PATTERN OF ARRHYTHMIAS AMONG PATIENTS WITH HEART FAILURE ADMITTED AT JKCI

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PATTERN OF ARRHYTHMIAS AMONG PATIENTS WITH HEART FAILURE ADMITTED AT JKCI

By

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A Dissertation Submitted in (Partial) Fulfilment for the Requirement of Degree in Master of Medicine in Internal Medicine of the Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that they have read and hereby recommends for acceptance by the Muhimbili University of Health and Allied sciences a dissertation entitled: "**Pattern of arrhythmias among patients with Heart failure admitted at JKCI**" in partial fulfilment requirement for the degree of master of medicine in Internal Medicine of the Muhimbili University of Health and Allied sciences.

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Date

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Dr Yona Gandye
(Co-supervisor)

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Date

DECLARATION AND COPYRIGHT

I Luginy'o Ilomo declare that this dissertation is my original work and has not been submitted elsewhere for examination, award of a degree or publication and will not be presented to any other university for a similar or any other degree award.

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My family; Starting with my wife then my children, parents brothers and sisters for standing with me during my postgraduate studies with constant encouragements whenever I was low in spirit, prayers, resources and unwavering support.

DEDICATION

This dissertation is dedicated to the management team of Consolata Hospital Ikonda under the supervision of Fr Willium. Also, my family (wife and children), my brothers and sisters for their endless love, support and encouragement.

ABSTRACT

Background: Arrhythmias significantly impact the mortality and morbidity of individuals with heart failure, placing a substantial burden on healthcare systems worldwide. However, a detailed understanding of the specific arrhythmia patterns among patients admitted to the Jakaya Kikwete Cardiac Institute (JKCI) remains lacking.

Aim: To determine the prevalence, types, and subtypes of arrhythmias in patients with heart failure admitted to JKCI

Methodology: We conducted a four-month hospital-based descriptive cross-sectional study involving 241 participants who met inclusion criteria and provided consent. All participants were diagnosed with heart failure based on the Framingham criteria, and necessary investigations, including electrocardiograms (ECGs), were efficiently performed. We used SPSS as the standard statistical software to analyse our data.

Results: Our study revealed a prevalence of arrhythmias among heart failure patients admitted to JKCI at 116(48.1%). Supraventricular arrhythmias were predominant, with atrial fibrillation (AF) accounting for 35(14.5%) of cases among all heart failure patients and 35(30.2%) among those with arrhythmias. Sinus tachycardia followed at 22(19.0%), and premature ventricular contractions (PVCs) at 14(12.1%). Heart blocks were also common, with first-degree heart block being the most prevalent at 13(11.2%).

Conclusion: Nearly half of heart failure patients at JKCI exhibit arrhythmias. Supraventricular arrhythmias, particularly atrial fibrillation, represent the most common subtype among arrhythmic heart failure patients, impacting 30.2% of this population and 14.5% of all heart failure patients Understanding the various arrhythmia types is crucial for improving management strategies.

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ABBREVIATIONS

ACC	American College of Cardiology
ACE	Angiotensin Converting Enzyme
AF	Atrial Fibrillation
AFL	Atrial Flutter
AHA	American Heart Association
AT	Atrial Tachycardia
AVNRT	Atrial Ventricular Nodal Reentrant Tachycardia
CHF	Congestive Heart Failure
DDD	Dual chamber ant bradycardia pacing
ECG	Electro Cardiography
GBD	Global Burden of Disease
HF	Heart Failure
HFSA	Heart Failure Society of America
HICs	High Income Countries
ICD	Implantable Cardiac Defibrillator
JKCI	Jakaya Kikwete Cardiac Institute
LMICs	Low- and Middle-Income Countries
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Science
NSVT	Non-Sustained Ventricular Tachycardia
PSVT	Paroxysmal Supra Ventricular Tachycardia
PVCs	Premature Ventricular Contractions
SCD	Sudden Cardiac Death
SVAs	Supra Ventricular Arrhythmias
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia
VVI	Single chamber ventricular pacing

DEFINITION OF KEY TERMS

Heart failure (HF): Is a clinical syndrome consisting of cardinal symptoms (e.g. breathlessness, ankle swelling, and fatigue) that may be accompanied by signs (e.g. elevated jugular venous pressure, pulmonary crackles and peripheral edema) which result from a structural or functional cardiac abnormality that compromises the ventricle's ability to fill with blood or expel blood. (1)

Arrhythmia: is a problem with the rate or rhythm of the heart which may be too quickly, too slow or with an irregular rhythm which maybe sinus or non-sinus. When the heart is in sinus rhythm, the electrocardiogram (ECG) P waves are normal, the heart rate is steady, and the heart rate is within the normal range.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Heart failure (HF) is a multi-faceted and life-threatening syndrome characterized by significant morbidity and mortality, poor functional capacity and quality of life, and high costs. In 2021, major worldwide scientific bodies proposed a consensus on a universal definition and classification of HF. The term "HF" refers to a clinical condition with symptoms and/or signs associated with structural and/or functional abnormalities of the heart, which are supported by high natriuretic peptide levels and/or conclusive proof of pulmonary or systemic congestion. (5)

1.1.1 Prevalence and Incidence of HF worldwide

There has been an increase in the prevalence of HF in the population over time. In one study, the average increase from 1989 to 1999 was 1/1000 and 0.9/1000 for females and males, respectively. This has been associated with a three- to fourfold rise in the rate of hospitalization for HF from 1971 to 1999. Several elements are contributing to this rise, particularly the aging of the population. In addition, improved treatment of hypertension and valvular and coronary disease is allowing patients to survive an early death only to later develop HF. The prevalence of HF in the United States is projected to rise over the next four decades, with an estimated 772,000 new HF cases projected in the year 2040 and a total of 8 million prevalent cases by 2030. (7)

The prevalence of HFpEF increases with age. In one review, the estimated prevalence of diastolic dysfunction among patients with HF was 15, 33, and 50 percent at ages less than 50, 50 to 70, and more than 70 years, respectively. In addition, another 15 percent of elderly patients with HF have mildly abnormal systolic function (LVEF 45 to 54 percent), which should not produce symptoms on its own and is therefore probably associated with an important component of diastolic dysfunction.

The incidence of HF, like its prevalence, increases with age. In the Framingham Study, the incidence approximately doubled over each successive decade of life, rising more steeply with age in females than in males. The annual incidence in males rose from 2 per 1000 at age 35 to 64 years to 12 per 1000 at age 65 to 94 years. Because the increase in risk with age is balanced by the decreased life expectancy with older age, the lifetime likelihood of developing HF is approximately 20 percent at all ages above 40. (8)

1.1.2 Worldwide HF mortality overview

The study done by Dr. Hisham et al. (2017), which enrolled 5823 patients with HF within 1 year (with 98% follow-up), Overall mortality was 16.5%: highest in Africa (34%), India (23%), intermediate in Southeast Asia (15%), and lowest in China (7%), South America (9%), and the Middle East (9%). Regional differences persisted after multivariable adjustment. Mortality between regions in patients with heart failure rates was higher in poorer regions and lower in richer regions; this could be the result of health-care infrastructure, quality, and access, or environmental and genetic factor. Further studies in large, global cohorts are needed. (9)

In the European Society of Cardiology Heart Failure Long-Term (ESC-HF-LT) registry that enrolled 12 440 patients with acute (i.e., either with incident or pre-existing HF in need of diuretics, inotropes, or vasodilators) and chronic HF from 21 European countries between 2011 and 2013, 1-year mortality was 23.6% for acute HF and 6.4% for chronic HF. Notably, mortality rates ranged across the different European countries involved in the registry, i.e., between 21.6% and 36.5% in patients with acute HF and from 6.9% to 15.6% in patients with chronic HF. (5)

1.1.3 Arrythmia overview

Cardiac arrhythmia is an irregular heartbeat that results from the aberrant genesis and/or spread of electrical impulses. They might be transient or irreversible, inherited (structurally normal or aberrant), acquired (toxin, infection, or infarction), urgent, or innocuous. (13)

There are essentially two varieties, depending on where they originated. They are referred to as ventricular if they originate in the ventricles and as supraventricular if they start in the atria. They are divided into groups based on how they influence resting heart rate. Bradycardia is characterized by a heart rate of 60 beats per minute or less, whereas tachycardia is characterized by a heart rate of 100 beats per minute or more. (14)

Tachyarrhythmias are brought on by changes in the mechanical, structural (cardiomyopathies, chamber hypertrophy, and stretch), neurohumoral, metabolic, and electrical characteristics of the failing heart. Bradyarrhythmia's can develop as a result of a drop in heart rate or a cessation of an impulse's conduction after it has already begun. (15)

1.1.4 Diagnosis of Arrythmia

Apart from medical history and physical examination, the diagnosis requires documentation with an Electrocardiogram (ECG) or a monitor. Due to the paroxysmal nature of many suspected arrhythmia patients, the ECG obtained in the absence of symptoms is frequently either normal or does not indicate a particular arrhythmia. There are four different kinds of outpatient monitoring systems (15). Traditional Holter (continuous recording of ECG, usually for 24 or 48 hours), Event Recorder, Mobile Continuous Outpatient Cardiac Telemetry, and Insertable Cardiac Monitor. These methods can improve the diagnosis of arrhythmia compared to the use of spot 12 lead ECG in which paroxysmal arrhythmias are frequently missed.

1.1.5 Treatment of arrythmia in heart failure

Herat failure (HF) and Atrial fibrillation (AF) are both treated with a number of the same medications. For instance, digoxin and beta-blockers can lower the heart rate, but ACE inhibitors may trigger reverse remodelling and lessen the severity of AF. Contrarily, antiarrhythmic medications are not very effective in treating heart failure (HF), so despite the rhythm management strategy's success in reducing AF, it has not been shown to improve patient survival rates. The two primary treatment methods for AF are rate control and rhythm control, and risk assessment for stroke is crucial in the care of HF patients with AF. (15) Most patients with structural heart disease who have both HF and AF need systemic anticoagulation to reduce their risk

of stroke. The CHA2DS2-VASc score should be used as the initial step in determining a patient's stroke risk, according to recommendations from the American College of Cardiology, American Heart Association, and Heart Rhythm Society. Those with a moderate-to-high stroke risk should begin anticoagulation. (14)

The majority of HF patients have asymptomatic Premature Ventricular Contractions (PVCs); in these patients, electrolyte abnormalities should be corrected (especially low serum potassium and magnesium levels), medications that could cause arrhythmias should be stopped, and HF medication therapy should be optimized. However, treating arrhythmias as a whole is typically not advised. (15) For symptomatic individuals, optimizing beta-blockers is the first line of antiarrhythmic therapy; amiodarone or sotalol are then suggested if this approach is unsuccessful in controlling symptoms. A steady rhythm with a physiologically suitable ventricular rate must be quickly restored in order to prevent organ damage or additional hemodynamic worsening during acute therapy for prolonged VT (defined by a period of 30 s).

Individuals who have intact atrio-ventricular conduction and sinus node dysfunction may be candidates for atrial pacing alone (AAI mode); Anyone with an AV block, whether real or potentially harmful, would require ventricular pacing. Particularly in the HF population, there is little clinical evidence to support dual-chamber ventricular pacing (DDD or DDDR) as being superior to single-chamber ventricular pacing (VVI or VVIR). Atrio-biventricular pacing is routinely considered in patients with HF and severe left ventricular dysfunction who are expected to need long-term ventricular pacing, even though there is substantial evidence that right ventricular pacing alone is deleterious in patients with left ventricular dysfunction. (15)

1.1.5.1 Catheter ablation

The current indications for this procedure are listed as symptomatic monomorphic sustained VT that recurs despite therapy with antiarrhythmic drugs or in patients who do not want to take or cannot tolerate antiarrhythmic medications in the European

Heart Rhythm Association and Heart Rhythm Society consensus document on catheter ablation of Ventricular Arrhythmias (VAs). (14)

Patients with many PVCs, non-sustained ventricular tachycardia (VT), or VT that leads to cardiac dysfunction may benefit if a hypothesised trigger (single PVC morphology) can be addressed (from tachycardia-related cardiomyopathy).

Candidates for catheter ablation include individuals with recurrent, prolonged polymorphic VT or ventricular fibrillation (VF) that is resistant to antiarrhythmic drugs, as well as VT from bundle branch re-entry or interfascicular VTs.

1.1.6 Co-existence of arrythmia and heart failure

All types of heart failure commonly involve cardiac arrhythmias, whether they are symptomatic or not, benign or fatally malignant. For instance, atrial fibrillation (AF) may be the most common arrhythmia in patients with mitral valve regurgitation. AF may cause CHF to worsen and the severity of mitral regurgitation to increase. On the other hand, ventricular tachycardia (VT) or ventricular fibrillation (VF) may appear in a patient with ischemic cardiomyopathy, which might result in abrupt cardiac death (SCD). Moreover, a patient may have both ventricular and atrial arrhythmias at the same time. (3)

VT, VF, and AF are the primary arrhythmias in CHF that have received a lot of attention. According to data from numerous studies, around 87% of CHF patients have premature ventricular beats and/or couplets, and the rate of non-sustained VT could be as high as 45–80%. According to the Euro Heart Failure survey on AF, not only do up to 45% of CHF patients also present with AF, but new-onset AF is also a reliable indicator of in-hospital mortality in CHF patients who are hospitalized. (17) Ventricular tachycardia is common in patients with HF, with up to 20% of patients developing VT in 5 years after an ICD was placed. In patients with HF, SCD occurs 6–9 times more often than in the general population. The most studied and proven predictor of ventricular tachyarrhythmia and SCD is left ventricle ejection

fraction (LVEF). It has been shown that once the LVEF recovers, the incidence of ventricular tachyarrhythmia decreases. (17)

The importance of ventricular arrhythmia is based on its association with sudden death. In certain groups of patients, ventricular arrhythmia, primarily non-sustained ventricular tachycardia (NSVT), is associated with an increased risk for sudden death. Although this relationship has been most often reported in patients with recent myocardial infarction, it has also been recognized in patients with dilated cardiomyopathy, regardless of etiology. Therefore, ventricular arrhythmia is common in patients with CHF due to cardiomyopathy. A number of studies have reported that 70–95% of patients with cardiomyopathy and congestive heart failure (CHF) have frequent ventricular premature beats, and 40–80% will manifest runs of NSVT. (18)

Arrythmia and heart failure (HF) frequently coexist due to shared risk factors. A worse prognosis may be associated with HF and arrythmia together than with either condition alone. (20) . A community-based cohort study found that 384 of the 1664 people with HF who were diagnosed between 1983 and 2006 also acquired AF. Of these, 553 had a history of AF. Those with past AF experienced 450 fatalities over a median follow-up of 4.0 years; patients with AF following heart failure had 314 deaths; and patients without prior AF experienced 572 deaths. Depending on when AF appears, the degree of this additional risk varies greatly, with AF appearing after HF imparting the highest elevated risk of mortality when compared to HF patients without AF. In fully adjusted models, patients with AF before HF had a 29% higher risk of dying compared to those without AF, and those with AF after HF had a >2-fold higher risk of dying. (19)

AF is associated with an increase in the number, incidence, and hospitalizations due to acute heart failure. Patients with HF who develop AF have a higher risk of acute heart failure hospitalization and haemorrhagic stroke, faster renal function reduction, and all-cause mortality. Heart failure is one of the most influential factors in

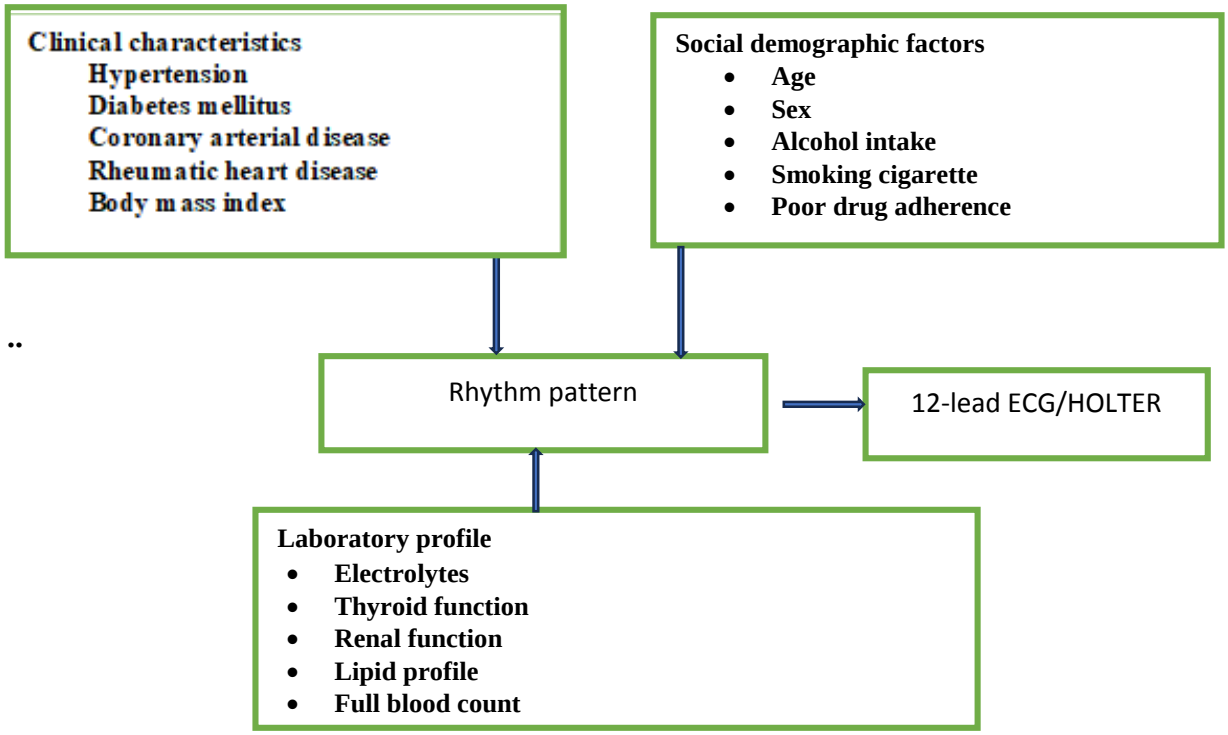
increasing the risk of AF. In fact, HF and age-per-HF are components of the all-score risk for AF. The increased risk of HF patients developing AF can primarily be explained by structural atrial remodelling, mitral valve regurgitation, and altered neurohumoral balances. (8)

1.2 Problem Statement

Despite the advanced and evidence-based approach to management of patients with heart failure, there is still a big challenge when there is co-existence with arrythmia, as it has been shown to be associated with an increment in incidence, number, hospitalization, and mortality rate. There is a lack of specific knowledge regarding the pattern of arrhythmias among patients admitted to JKCI. This knowledge gap hinders the development of targeted management strategies and optimized care for this patient population.

1.3 Conceptual Framework

Arrhythmias in heart failure indicate a poor prognosis, influenced by age, co-existing conditions, and lifestyle factors. Timely intervention is essential to lower the risks of complications and death. Managing these risks enhances patient outcomes**.**



..

Figure 1: Framework showing the interaction of social-demographic, clinical characteristics and laboratory profile influencing the rhythm pattern in HF hence need for ECG testing.

1.4 Rationale

Addressing arrhythmia in heart failure is essential for improving the management among patients with heart failure. This research aims to fill the existing knowledge gap and provide valuable insights that can guide evidence-based interventions and enhance the overall care provided to patients with heart failure in our own setting.

1.5 Research Questions

1. What is the prevalence of arrhythmias among patients with heart failure admitted at JKCI?
2. What are the types of arrhythmias observed in patients with heart failure at JKCI?
3. What are the subtypes of arrhythmias observed in patients with heart failure at JKCI?
4. What is the relationship between arrhythmia and cardiac structural changes in heart failure

1.6 Objectives

1.6.1 Broad objective

To determine the prevalence, types, and subtypes of arrhythmias in patients with heart failure admitted to JKCI

1.6.2 Specific objectives

1. To determine the prevalence of arrhythmias among patients with heart failure admitted at JKCI
2. To identify the types of arrhythmias observed in patients with heart failure
3. To identify the subtypes of arrythmias observed in patients with heart failure
4. To determine the relationship between arrhythmia and cardiac structural changes in heart failure

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Worldwide prevalence of arrhythmia in heart failure

The prevalence of arrhythmias in heart failure can vary depending on several factors, including the severity of heart failure, the underlying cause of heart failure, and the population being studied. However, it is generally recognized that arrhythmias are highly prevalent in individuals with heart failure. The exact prevalence rates of arrhythmias in heart failure can vary among studies. However, it is estimated that approximately 30-50% of patients with heart failure experience some form of arrhythmia during the course of their illness.

Ajoyi OE et al. Found that cardiac arrhythmias, including tachycardia and ventricular extrasystoles, are more frequent and severe in CHF patients compared to those with hypertensive heart disease and healthy individuals. (20)

2.2 Worldwide prevalence of AF in heart failure

Atrial fibrillation (AF) is the most common sustained arrhythmia in heart failure patients. Its prevalence in heart failure varies widely depending on the severity of heart failure, the population studied, and other factors. Studies have reported that AF is present in approximately 25–50% of patients with heart failure worldwide. (21)

According to data from the Global Burden of Disease (GBD), the estimated number of people affected by AF worldwide in 2010 was 33.5 million. In high income countries (HICs) like the United States, it currently affects 2–6 million individuals, and by 2060, that figure is expected to rise. The prevalence and incidence of AF are still much higher in HICs than in LMICs. Nevertheless, while assessing this gap, it is important to take into consideration the significant data deficiency in LMICs, which likely grossly underestimates the real illness burden. According to the 2010 GBD research, the estimated incidence rates for men were 53.0 (33.8-76.8) and for women, 40.0 (27.2-62.6), whereas in LMICs, the estimated prevalence rates for men were 565.7 (95% CI, 522.9-617.6) and for women, 366.1 (337.4-400.8). (22)

According to a study conducted in America from 2008 to 2017, 10 392 189 individuals hospitalized for HF showed a higher rate of concomitant AF in those with an intact ejection fraction than those with a reduced ejection fraction (44.9% versus 40.8%). Comorbid AF's prevalence grew over time, from 35.4% in 2008 to 45.4% in 2017, and patients were typically younger, male, and black or Hispanic. Over time, vascular disease, diabetes mellitus, and comorbid hypertension all got worse. In-hospital mortality was greater for HF hospitalizations with AF (3.6% versus 2.6%). (23)

2.3 Prevalence of ventricular arrhythmia in heart failure

The prevalence of ventricular arrhythmias in heart failure varies based on the severity of heart failure, the presence of underlying coronary artery disease, and other factors. It has been estimated that approximately 10–30% of heart failure patients may experience ventricular arrhythmias.

In a research study by C.S. Maskin et al., the incidence of ventricular arrhythmias was evaluated in 35 patients with severe congestive heart failure (CHF) in New York Heart Association functional classes III to IV. 71% of these people experienced repeated VT episodes over the course of 24-hour ambulatory Holter monitoring; 92% of them experienced multifocal ventricular ectopic beats, and 88% had fewer than 10 ventricular ectopies per 1000 normal heartbeats. Between one and 72 weeks following the Holter monitoring, 25 people passed away. One patient's passing could have been caused by VT. In every other instance, worsening CHF occurred before passing away. (24)

According to the 2015 Euro Heart Failure Study (n = 11016), about 8% of the cohort had pacemakers placed, and almost one in six patients had a bradyarrhythmia complicate their clinical course. About 8% of patients with HF-related hospitalizations also had pacemakers installed, and bradycardia occurred in 6% of these patients. (25)

2.4 Prevalence of arrhythmia in heart failure in Africa

Limited studies focusing solely on the prevalence of arrhythmias in heart failure, specifically in Africa, are available. However, broader studies on heart failure in Africa have reported that arrhythmias are a significant concern in this population.

Research published in the Pan African Medical Journal in 2016 revealed that atrial fibrillation affected about 23% of heart failure patients across various African countries. Another study from South Africa, published in the Cardiovascular Journal of Africa in 2017, showed that 48% of heart failure patients experienced atrial fibrillation. (26)

A 2012 study in Nigeria found that heart failure patients had significantly higher rates of ventricular arrhythmias, including frequent PVCs, ventricular couplets, and NSVT, compared to healthy controls. The prevalence and severity of these arrhythmias were notably greater in heart failure patients, highlighting a substantial difference from the healthy population. (20)

2.5 Prevalence of arrhythmia in heart failure in Tanzania

Information specific to the prevalence of arrhythmias in heart failure in Tanzania is limited, and there is a scarcity of comprehensive studies on this specific topic in the country. However, below are general insights based on available data.

A study published in 2019 in the Journal of the American Heart Association examined the burden of heart failure in Tanzania. The study reported that among the heart failure patients included in the study, 25.5% had AF as a comorbidity. While this study did not specifically focus on the prevalence of arrhythmias in heart failure, it suggests that AF is present among heart failure patients in Tanzania.

A prospective cohort study between October 2018 and May 2020 based on an outpatient clinic at a tertiary hospital in Mwanza, involving 403 patients with HF (234 (58%) females, mean age 60 ± 19 years), 17% of participants had AF. By the end of the three-month follow-up, 120 out of 403 individuals (30%) had passed away, including 44% (31/70) of those with AF. (27)

A hospital-based cross-sectional study conducted among 390 patients with an echocardiography diagnosis of RHD aged 18 years and older attending JKCI, Arrhythmias were found in 276 (70.77%) patients, of which 193 (49.5%) patients had resting ECGs and 83/197 (44.7%) patients had Holter electrocardiography. The study revealed a high prevalence of arrhythmias among patients with RHD (one of the common causes of HF). (28)

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This was a hospital based descriptive cross-sectional study

3.2 Study population

All adult patients admitted at JKCI confirmed with diagnosis of heart failure

3.3 Study area

The research was conducted at Jakaya Kikwete Cardiac Institute which is a famous healthcare institution located in Dar- es- Salaam, Tanzania established on September 1, 2015. It is a specialized centre that focuses on the diagnosis, treatment, and management of cardiovascular diseases. It can accommodate 103 patients, and on a weekly basis, it sees 700 outpatients and 100 inpatients. The institute serves as a leading center for cardiac care in Tanzania and is dedicated to providing comprehensive, evidence-based, and patient-centred cardiovascular services.

The institute features advanced infrastructure and diagnostic tools, including cardiac wards, ICUs, operating theatres, catheterization labs, and imaging facilities. It employs a specialized multidisciplinary team and provides education and training through residency programs, workshops, and conferences to advance cardiology knowledge and skills in the region.

3.4 Study duration

The study was conducted within four months from the beginning of October 2023 to the end of January 2024.

3.5 Sample size estimation

241 patients were involved in the study as they met inclusion criteria and gave a consent. The sample size was estimated based on the published research from a Tanzanian (in Mwanza) study Given that AF in HF was shown to be prevalent in 2022 at 17% (12), the following formula was applied;

$n = Z^2 P (100 - P)/\varepsilon^2$

n = minimum sample size required Z = SD set at 1.96 (CI of 95%)

P = Prevalence of arrhythmia in HF.

ε = marginal error to be used of 5.0%

n = 1.96*1.96X 17 (100 – 17) / 5*5

n = 217

With the inclusion of an error due to a non-response rate of (f) of 10%, the final sample size was calculated using the formula: $N = (n\ X\ 100)/(100 - f)$ N = (217 x 100)/ (100 – 10)=241

3.6 Sampling method

Consecutive sampling method was applied

3.6.1 Inclusion criteria

1. Adult patients with a diagnosis of heart failure
2. Patients admitted to JKCI for the management of heart failure

3.6.2 Exclusion criteria

None

3.6.3 Enrollment of study participants

During enrolment of study participant, the following steps were followed

1. Identification of adult patients with heart failure who were admitted to JKCI
2. Eligible patients or their legal representatives were being provided with information about the study
3. We got Informed consent from all those who participated
4. The consenting participants were enrolled in a study and all necessary data were being collected

The enrollment was consecutive with the aim of reaching 241 participants who met Framingham criteria for heart failure and consenting for a study.

3.6.4 Procedure

To all participants consenting for a study their demographic data were recorded which included age, address, sex education level and marital status. Their names were not recorded but each participant was given a number to replace the name.

All patients who consented for the study were re clerked to get full medical history as well as general and systemic examination was done with more consideration in cardiovascular system by the principal investigator or assistant. We reached the diagnosis of HF based on Framingham criteria which comprise major and minor criteria's as follows

Major criteria

i. Acute pulmonary edema
ii. Cardiomegaly
iii. Hepatojugular reflex
iv. Neck vein distension
v. Paroxysmal nocturnal dyspnea or orthopnea
vi. Rales

Minor criteria

i. Ankle edema
ii. Dyspnea on exertion
iii. Hepatomegaly
iv. Nocturnal cough
v. Pleural effusion
vi. Tachycardia

Those with two main criteria, or one major and two minor criteria, were diagnosed to have HF.

To each participant diagnosed with heart failure, a 12 lead ECG testing using Phillips machine was done. The procedure was being conducted by the trained medical

personnel. All ECG results were being interpreted by the cardiologist and recorded for analysis.

Other investigations

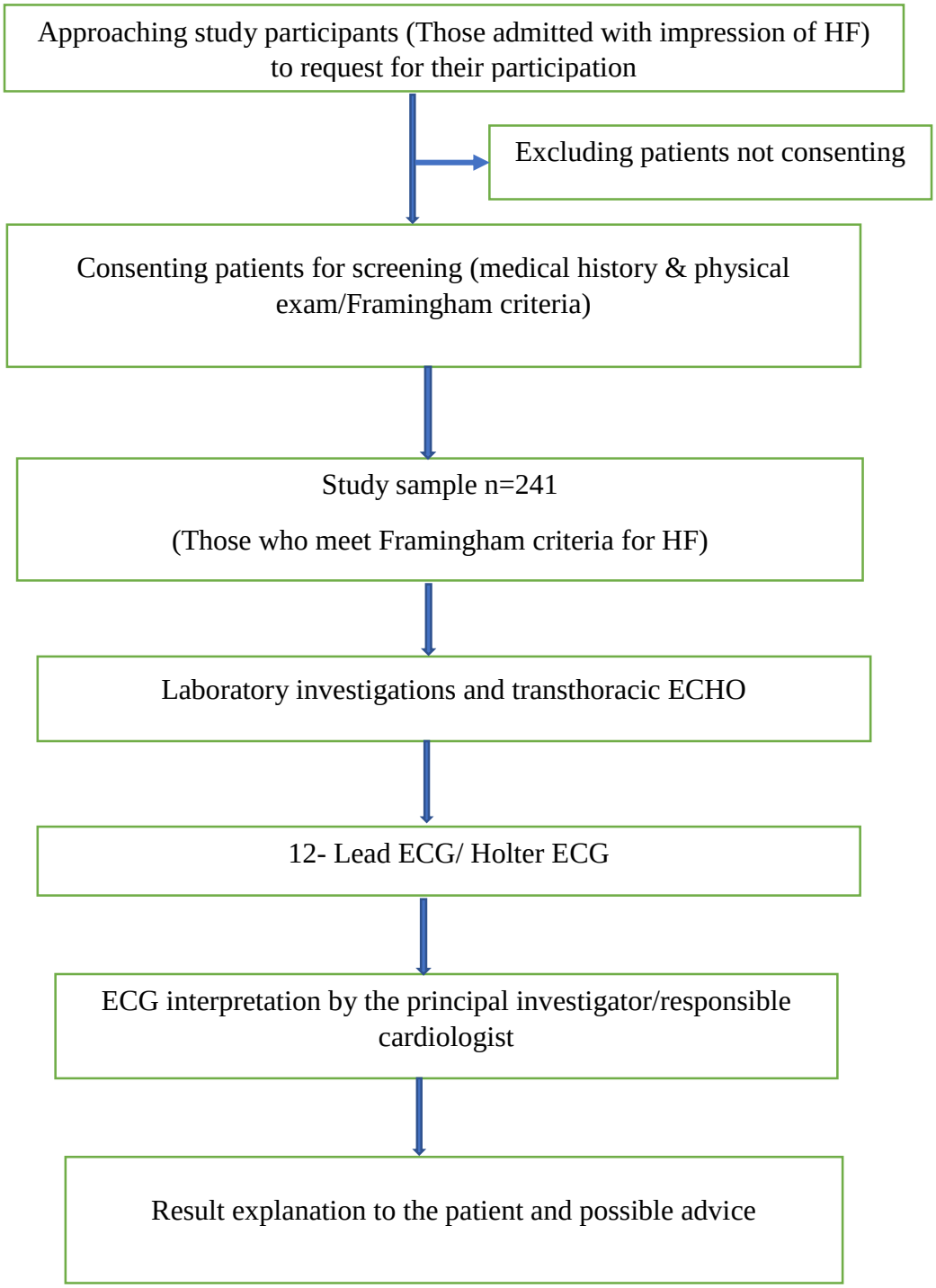
Other possible investigations were being done of which their derangements most of the time lead to development of arrhythmia. These investigations included: full blood count, serum electrolytes, and renal function test.

Echocardiogram (ECHO)

For eligible patients, an echocardiography examination was being conducted by the Echocardiographer in accordance with the recommendations of the American Society of Echocardiography, and the outcomes were examined by an investigator with assistance from the cardiologist.

The four-chamber views of the organs, which include apical, subcoastal, suprasternal, as well as parasternal long axis views, were being incorporated in ECHO. Two-dimensional guided M-mode images taken at the end of diastole were utilized to measure the left ventricle's internal diameters. 2D guided M-mode images were utilized to assess the left atrium's size during end systole. The Teicholz technique was used to determine the left ventricular ejection fraction in M-mode guided parasternal long axis images of the left ventricle.

Flow chart


Approaching study participants (Those admitted with impression of HF) to request for their participation
Excluding patients not consenting
Consenting patients for screening (medical history & physical exam/Framingham criteria)
Study sample n=241
(Those who meet Framingham criteria for HF)
Laboratory investigations and transthoracic ECHO
12- Lead ECG/ Holter ECG
ECG interpretation by the principal investigator/responsible cardiologist
Result explanation to the patient and possible advice

3.7 Data analysis

The collected data was thoroughly reviewed and any incomplete or inconsistent entries were addressed before being analyzed with SPSS (IBM SPSS statistics 2023)

Prevalence Calculation

The prevalence of arrhythmias among patients with heart failure was determined by dividing the number of heart failure patients with arrhythmias by the total number of heart failure patients. The association between categorical variables was explored using the chi-square test. A two-tailed p-value of <0.05 was used as the cutoff for statistical significance.

Subtype Analysis

The distribution and frequencies of different arrhythmia subtypes was analyzed to gain insights into the specific types prevalent among heart failure patients at JKCI.

Statistical Analysis

The prevalence of arrhythmias and the distribution of arrhythmia subtypes is presented using proportions

Reporting and Interpretation

The results of the analysis are summarized in a clear and concise manner, including tables, figures, and narrative descriptions. The prevalence of arrhythmias and the types/subtypes observed in patients with heart failure are reported.

3.8 Ethical consideration

The MUHAS Research and Publishing Committee was consulted for ethical approval.

All participants signed a written agreement before taking part, and the participation was entirely voluntary.

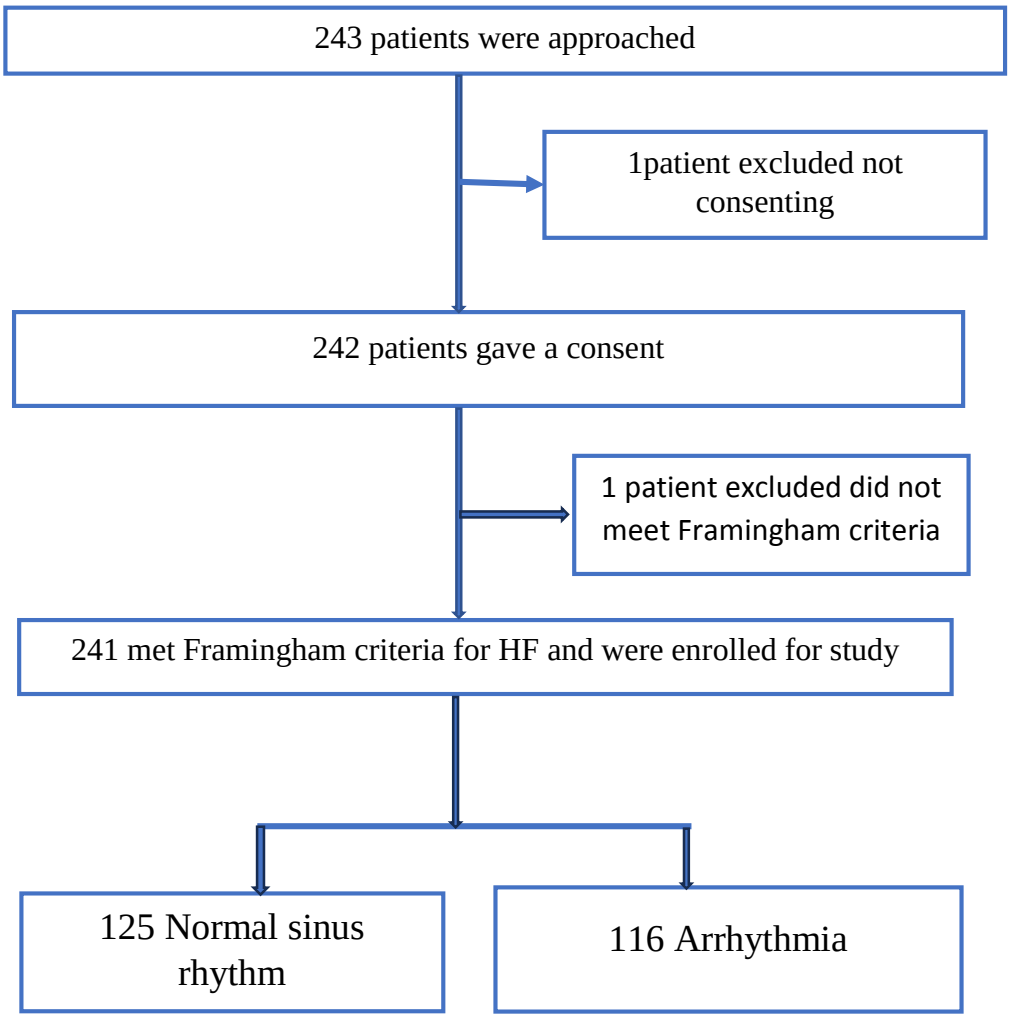
3.9 Data dissemination

The study findings were presented to the Department of Internal Medicine and at academic conferences. The dissertation was submitted to the Jakaya Kikwete Cardiac Institute (JKCI) and the MUHAS Library, and a manuscript was prepared for publication in a peer-reviewed medical journal.

CHAPTER FOUR

4.0 RESULTS

Flow diagram of study participant



4.1 Participant characteristics

From October 2023 to January 2024, a total of 243 patients were approached for study enrolment, of whom 1 patient did not give consent and 1 patient did not meet the framing harm criteria for heart failure; hence, the remaining 241 patients were involved in the study.

Among the participants, 114 (47.3%) were aged 60 years and older, with a median age of 62 years (IQR: 48-70) (Table 1). Female participants comprised more than half of the total, accounting for 133 individuals (55.2%). Most participants had received some level of formal education, ranging from primary school to university, with the majority (n = 131, 54.4%) having attained primary school education. However, 11 participants (4.6%) had no formal education. A total of 101 participants (41.9%) were hypertensive, 6 (2.5%) were diabetic, and 50 (20.7%) were both hypertensive and diabetic.

Table 1: Socio-demographic and clinical characteristics of the study participants

Variable	Frequency (n)	Percent (%)
Age group (years)		
≤ 60	114	47.3
>60	127	52.7
Median age in years (IQR)	62 (48, 70)	
Sex		
Male	108	44.8
Female	133	55.2
Level of education		
No formal education	11	4.6
Primary	131	54.4
Secondary	23	9.5
College / University	76	31.5
Marital status		
Single	31	12.9
Married	198	82.2
Separated	5	2.1
Divorced	2	0.8
Widowed	5	2.1
Chronic condition		
Hypertension	101	41.9
Diabetes mellitus	6	2.5
Hypertension and Diabetes mellitus	50	20.7
Unspecified	84	34.9
HIV status		
Positive	1	0.4
Negative	240	99.6

4.2 Prevalence of arrhythmia

Among the 241 patients with heart failure who participated in this study, almost half of the participants 116 (48.1%) were found to have various types of arrhythmias, see fig 2

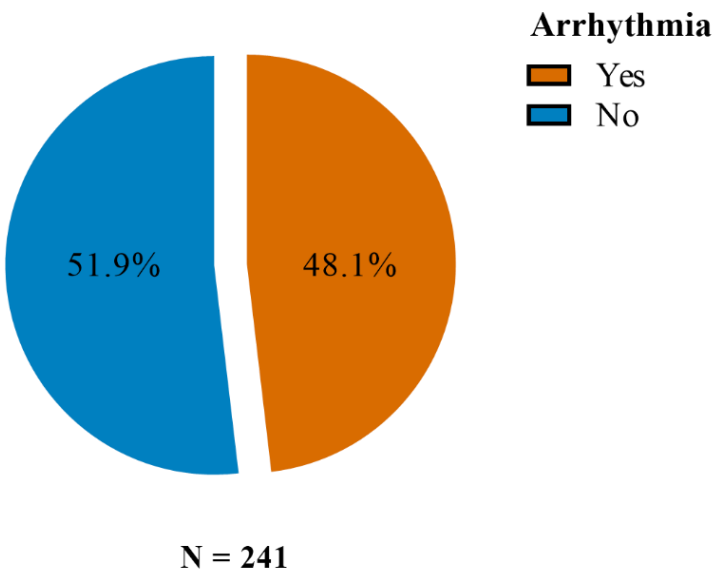


Figure 2: Prevalence of arrhythmia among patients with heart failure admitted at JKCI

4.3 Types and subtypes of arrhythmias

In this study arrhythmias were categorized into three main types, supra ventricular and ventricular arrhythmia the third type involved those with both supraventricular and ventricular arrhythmia (Regarded as mixed type) as shown in fig 3 below. Supra ventricular arrhythmia involved atrial fibrillation, atrial flutter, premature atrial contraction sinus bradycardia, sinus tachycardia, junctional rhythm, atrial flutter with variable AV block and AV-blocks (first to third degree). Ventricular arrhythmias included ventricular tachycardia and premature ventricular contractions. One patient had both supraventricular (AF) and ventricular (PVC) arrhythmia which in this study was regarded as mixed type. Among the two common types of arrhythmias based on the originating site supraventricular arrhythmia was found to be predominant representing the prevalence of 85.34%, where by ventricular arrhythmia was found to contribute 13.79%.

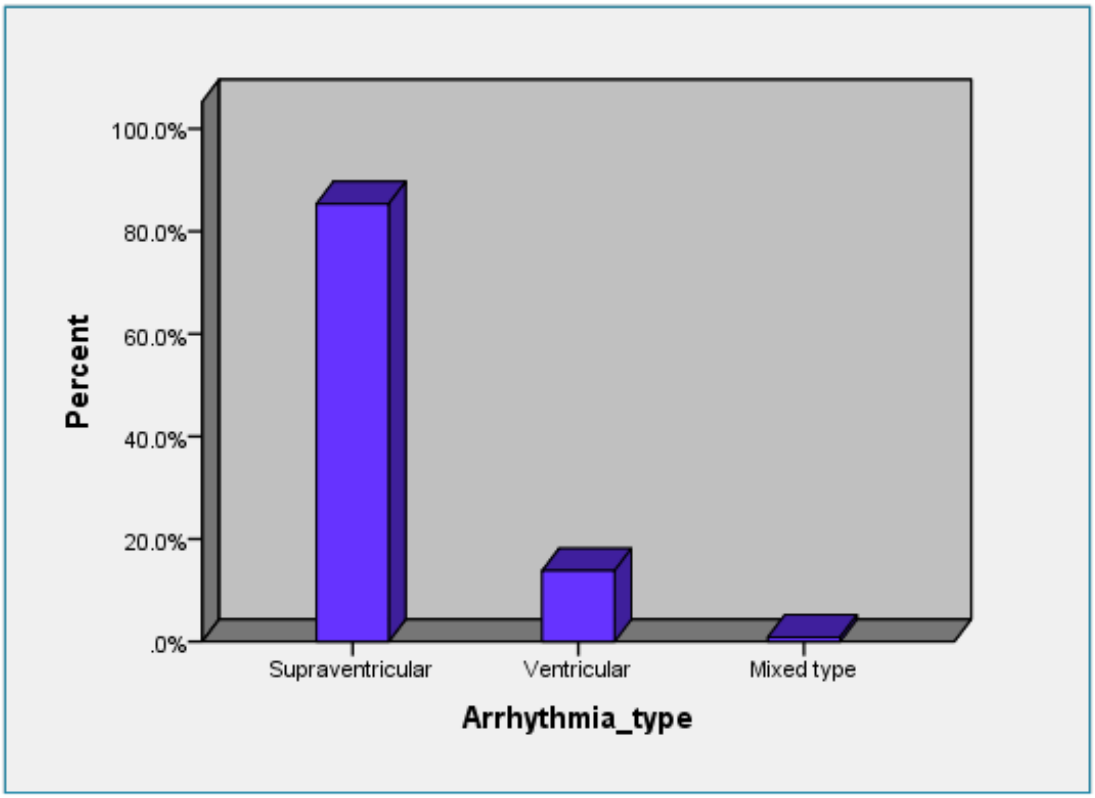


Figure 3: The proportion of arrhythmia types in heart failure patients

Figure 4 shows the different types of arrhythmias found in patients with heart failure. Among these patients, 30.2% had atrial fibrillation (AF). When looking at all heart failure patients, 14.5% had atrial fibrillation, as shown in Figure 5.

Sinus tachycardia was the second most common arrhythmia pattern, occurring in 19.0% of heart failure patients with arrhythmia. Premature ventricular contractions (PVCs) were the most frequent ventricular subtype, found in 12.1% of cases. Heart block was also common, with first-degree heart block seen in 11.2% of patients. Several other arrhythmia patterns were identified, each occurring in less than 10% of cases.

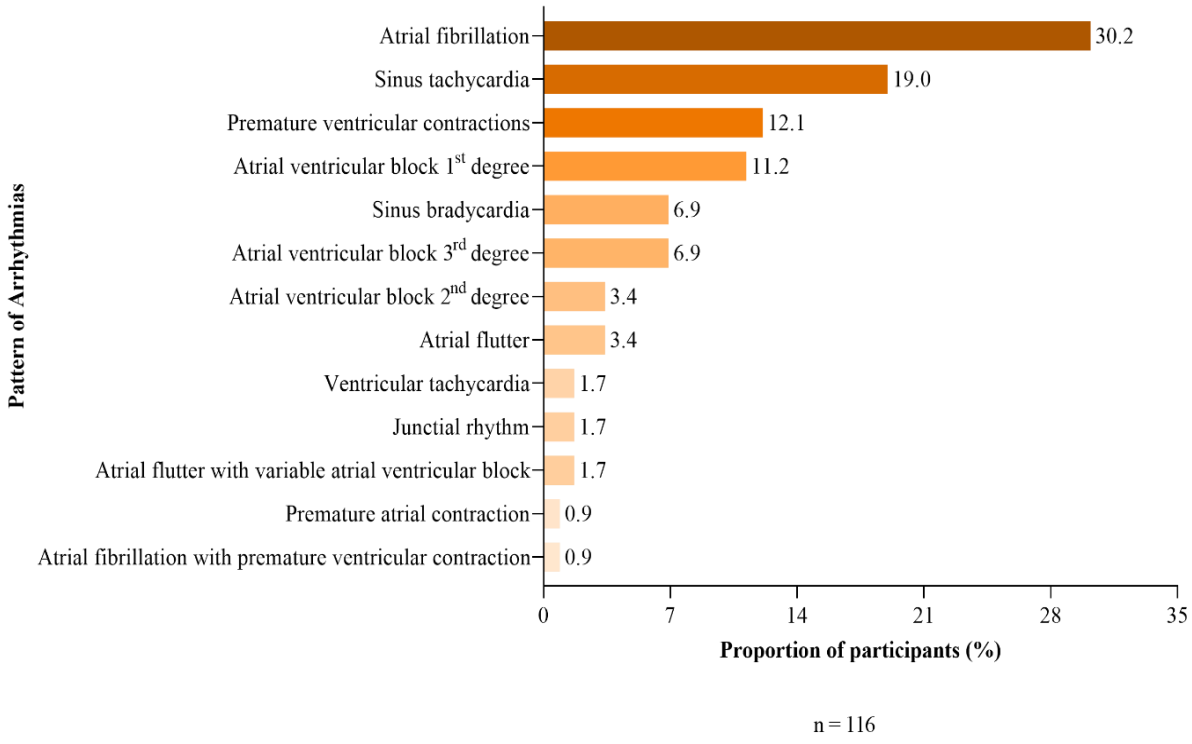


Figure 4: The proportion of arrhythmia patterns among patients with arrhythmia in heart failure admitted at JKCI

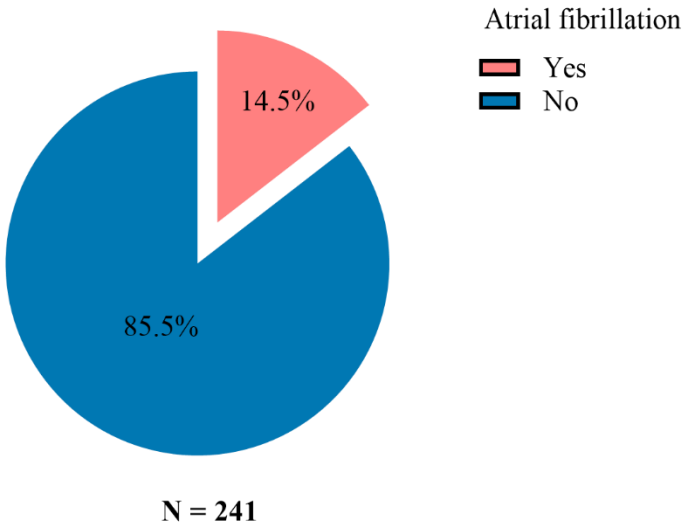


Figure 5: The proportion of atrial fibrillation among patients with Heart Failure admitted at JKCI.

4.4 Arrhythmia in relation to left ventricle functional status and other cardiac morphological changes

In this study, we went further to see whether there is any association between the arrhythmia occurrence and LV-functional changes (EF) as well as other cardiac morphological changes, including left atrial diameter (LAD) left ventricle internal end diastolic diameter (LVIDd), left ventricle end systolic diameter (LVDs), and left ventricle mass index. There was no association in most of the parameter's morphological changes except for the left ventricle mass index (LVMI), which showed a significant association (Table 2) below.

Table 2: Association between arrhythmia and LV-function and cardiac morphological changes

	Arrhythmia		
Variable	**Yes (%)**	**No (%)**	**p – value**
Left atrial diameter			
Altered	90 (77.6)	98 (78.4)	0.879
Normal	26 (22.4)	27 (21.6)	
LVIDd			
Altered	61 (52.6)	70 (56.0)	0.595
Normal	55 (47.4)	55 (44.0)	
LVDs			
Altered	54 (46.6)	66 (52.8)	0.332
Normal	62 (53.4)	59 (47.2)	
EF			
Preserved	55 (47.4)	62 (49.6)	0.454
Mildly reduced	15 (12.9)	10 (8.0)	
Reduced	46 (39.7)	53 (42.4)	
LVMI			
Altered	104 (89.7)	99 (79.2)	**0.026**
Normal	12 (10.3)	26 (20.8)	

Abbreviations: LVIDd, Left Ventricle Internal diastolic diameter; LVDs, Left Ventricle systolic diameter; EF, Ejection Fraction; LVMI, Left Ventricle Mass Index.

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4.5 Laboratory characteristics of the study participants

In this study some lab investigations were evaluated to see where could be one of the confounding factors for arrhythmia among the observed lab findings patients with low hemoglobin level were 68 (28.2%), those with elevated creatinine and blood urea were 54 (22.4%) and 59 (23.7%) respectively (table 3). These findings have implications to the development of cardiorenal syndrome, low HB could be one of the underlying causes of decompensation. The other significant parameter was low sodium 70 (29%) which could be due to salt limitation and diuretics use.

Table 3: Laboratory characteristics of the study participants

Variable	Frequency (n)	Percent (%)
Haemoglobin level		
Low	68	28.2
Normal	169	70.1
High	4	1.7
Median haemoglobin level (IQR)	12.0 (10.0, 14.0)	
Sodium level		
Low	70	29.0
Normal	168	69.7
High	3	1.2
Median sodium level (IQR)	138.0 (131.0, 141.0)	
Potassium level		
Low	14	5.8
Normal	212	88.0
High	15	6.2
Median Potassium level (IQR)	4.2 (3.9, 4.7)	
Magnesium levels		
Low	1	0.4
Normal	240	99.6
Median magnesium levels (IQR)	0.8 (0.7, 0.8)	
Chloride levels		
Low	22	9.1
Normal	219	90.9
Median chloride levels (IQR)	102.0 (99.0, 104.0)	
Calcium level		
Low	6	2.5
Normal	235	97.5
Median calcium levels (IQR)	2.3 (2.2, 2.4)	
Creatinine		
Low	15	6.2
Normal	172	71.4
High	54	22.4
Blood urea nitrogen	95.0 (85.0, 106.5)	
Low	6	2.5
Normal	178	73.9
High	57	23.7
Median blood urea nitrogen (IQR)	5.0 (4.4, 6.5)	

CHAPTER FIVE

5.0 DISCUSSION

5.1 Discussion

Among the 241 participants in the study who were admitted at JKCI with heart failure, arrhythmia was found in almost half of all study participants 116 (48.1%). The data highlights the significant prevalence of arrhythmias among heart failure patients, emphasizing the need for routine monitoring and management of arrhythmias in this population

Few studies have focused exclusively on the prevalence of arrhythmias in heart failure, and most of these have concentrated on specific types of arrhythmias. A 2015 study in Nigeria by Olufemi E et al. used a 24-hour Holter ECG and found that all participants with chronic heart failure (CHF) had arrhythmias, particularly ventricular extrasystole (VES). However, this study differed from ours as it used a different method (Holter ECG vs. conventional 12-lead ECG) and had a much smaller sample size.(20)

When examining the specific types of arrhythmias among the 116 participants who were found to have arrhythmias, supraventricular arrhythmias were the most common, with atrial fibrillation (AF) occurring in 35(30.2%) of cases. This finding aligns with a 2022 meta-analysis by Valirie Ndip et al., which reported that 15.6% of heart failure patients in Sub-Saharan Africa had AF. (29) Similar to our study's finding of 35(14.5%) AF prevalence among heart failure patients at JKCI. Additionally, a 2022 study in Mwanza, Tanzania by Yunchan Chen et al. reported a 17% prevalence of AF in heart failure outpatients, (27) which is consistent with our results.

A 2003 study by Thomas J. et al. in America examined the relationship between atrial fibrillation (AF) and heart failure (CHF) and found that patients with one condition who later develop the other have a poorer prognosis. (29) Therefore, as physicians, it is crucial to closely monitor patients with either AF or CHF, regularly

evaluating them to ensure the other condition does not develop. This approach is essential for reducing mortality in patients with cardiac diseases.

In this study, which was not specific to a single pattern of arrhythmia, the second prevalent pattern was sinus tachycardia, which occupied 22(19%) of all patients with arrhythmia in heart failure. However, sinus tachycardia could be more of a physiological compensation, clinicians should always seek to know the underlying cause of decompensation of heart failure and manage it appropriately.

In this study, premature ventricular contractions (PVCs) were identified as a common type of arrhythmia, occurring in 14(12.1%) of patients with heart failure. A 2014 study by Madiha Sarwer et al. at the Armed Forces Institute of Cardiology in Pakistan used a 48-hour Holter ECG to monitor heart failure patients. Among 42 patients with ventricular arrhythmias, non-sustained ventricular tachycardia was the most common, followed by isolated PVCs in 23.8% of cases. (30) Since ventricular arrhythmias are a leading cause of sudden cardiac death, routine Holter ECG monitoring for heart failure patients with PVCs detected on a standard 12-lead ECG may improve arrhythmia diagnosis, management, and follow-up.

In this study, heart block has been identified as a prevalent condition among patients with heart failure, with first-degree heart block being the most common, observed in 11.2% of cases. In contrast, second and third-degree heart blocks were less frequent, occurring in 3.4% and 6.9% of patients, respectively. These findings align with the results of a 2011 study by Ryan K et al. in Europe, which reported that 9.3% of patients with first-degree heart block were associated with the development of heart failure (31). This suggests that heart block, particularly first-degree, may be a significant risk factor for the progression to heart failure, emphasizing the importance of early intervention to prevent further deterioration.

In this study, when evaluating left ventricular function in relation to arrhythmia, it was observed that a higher proportion of patients with arrhythmia had preserved ejection fraction (HFpEF) at 114(47.4%), compared to those with mildly reduced 31(12.9%) or significantly reduced ejection fraction 96(39.7%) as shown in Table 2.

However, when analysing the overall association between arrhythmia and left ventricular dysfunction, no significant correlation was found.

The study demonstrated a significant association between arrhythmia and an increased left ventricular mass index (LVMI) (see Table 2). Hypertension, being the most common acquired cause of left ventricular hypertrophy and heart failure, likely contributed to these findings. Effective management of hypertension may help mitigate this impact.

5.2 Strength and limitations of the study

5.2.1 Strength

This is the first hospital-based study in Tanzania hence pioneering local data and foundation for future research.

5.2.2 Limitations

The use of a conventional 12-lead ECG may result in variations in findings compared to those obtained with a Holter ECG. Furthermore, this study was conducted at a single centre, which limits the generalizability of our results

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The study revealed that 48.1% of heart failure patients at JKCI have arrhythmias, with supraventricular arrhythmias being the most common. Atrial fibrillation (AF) was particularly prevalent, affecting 30.2% of those with arrhythmias and 14.5% of all heart failure patients.

6.2 Recommendation

To improve patient outcomes, it is recommended to implement routine screening for arrhythmias, particularly atrial fibrillation, in heart failure patients. Strengthening follow-up protocols is essential for monitoring arrhythmia progression. Further research across multiple centers is needed to better understand the impact of arrhythmias on heart failure and to generalize these findings.

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APPENDICES

Appendix I: Informed consent form (English version)



MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED HEALTH SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS

ID. NO

CONSENT FORM FOR PARTICIPATING IN A RESEARCH STUDY

Introduction

Hi,

My name is Luginy'o Ilomo a student of Masters of Medicine in Internal medicine at Muhimbilis University of Health and Allied Sciences (MUHAS). I am conducting research on Pattern of Arrhythmia among patients with Heart failure admitted at Jakaya Kikwete Cardiac institute

Aim of the Study

The study is intended to investigate and analyse the prevalence, types, and characteristics of arrhythmias in patients with heart failure admitted to JKCI. Findings from this study has a potential to fill a critical knowledge gap and contribute valuable insights to the field of cardiology in our own setting.

Procedure

I would like you to participate in this study. You have been chosen to participate in this study because you're eligible for this study; If you consent to participate in this

study, you will be interviewed by the researcher, and taken some clinical and laboratory investigations.

After the clinical and laboratory assessment, no harmful procedures will be performed to you.

Confidentiality

All responses you provide will be kept confidential and the information will be used for this study only. No identification information shall be collected from you except for socio-demographics information.

Right to refuse/withdraw

It is your choice to participate in this study and you are free to withdraw at any time. However, I encourage you to consent for participation because the information that you will provide is very important in this study.

Benefits

Participating in this study will benefit you by getting some clinical and laboratory investigations and knowing your health status.

Risks

There will be no any harm to you as a result of participation in this study.

Whom to Contact

In case of any question or query concerning this study, please contact the principal investigator Dr Luginy'o Ilomo at 0764513503, email **ilomolugo@gmail.com** or my Supervisor Prof. Mohamed Y. Janabi at 0755495270 from MNH.

If you have any questions about your rights as a participant you may contact; The Chairman of the research and Publications Committee. Prof. Bruno Sunguya, MUHAS P.O.BOX 65001, Dar es Salaam-Tanzania, Tel +2552150302-6

Signature

I, ……... have read the contents of this form and understood. My questions have been answered I agree to participate in this study.

Signature of participant ……...Date…….

Signature of researcher ……. Date…….

Appendix II: Informed consent (Swahili version)

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI MUHIMBILI

NAMBA YA UTAMBULISHO

FOMU YA IDHINI YA KUSHIRIKI KATIKA UTAFITI

Utangulizi

Salamu,

Jina langu ni Luginy'o Ilomo mwanafunzi wa Shahada ya uzamili katika udakatari wa magonjwa ya binadamu ya ndani katika Chuo kikuu cha Afya na Sayansi shirikishi cha Muhimbili (MUHAS). Kwa niaba ya MUHAS, ninafanya utafiti juu ya mapigo ya moyo yasio ya kawaida yanayo ambatana na tatizo la kufeli kwa moyo baina ya wagonjwa walio lazwa taasisi ya moyo ya Jakaya Kikwete, Tanzania

Dhumuni la utafiti

Dhumuni la utafiti huu ni kubainisha ukubwa wa tatizo la mapigo ya moyo yasio ya kawaida na aina zake kwa watu wenye tatizo la kufeli kwa moyo. Matokeo ya utafiti huu yatasaidia kwa madaktari/wahudumu na mamlaka husika inayohusika na hatimae kutafuta mbinu za kupunguza tatizo hili kwenye kituo chetu na nchini.

Utaratibu

Ningependa ushiriki katika utafiti huu. Umechaguliwa kushiriki katika utafiti huu kwa sababu unakidhi vigezo vya kuwepo kwenye utafiti huu. Ikiwa unakubali kushiriki katika utafiti huu, utashiriki katika dodoso fupi, na utachukuliwa baadhi ya vipimo kwa ajili ya tathmini.

Baada ya tathimini ya vipimo, hakuna utaratibu wowote mbaya utakaofanywa kwako.

USIRI

Majibu yote unayotoa yatahifadhiwa kwa siri na habari zote zitatumika kwa utafiti huu tu. Hakuna taarifa ya utambulisho itakayokusanywa kutoka kwako isipokuwa taarifa za kidemografia.

Haki ya kukataa au kujitoa

Ni uamuzi wako kuruhusu / kukataa ushiriki wako katika utafiti huu na uko huru kujiondoa wakati wowote. Hata hivyo, ninakuhimiza kukubali kushiriki kwa sababu taarifa utakazotoa ni muhimu sana katika utafiti huu.

Faida

Kushiriki katika utafiti huu kutakunufaisha kupata vipimo na kujua hali yako ya kiafya bila malipo yoyote.

Hatari

Hakutakuwa na madhara yoyote kwako kutokana na ushiriki katika utafiti huu

Mawasiliano

Ikiwa kuna swali au tatizo lolote kuhusu utafiti huu, tafadhali wasiliana na mtafiti mkuu Dr. Luginy'o Ilomo kwa nambari 0764513503, barua pepe **ilomolugo@gmail.com** au msimamizi Prof. Mohamed Y. Janabi kwa nambari 0755495270, Hospitali ya Taifa Muhimbili. Ikiwa una maswali yoyote juu ya haki zako kama mshiriki unaweza kuwasiliana na;Mwenyekiti wa Kamati ya Utafiti na Uchapishaji. Prof. Bruno Sunguya, MUHAS S.L.P 65001, Dar es Salaam-Tanzania, Simu +2552150302-6.

Sahihi

Mimi …….... nimesoma yaliyomo kwenye fomu hii na kuelewa na maswali yangu yamejibiwa vya kutosha. Ninakubali kushiriki katika utafiti huu.

Sahihi ya mshiriki ……. Tarehe ……

Sahihi ya mtafiti ……. ...Tarehe ……

Appendix III: Data collection tool

Study participants ID			
			CODE
1	Date of Interview		
2	Telephone contact		
Socio demographic characteristics			
3	Sex (Male/Female as observed)	1=M 2=F	
4	Age	In years	
5	Educational level	1=No formal education 2=Primary school completed 3=Secondary school completed 4=college/university completed	
6	Marital status	1=Single 2=Married 3=Separated 4=Divorced 5=Widowed	
Comorbidities			
7	Diabetes Mellitus	1=Yes 2=No	
8	Hypertension	1=Yes 2=No	
9	HIV status	1=Positive 2=Negative	
ECG rhythm patterns			
10	Supra ventricular	1= Atrial fibrillation 2=Atrial flutter 3=Premature atrial contraction	

11	Ventricular	1= Ventricular fibrillation 2= Ventricular tachycardia 3=Premature ventricular contractions 4= Torsade de pointes	
12	Sinus rhythm	1=Sinus tachycardia 2=Sinus bradycardia 3=Normal sinus rhythm	
13	AV-Block	1= First degree 2=Second degree 3= Third degree	
14	Unspecified rhythm	1=Unspecified	
ECHO results			
15	LA	1=Normal 2=Altered	
16	LVIdd	1=Normal 2=Altered	
16	LVDs	1=Normal 2=Altered	
18	EF	1= Preserved 2= Mildly reduced 3=Reduced	
19	LVMI	1=Normal 2=Altered	
Lab investigations			
20	HB	1=Low 2=Normal 3=High	
21	Na	1=Low 2=Normal 3=High	
22	K	1=Low 2=Normal 3=High	

25	Mg	1=Low 2=Normal 3=High	
26	Cl	1=Low 2=Normal 3=High	
27	Ca	1=Low 2=Normal 3=High	
28	Creatinine	1=Low 2=Normal 3=High	
29	BUN	1=Low 2=Normal 3=High	

Where by: HIV-Human Immune Virus, AV- Atrial Ventricular, LA-Left Atrial diameter, EF-Ejection Fraction, LVDs-Left Ventricular end-systolic diameter, LVDd-Left ventricular end-diastolic diameter, LVMI-Left ventricular mass index, k-serum potassium, Ca- serum calcium, Cl- serum chloride, Na- serum sodium, Mg-serum magnesium, BUN- Blood urea nitrogen, HB-Hemoglobin level.

Appendix IV: Ethical clearance letter

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

P.O. Box 65001
DAR ES SALAAM
TANZANIA
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E-mail: drp@muhas.ac.tz

Ref. No.DA.282/298/01.C/

Date: 13/08/2023

MUHAS-REC-08-2023-1862
Dr. Luginy'o Ilomo
School of Medicine
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: PATTERN OF ARRHYTHMIAS AMONG PATIENTS WITH HEART FAILURE ADMITTED AT JKCI

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 13/08/2023
EXPIRATION DATE OF APPROVAL: 13/08/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this hospital based descriptive cross-sectional study is to To investigate and analyze the prevalence, types, and characteristics of arrhythmias in patients with heart failure admitted to JKCI

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014641.pdf and in the MUHAS archives.

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain Data Transfer Agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain Material Transfer Agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
8. Apply for and obtain permission to publish the results from National Institute for Medical Research. The application should be before submitting to a publisher and not concurrently through the email publications@nimr.or.tz.
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,
CHAIRPERSON, MUHAS RESEARCH AND ETHICS COMMITTEE

University of Health and Allied Sciences
DIRECTOR
Research, Publications & Innovations

Appendix V: Permission letter

UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

JAKAYA KIKWETE CARDIAC INSTITUTE
(JKCI)

JAKAYA KIKWETE CARDIAC INSTITUTE

In reply please quote;
Ref No: AB.123/307/01J/55

02/10/2023

~~Luginy'o Ilomo~~
HD/MUH/T.94/2021
MMed. Internal Medicine - MUHAS

RE: PERMISSION TO CONDUCT RESEARCH AT JKCI

Reference is made to your letter request to do a research study entitled **"Pattern of Arrhythmias among patients with Heart failure admitted at JKCI"** here at JKCI.

This letter serves as an official document that permits you to do the above-mentioned task as requested.

It is our sincere hope that you will abide by the rules and regulations of good clinical practice. We wish you the best and hope your stay at JKCI will be fruitful.

Best Regards,

JAKAYA KIKWETE CARDIAC INSTITUTE
P. O. Box 65141
Dar-es-Salaam
JKCI

Dr. Pedro Pallangyo
Head of Research, Training and Consultancy.
CC: ALL DIRECTORATES