to ensure that a specific machine is being utilized as stated in the protocol.
2. Wash hands and gather the following equipment and supplies:
    - 12-lead ECG Machine
    - ECG Electrodes
    - Alcohol swabs
    - Adhesive remover swabs
    - 2 x 2 gauze pads
    - Razor (optional)
3. Introduce yourself and verify the subject's name and date of birth. Subject identifiers must match the research chart.
4. Ask the subject to remove clothing from the waist up and don a hospital gown with the opening to the front. Ensure privacy by closing the curtain and door.
5. Explain the ECG procedures and answer questions, as appropriate, the subject may have regarding the ECG. Refer the subject to the investigator or study coordinator if you are not sure of the answer.
6. Ask the subject to lay flat on the exam table with legs uncrossed and arms to the side.

7. Wash your hands and stand on the left side of the subject. Prepare the skin, where the electrodes will be placed, by rubbing the lower legs, lower forearms, and chest area with alcohol swabs. Dry the areas with gauze pads.

8. Apply the electrodes starting with the lower legs, lower forearms, and chest area. See the diagram below.





Electrode placement

(RL) On the right leg, lateral calf muscle

(LL) In the same location that RL was placed, but on the left leg.

(RA) On the right arm, avoiding thick muscle.

(LA) In the same location that RA was placed, but on the left arm.

(V1) In the fourth intercostal space (between ribs 4 & 5) just to the right of the sternum (breast bone).

(V2) In the fourth intercostal space (between ribs 4 & 5) just to the left of the sternum.

(V3) Between leads V2 and V4. V4 In the fifth intercostal space (between ribs 5 & 6) in the mid-clavicular line (the imaginary line that extends down from the midpoint of the clavicle).

(V5) Horizontally even with V4, but in the anterior axillary line. (The anterior axillary line is the imaginary line that runs down from the point midway between the middle of the clavicle and the lateral end of the clavicle; the lateral end of the collarbone is the end closer to the arm.)

(V6) Horizontally even with V4 and V5 in the mid-axillary line. (The mid-axillary line is the imaginary line that extends down from the middle of the subject's armpit).

9. Connect lead wires to the corresponding electrodes. Attach the limb lead wires first beginning with the right leg. Cover the subject with a sheet to keep warm.

10. Turn on the machine and enter the subject’s name, date of birth, subject ID number or other protocol specific information. Verify information against the chart.

11. Ask the subject to breathe normally, relax, and remain still.

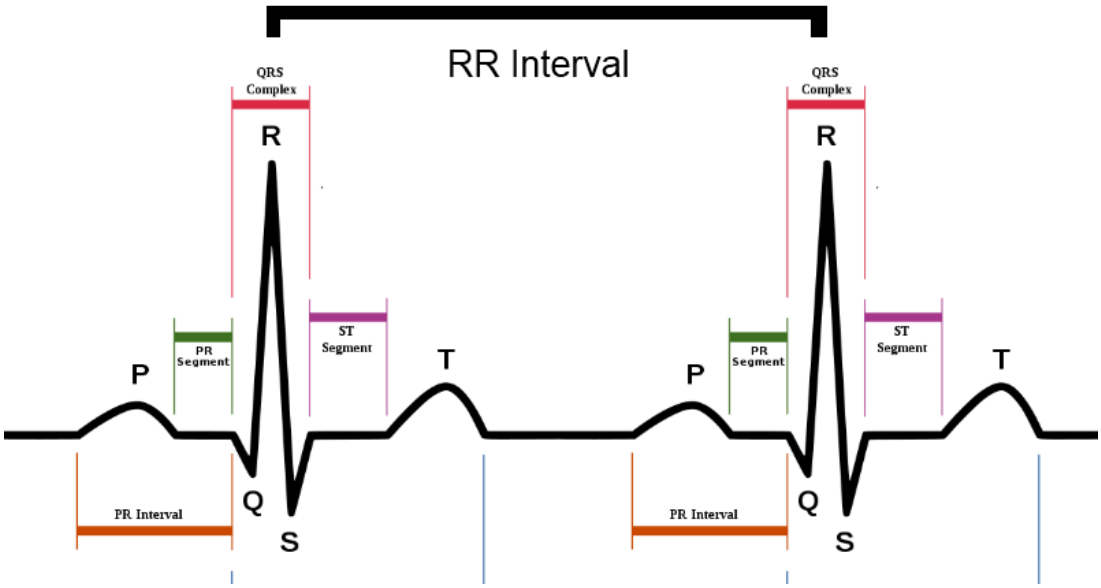
12. Acquire the ECG reading. Refer to the manufacturer’s operational instructions for each specific machine.

13. When a satisfactory ECG is acquired, save, and print. Follow manufacturer’s operational instructions if additional copies for the ECG tracing are needed.

14. Remove lead wires and electrodes from the subject. Adhesive swabs or a warm, moist wash cloth may be used to remove adhesive gel from the skin.

15. ECG tracings should be placed in the subject’s chart. The investigator or authorized designee should read and determine the urgency of advising the subject and the subject’s physician if the he requires urgent care.

A Normal ECG Waves



Waves and intervals

A typical ECG tracing of the cardiac cycle (heartbeat) consists of a P wave, a QRS complex, a T wave, and a U wave which is normally visible in 50 to 75% of ECGs. The baseline voltage of the electrocardiogram is known as the isoelectric line. Typically the isoelectric line is measured as the portion of the tracing following the T wave and preceding the next P wave.

Feature	Description	Duration
RR interval	The interval between an R wave and the next R wave. Normal resting heart rate is between 60 and 100 beat per minute.	0.6 to 1.2 seconde
P wave	During normal atrial depolarization, the main electrical vector is directed from the SA node towards the AV node, and spreads from the right atrium to the left atrium. This turns into the P-wave on the ECG.	80millisecondes (ms)
PR interval	The PR interval is measured from the beginning of the P wave to the beginning of the QRS complex. The PR interval reflects the time the electrical impulse takes to travel from the sinus node through the AV node and	120 to 200ms

	entering the ventricles. The PR interval is therefore a good estimate of AV node function.	
PR segment	The PR segment connects the P wave and the QRS complex. This coincides with the electrical conduction from the AV node to the bundle of His to the bundle branches and then to the Purkinje Fibers. This electrical activity does not produce a contraction directly and is merely traveling down towards the ventricles and this shows up flat on the ECG. The PR interval is more clinically relevant.	50 to 120ms
QRS complex	The QRS complex reflects the rapid depolarization of the right and left ventricles. They have a large muscle mass compared to the atria and so the QRS complex usually has much larger amplitude than the P-wave.	80 to 120ms
J-point	The point at which the QRS complex finishes and the ST segment begins. Used to measure the degree of ST elevation or depression present.	N/A
ST segment	The ST segment connects the QRS complex and the T wave. The ST segment represents the period when the ventricles are depolarized. It is isoelectric.	80 to 120ms
T wave	The T wave represents the repolarization (or recovery) of the ventricles. The interval from the beginning of the QRS complex to the apex of the T wave is referred to as the absolute refractory period. The last half of the T wave is referred to as the relative refractory period (or vulnerable period).	160ms
S T interval	The ST interval is measured from the J point to the end of the T wave.	320ms
QT interval	The QT interval is measured from the beginning of the QRS complex to the end of the T wave. A prolonged QT interval is a risk factor for ventricular tachyarrhythmias and sudden death. It varies with heart rate and for	300 to430ms

	clinical relevance requires a correction for this, giving the QTc.	
U wave	The U wave is hypothesized to be caused by the repolarization of the interventricular septum. They normally have low amplitude, and even more often completely absent. They always follow the T wave and also follow the same direction in amplitude. If they are too prominent we suspect hypokalemia, hypercalcemia or hyperthyroidism usually	N/A
J wave	The J wave, elevated J-Point or Osborn Wave appears as a late delta wave following the QRS or as a small secondary R wave. It is considered pathognomonic of hypothermia or Hypocalcaemia.	N/A

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Appendix B: Modified Framingham criteria

Major criteria:

- Paroxysmal nocturnal dyspnea or orthopnea
- Neck vein distension
- Cardiomegaly
- Basal crepitations
- S3 gallop
- Clinical acute pulmonary edema or pulmonary edema on chest X-ray
- Hepatojugular reflux
- Weight loss of 4.5 kg in 5 days in response to treatment and
- Central venous pressure greater than 16 cm water
- Circulation time ≥ 25 sec.

Minor criteria (the minor criteria were accepted only if they could not be attributed to other medical condition):

- Tachycardia (rate ≥ 120 bpm)
- Exertional dyspnea
- Nocturnal cough
- Hepatomegaly
- Pleural effusion
- Bilateral ankle edema and
- A decrease in vital capacity by one third the maximal value recorded.

Interpretation: Heart failure is defined by:

- Two (2) major criteria or
- One (1) major criterion + two (2) minor criteria.

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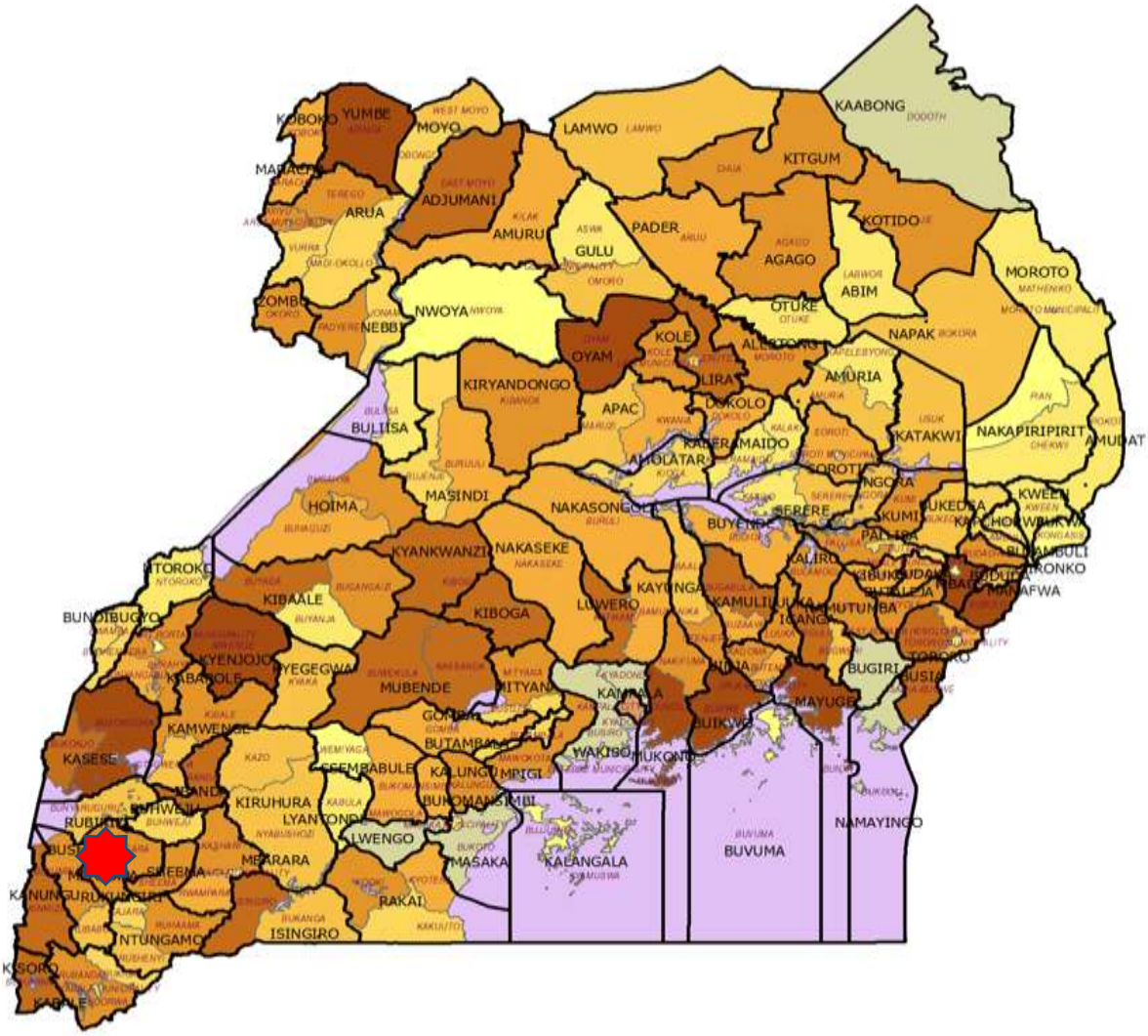
Appendix C: Map of Uganda Showing Location of Bushenyi District (Red Star)



Appendix D: Investigator administered questionnaire (English Version)

<table>
<tr><td colspan="4">ID number: |___|___|___|</td></tr>
<tr><td>1.</td><td>Date of baseline interview:</td><td colspan="2">|___|___|/|___|___|/|___|___|___|___| (dd/mm/yyyy)</td></tr>
<tr><td colspan="4">A. SOCIO - DEMOGRAPHIC DATA</td></tr>
<tr><td>2.</td><td>Gender

1= Male 2= Female</td><td>3.</td><td>What is your age?

|___|___||___| Completed years</td></tr>
<tr><td>4.</td><td colspan="3">What is your district of residence? |_____|</td></tr>
<tr><td>5.</td><td colspan="3">What is your occupation?

1= Unemployed

2= Business

3= Peasant Farmer

4= Student

5= Professional

6= Manual

7= Self employed

8= Other. If Other occupation, specify:</td></tr>
<tr><td>6.</td><td colspan="3">Highest level of education:

1. None
2. Primary
3. Secondary
4. Tertiary</td></tr>
<tr><td colspan="4"></td></tr>
</table>

B. MEDICAL HISTORY

7.	Duration of heart failure a. Onset heart failure b. |___|___| years b. |___|___| months (if less than a year)			
8.	Are you currently on any of the following medication?			Duration on medication
	a. Digoxin	0= No	1= Yes	|___|___| months
	b. Beta-blockers	0= No	1= Yes	|___|___| months
	c. ARBs	0= No	1= Yes	|___|___| months
	d. ACEIs	0= No	1= Yes	|___|___| months
	e. Diuretics	0= No	1= Yes	|___|___| months
	f. Statins	0= No	1= Yes	|___|___| months
	g. Cardiac aspirin or Clopidogrel	0= No	1= Yes	|___|___| months
	h. Others	0= No	1= Yes	|___|___| months
	If other, specify: |_____|			|___|___| months
	i. Not on medication			
9.	How often do you attend a specialized heart clinic per year? |_____|		10.	Presence of a pacemaker 0= No 1= Yes
11.	History of congenital heart disease 0= No 1= Yes		12.	History of Rheumatic heart disease 0= No 1= Yes

C. COMORBIDITIES

13.	Hypertension 0= No 1= Yes	Duration since diagnosis |_____| years |_____| months (if incomplete year)
14.	COPD 0= No 1= Yes	Duration since diagnosis |_____| years |_____| months (if incomplete year)

15.	DM 0= No 1= Yes	Duration since diagnosis |_____| years |_____| months (if incomplete year)
16. Other current comorbidities: 0= No 1= Yes If other, specify: |_____|		

D. BEHAVIOURAL FACTORS

17.	Have you ever smoked cigarettes? 0 = No 1 = Yes If yes, continue with the question 18.	18.	What do you smoke? 1. Cigarette 2. Pipe 3. Local tobacco 4. Tobacco chewing
19.	If ever smoked, how long have you been or did you smoke? a. |___|___| years b. |___|___| months (if incomplete year)		
20.	If ever smoked, Are you currently smoking? 0 = No 1 = Yes	21.	If stopped smoking, how long since you stopped? |___|___| years |___|___| months if incomplete year
22.	Number of cigarette smoked per day |___|___|	23.	How many days a week do you smoke? |___|___| days
24.	Have you ever drunk alcohol? 0= No 1= Yes If yes complete questions 25-35		
25.	How often do you take a drink containing alcohol? 0 = Never 1 = monthly or less 2= 2-4 times a month 3= 2-3 times a week 4= 4 or more times a week	26.	How often do you take 5 or more alcoholic drinks in one occasion? 0= Never 1= less than monthly 2= monthly 3= weekly 4= Daily

27.	How many drinks containing alcohol do you take on a typical day when you are drinking? 0= Never 1= 3-4 2= 5-6 3= 7-9 4= 10 or more	28.	How often during the last year have you found that you were not able to stop drinking alcohol once you had started? 0= Never 1= less than monthly 2= monthly 3= weekly 4= Daily
29.	How often during the last year have you failed to do what was normally expected of you because of drinking alcohol? 0= Never 1= less than monthly 2= monthly 3= weekly 4= Daily	30.	How often during the last year have you needed a first alcoholic drink in the morning to get yourself going after a heavy drinking session? 0= Never 1= less than monthly 2= monthly 3= weekly 4= Daily
31.	How often during the last year have you had a feeling of guilt or remorse after drinking alcohol? 0= Never 1= less than monthly 2= monthly 3= weekly 4= Daily	32.	How often during the last year have you been unable to remember what happened the night before because of drinking alcohol? 0= Never 1= less than monthly 2= monthly 3= weekly 4= Daily
33.	Have you or someone else been injured because of drinking alcohol? 0= No 2= Yes, but not in the last year 4= Yes, during the last year	34.	Has relative, friend, doctor or other health care worker been concerned about your alcoholic drinking or suggested you cut down? 0= No 2= Yes, but not in the last year 4= Yes, during the last year.
35.	Total score (AUDIT score) 0. < 8: Low risk 1. 8-12 : harmful or hazardous drinking 2. >= 13 in women : alcohol dependence 3. >= 15 in men : alcohol dependence		

E. CLINICAL FINDINGS

36. Patients complains

a. Palpitations : 0= No 1=Yes

b. Dyspnea on exertion : 0= No 1=Yes

c. Paroxysmal nocturnal dyspnea: 0= No 1=Yes

d. Determine the NYHA class: 1= I 2= II 3. III 4. IV

e. Fatigue : 0= No 1=Yes

f. Precordial chest pain : 0= No 1=Yes

g. Loss of consciousness : 0= No 1=Yes

h. Lower limbs swelling : 0= No 1=Yes

i. Cough **:** 0= No 1=Yes

j. Others **:** 0= No 1=Yes

If other, specify: |_____ | **Note: can be more than one.**

General examination findings

37.	Height: |___|___|___| centimeters	38.	Weight: |___|___|:|___| kg
39.	a. Pulse rate: |___|___|___| bpm b. Pattern of PR 1= Regular pulse 2= Irregular pulse	40.	Respiratory rate: |___|___| cpm SPO2: |___|___|___|%
41.	Systolic blood pressure: |___|___|___| mmHg	42.	Diastolic BP: |___|___|___| mmHg

Cardiovascular system examination		0= No	1 = Yes
43.	Distended jugular vein	□	□
44.	Normal Heart sound 1 and 2	□	□
45.	a. Presence of murmur b. Type of murmur : 1= systolic murmur 2= diastolic murmur	□	□

46.	S3 gallop	□	□
47.	Bilateral basal crackles	□	□
48.	Pleural effusion (chest stoney dull percussion)	□	□
49.	Hepatomegaly	□	□
50.	If other, specify |_____|		

F. ECG FINDINGS

51. ECG findings :

a. Major abnormalities

- Q-wave myocardial ischemia : 0= No 1= Yes
- LVH with ST-T abnormalities :0= No 1= Yes
- WPWS : 0= No 1= Yes
- Left bundle branch block : 0= No 1= Yes
- Right bundle branch block or intraventricular bloc : 0= No 1= Yes
- Atrial fibrillation or atrial flutter : 0= No 1= Yes
- Isolated ischemic abnormalities : 0 = No 1= Yes
- Other arrhythmia : SVT, VT, Ventricular preexcitation : : 0= No 1= Yes

b. Minor abnormalities

- First and second degree AV-block : 0 = No 1= Yes
- LVH without ST-T abnormalities : 0 = No 1= Yes
- Left atria enlargement : 0 = No 1= Yes
- Atrial or ventricular premature beats : 0 = No 1= Yes
- Fascicular block : 0 = No 1= Yes

c. Normal ECG findings : 0 = No 1= Yes

d. Other ECG findings : 0 = No 1= Yes If other ECG findings, specify :_____

Thank you for your participation

Appendix E: Investigator administered questionnaire (Runyakole Version)

ID number: |___|___|___|			
1.	Ebiro Byokwezi |___|___|/|___|___|/|___|___|___|___| (dd/mm/yyy)		
A. Ebirikukukwataaho			
2.	Gender 1= Omushaija 2= Omukazi	3.	Oyine emyaka engahi? |___|___|___| (Completed years)
4.	Disiturikiti yaawe neeha |_____|		
5.	Nookora murimo ki? 1= Toyine murimo 2= Nooshubura 3= Ory'omuhingi 4= Nooshoma 5= Purofeshonolo 6= Nookozesa emikono 7= Nooyekozesa 8= Ebiindi.		
6.	Waaba oyine omurimo ogundi niguuha?		
B. EBYAMAGARA			
7.	Obwiire bwoburwaire Bwomutima a. Onset heart failure b. |___|___| years c. |___|___| months (if < a year)	8.	Ori hamubazi kyi?
9.	Obwiire buwamara ahamubazi	10.	Okushemezibwaho infacts (pace maker) 0= No 1= Yes
12.	History of Rheumatic heart disease? 0= No 1= Yes		11. History of congenital heart disease? 0= No 1= Yes

C. EZINDI ENDWARA		
13.	Presha 0= No 1= Yes	If yes Waamara emyaka engahi ahamubazi kyi? |___|___| emyaka |___|___| months (if incomplete year)
14.	COPD 0= No 1= Yes	If yes Waamara emyaka engahi ahamubazi kyi? |___|___| emyaka |___|___| months (if incomplete year)
15.	Sukaari 0= No 1= Yes	If yes Waamara emyaka engahi ahamubazi kyi? |___|___| emyaka |___|___| months (if incomplete year)
16.	Ezindi endwaara zigambe	

D. BEHAVIORAL FACTORS			
17.	Oraretsizeho sigara? 1= Yes 0= No	18.	What do you smoke? 1. Cigarette 2. Pipe 3. Local tobacco 4. Tobacco chewing
19.	If yes, waamara bwire ki orikureetsa? a. |___|___| emyaka b. |___|___| months (if < a year)		
20.	Waaba oraretsizeho, nahati nookiretsa? 0= No 1= Yes	21.	Waaba wakurekire wamara bwireki okurekire? |___|___| emyaka |___|___| months
22.	Nooretsa eminwa engahi buri izooba Yaaba netaabe ninga enyungu nooretsa emirundi engahi? |___|___|	23.	Omusande nooretsa emirundi engahi? |___|___| days
24.	Oranywiireho amaarwa? 0= No 1= Yes If yes yijuza ebibuuzo 25-35		
25.	Noomara emirundi engahi oine ekyokunywa kirimu amaarwa? 0=Tikiriho 1= Okweezi ninga obutahika 2= Emirundi 2-4 omukweezi	26.	Noomara emirundi engahi obworikunywa ebyokunywa 5 ninga okukiraho omurundi gumwe 0= Tiburiho 1= Okwezi tikurikwihika

	3= Emirundi 2-3 omusande 4= Emirundi 4 omusande ninga okukiraho		2= Buri kweezi 3 = Buri Sande 4= Buri eizooba
27.	Nebyokunywa bingahi ebirikuba birimu amaarwa ebyorikuba oine ahabiro ebyorikunyweraho? 0= Tibiriho, 1= 3-4, 2= 5-6, 3= 7-9, 4= 10 or nokukiraho	28.	Nemirundi engahi omwaka oguhwaire obuwabaire oshanga otakyemereza kunywa waaba watandikire? 0=Tiburiho 1= ahansi yokwezi 2= Burikweezi 3 = Burisande 4=Buri izooba.
29.	Nemirundi engahi emyaka oguhwaire obuwaremirwe kukora ekyoshemereire kuba nookora ahabwokunywa amaarwa? 0= Tiburiho 1= Ahansi yokwezi 2= Burikweezi 3= Buri Sande 4= Buri izooba	30.	Nemirundi engahi omwaka oguhwaire obuwabiire oyenda kunywa akasheeshe okabona kutambura waaba origire kunyweera kimwe. 0= Tiburiho 1= Ahansi yokwezi 2= Burikweezi 3= Buri Sande 4= Buri izooba
31.	Nemirndi engahi omwaka oguhwaire eyiwayefurize ahabwokunywa amaarwa? 0= Tiburiho 1= Ahansi yokwezi 2= Burikweezi 3= Buri Sande 4= Buri izooba	32.	Nemirndi engahi omwaka oguhwaire eyiwabiire oyebwa ebibbireho omukiro ahabwokunywa? 0= Tiburiho 1= Ahansi yokwezi 2= Burikweezi 3= Buri Sande 4= Buri izooba
33.	Orafunireyo obuhuta ninga omuntu ondiijo ahabwokunywa kwaawe? 0= Apaana 2= Ego kwonka gutarimwaka oguhwaire 4 = Ego omwaka oguhwaire	34.	Hariho obwomunyabuzaare waawe, ninga omushaho barakugambireho ngo oceendeze okunywa amarwa 0= Tiburiho 2= Ego kwonka gutarimwaka oguhwaire 4 = Ego omwaka oguhwaire

35.	Total score (AUDIT score) 0. < 8: Low risk 1. 8-12 : harmful or hazardous drinking 2. >= 13 in women : alcohol dependence 3. >= 15 in men : alcohol dependence

E. CLINICAL FINDINGS

36. Okushaasha Kwomurwaire

a.	Okwehuuba omutima	0= No	1 = Yes
b.	Okwitsyakubi wakora omurimo	0= No	1 = Yes
c.	Okufundaana omukiro	0= No	1 = Yes
d.	Oburihe	0= No	1 = Yes
e.	Okushaasha ekifuba	0= No	1 = Yes
f.	Okugwa kihuumura	0= No	1 = Yes
g.	Okuzimba ebigyere	0= No	1 = Yes
h.	Okukorora	0= No	1 = Yes
i.	Ebindi	0= No	1 = Yes
j.	Others	0= No	1 = Yes

If other, specify : |_____|

Manya: Nibibaasa kukira ahakabonero kamwe

Ebyaruga omukucebera

37.	Height |___|___|___| centimeters	38.	Weight |___|___|___| Kg
39.	a. Pulse Rate : |___|___|___| bpm b. Pattern of PR 1 = Regular pulse 2 = Irregular pulse	40.	Respiratory rate : |___|___| cpm SPO2 : |___|___|___| %
41.	Systolic BP : |___|___|___| mmHg	42.	Diastolic BP : |___|___|___| mmHg

Cardiovascular system examination (ebyomutima)		1 = No	2 = Yes
43.	Distended jugular vein	☐	☐
44.	Normal heart sound 1 and 2	☐	☐
45.	a. Presence of murmur b. Type of murmur 1= systolic murmur 2= diastolic murmur	☐	☐
46.	S_3 gallop	☐	☐

47.	Bilateral Basal crackles	☐	☐
48.	Pleural effusion (stoney dullness percussion)	☐	☐
49.	Hepatomegaly	☐	☐
50.	Others to be specified :		

F. ECG FINDINGS

51. ECG findings :

a. Major abnormalities

- Q-wave myocardial ischemia : 0= No 1= Yes
- LVH with ST-T abnormalities :0= No 1= Yes
- WPWS : 0= No 1= Yes
- Left bundle branch block : 0= No 1= Yes
- Right bundle branch block or intraventricular bloc : 0= No 1= Yes
- Atrial fibrillation or atrial flutter : 0= No 1= Yes
- Isolated ischemic abnormalities : 0 = No 1= Yes
- Other arrhythmia : SVT, VT, Ventricular preexcitation : : 0= No 1= Yes

b. Minor abnormalities

- First and second degree AV-block : 0 = No 1= Yes
- LVH without ST-T abnormalities : 0 = No 1= Yes
- Left atria enlargement : 0 = No 1= Yes
- Atrial or ventricular premature beats : 0 = No 1= Yes
- Fascicular block : 0 = No 1= Yes

c. Normal ECG findings : 0 = No 1= Yes

d. Other ECG findings : 0 = No 1= Yes If other ECG findings, specify :_____

Webare munonga

Appendix F: REC Approval Letter

KAMPALA
INTERNATIONAL
UNIVERSITY

Western Campus
P O BOX 71 Ishaka, Uganda
Tel: +256 758 096 775
Email: kiurec2017@kiu.ac.ug
Website: www.kiu.ac.ug

RESEARCH ETHICS COMMITTEE (REC)

23rd December 2019

Our ref: SE/201937

DR. YVES IBAMWENDA BAFWA
MMED/8851/171/DF
Student

APPROVAL OF YOUR PROPOSAL

Submitted Proposal: CLINICAL CHARACTERISTICS AND FACTORS ASSOCIATED WITH ELECTROCARDIOGRAPHIC ABNORMALITIES AMONG HEART FAILURE PATIENTS AT KAMPALA INTERNATIONAL UNIVERSITY TEACHING HOSPITAL

Nr. UG-REC-023/201937

Reference is made to the above Protocol which you submitted to the Research Ethics Committee (REC) for ethical review and approval. It has been noted that all the concerns raised earlier by the Committee, in its meeting of 27th November 2019, have been properly responded to.

This is, therefore, to inform you that your study has been approved. You may now proceed with preparations to implement the research. Please note that this approval is for a period of one year.

As Principal Investigator, you are expected to fulfill the following conditions, which are part of the approval process regarding your study:

1. You are required to register the Protocol with the Uganda National Council for Science and Technology, according to the guidelines of the Council, for final clearance to undertake the research.
2. Any changes/amendments and/or additions to the Protocol, Consent Form and/or Data Collection Tools must be submitted to the REC for review and approval prior to activation of the changes.
3. Reports of unanticipated problems involving risks to participants should be submitted to REC.
4. Only the approved Consent Forms should be used in enrolling participants. For that purpose, therefore, you should retain all signed Consent Forms on file.

KIU RESEARCH ETHICS COMMITTEE (REC)
APPROVED
VALID UNTIL
23 DEC 2020
P.O. Box 71, Bushenyi - Ishaka

KAMPALA
INTERNATIONAL
UNIVERSITY

Western Campus
P O BOX 71 Ishaka, Uganda
Tel: +256 758 096 775
Email: kiurec2017@kiu.ac.ug
Website: www.kiu.ac.ug

RESEARCH ETHICS COMMITTEE (REC)

5. In order to continue with the study beyond the approved period, a Continuing Review Application must be submitted to the REC ten weeks prior to the indicated expiration date of the approval.

The documents approved in this Application Process are listed below:

Document	Language	Version
Protocol	English	Version 3
Protocol Application Form	English	Version 1
Data Collection Tools (Questionnaire)	English & Runyankole	Version 3
Informed Consent Document	English & Runyankole	Version 3
Assent Form Document	English & Runyankole	Version 3

Dr. Patrick Mbyemeire (Fr.)
REC CHAIR

KIU RESEARCH ETHICS COMMITTEE(REC)
APPROVED
VALID UNTIL
23 DEC 2020
P.O. Box 71, Bushenyi - Ishaka

Appendix G: KIU-TH Approval Letter

Dr. Yves Tibamwenda Bafwa

MMED/8851/171/DF

Tel. +256700970889

Email: ybafwa@gmail.com

yves.bafwa@kiu.ac.ug

24th December 2019

To the Executive Director (E.D.)

of Kampala International University-Teaching Hospital (KIU-TH)

RE: APPROVAL FOR DATA COLLECTION

Dear Sir,

I humbly submit the above mentioned subject into your office for consideration.

In fact, I have been given the approval letter from the Research Ethics Committee (REC), to start collecting for my Research titled: "***Clinical characteristics and factors associated with Electrocardiographic abnormalities among heart failure patients at Kampala International University-Teaching Hospital***".

Therefore, I am requesting for your official approval to carry out this research in KIU-TH/Internal Medicine. Find attached the copy of the KIU-REC approval.

I am looking forward to your positive response and hope my request will be greatly considered.

Yours faithfully.

.....

***Dr.* Yves Tibamwenda Bafwa**

No objection
7.01.2020

CC.: -Internal Medicine (HOD OFFICE/KIU-T.H.)

07 JAN 2020

Appendix H: Consent form (English Version)

KAMPALA INTERNATIONAL UNIVERSITY (KIU) WESTERN CAMPUS (WC)

RESEARCH ETHICS COMMITTEE (REC)

PO Box 71, Bushenyi, Uganda; Tel: +256 758 096 775

E-mail: kiurec2017@kiu.ac.ug; Website: www.kiu.ac.ug

INFORMED CONSENT DOCUMENT

Study Title: "Prevalence and Factors Associated with Electrocardiographic Abnormalities among Heart Failure Patients at Kampala International University Teaching Hospital".

Principal investigator: Dr. Yves Tibamwenda Bafwa, a postgraduate student in the Department of Internal Medicine at Kampala International University Teaching Hospital (KIU-TH).

Qualification: Bachelor of Medicine and Bachelor of Surgery (UNIKIS, 2011).

Introduction:

What you should know about this study:

- You are being asked to join a research study
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.

• **Leave blank (for REC Office only):** • NAME OF REC CHAIR: ***Dr. Patrick Mbyemeire*** • TELEPHONE: ***+256 772601482*** • KIU REC STAMP:	**For REC Office use only:** APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO: ***UG-REC- 023***

VERSION: THREE

- You are a volunteer. You can choose not to take part and if you join you may decide to withdraw from the study any time and there will be no penalty if you decide to do so.

Background of the study:

Heart failure is associated with widespread electrophysiological remodelling of the cardiac conduction system, resulting in electrocardiographic (ECG) abnormalities (reduced RR variability, prolongation of the QRS and PR intervals, and atrial fibrillation). The main ECG abnormalities among heart failure patients included left ventricular hypertrophy (42.9%), left axis deviation (39.8%), left bundle branch block (LBBB) (19.4%) and left atrial enlargement (25.80%). Arrhythmias included ventricular extrasystoles (11.8%), atrial fibrillation (9.1%), complete heart block (5.7), and ventricular tachycardia (3.9%).

Purpose of the research study

The study will determine the prevalence, the ECG pattern and factors associated with ECG abnormalities among heart failure patients at KIU-TH. It will help for the reduction of the high costs of management and to reduce the morbidity and mortality among heart failure patients.

Why are you being requested to participate in the study?

You have been chosen to participate in this study because you meet the designed inclusion criteria of the study. When you take part in the study, the information generated will be used to show the prevalence of heart failure patients with abnormal ECG in this part of the country; factors associated with ECG abnormalities and the ECG pattern of HF patients will be revealed and therefore it will help to improve the follow up of HF patients by the use of an electrocardiogram.

• **Leave blank (for REC Office only):** • NAME OF REC CHAIR: ***Dr. Patrick Mbyemeire*** • TELEPHONE: ***+256 772601482*** • KIU REC STAMP:	**For REC Office use only:** APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO: ***UG-REC- 023***

VERSION: THREE

Procedure

If you agree to participate in the study you will be given more information regarding the study and asked to sign the consent form. You will be interviewed for 30 minutes in order to obtain relevant information regarding research objectives. You will benefit of a full physical examination and a 12-Leads electrocardiography will be recorded according to the standard operating procedures, which will help to assess any abnormality of the electrical conduction in your heart.

Risks/Discomforts

Study respondents will not undergo any pain during ECG procedures. Physical examination shall not induce pain or any form of harm. However there is a minor risk for some patients to present skin allergic reaction which is not a life-threatening reaction and an appropriate management of the allergy will be provided by the principal investigator.

Benefits of the study

Respondents will benefit from a free of charge electrocardiography which will help to adjust their management.

Rewards/incentives for participating

There shall be no incentives like meals, transport refunds or gifts awarded to respondents

Protecting data confidentiality

All information that will be obtained will remain confidential and will be used for the purpose of this study. You are not supposed to write down your name but we will only use an identification number.

Protecting subject privacy during data collection

Data shall be obtained from an enclosed place designated in the study site. We shall also ensure privacy is adhered during electrocardiographic procedure.

• **Leave blank (for REC Office only):** • NAME OF REC CHAIR: ***Dr. Patrick Mbyemeire*** • TELEPHONE: ***+256 772601482*** • KIU REC STAMP:	**For REC Office use only:** APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO: ***UG-REC- 023***

VERSION: THREE

Right to refuse/withdraw

The study respondent will be free to withdraw from the study any time he feels like and that decision will not affect quality of care expected from the hospital.

What happens if you leave the study?

The decision to withdraw from the study will not influence the quality of care you are supposed to get from the doctors.

Who do I contact in case I have questions or a problem?

In case of any matters which are not clear, please contact; Dr. Yves TIBAMWENDA BAFWA, MMED student, Department of Internal Medicine, Kampala International University, Tel. +256700970889 and/or KIU-TH Research Ethics Committee at +256-758-096775.

• **Leave blank (for REC Office only):** • NAME OF REC CHAIR: ***Dr. Patrick Mbyemeire*** • TELEPHONE: ***+256 772601482*** • KIU REC STAMP:	**For REC Office use only:** APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO: ***UG-REC- 023***

VERSION: THREE

What does your signature (or thumbprint/mark) on this consent form mean?

- You have been informed about this study's purpose, procedures, benefits and risks.
- You have been given the chance to ask questions before you sign it.
- You have voluntarily agreed to be in the study.

_____	_____		_____
Name of respondent/ Authorized person	Signature of respondent/legally	Thumb print	Date
_____	_____		_____
Name of person obtaining Consent	Signature	Thumb print	Date
_____	_____		_____
Names of witness	Signature of witness	Thumb print	Date

• **Leave blank (for REC Office only):** • NAME OF REC CHAIR: ***Dr. Patrick Mbyemeire*** • TELEPHONE: ***+256 772601482*** • KIU REC STAMP:	**For REC Office use only:** APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO: ***UG-REC- 023***

VERSION: THREE

Appendix I: Consent form (Runyakole Version)



KAMPALA INTERNATIONAL UNIVERSITY (KIU) WESTERN CAMPUS (WC)

RESEARCH ETHICS COMMITTEE (REC)

PO Box 71, Bushenyi, Uganda; Tel: +256 758 096 775

E-mail: kiurec2017@kiu.ac.ug; Website: www.kiu.ac.ug

OKUSHABWA OKWIKIRIZA OKWETABA OMUKUKYONDOOZA

Omutwe Gw'omushomo: Ebikwatirine na akatiivi k'okucebera omutima omubarwire bomutima ahairwariro rya KIU.

Omucebezi mukuru: Dokita Yves Tibamwenda Bafwa omwegi kuruga omu itaagi rya internal medicine ahari Kampala International University Teaching Hospital.

Okwanjura

Ebyoshemereire kumanya ahakucoondooza oku.

- Noshabwa okwetaba omu kucoondooza oku.
- Orupapura oru nirushoborora okucoondooza oku nana ekicweka kyawe.
- Noshabwa kukishoma gye oyetwaire.
- Nokusharamu kwaawe, nobaasa kusharamu obutejumba omukucoondooza oku nobuwakuba wakwejumbiremu nobaasa kusharamu okukurigamu hatariho mushango gwona.

• **Leave blank (for REC Office only):** • NAME OF REC CHAIR: ***Dr. Patrick Mbyemeire*** • TELEPHONE: ***+256 772601482*** • KIU REC STAMP:	**For REC Office use only:** APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO: ***UG-REC- 023***

VERSION: THREE

Omugasho gw'okucoondooza oku

Okucoondooza oku nikwija kumanya ebikwatiraine na akatiivi kokucebera omubarweire b'emutima ahairwariro rya KIU-TH. Kuyambehookucendeza ebishare byokuraguriza omurwaire, kucendeze oburema nokufa kwabarwaire b'emitima.

Ahabwenki noshabwa kwetaba omukucoondooza oku?

Otooriinwe kwetaba omukucoondooza oku ahobwokuba ori omwe ahabantu abiturikwenda kiyambeho okumanya omuhendo gwabarwaire b'emitima okurugirira aha akatiivi kokucebera omutima omukicweeka eki kandi babakuratire omukubaragurira.

Okweerakorwe

Ku'orikwikiriza kwetaba omukucoondooza oku;Noija kushoborokyerwa ahabikwatiraine nomutima. Ohebwe akapapura osayiningeho (Oteho omukono).

Noyija kubuuzibwa kumara edakiika 30 okukwihaho ebyorukumanya ebikwatiriine nokucoondooza oku. Noija kugoba omukucebererwa busha omubiri gwoona, nanokuceberwa n'akatiivi komutima okwomutindo.

Obuzibu

Okucoondooza oku tiharimu kushaasha kwoona. Okwihaho bakye abakubaasa kuba baine efumbi (Alaji) yomubiri konka nabwe terikubaasa kuba eyakabi kandi neija kujanjabwa.

Amagoba g'okucoondooza oku

Okucebera omutima nanakatiivi nikyo kyitarikuseerwa kandi kirungi okukuratiriza abarwaire bomutima kandi noija kucebererwa busha.

• **Leave blank (for REC Office only):** • NAME OF REC CHAIR: ***Dr. Patrick Mbyemeire*** • TELEPHONE: ***+256 772601482*** • KIU REC STAMP:	**For REC Office use only:** APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO: ***UG-REC- 023***

VERSION: THREE

Akasiimo kabarayetabe omukucoondooza

Tiharaije kubaho akasiimo koona, ebirabo neinga okugarurirwa sente za turansipooti ahabarayetabe omukucoondooza oku.

Okukuma Ebirarugye Omukucoondooza.

Ebirarugye omukucoondooza oku nibyeija kuguma biri ebyekihama kandi bikozesibwe omukucoondooza oku kyonka .Torikwikirizibwa kuhandiika eizina ryawe okwihaho noija kukozesa enamba

Okukuma Ebihama byomurwaire

Okucoondooza oku nikwija kuba omukashenje kehereire aha medical ward ninga Private ward.Nitwija kurebekangu omurwaire yayehereera omukuceberwa omutima.

Obugabe bwokwanga nainga Okurugamu

Orikucoondozibwaho / arikushomwaho naija kuba aine obugabe okurugamu eshaha yoona aharikwendera kandi eki tikyiine kakwate nebirarugye omukucebera oku .

Nihabahoki waruga omukucebera oku?

Warugamu tihaine kirakubeho omukujanjabwa kwawe okuruga omubashaho

Nimbuuza Oha kunakugira Ekizibu nainga Ekibuzo?

Wajira ekyakushobera obuze dokita Yves Tibamwenda Bafwa omwegi wa Masitazi aha KIU aha simu 0700970889 nainga abebyokucoondooza ahairwariro rya KIU aha +256-758096775.

• **Leave blank (for REC Office only):** • NAME OF REC CHAIR: ***Dr. Patrick Mbyemeire*** • TELEPHONE: ***+256 772601482*** • KIU REC STAMP:	**For REC Office use only:** APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO: ***UG-REC- 023***

VERSION: THREE

Omukono gwawe ahakipapura eki nikimanyisaki?

- Ngu wamanyisibwa ahamushomo ogu,omugasho gwagwo okugurakorwe ,amagoba nobuzibu bwagwo.
- Ngu waheebwa omugisha gwokubuza ebibuzo otakasayiningire (otakatireho omukono gwawe).
- Ngu wayeshariramu okwikiriza okushomwaho.

_____	_____	☐	_____
Eizina ryawe	**Omukono gwawe**	**Ekinkumu**	**Ebiro byokweezi**
_____	_____	☐	_____
Eizina ry'arikushaba Orusa	**Omukono gwe**	**Ekinkumu**	**Ebiro byokweezi**
_____	_____	☐	_____
Eizina Ry'ayabariho	**Omukono gwe**	**Ekinkumu**	**Ebiro byokweezi**

• **Leave blank (for REC Office only):** • NAME OF REC CHAIR: ***Dr. Patrick Mbyemeire*** • • TELEPHONE: ***+256 772601482*** • • KIU REC STAMP:	**For REC Office use only:** APPROVAL DATE: APPROVED CONSENT REC VERSION NUMBER: PI's NAME: REC NO: ***UG-REC- 023***

VERSION: THREE

Appendix J: Assent form (English Version)

KAMPALA INTERNATIONAL UNIVERSITY (KIU) WESTERN CAMPUS (WC)

RESEARCH ETHICS COMMITTEE (REC)

PO Box 71, Bushenyi, Uganda; Tel: +256 758 096 775

E-mail: kiurec2017@kiu.ac.ug; Website: www.kiu.ac.ug

ADOLESCENT ASSENT FORM

Your parent has given permission for you to be in a project called a research study. But first, we want to tell you all about it so you can decide if you want to be in it. If you don't understand, please ask questions. You can choose to be in the study, not be in the study or take more time to decide.

Study Title: "Prevalence and Factors Associated with Electrocardiographic Abnormalities among Heart Failure Patients at Kampala International University Teaching Hospital".

Principal investigator: Dr. Yves Tibamwenda Bafwa, a postgraduate student in the Department of Internal Medicine at Kampala International University Teaching Hospital (KIU-TH).

Qualification: Bachelor of Medicine and Bachelor of Surgery (UNIKIS, 2011).

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VERSION: THREE

Introduction

What you should know about this study:

- You are being asked to join a research study.
- This assent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join you may decide to withdraw from the study any time and there will be no penalty if you decide to do so.

Background of the study:

Heart failure is associated with widespread electrophysiological remodelling of the cardiac conduction system, resulting in electrocardiographic (ECG) abnormalities (reduced RR variability, prolongation of the QRS and PR intervals, and atrial fibrillation). The main ECG abnormalities among heart failure patients included left ventricular hypertrophy (42.9%), left axis deviation (39.8%), left bundle branch block (LBBB) (19.4%) and left atrial enlargement (25.80%). Arrhythmias included ventricular extrasystoles (11.8%), atrial fibrillation (9.1%), complete heart block (5.7) and ventricular tachycardia (3.9%).

Purpose of the research study

The study will determine the prevalence, the ECG pattern and factors associated with ECG abnormalities among heart failure patients at KIU-TH. It will help for the reduction of the high costs of management and to reduce the morbidity and mortality among heart failure patients.

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Why are you being requested to participate in the study?

You have been chosen to participate in this study because you meet the designed inclusion criteria of the study. When you take part in the study, the information generated will be used to show the prevalence of heart failure patients with abnormal ECG in this part of the country; factors associated with ECG abnormalities and the ECG pattern of HF patients will be revealed and therefore it will help to improve the follow up of HF patients by the use of an electrocardiogram.

Procedure

If you agree to participate in the study you will be given more information regarding the study and asked to sign the assent form. You will be interviewed for 30 minutes in order to obtain relevant information regarding research objectives. You will benefit of a full physical examination and a 12-Leads ECG will be recorded according to the standard operating procedures, which will help to assess any abnormality of the electrical conduction in your heart.

Risks/Discomforts

Study respondents will not undergo any pain during ECG procedures. Physical examination shall not induce pain or any form of harm. However there is a minor risk for some patients to present skin allergic reaction which is not a life-threatening reaction and an appropriate management of the allergy will be provided by the principal investigator.

Benefits of the study

Respondents will benefit from a free of charge electrocardiography which will help to adjust their management.

Rewards/incentives for participating

There shall be no incentives like meals, transport refunds or gifts awarded to respondents

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Protecting data confidentiality

All information that will be obtained will remain confidential and will be used for the purpose of this study. You are not supposed to write down your name but we will only use an identification number.

Protecting subject privacy during data collection

Data shall be obtained from an enclosed place designated in the study site. We shall also ensure privacy is adhered during electrocardiographic procedure.

Right to refuse/withdraw

You will be free to withdraw from the study any time you feel like and that decision will not affect the quality of care expected from the hospital.

What happens if you leave the study?

The decision to withdraw from the study will not influence the quality of care you are supposed to get from the doctors.

Who do I contact in case I have questions or a problem?

In case of any matters which are not clear, please contact; Dr. Yves TIBAMWENDA BAFWA, MMED student, Department of Internal Medicine, Kampala International University, Tel. +256700970889 and/or KIU-TH Research Ethics Committee at +256-758-096775.

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What does your signature (or thumbprint/mark) on this consent form mean?

- You have been informed about this study's purpose, procedures, benefits and risks.
- You have been given the chance to ask questions before you sign it.
- You have voluntarily agreed to be in the study.

_____	_____	☐	_____
Name of respondent/ Authorized person	Signature of respondent/legally	Thumb print	Date

_____	_____	☐	_____
Name of person obtaining assent	Signature	Thumb print	Date

_____	_____	☐	_____
Names of witness	Signature of witness	Thumb print	Date

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Appendix K: Assent form (Runyakole Version)



KAMPALA INTERNATIONAL UNIVERSITY (KIU) WESTERN CAMPUS (WC)

RESEARCH ETHICS COMMITTEE (REC)

PO Box 71, Bushenyi, Uganda; Tel: +256 758 096 775

E-mail: kiurec2017@kiu.ac.ug; Website: www.kiu.ac.ug

FOOMU Y'ORUSA RWABATO

Omuzaire waawe yayikiriza ku oyetaba omukushomwaho kwonka nitwenda kubanza kukushobororera ahamushomo ogu naiwe oyeshariremu .

Waaba otetegyereize obuze ebibuzo bambi.

Nobaasa kugwetabamu naingashi okwanga nainga ohebwe akaire kokusharamu.

Omutwe gwomushomo /okucoondooza

Ebikwatiraine nakatiivi kokucebera omutima omubarwaire bemitima ahairwariro rya KIU TH

Omucondooza Omukuru

Dr Yves Tibamwenda Bafwa omwegi arikushoma masitaazi za Internal Medicine aha irwariro rya KIU-TH

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Okwanjura

Eby'oshemerire kumanya ahamushomo ogu

- Noshabwa kwetaba omukucoondooza oku
- Ekipapura eki nikishoborora omwoga gwawe omukucoondooza oku .
- Bambi kishomegye otware obwire burikumara.
- Noshabwabuhsabwa, noobaasa kwanga nainga waikiriza noobaasa kurugamu bwanyima hatariho kufubirwa

Omugasho gwokucoondooza oku:

Omushomo ogu nigwija kushwijuma ebikwatireine nakatiivi kokucebera omutima omubarweire bemitima ahairwriro rya KIUTH, kuyambeho okucendeeza ebishare byokuraguriza omurwaire, kucendeeze oburema/akabi n'okufa kwabarwaire bemitima.

Ahabwenki noshabwa kwetaba omukucoondooza oku

Otoorinwe kwetaba omukucoondooza oku ahabwokuba ori omwe ahabantu abiturikwenda kiyambeho kumanya omuhendo gwabarwaire bemitima okurugirira aha katiivi kokucebera omutima omukicweeka eki kandi babakuratire omukubaragurira.

Okwerakorwe

Ku' orikwikiriza kwetaba omukucoondooza oku, noija kushoborekyerwa ahabikwatiraine nomutima ohebwe akapapura osayiningeho (otekeho omukono gwawe)

Noija kubuzibwa kumara edakiika 30 okukwihahoebyorikumanya ebikwatiraine nokucoondooza oku.

Noija kugoba omukucebererwa busha omubiri gwoona, nanokuceberwa n'akatiivi komutima okwomutindo.

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Obuzibu

Okucondooza oku tiharimu kushaasha kwoona okwihaho bakye abakubasa kuba baine efumbi (Alaji) y'omubiri konka nabwe terikubasa kuba eyakabi kandi neija kujanjabwa.

Amagoba g'okucoondooza oku:

Okucebera omutima nakatiivi nikyo kyitarikuserwa kandi kirungi okukuratiriza abarwaire bomutima kandi noija kucebererwa busha.

Akasiimo kabarayetabe omukucoondooza:

Tiharaije kubaho akasiimo koona, ebirabo neinga okugarurirwa sente zentambura (turansipooti) ahabarayetabe omukucoondooza oku.

Okukuma Ebirarugye omukucoondooza.

Ebirarugye omukucoondooza oku nibyeija kuguma biri ebyekihama kandi bikozesebwe omukucoondooza oku kyonka.

Torikwikirizibwa kuhandika eizina ryawe okwihaho noija kukozesa enamba.

Okukuma Ebihama byomurwaire.

Okucoondooza oku nikwija kuba omukishengye kyehereire aha medical ward nainga Private ward.Nitwija kurebekangu omurwaire yayeherera omukuceberwa omutima.

Obugabe bwokanga nainga okurugamu.

Orikucondozibwaho /orikushomwaho naija kuba aine obugabe okurugamu eshaha yoona aharikwendera kandi eki tikyine kakwate nebirarugye omukucebera oku.

Nihabaho ki waruga Omukuceberwa oku?

Warugamu tirakubeho omukujanjabwa kwaawe okuruga omubashaho.

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Nimbuza oha kunakugira Ekibuuzo nainga ekizibu?

Wajira ekyakushobera obuze dokita Yves Tibamwenda Bafwa omwegi wa masitazi aha KIU TH aha simu +256700970889 nainga abebyokucoondooza ahairwariro rya KIU aha +256758096775.

Omukono gwawe ahakipapura eki nikimanyisaki?

- Ngu wamanyisibwa ahamushomo ogu,omugasho gwagwo okugurakorwe ,amagoba nobuzibu bwagwo.
- Ngu waheebwa omugisha gw'okubuuza ebibuuzo otakasayiningire (otakatireho omukono gwawe)
- Ngu wayeshariramu okwikiriza okushomwaho.

_____	_____	☐	_____
Eizina ryaawe	Omukono gwaawe	Ekinkumu	Ebiro byokweezi
_____	_____	☐	_____
Eizina ry'arikushaba Orusa	Omukono gwe	Ekinkumu	Ebiro byokweezi
_____	_____	☐	_____
Eizina Ry'ayabariho	Omukono gwe	Ekinkumu	Ebiro byokweezi

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Appendix L: Work Plan

Activity	December 2018	Jan – May 2019	September-October 2019	January-march 2020	April 2020
Concept					
Proposal writing and development					
Proposal submission to Research Ethical Committee (REC)					
Data collection and analysis					
Thesis writing and dissemination of results					

Appendix M: Budget

ITEM	QUANTITY	COST (UGX)	TOTAL	PURPOSE
Data manager	01	200,000	200,000	To guide data processing
ECG	122	10,000	1,220,000	Data collection
Assistant	04	100,000	400,000	Data collection
Cardiologist allowance	01	20,000/ECG	2,440,000	Data collection
Air time		100,000	100,000	Communication
Transport	01		50,000	Facilitate movement
Stationary		600,000	600,000	Printing paperwork
Publication		1,000,000	1,000,000	Dissemination of results
Miscellaneous		----------	400,000	Any other incoming expenses
GRAND TOTAL			**6,410,000**	----------