POSTOPERATIVE ARRHYTHMIAS AFTER OPEN HEART SURGERY: INCIDENCE, RISK FACTORS, THERAPEUTIC MANAGEMENT AND OUTCOMES AMONG PATIENTS AT JAKAYA KIKWETE CARDIAC INSTITUTE, DAR ES SALAAM, TANZANIA

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M.Pharm (Hospital and Clinical Pharmacy) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2024

Muhimbili University of Health and Allied Sciences

Department of Clinical Pharmacy and Pharmacology

POSTOPERATIVE ARRHYTHMIAS AFTER OPEN HEART SURGERY: INCIDENCE, RISK FACTORS AND THERAPEUTIC MANAGEMENT AMONG PATIENTS AT JAKAYA KIKWETE CARDIAC INSTITUTE, DAR ES SALAAM, TANZANIA

By

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A Dissertation Submitted in a (Partial) Fulfilment of the Requirement for the Degree of Master of Pharmacy (Hospital and Clinical Pharmacy) of

Muhimbili University of Health and Allied science
October, 2024

CERTIFICATION

The undersigned certifies that they have read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; **‘‘Postoperative Arrhythmias after open heart surgery: Incidence, Risk factors and Therapeutic management among patients at Jakaya Kikwete Cardiac Institute, Dar es Salaam, Tanzania”,** in (partial) fulfilment of the requirements for the Degree of Master of Pharmacy in Hospital and Clinical Pharmacy of Muhimbili University of Health and Allied Sciences.

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Date

DECLARATION AND COPYRIGHT

I, **Wilson Samson Misinzo**, declare that this **dissertation** is my original work and that it has not been presented and will not be presented to any other university for similar or any other degree award.

Signature…… **Date**……..……

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ACKNOWLEDGEMENT

First, I would like to express my sincere gratitude to the Almighty God for the gift of healthier life throughout my career path. He is most merciful and compassionate to me.

My sincere thanks to my supervisor and the Head of Department of Clinical pharmacy and Pharmacology Dr. Ritah Mutagonda for her implausible guidance and motivation through my study period.

To my co-supervisors, Pharm. Manase Kilonzi, Pharm. Betha Mallya and Pharm. Leonard Buganda, I appreciate all the hard work which made this work easier.

I sincerely thank the Management of the Muhimbili National Hospital specifically the Head of Department of Pharmacy Mr. Nelson Njau for allowing me to advance my career.

Thanks to the entire Department of Clinical Pharmacy and Pharmacology for their restless support during my study period.

My sincere thanks to the management and staffs of the JKCI specifically ICU team that aided in data collection.

Finally, I would like to express my heartfelt appreciation to my family, my parents and friends for their unwavering encouragement, emotional support and understanding throughout the duration of my study.

DEDICATION

This research is dedicated to my family, parents, brothers and sisters, instructors, and MNH management to repay the sacrifice they have made to my career advancement.

ABSTRACT

Background: Arrhythmias are a major cause of morbidity and mortality following heart surgery and are a fairly common complication. It has been discovered that the percentage of heart failure patients who simultaneously have post-cardiac surgery arrhythmia ranges between 10 and 57%. Despite the apparent maturity of the cardiac procedure, risks and postoperative consequences, there is scarce data in developing countries. Postoperative arrhythmias can lead to complications and negatively impact patient recovery following open heart surgery. Understanding the incidence and associated factors is essential for targeted intervention and improved patient outcomes.

Objective: This study aimed to assess the incidence, factors associated with arrhythmias, therapeutic management and treatment outcomes among patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute (JKCI) in Dar es Salaam, Tanzania.

Methods: A prospective observation study involving 100 post-cardiac surgery patients who meet the specified criteria was conducted from March to May 2024 at the JKCI in Dar es Salaam. Patients were selected consecutively until the sample size was reached then followed for the four (4) consecutive days post-surgery. Post-cardiac surgery arrhythmias were diagnosed with electrocardiography (ECG) monitoring and confirmed with ECG re-examinations, data were collected using case report form (CRF) that contained three sections. The first section included demographic information and preoperative variables e.g. obesity, impaired renal function, the second section included clinical information and operative variables like the types of cardiac surgery, cardiopulmonary bypass time, and the third section included information on post cardiac surgery e.g. occurrence of postoperative arrhythmia, the types of arrhythmias, management of arrhythmia, complication of postoperative arrhythmia. Data were then analyzed by SPSS version 23. A p-value of < 0.05 for the association between dependent and independent variables were considered statistically significant.

Results: Out of 100 participants in the study, Of the participants, 52 (52.0%) had a previous history of arrhythmia before admission, 96 (96.0%) had rheumatic heart disease, and 26 (26.0%) had pre-operative arrhythmia during admission of which 18 (69.2%) had ventricular tachycardia and the remaining had atrial fibrillation. Hypertension was present in 78 (78.0%), smoking in 15 (15.0%), COPD in 7 (7.0%), and diabetes in 35 (35.0%). Normal weight was seen in 57 (57.0%), overweight in 36 (36.0%), and underweight in the remainder. The majority underwent valve replacement 55 (55.0%), with 23 (23.0%) having CABG. The study found that 54 (54.0%) of patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute developed postoperative arrhythmias, with sinus tachycardia 36 (66.7%) and atrial fibrillation 32 (59.2%) being the most common types. Significant factors associated with these arrhythmias included higher BMI (ARR 1.72, p=0.038), a history of arrhythmia (ARR 1.25, p=0.045), pre-operative arrhythmia (risk ratio 7.19, p=0.011), and hemodynamic instability (risk ratio 4.41, p=0.004). Treatment modalities included cardiac membrane stabilizers (69.2%), hydration fluids (69.2%), beta-blockers (61.5%), and anticoagulants (59.0%). The outcomes revealed that 59 (59.0%) of patients experienced hemodynamic instability, 33 (33.0%) had extended hospital stays, and 33 (33.0%) faced bleeding complications, with a very low mortality rate of 1 (1.0%).

Conclusion: This study highlights the urgent need to address postoperative arrhythmias following open heart surgery, with a notable incidence observed among patients. Key factors associated with arrhythmias include higher BMI and a history of pre-operative arrhythmia. While pharmacological interventions were commonly used, treatment outcomes were generally positive, though complications such as prolonged hospital stays, and bleeding were noted. The low mortality rate underscores the effectiveness of current management practices but continued focus on optimizing arrhythmia management is essential.

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LIST OF ABBREVIATIONS/ACRONYMS

AFib	-	Atrial fibrillation
AFlu	-	Atrial flutter
AVB	-	Atrioventricular blockages
BMI	-	Body Mass Index
CABG	-	Coronary artery bypass grafting
CHF	-	Congestive heart failure
CVDs	-	Cardiovascular diseases
ECG	-	Electrocardiogram
JKCI	-	Jakaya Kikwete Cardiac Institute
SPSS	-	Statistical Package for Social Sciences
SSS	-	Sick sinus syndrome
WHO	-	World Health Organization
POA	-	Post Operative Arrhythmias
COPD	-	Chronic Obstructive Pulmonary Diseases
LVEF	-	Left Ventricular Ejection Fraction.
CRE	-	Case Report Form.

DEFINITION OF TERMS

Atrial fibrillation (AF): Is a heart rhythm disorder in which the atria beat irregularly and inefficiently. In atrial fibrillation, the heart rate can exceed 300 beats per minute.

Atrial flutter: Is a type of abnormal heart rhythm (arrhythmia) that is characterized by rapid and regular beating of the atria (the upper chambers of the heart). In atrial flutter, there are typically 250-350 beats per minute. According to the World Health Organization (WHO), atrial flutter is classified as a supraventricular tachycardia, meaning that the rapid heart rate originates above the heart's ventricles. This condition is often associated with an abnormal electrical circuit within the atria, leading to a fast and coordinated contraction of the atrial muscle.

Cardiac arrhythmias: According to the World Health Organization (WHO), cardiac arrhythmias are abnormalities in the heart's electrical activity that result in irregular heart rhythms, causing the heart to beat too fast (tachycardia), too slow (bradycardia), or erratically (fibrillation or flutter). These arrhythmias can range from non-fatal forms, such as atrial fibrillation or premature ventricular contractions, which may cause symptoms like palpitations or dizziness and increase the risk of stroke or heart failure, to fatal forms, such as ventricular fibrillation or sustained ventricular tachycardia, which can lead to sudden cardiac arrest and death if not promptly treated.

Coronary artery bypass grafting: Is a surgical procedure used to treat coronary artery disease. In this procedure, a healthy blood vessel is taken from another part of the body, such as the chest or leg, and is used to bypass a blocked or narrowed coronary artery. This creates a new pathway for blood to flow to the heart muscle, bypassing the blockage and restoring blood flow to the heart.

Sinus rhythm: Is the normal rhythm of the heart generated by the sinoatrial (SA) node, the heart's natural pacemaker. In sinus rhythm, the heart beats at a regular rate, typically between 60 to 100 beats per minute in adults. It represents the normal electrical activity of the heart and is essential for maintaining effective heart function.

Cardiopulmonary bypass time: refers to the duration during which a patient's blood circulation and oxygenation are maintained by a heart-lung machine during cardiac surgery. This machine temporarily takes over the function of the heart and lungs, allowing surgeons to operate on a still, bloodless heart. The cardiopulmonary bypass time is a critical measure because prolonged duration is associated with increased risks of complications such as bleeding, inflammation, organ dysfunction, and longer postoperative recovery. It is typically recorded from the moment the patient is placed on the bypass machine until normal heart and lung function are restored.

Hemodynamic instability: is a condition characterized by an abnormal or unstable blood flow that results in inadequate blood supply to the body's organs and tissues. This instability may manifest as significant changes in blood pressure, heart rate, cardiac output, or other vital signs, and can result from a variety of underlying causes, such as blood loss, heart failure, arrhythmias, or septic shock. Hemodynamic instability often presents with symptoms like dizziness, fainting, chest pain, shortness of breath, and altered mental status, indicating that the body's circulatory system is not adequately maintaining the perfusion and oxygenation necessary for normal cellular function. It is considered a medical emergency requiring prompt evaluation and intervention to stabilize the patient.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Cardiovascular diseases (CVDs) are a major global health concern, often requiring open heart surgery especially when non-surgical treatments are insufficient (1). Common conditions managed through such surgical interventions include coronary artery disease (CAD), valvular heart diseases, and congenital heart defects. CAD, characterized by the narrowing or blockage of coronary arteries due to atherosclerosis, Valvular heart diseases, such as aortic stenosis or mitral regurgitation, involve dysfunction of the heart valves, necessitating repair or replacement to restore normal heart function. Congenital heart defects, including atrial septal defects (ASD) and ventricular septal defects (VSD) (2,3). Understanding the nature of these diseases sets the stage for exploring the specific types of open-heart surgeries used to treat them. Studies done in Africa have revealed that Rheumatic and Congenital Heart Diseases are the most common CVDs managed by cardiac surgery (4,5).

Open heart surgery encompasses several types of interventions tailored to address various cardiovascular problems. CABG involves grafting blood vessels from other parts of the body to bypass blocked coronary arteries and improve blood flow. Valve repair or replacement procedures aim to correct or replace malfunctioning heart valves, with options including mechanical or biological valves (6,7). For congenital heart defects, corrective surgeries might involve patching holes in the heart's septum or reconstructing malformed structures, these surgeries are performed with the aid of cardiopulmonary bypass machines, which temporarily take over the heart and lung functions to allow surgeons to operate on a still and bloodless heart (2). While these interventions are essential for treating severe cardiovascular conditions, they come with risks, One of the most frequent and dangerous postoperative complications is postoperative arrhythmia (POA) (8,9).

Postoperative arrhythmias (POA) are a significant complication following open heart surgery, impacting patient outcomes and recovery. The global prevalence of arrhythmia is approximated to be around 60 million cases and contributes to more than 8 million disability-adjusted life years among which occur postoperatively (10). There is considerable variability in the incidence of POA, ranging from 11% to 54%, reflecting the complexity of postoperative care. The most common types of POAs include atrial fibrillation (AF), ventricular tachycardia (VT), and premature ventricular contractions (PVCs). Atrial fibrillation is the most prevalent, affecting approximately 30% to 50% of patients post-surgery, according to recent data (11). Ventricular tachycardia, though less common, occurs in about 5% to 10% of patients and poses a higher risk due to its potential for causing severe hemodynamic instability (12). Premature ventricular contractions, while often benign, can also contribute to patient discomfort and complicate recovery (13). Despite advances in surgical techniques and perioperative care, the incidence of POA remains a concern, with implications for both immediate and long-term health.

Post-surgical patients are at risk of arrhythmias due to several surgery-related factors. To start with; trauma and inflammation, predispose patients to atrial and ventricular arrhythmias (14). Given that the prevalence of postoperative arrhythmias rises between surgical days 2-3, theories about its formation have focused on inflammatory pathways (14). Second, hemodynamic stress; acute atrial enlargement, ischemia, hypertension, and trauma from cannulation are examples of atrial modifications that occur during surgery that are recognized risk factors for postoperative arrhythmias (14). Third, Ischemic Injury; postoperative arrhythmias may be initiated by atrial and ventricular ischemia and/or infarction (15). Additionally, Age, sex, and race are patient-level factors that affect the estimated lifetime risk of arrhythmia, which is roughly 33% (10). Independent of genetic risk, modifiable risk factors such as physical inactivity, type 2 diabetes mellitus, and hypertension increase the lifetime risk of arrhythmia (10). Epigenetic markers of biological age and body composition are considered novel risk factors for arrhythmia (16). Treatment modalities for POA typically involve a combination of pharmacological interventions and electrical therapies. However, the effectiveness of these treatments can vary depending on individual patient characteristics and the underlying causes of the arrhythmia.

Controversies exist regarding the optimal management strategies for POA and the relative impact of different risk factors. These treatment modalities include pharmacological interventions, electrical cardioversion, and device implantation (17). Common pharmacological treatments involve antiarrhythmic drugs such as beta-blockers, amiodarone, and digoxin, which aim to restore normal heart rhythm and prevent recurrence (14). Electrical cardioversion is used for more severe cases, particularly for atrial fibrillation, to reset the heart's rhythm using electric shocks (18). For patients with recurrent or persistent arrhythmias, implantation of a pacemaker or an implantable cardioverter-defibrillator (ICD) may be considered to manage and prevent arrhythmias (19). Despite these treatment options, several gaps remain in understanding their efficacy and optimal use. For instance, while beta-blockers are widely used, the specific timing and dosage that best prevent POAs are not well established. Similarly, the long-term benefits of different antiarrhythmic medications versus electrical interventions remain debated, and there is limited consensus on the best management practices for arrhythmias post-surgery, additionally, there is debate over the efficacy of various treatment approaches, such as the use of antiarrhythmic drugs versus electrical cardioversion (17,18). These differing perspectives underline the need for targeted research to clarify the most effective management strategies and to understand better, the mechanisms driving POA. This study is particularly relevant in light of the increasing number of open-heart surgeries.

A deeper comprehension of the mechanisms underlying the onset and development of arrhythmia in patients recovering from surgery could lead to a decrease in the use of medications and electrical techniques intended to lower ventricular rate or maintain normal sinus rhythm. This study aims to assess the incidence, factors associated with arrhythmias, therapeutic management and treatment outcome among patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute in Dar es Salaam, Tanzania.

1.2 Problem Statement

Arrhythmias are a major cause of morbidity and mortality following heart surgery and are a fairly common complication (7,14). Studies on various forms of post-surgical arrhythmias show that at the age of 55, the lifetime risk of getting post-surgical arrhythmias is 23.8% in men and 22.2% in women (20). Age, gender, hypertension, heart failure, diabetes, and myocardial infarction are the primary risk factors for post-surgical arrhythmias (21).In Tanzania, one study reported the majority of cases managed by open heart surgery were due to Rheumatic heart diseases (47.6%), congenital heart disease (35.2%), myxomatous valvular degeneration (16.2%), and pericardial disease 1%. Mitral valve disease was the most common cause of cardiac disease (58.1%) (22). Though few studies have highlighted the common cardiac conditions and types of surgeries in Tanzania there is missing data on the exact incidence, factors associated, management, and the management outcomes of post-operative arrhythmias.

Studies on post-surgery arrhythmia, its extent, and associated factors are limited at the moment in Tanzania. On the other hand, the effects of some mortality factors remain controversial (23). It is vital to focus studies in this area to enrich information which will help in developing appropriate interventions.

1.3 Study rationale

The finding of this study will help the Ministry of Health, the institute, and other stakeholders to know the incidence, factors associated with post-cardiac arrhythmia, and management outcomes among patients undergoing cardiac surgeries hence reducing the mortality, morbidity, and over-hospital stay. There is a lack of local data on arrhythmias among patients undergoing open heart surgery for cardiac conditions such as rheumatic heart disease, congenital heart diseases and valvular heart diseases that are managed at the JKCI hence generating this information is critical for tailoring care to the specific needs of the patient population in Tanzania. Also, this knowledge can lead to better management of post-operative arrhythmia risk and improved patient outcomes through more tailored treatment plans. About the scientific

community the findings provide more knowledge that can guide further research, potentially leading to the development of more effective preventative measures and treatment strategies.

Clinical Significance: Postoperative arrhythmias can lead to complications and negatively impact patient recovery following open heart surgery. Understanding the incidence and associated factors is essential for targeted intervention and improved patient outcomes.

Quality Improvement: By identifying gaps in the management of postoperative arrhythmias, the study can contribute to the development of evidence-based protocols and interventions aimed at reducing the incidence and improving the management of arrhythmias in this patient population.

Research Gap: The scarcity of data on this topic in the local context highlights the need for a comprehensive study to fill this gap and provide valuable insights for clinical practice and future research.

1.4 Conceptual framework

Figure 1 describes the relationship on how occurrence of post-cardiac surgery arrhythmia can be influenced or changed by different factors. Factors such as age, BMI, sex, structural heart disease and non- cardiac comorbidities can put the patients into the risks of Post cardiac-surgery Arrhythmia. In addition, factors like preoperative arrhythmia, postoperative pain, hypoxemia, trauma and inflammation, hemodynamic stress, ischemic injury and electrolytes disorders may increase the likelihood of occurrence of post cardiac-surgery arrhythmia.

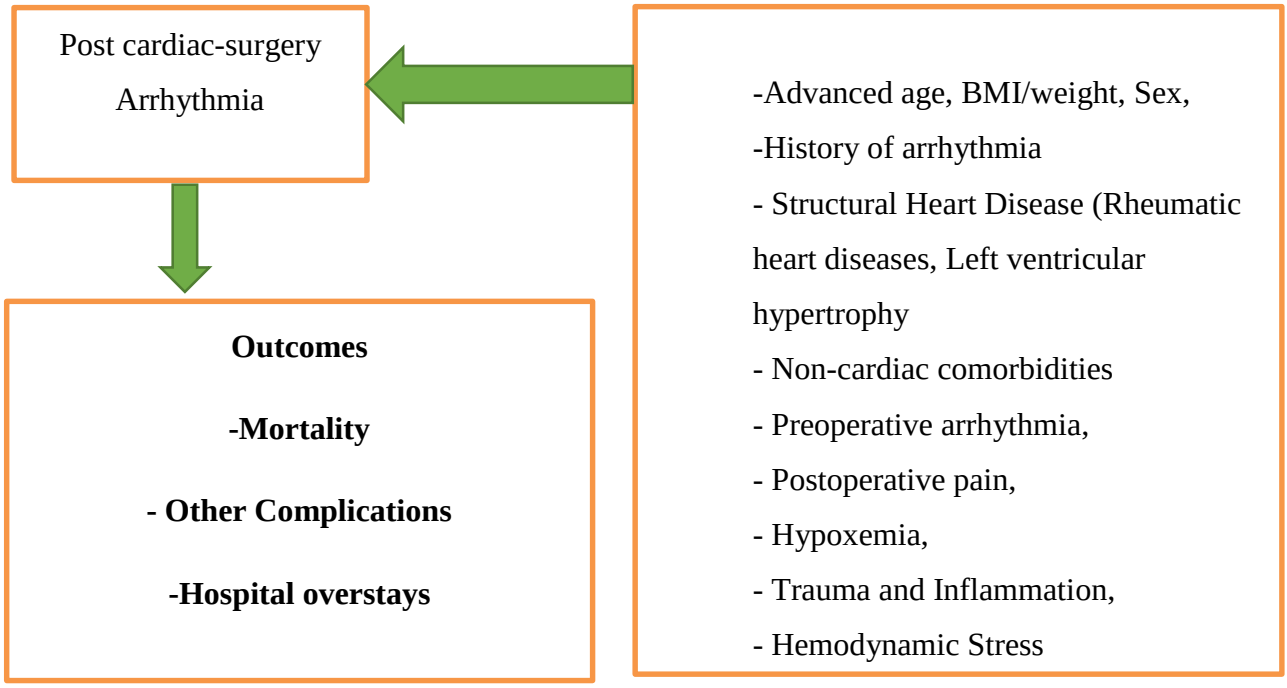


Figure 1: Post cardiac-surgery Arrhythmia can be influenced by several factors

1.5 Research questions

1.5.1 Broad research question

What is the incidence, factors associated with postoperative arrhythmias, therapeutic management and treatment outcome among patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute in Dar es Salaam, Tanzania?

1.5.2 Specific research questions

1. What is the incidence of post cardiac-surgery arrhythmias among patients undergoing open heart surgery?
2. What are the factors associated with post cardiac-surgery arrhythmias among patients undergoing open heart surgery?
3. What are the treatment modalities of post cardiac surgery arrhythmias among patient undergoing open heart surgery?
4. What are treatment outcomes of post cardiac surgery arrhythmias among patients?

1.6 Research Objectives

1.6.1 Broad objective

To assess the the incidence, factors associated with arrhythmias, therapeutic management and treatment outcome among patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute in Dar es Salaam, Tanzania.

1.6.2 Specific Objectives

1. The aim of this study was to determine the incidence of post cardiac-surgery arrhythmias among patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute located in Dar es Salaam, Tanzania.
2. To determine the factors associated with post cardiac-surgery arrhythmias among patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute located in Dar es Salaam, Tanzania.
3. To evaluate the treatment modalities of POA among patients undergoing open heart surgery at JKCI in Dar es salaam, Tanzania.
4. To evaluate the treatment outcome of post cardiac surgery arrhythmias among patients at Jakaya Kikwete Cardiac Institute located in Dar es Salaam, Tanzania.

CHEPTER TWO

2.0 LITERATURE REVIEW

2.1 Overview

Open heart surgery is a critical intervention for several common cardiac conditions that significantly impact patient morbidity and mortality (1). One of the most prevalent conditions managed by open heart surgery is coronary artery disease (CAD), characterized by the narrowing or blockage of the coronary arteries, which can lead to myocardial ischemia, angina, and ultimately, myocardial infarction (2). Valvular heart diseases, such as aortic stenosis, mitral regurgitation, and tricuspid regurgitation, also frequently require surgical management due to their progressive nature, which can result in heart failure, arrhythmias, and other life-threatening complications if left untreated (3.8). Additionally, congenital heart defects like atrial septal defects (ASD), ventricular septal defects (VSD), and more complex conditions like tetralogy of Fallot often necessitate surgical correction to restore normal cardiac function and prevent long-term complications (7). Another significant indication for open heart surgery is the management of aortic aneurysms and dissections, conditions characterized by abnormal dilation or tearing of the aorta, which pose a high risk of rupture and sudden death. Furthermore, cases of end-stage heart failure or severe cardiomyopathies, which are unresponsive to medical therapy, often require surgical intervention (1). Collectively, these conditions represent a substantial burden on global healthcare systems, necessitating advanced surgical approaches to improve survival rates and quality of life for affected patients. In Tanzania, studies have reported that the majority of cases managed by open heart surgery were due to Rheumatic heart diseases (47.6%), congenital heart disease (35.2%), myxomatous valvular degeneration (16.2%), and pericardial disease 1%. Mitral valve disease was the most common cause of cardiac disease (58.1%) (22).

The types of open-heart surgeries available to manage these conditions are diverse, each tailored to the specific pathology and patient characteristics. Coronary artery bypass grafting (CABG) is one of the most common open-heart surgeries, where a graft is used to bypass blocked coronary arteries, enhancing blood flow to the heart muscle (5). Valve surgeries, which include

valve repair and valve replacement, are performed to address dysfunctional heart valves, valve repair involves techniques such as leaflet resection or ring annuloplasty to restore valve function, while valve replacement utilizes mechanical or biological prosthetics to substitute the damaged valve (5,8). Procedures such as patch closure for septal defects or complete repair for more complex anomalies like tetralogy of Fallot are performed for congenital heart defects (24). For aortic aneurysms, the surgical approach might involve aortic root replacement or complex reconstructions with grafts to strengthen or replace the weakened sections of the aorta (10). A study done in Tanzania reported that the majority of the operations done at JKCI were Valvular repair from RHD in 47.6% of the cases and Mitral Valve Diseases in 58.1% of the cases (22).

Despite advancements in surgical techniques, open heart surgery remains associated with significant risks, including postoperative arrhythmias, which are among the most common complications (8,9). Recent advancements, such as minimally invasive and robotic-assisted cardiac surgeries, are being explored as alternatives to traditional open heart procedures, aiming to reduce recovery time, minimize complications, and improve overall outcomes (3). However, these newer techniques are not yet widely available or suitable for all patients especially in resource-limited settings, underscoring the continued reliance on conventional open heart surgeries for managing complex cardiac conditions (4). The evolving landscape of cardiac surgery emphasizes the need for ongoing research to refine these surgical approaches and optimize patient outcomes, especially in resource-limited settings where access to advanced technologies may be restricted (2).

2.2 Post cardiac surgery arrhythmia

Arrhythmias are a major cause of morbidity and mortality following heart surgery and are a fairly common consequence. The most frequent arrhythmia following heart surgery is atrial fibrillation (A Fib), which is frequently linked to other atrial tachyarrhythmias including multifocal atrial tachycardia, premature atrial complexes, and atrial flutter (A Flu) (18,19). Reports show that, up to 15–40%, 37–50% and 11–24% of patients in the early postoperative phase following coronary artery bypass grafting (CABG), valve surgery, heart transplantation

respectively, 60% experience A Fib (14). As patients age, the prevalence of A Fib in coronary artery bypass grafting (CABG) patients steadily rises (14). The majority of the time, postoperative A Fib and A Flu happen in the initial days following surgery, peaking on days two and three (8). According to reliable data obtained from a prospective multicenter study involving 4,657 patients having surgery, most AFib episodes started by day two and most recurring episodes by day three. Over 40% of AFib patients experienced several episodes.

AFib is typically self-limited in patients with postoperative AFib who do not have a history of atrial arrhythmias, with up to 80% of patients returning to sinus rhythm in less than 24 hours and 15 to 30% within two hours (8). In one case, the average length of an episode of AFib was 11 to 12 hours, and six to eight weeks following surgery, over 90% of patients returned to sinus rhythm (25).In a different study, at six weeks, just three of the 116 patients who had AFib following coronary artery bypass grafting (CABG) were still experiencing it (26). Antiarrhythmic medication did not seem to change the course of events.

Bradyarrhythmia following heart surgery are not uncommon (27). They are mostly comprised of brief periods of decreased ventricular heart rate. Sick sinus syndrome (SSS) and varying degrees of atrioventricular blockages (AVB) are typically among them (14). bradyarrhythmia in patients with comparatively fixed stroke volumes may result in a decrease in cardiac output. Bradyarrhythmia, which result from both direct surgical damage and local edema, are especially common following valve surgery (28). Bradycardia following valve replacement and CABG is typically brought on by full or high-degree atrioventricular blockages (AVB) and affects 2% to 4% of patients, necessitating long-term pacing (14). In 0.8% to 3.4% of patients following coronary artery bypass grafting (CABG) surgery, persistent pacing is necessary due to sinus node dysfunction or atrioventricular conduction abnormalities.

2.3 Factors associated with post-cardiac-surgery arrhythmias

Several studies report the association between post-surgery arrhythmias and patient-related factors. These include age, BMI/weight, Sex, history of arrhythmia, preoperative arrhythmia, postoperative pain, hypoxemia, trauma and inflammation, hemodynamic stress, ischemic injury

electrolytes disorders, structural heart disease, and extracardiac comorbidities (29–31). A major risk factor for post-cardiac-surgery arrhythmias is indicated to be advanced age (15). The history of arrhythmia is also reported to be the most important factor (32). In a prospective observational study of 4657 patients undergoing Cardiac surgery, it was observed that risk factors associated with post-cardiac-surgery arrhythmias were advanced age (odds ratio [OR] for 10-year increase, 1.75; 95% confidence interval [CI],1.59-1.93) and history of arrhythmias (OR, 2.11; 95% CI, 1.57-2.85) (32). A study on the effect of obesity and arrhythmia found that obese patients had significantly higher odds of post-cardiac-surgery arrhythmias when compared with non-obese patients; p value= 0.006 (31). In a similar study, The interaction of waist circumference with sex suggested a worse impact on POAF risk among women [AOR 1.97; (95% CI, 1.48-2.62)] as compared to men [AOR 1.33; (95% CI, 1.17-1.50)] (33).

An additional study by Vural et al found that patients with extra non-cardiac comorbidities (diabetes mellitus and hypertension) and obesity, at the ages of 56–78 were 2.46, 2.3, and 1.6 more likely to get post-cardiac-surgery arrhythmias respectively (29).

In a study by Zhu and colleagues, preoperative arrhythmia [odds ratio (OR) =9.17; 95% confidence interval (CI): 4.49-18.10], postoperative discomfort (OR =4.70; 95% CI: 1.55-6.12), and postoperative hypoxemia (OR =3.25; 95% CI: 1.04-6.28) were all independently linked with POA, according to logistic regression analysis (15). Pain can excite the sympathetic nervous system, resulting in ectopic atrial rhythms and arrhythmia (34). Hooten et al. (35) discovered that adequate postoperative analgesia can successfully minimize post cardiac-surgery arrhythmias. Pain can be treated by blocking the paravertebral nerves during the operation, using an analgesia pump, or using analgesics intermittently following the operation. Hypovolemia, anemia, hypoxia, and carbon dioxide retention can all cause the sympathetic nervous system to over-activate, resulting in excessive endogenous catecholamine release and arrhythmia (36).

The association between postoperative hypoxemia and post cardiac-surgery arrhythmias could be to several reasons. Electrolyte imbalances can result in aberrant cardiac myocyte activation, increased sensitivity of the heart muscle, and arrhythmia (37). Furthermore, Hernández-Leiva

et al. demonstrated that high preoperative B-type natriuretic peptide levels are associated with a worse postoperative outcome (38).

Diuretics are prescribed to treat edematous conditions, hypertension, and congestive heart failure (9,10). Guidelines acknowledge the usefulness of diuretic treatments in treating congestion(40). The prevalence of diuretics use globally is estimated to be up to up to 90% (41), in Africa it is 55.0% (42). Diuretic drugs, on the one hand, cause neurohumoral activation, which is assumed to be the primary cause of arrhythmias, and they could also result in issues related to electrolytes and deteriorate renal function, which could lead to the stopping of renin-angiotensin-aldosterone system (RAAS) inhibitors (43). Diuretics have also been shown to minimize hospitalizations (44). Nonetheless, reports demonstrate that diuretics has an effect on mortality in heart failure patients (45).

2.4 Management of arrhythmias

The kind of arrhythmia, underlying cardiac disease, patient response to treatment, and possible adverse effects all influence the medication selection and length of therapy. Careful observation by medical professionals is necessary to guarantee the efficacy and security of arrhythmia treatment following open cardiac surgery. Quinidine and Procainamide, for example, slow down electrical conduction in the heart by inhibiting sodium channels (14). Therapy duration varies according to the kind and degree of arrhythmia. This is usually known as class I Antiarrhythmic. Class III Antiarrhythmics such as dofetilide and amiodarone) lengthen the heart's refractory period and action potential duration, which aids in cardiac rhythm stabilization. Long-term therapy is usually required for maintenance (46). Another management is referred to Beta-Blockers (32), Metoprolol and Atenolol, for example lower blood pressure and heart rate and aid in the management of arrhythmias brought on by excessive sympathetic activity. Long-term treatment is frequently administered to stop arrhythmia recurrence. Calcium Channel Blockers such as Diltiazem and Verapamil limit the entry of calcium into cardiac cells, lowering contractility and slowing heart rhythm (14). The patient's response and the arrhythmia will determine how long therapy takes. The last group is Digoxin: they improve the contractility of

the cardiac muscle and aids in the regulation of heart rate in certain arrhythmias, such as atrial fibrillation. The length of therapy is determined by the patient's reaction (14).

In addition to the above management, anticoagulant therapy also contributes significant to the management of arrythmia (14). Anticoagulant therapy prevent stroke and therefore patients' blood clotting levels (INR for warfarin) must be checked on a regular basis. Blood clots may form because of blood pooling in the heart's atria due to atrial fibrillation. Anticoagulants assist in preventing the formation of these clots and lower the risk of stroke. Anticoagulants, such as warfarin or direct oral anticoagulants (DOACs) like apixaban, dabigatran, or rivaroxaban, work by inhibiting the blood's ability to clot, making it less likely for clots to form (47).

2.5 Outcome following postoperative arrhythmias

The treatment urgency and management options for postoperative arrhythmias are determined by the clinical presentation of the arrhythmia. Generally management of postoperative arrhythmias involves optimizing the patient's condition preoperatively, careful attention to hemodynamic changes during surgery, and correction of temporary predisposing factors postoperatively(10). To be specific, management of post cardiac-surgery arrhythmias vary. For example, in patients with bradyarrhythmia’s, the use of pacemakers has been reported to reduce morbidity and mortality significantly (9). The treatment of postoperative supra ventricular tachyarrhythmias requires a comprehensive management: (a) antithrombotic therapy to prevent thromboembolic events; (b) antiarrhythmic treatment, including both rate and rhythm control strategies. Studies have reported outcomes following postoperative cardiac arrhythmias. A study by Rühlmann and his colleagues reported that Postoperative arrhythmias was associated with increased rates of in-hospital deaths, prolonged stay in the intensive care unit, and progress of a stable arrhythmias after discharge (48). Bhave at el reported that, patients with Postoperative arrhythmias had higher mortality rates, noticeably longer length of hospital stay and increased costs (49). In addition, a study by El-Chami and his colleagues reported that over a follow-up of 3.5 years, Postoperative arrhythmias was linked to significantly higher adjusted long-term

mortality (50). Furthermore, in their study, Fuchs and his colleagues reported increased postoperative extracorporeal membrane oxygenation
and in-hospital mortality for patients with Postoperative arrhythmias (51).

2.6 Application of electric current in managing arrythmias

This process is known as electrical cardioversion or defibrillation, and it involves aspects including cardioversion and defibrillation (14). Cardioversion is the process of giving the heart a coordinated electrical shock in order to return an irregular heart rhythm (such as atrial fibrillation or atrial flutter) to a normal sinus rhythm (52). The purpose of this shock is to reset the electrical activity of the heart by occurring at a precise moment in the cardiac cycle. When ventricular fibrillation or pulseless ventricular tachycardia poses a life-threatening risk, defibrillation is a procedure that is employed. In order to temporarily interrupt the heart's electrical activity and enable the heart's natural pacemaker to take over and restore a normal rhythm, a high-energy electrical shock is administered to the heart (52).

2.7 Drugs that induce arrythmias

Several drugs/medications have been reported to induce arrythmias. These include i) Antiarrhythmic Medications: Although antiarrhythmic medications are used to cure arrhythmias, they occasionally have proarrhythmic side effects that can cause arrhythmias to worsen or develop entirely new. i) Digoxin: When taken in excess, glycosides like digoxin, which are frequently used to treat heart failure and certain arrhythmias, can induce arrhythmias (53). ii) Antibacterial: Several antibacterial, especially macrolides (like erythromycin), can lengthen the QT interval and raise the chance of developing serious arrhythmias like Torsade's de Pointes, in a systematic literature review a total of 80 studies with 39,374,874 patients, the results showed, compared to non-macrolide users, those taking macrolides had a significantly higher risk of ventricular arrhythmia or sudden cardiac death (VA or SCD) (54). iii) Antidepressants: Certain antidepressants can alter heart rhythm and raise the risk of arrhythmias, especially tricyclic antidepressants and selective serotonin reuptake inhibitors (SSRIs) (55). iv) Antipsychotic Medications: A patient's risk of arrhythmias can be increased by certain

antipsychotic medications, particularly those that are older and lengthen the QT interval, such as haloperidol (56). V) Non-steroidal anti-inflammatory Drugs (NSAIDs): NSAIDs, when used in high doses or for prolonged periods, can lead to fluid retention and electrolyte imbalances that may contribute to arrhythmias (14).

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study design

A prospective observation study involving 100 post-cardiac surgery patients who met the specified criteria were monitored continuously for the first 4 days following surgery. The study was conducted from March to May 2024 at the JKCI in Dar es Salaam whereby patients were selected consecutively until the sample size was reached. The design is proposed because of its ability to establish a causal relationship between variables of interest, for this study; post cardiac-surgery arrhythmias and its factors.

3.2 Study Area

The study site for this investigation was JKCI. The JKCI is a public specialized cardiovascular teaching and research hospital located in the Upanga West ward of Ilala district in the Dar es Salaam region of Tanzania. It caters to both pediatric and adult populations with patients referred to from across the country and nearby countries. Services offered at JKCI include various cardiovascular clinics, diagnostic and imaging, interventional procedures, and cardiothoracic surgery. The institute attends over 1800 outpatients and 100 in-patients weekly and has a 157-bed capacity. Up to three patients undergo cardiac surgery daily which makes up an average of 75 patients per month.

3.3 Study Population

The study recruited post-cardiac surgery patients who attended at the JKCI.

3.3.1 Inclusion criteria

1. Patients with heart disease undergoing open heart surgery of both genders
2. Patients 18 years and above who underwent open heart surgery.
3. Patients who consented to the study

3.3.2 Exclusion criteria

1. Patients with incomplete medical records or missing data. For example, for patients who experienced pre-operative arrhythmias, If the information on whether they were treated before the operation was missing, they were excluded.
2. Patients with other significant medical conditions that may confound the results, such as severe electrolyte imbalances or uncontrolled heart failure.

3.4 Sample size and Sample size estimation

The sample size was obtained using a formula by Cochran's formula (18). P is the prevalence of post-cardiac-surgery arrhythmias. The level of significance is 0.05. After Adjusting for 10% incomplete data, the sample size estimated will be 108 patients. A minimum of 108 patients were recruited in this study.

$$n = \frac{P\,(1- P)}{(e)^2}$$

Where,

n= Sample size

P=The proportion of post-cardiac-surgery arrhythmias assuming 50% for any type of open-heart surgery.

Z= Desired level of statistical significance, for 0.05 significance level= 1.96

Z= for 0.05 significance level= 1.96

p= 0.5

$$n = \frac{1.96^2 \times 0.5\,(1- 0.5)}{0.05^2}$$

Sample size (n) = 384

For adjusted sample size

$$n_{adjusted} = \left(\frac{n}{1+ \frac{n-1}{N}} \right)$$

N= Patients undergoing cardiac surgery for the study period which is 150

n = Unadjusted sample size which is 109

$n_{\text{adjusted n}} = 109$

Considering 10% non-response = 119 patients. The adjusted sample size was adequate for analysis after considering the 10% non-response rate with a sample size ≥100 (57).
Out of 119 participants, only 100 had complete data, and the response rate was 84.03% which was acceptable, according to the American Journal of Pharmaceutical Education a response rate ≥ 60% is considered acceptable for analysis (58).

3.5 Sampling procedures

Patients were consecutively enrolled in the study until a pre-defined sample size of 108 patients was reached.

3.6 Data collection tools

Data was collected using a case report form (CRF). The tool was developed through collective approaches including reviewing the literature and expertise consultation. The language used during the generation of the tool was English. However, the tool's language was also translated into Swahili which was used during data collection. The tools contained three sections. The first section included demographic information, the second section included clinical information, and the third section included information on post cardiac-surgery arrhythmia.

Pretesting of tools involved a pilot study to evaluate the effectiveness and reliability of the data collection tool. Here's how the pretesting process for the CRF might be conducted:

A small sample of patients who meet the study's inclusion criteria and who are similar to the target study population in terms of demographics characteristics and medical history were selected for the pretesting, typically around 5-10% of the intended sample size. The CRF was used to collect information from the selected patients. This form included demographic details, medical history, surgical details, and postoperative outcomes related to arrhythmias.

The individuals who were responsible for collecting the data provided feedback on the clarity, comprehensiveness, and ease of use of the CRF. They also reported any challenges encountered during data collection. The research team reviewed the completed CRFs and the feedback from data collectors to identify any areas of ambiguity, inconsistency, or difficulty in data collection. Based on the feedback and review, necessary modifications and refinements were made to the CRF to improve its effectiveness and reliability in capturing the required data. The modified CRF were then retested with a different sample of patients to ensure that the changes have addressed any issues identified during the initial pretesting phase.

3.7 Data collection procedures

The source of information included patient interviews, patients' files, laboratory results (blood test results), and a Bedside patient ECG monitor. Patients were monitored continuously for the first 4 days following surgery by ECG to assess baseline cardiac rhythm, at the same time regular clinical assessments of patients were done to evaluate their cardiac status and identify any signs or symptoms of post-cardiac arrhythmia.

3.7.1 Bedside Patient ECG Monitor

This collected information on variables such as:

i. Heart Rate: ECG provides information on heart rate by measuring the time between consecutive R waves (R-R interval). Abnormal heart rates can indicate different types of arrhythmias, such as tachycardia or bradycardia.
ii. Rhythm: ECG helps determine the regularity of heart rhythm by analyzing the pattern of P waves, QRS complexes, and T waves. Irregularities in these waveforms can indicate arrhythmias like atrial fibrillation or atrial flutter.
iii. P Wave: The presence, shape, and duration of P waves on ECG can provide information about atrial depolarization. Absent or abnormal P waves may suggest atrial arrhythmias.
iv. QRS Complex: The QRS complex represents ventricular depolarization. Changes in QRS duration or morphology can indicate ventricular arrhythmias or conduction abnormalities.

v. QT Interval: The QT interval reflects ventricular depolarization and repolarization. Prolongation of the QT interval on ECG can predispose to dangerous arrhythmias like Torsade's de Pointes.

vi. ST Segment: Changes in the ST segment can indicate myocardial ischemia or infarction, which may predispose to arrhythmias.

3.7.2 Interpreting ECG data

This involved analyzing these parameters to identify abnormalities in heart rhythm, conduction, and repolarization. Any deviations from normal patterns are carefully assessed to diagnose specific arrhythmias. Diagnosis with ECG Monitoring: Postoperative arrhythmias were initially detected through continuous ECG monitoring in the cardiac care unit or postoperative recovery area. This monitoring was conducted by trained healthcare professionals such as a cardiologist to ensure accurate interpretation of ECGs. By utilizing ECG monitoring and re-examinations, the healthcare team at Jakaya Kikwete Cardiac Institute together with cardiologists accurately diagnosed the postoperative arrhythmias.

3.7.3 Confirmation with 12 lead ECG Reexaminations.

If an arrhythmia is suspected based on ECG monitoring, further confirmation was obtained through repeated 12 lead ECG examinations to assess the rhythm over time. These were performed by the healthcare team, which included cardiologists, electrophysiologists, or specialized cardiac technicians. Post cardiac-surgery arrhythmias include AFib, atrial premature beat, ventricular premature beat, conduction block, ventricular tachycardia, and sinus bradycardia. For patients with multiple arrhythmias, the types of arrhythmias were recorded separately but counted as arrhythmia once**.**

3.7.4 Laboratory analysis

Blood tests was done to assess electrolyte levels and renal function, which could be relevant due to diuretic use and other contributing factors, where by electrolyte imbalances, such as low potassium (hypokalemia) or low magnesium (hypomagnesemia), may predispose patients to arrhythmias by affecting the heart's electrical conduction system and increase the risk of developing dangerous arrhythmias, monitoring electrolyte levels through blood tests allows

healthcare providers to identify and correct any imbalances promptly, helping to stabilize heart rhythm and reduce the risk of arrhythmias in postoperative patients.

Impaired renal function can lead to the accumulation of toxins and electrolyte imbalances, which can impact heart function and contribute to arrhythmias. Additionally, some medications used in arrhythmia management may require dose adjustments based on renal function, so assessing renal function through blood tests helps healthcare providers evaluate the patient's overall health status, identify any potential factors contributing to arrhythmia, and ensure appropriate medication dosing and management strategies tailored to the patient's renal function.

3.7.5 Reviewing patients' medical records

Reviewing patients' medical records to gather information on postoperative arrhythmia, including details of any documented arrhythmias, other relevant patient information, such as demographics, treatment interventions, and patient outcomes were done whereby information obtained were recorded in a CRF by the attending physician or data collector.

When necessary, interviews with patients were conducted to gather subjective information about their experiences, symptoms, and any arrhythmia they may have experienced post-surgery.

3.7.6 Information collected at baseline may include

Demographic data (age, gender, etc.), Medical history, including cardiovascular health and previous arrhythmia, Details of pre-operative diuretic use and dosage.

3.7.7 Tests conducted at baseline

Electrocardiogram (ECG) to assess baseline cardiac rhythm, Blood tests to assess electrolyte levels and renal function, which may be relevant due to diuretic use, Physical examination to assess overall health status. Post cardiac-surgery arrhythmias was diagnosed with ECG monitoring and confirmed with ECG re-examinations.

Research assistants

Prior to undertaking the study, three (3) research assistants or data collectors: one pharmaceutical technician, one nurse and one medical doctor were oriented on all research

objectives for them to be precise on what data to retrieve. The involvement of multiple cadres allows for efficient coordination, comprehensive data collection, and rigorous analysis, contributing to the overall success of the study.

During data collection researcher was focusing on the following aspects: Ensuring ethical and regulatory compliance in obtaining patient data, collecting relevant patient information, such as demographics, medical history, and medication usage, ensuring data accuracy and completeness, Maintaining patient confidentiality and privacy, Documenting data collection procedures for transparency and reproducibility. Participant recruitment process typically involved: Identifying eligible participants from the pre-operative patient population and obtaining informed consent from eligible participants to participate in the study.

3.8 Variables and Measures

Dependent: Post cardiac-surgery arrhythmias

Independent: patient factors like age, BMI, sex, preoperative diuretics use, structural heart disease, and non-cardiac comorbidities. Surgery-related factors like preoperative arrhythmia, postoperative pain, hypoxemia, trauma and inflammation, hemodynamic stress ischemic injury, electrolytes disorders, and post-operative anti-arrhythmic use.

The previous history of arrhythmias was defined as any arrhythmias experienced before admission, while pre-operative arrhythmias were defined as any arrhythmias experienced after admission for surgery.

3.9 Data management and analysis

This part began by ensuring that data collected daily were precise and appropriate. In case there were any discrepancies or missing data, the medical records and other patient's relevant sources of information were re-checked to make vital adjustments. Data was analyzed by using a Statistical Package for Social Sciences version 23. Descriptive statistics were used to summarize data. The bivariate association was determined using the chi-square test and the t-test was used for continuous variables. The association between the dependent variable (post-cardiac-surgery arrhythmias) and the independent variable was determined using a Poisson regression model.

Relative risk (RR) from the chi-square test was also used to compare the strength of effects where RR>1 was considered as risky and when RR<1 was considered protective. The following variables were also adjusted in the model: age, male gender, body mass index, smoking, diabetes mellitus, and hypertension. In interpretation, significant results were confirmed by a p-value of less than 0.05.

3.10 Ethical issues

Ethical approval was requested from institutional review board of MUHAS. On other hand, permission to collect data was sought from the management of JKCI. To maintain confidentiality of the patient's information, interviews were conducted privately, and retrieval of information was conducted in such that patient's identity like names are not needed. No consent was sought as there was no interview.

CHAPTER FOUR

4.0 RESULTS

Descriptive statistics

4.1 Socio-demographic characteristics

The study involved 100 participants, consisting of 51 (51.0%) females. The median age was 50.50 years, with 50 (50.0%) aged over 50 years. Regarding marital status, 73 (73.0%) were married and the rest were single. The majority of the respondents, 88 (88.0%) resided outside Dar es Salaam. Educational attainment varied, with 30 (30.0%) having primary education. Employment status showed that 82 (82.0%) had any form of employment (self-employed, private employment, government employment), and the rest were unemployed. Health insurance coverage was prevalent among 73 (73.0%) of participants. The socio-demographic characteristics of participants are presented, See summary in [Table 1]

Table 1: Socio-demographic characteristics (N = 100)

Variable	Frequency (n)	Percent (%)
Sex		
Male	49	49.0
Female	51	51.0
Age (median =50.50)		
18-29	18	18.0
29-39	10	10.0
40-50	22	22.0
>50	50	50.0
Marital status		
Married	73	73.0
Single	27	27.0
Residence		
Inside DSM	12	12.0
Outside DSM	88	88.0
Level of education		
Primary education	30	30.0
Secondary education	24	24.0
College	27	27.0
University	19	19.0
Employment status		
Self employed	41	41.0
Private employment	21	21.0
Government employment	20	20.0
Unemployed	18	18.0
Health insurance coverage		
Yes	73	73.0
No	21	21.0

4.2 Clinical characteristics of the patients

Regarding medical history, 52 (52.0%) had a previous history of arrhythmia. A significant 96 (96.0%) had a history of rheumatic heart disease. Pre-operative arrhythmia was present in 26 (26.0%) of participants among which 18 (69.2%) experienced V-tach, and the rest experienced AtFib. Among those who developed pre-operative arrhythmias, 25(96.2%) were treated for arrhythmias before undergoing open heart surgery. Hypertension was reported by 78 (78.0%) of participants. Smoking history was reported in 15 (15.0%) of participants. According to the WHO BMI categories, 57 (57.0%) had normal weight, and 36 (36.0%) were overweight, the remaining were underweight. The history of COPD was reported by only 7 (7.0%) of participants while diabetes mellitus was present in 35 (35.0%) of participants. The types of cardiac surgeries undertaken included mainly valve replacement, 55 (55.0%) followed by CABG, 23 (23.0%). The clinical characteristics of patients are further described in Table 2. See summary in [Table 2]

Table 2: Clinical characteristics of patients (N = 100)

Variable	Frequency (n)	Percent (%)
Previous history of arrhythmias	52	52.0
History of rheumatic heart disease	96	96.0
Pre-operative arrhythmias	26	26.0
Type of pre-operative arrhythmia		
Ventricular tachycardia	18	69.2
Atrial fibrillation	8	31.8
Pre-OA treated before surgery	25	96.2
History of hypertension	78	78.0
Impaired renal function	7	7.0
History of smoking	15	15.0
BMI WHO category		
Underweight	7	7.0
Normal weight	57	57.0
Overweight	36	36.0
History of COPD	7	7.0
History of diabetes mellitus	35	35.0
Type of cardiac surgery undertaken		
CABG	23	23.0
Valve replacement	55	55.0
CABG + valve replacement	13	13.0
Ventricular septal defect repair	9	9.0

4.3 Incidence of arrhythmias

Out of 100 participants in the study, the incidence of arrhythmia was observed in 54 (54.0%) of the participants, indicating that more than half of the subjects experienced some form of arrhythmia. Among those who experienced arrhythmias, the common types identified included sinus tachycardia 36 (66.7%), atrial fibrillation 32 (59.2%), sinus bradycardia 5 (9.4%), supraventricular fibrillation 4 (7.4%), and slow ventricular response 4 (7.4%) with a median duration of 6 hours occurring about 2 hours post-surgery. See summary in [Figure 2]

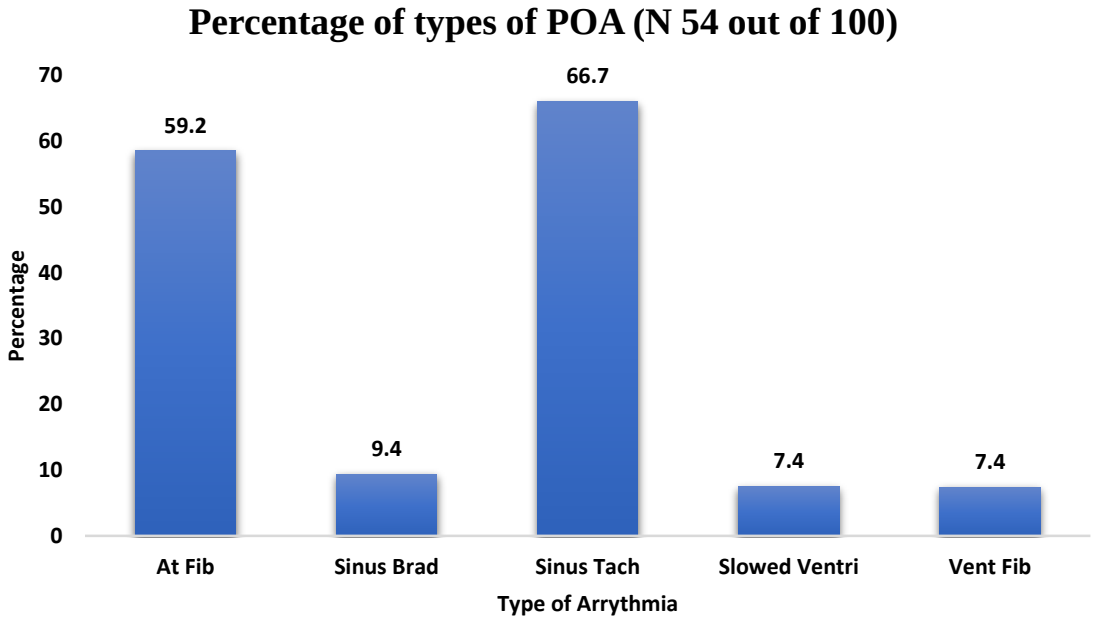


Figure 2: Types of POA

Key: At Fib- Atrial Fibrillation, Sinus Brad- Sinus Bradycardia, Sinus Tach- Sinus Tachycardia, Slowed Vent- Slowed Ventricular Response, Vent Fib- Ventricular Fibrillation

4.4 Factors associated with post-cardiac surgery arrhythmias

The multivariable Poisson regression analysis revealed several significant arrhythmia-related factors following cardiac surgery. After adjusting for other variables, certain risk factors emerged as particularly noteworthy. Body mass index (BMI) showed a statistically significant association, with patients with higher BMI exhibiting a 1.72 times greater risk of developing arrhythmia than those with lower BMI values [ARR 1.72, (0.98-2.27) p-value 0.038). Patients with a previous history of arrhythmias **(**any documented episode experienced) were 1.25 times more likely to develop arrhythmia post-surgery than those without a history of arrhythmia [ARR 1.25 (0.45-3.85) p-value 0.045]. Additionally, patients with a history of pre-operative (that were to be intervened prior the procedure) arrhythmia were found to face a substantially heightened risk post-surgery, with a risk ratio of 7.19 (95% CI 1.63-32.25, p-value 0.011) compared to those who did not experience pre-operative arrhythmia. Hemodynamic instability also proved to be a significant predictor, increasing the risk by 4.41 times (95% CI 1.59-12.05, p = 0.004) as compared to patients without any history of hemodynamic instability such as hypertension. See summary in [Table 3]

Table 3: Regression analysis of determinants for Occurrence of POA

Variable	Univariate CRR (95% C.I)	p-value	Multivariable ARR (95% C.I)	p-value
Age	0.76 (0.57-1.34)	0.156	1.02 (0.98-1.06)	0.248
BMI	1.24 (0.82-1.79)	0.095	1.72 (0.98-2.27)	0.038
Previous history of arrhythmias				
Yes	0.86 (0.34-2.12)	0.143	1.25 (0.45-3.85)	0.045
No	Ref			
History of rheumatic heart disease				
Yes	0.93 (0.90-9.70)	0.200	1.85 (0.17-20.50)	0.617
No	Ref			
Pre-operative arrhythmias				
Yes	1.71 (0.52-5.60)	0.076	7.19 (1.63-32.25)	0.011
No	Ref			
History of hypertension				
Yes	0.58 (0.12-2.71)	0.114	2.38 (0.65-8.67)	0.190
No	Ref			
History of diabetes mellitus				
Yes	0.29 (0.05-1.82)	0.765		
No	Ref			
Hemodynamic instability				
Yes	2.90 (0.66-12.77)	0.034	4.41 (1.59-12.05)	0.004
No	Ref		Ref	
Electrolyte disorder				
Yes	3.17 (0.85-11.84)	0.087	0.71 (0.16-3.28)	0.664
No	Ref		Ref	
Hypoxemia				
Yes	0.87 (0.27-2.80)	0.843	-	
No	Ref			
History of COPD				
Yes	0.75 (0.08-7.05)	0.558	-	
No	Ref			

4.5 Management of Patients with Post-operative Arrhythmia

In managing arrhythmia post-cardiac surgery, the study investigated various pharmacological and procedural interventions. Among those who used medication (n=39), cardiac membrane stabilizers were used in 27 (69.2%) patients, also, 27 (69.2%) patients were given hydration fluids, 24 (61.5%) patients received beta-blockers, anticoagulants were provided in 23 (59.0%) patients, and antipain medications were given in 22 (56.4%) patients. Others included amiodarone, lidocaine, CCB, digoxin, adenosine, sotalol and cardioversion, which were less employed.

4.6 Treatment outcome of post-cardiac surgery arrhythmias

From 100 study participants, the treatment outcomes of post-cardiac surgery arrhythmias in the study revealed several important findings categorized into positive and negative outcomes. A substantial portion of the participants, 59 (59.0%) hemodynamic instability, 33 (33.0%) of the respondents experienced an extended hospital stay and 33 (33%) experienced bleeding complications. The study found a very low mortality rate, with only 1 (1.0%) of participants dying following the surgery.

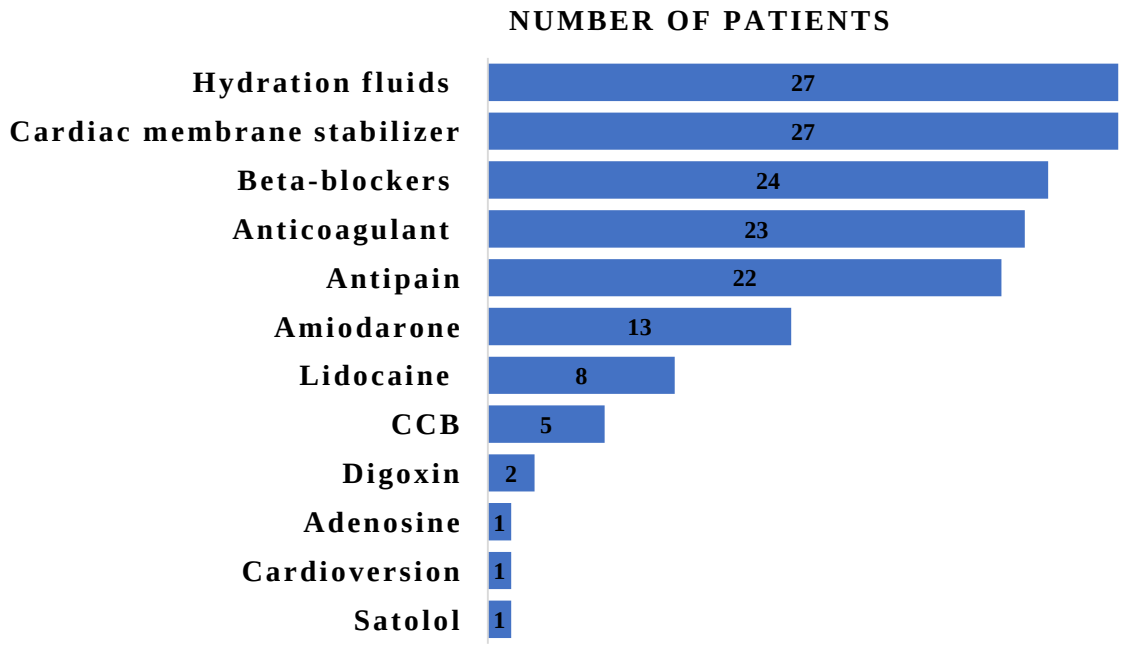


Figure 3: Management of patients with POA (n = 39)

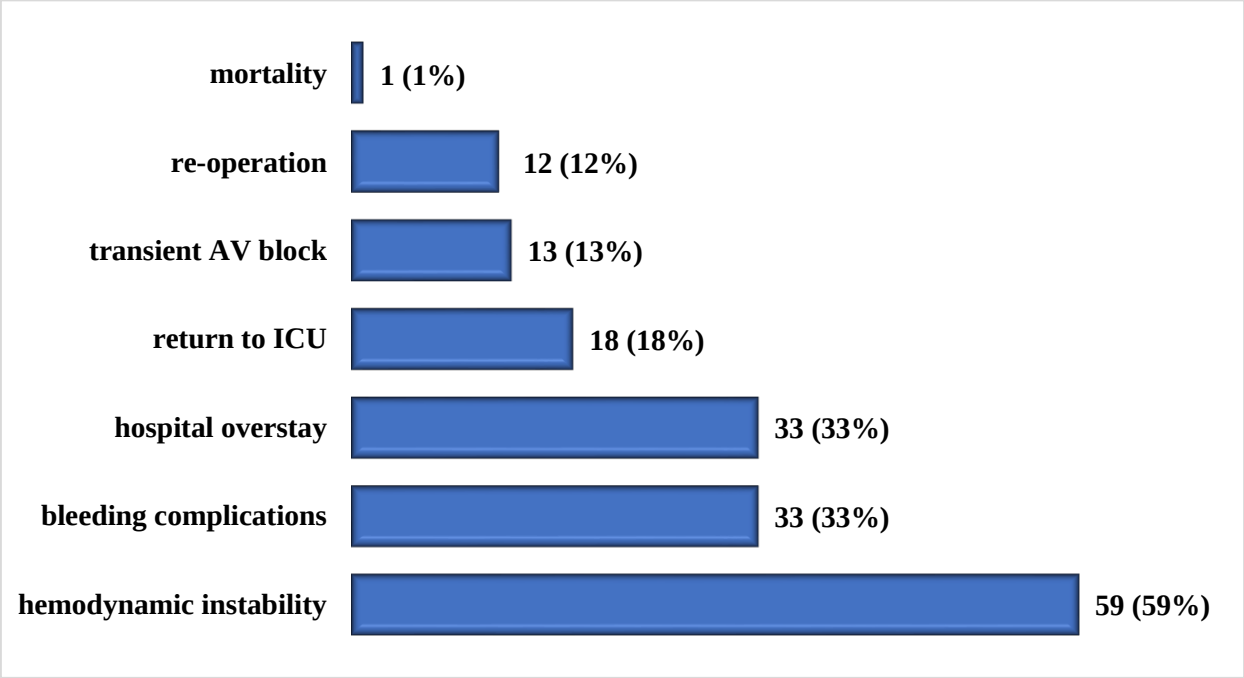


Figure 4: Treatment Outcomes among Patients with POA (N=100)

CHAPTER FIVE

5.0 DISCUSSION

This study explored the incidence of postoperative arrhythmias after cardiac surgeries and the issues that accompany their management. The study had 100 patients with a 54% incidence rate of POA signifying that nearly half the patients suffered from some type of arrhythmia after surgery. The most common of these arrhythmias were sinus tachycardia, atrial fibrillation, and sinus bradycardia, and appeared within 2 hours after the operations and lasted for a median of 6 hours. The incidence of POA was associated with factors like, BMI, previous history of arrhythmia, pre-operative arrhythmia, and hemodynamic instability. These findings show the importance of comprehensive and continuous monitoring of patients after surgery and rigorous intervention measures regarding the available management of arrhythmias among such patients.

The clinical profile of the study population at JKCI provide important insights into the potential risk factors associated with post-cardiac-surgery arrhythmias (POA). The study revealed a predominance of older patients and those from rural areas suggests a potential delay in accessing healthcare services, which may contribute to the high incidence of POA observed. The high rates of hypertension, rheumatic heart disease, and diabetes mellitus further suggest that these patients present with multiple comorbidities, increasing their vulnerability to POA. This profile aligns with findings from a global systematic review, which identified a higher incidence of POA among older age, female gender, and pre-existing conditions like hypertension and diabetes (59). Another study by Filardo et al. reported similar findings, highlighting that patients with multiple comorbidities undergoing cardiac surgery developed more arrhythmias (60). In Africa, the demographic characteristics of patients undergoing cardiac surgery vary, but some studies indicate a comparable trend, a high prevalence of hypertension, and older age among patients experiencing POA, reflecting similar risk factors (5). Another study found that younger patients were more likely to undergo cardiac surgery, potentially due to earlier interventions in rheumatic heart disease (4). The findings also align with a reported prevalence of cardiac conditions managed by surgery in Tanzania, one study at JKCI reported the prevalence of RHD to be 47.6% followed by CHD in 35.2% of the cases (22). Additionally, most participants

underwent Valvular replacement surgery and CABG, which was in line with previous studies done in Tanzania reporting that about 68% of cardiac surgeries were valvular replacement (61). These demographic and clinical characteristics underscore the need for targeted perioperative care tailored to high-risk groups, particularly in settings where healthcare access may be delayed, and comorbidities are prevalent, to mitigate the risk and improve outcomes in post-cardiac surgery patients.

The incidence of post-cardiac-surgery arrhythmias (POA) in this study was 54%, indicating that more than half of the patients undergoing open heart surgery at JKCI developed arrhythmias postoperatively. This high rate reflects a substantial burden of POA, which can lead to increased hospital stays, higher healthcare costs, and greater mortality risk if not effectively managed, underscoring the need for vigilant perioperative monitoring and targeted therapeutic strategies, particularly in resource-limited settings. Comparatively, this incidence aligns with global findings, POA is estimated to affect about 30- 60 % of the patients after cardio surgeries (62,63), suggesting that POA is a common complication across different cardiac surgery types worldwide. In contrast, African studies reveal varying incidence rates, potentially reflecting differences in healthcare access, surgical expertise, and patient management. For example, a study in Egypt reported around 10%–60% of patients undergoing coronary artery bypass graft and valvular surgery experienced new-onset atrial fibrillation (64), while a study in South Africa reported an incidence rate of 5.9%, which was likely influenced by differences in preoperative care and patient selection (65). The relatively higher POA incidence at JKCI may be due to the distinct patient profile in Tanzania, where many patients have pre-existing conditions like rheumatic heart disease and hypertension, both known risk factors for POA. These findings highlight the importance of context-specific strategies for managing post-cardiac surgery arrhythmias and emphasize the need for optimizing preoperative conditions and perioperative care to reduce the POA burden, particularly in settings with limited healthcare resources

The study revealed several factors significantly associated with the incidence of POA among patients undergoing cardiac surgery at JKCI, such as high BMI, a previous history of arrhythmia, pre-operative arrhythmia, and hemodynamic instability. Patients with a higher BMI were 1.72

times more likely to develop POA, a finding consistent with studies conducted in other settings. Obesity is associated with factors like enhanced inflammation and disruptions to normal heart rhythm, which can contribute to the development of postoperative arrhythmias (66,67). For instance, A study in China reported a similar association where patients with a BMI greater than 30 had a 2.8-fold increased risk of developing arrhythmias post-surgery obesity (OR, 2.803; 95% CI, 1.589–4.944; P<0.001) (68). Similarly, another study found that patients with elevated BMI were more likely to experience POA, with an odds ratio of 1.1 (95%CI 1.03–1.2,p = 0.006), indicating a comparable relationship between obesity and arrhythmia risk in both studies (69). Additionally, the study also found that a pre-operative history of arrhythmias was an independent risk factor for POA. Patients with a prior diagnosis of arrhythmia had a 1.25 times higher risk of developing POA compared to those without this medical history. This finding aligns with existing literature, underscoring the importance of carefully evaluating a patient's arrhythmic history when assessing their susceptibility to postoperative rhythm disturbances (70,71). For patients with a known pre-operative history of arrhythmias, the data suggests the need for heightened monitoring, preventive measures, and proactive management strategies to mitigate the elevated risk of POA in this high-risk population (72). Elevated risk of POA among patients with a prior diagnosis of arrhythmia also suggests that pre-existing electrical disturbances in the heart can be exacerbated by the physiological demands placed on the heart during the surgical procedure (73). In the African context, the findings also align partially with the literature. Studies observed that patients with a history of rheumatic heart disease (RHD) and arrhythmias had a higher incidence of POA, particularly atrial fibrillation, (61). This discrepancy could be due to differences in the prevalence of hypertension or perioperative management practices between the two regions, emphasizing the importance of tailoring POA management strategies to local patient demographics and healthcare settings.

Additionally, the study also identified hemodynamic instability as a risk factor, with patients experiencing this complication having 4.41 times higher odds of developing postoperative arrhythmia. This suggests that disruptions to normal cardiovascular function and perfusion can further predispose patients to rhythm disturbances in the postoperative setting (74). This finding is consistent with other studies that have highlighted the importance of changes in

hemodynamics in aggravating patients, at some point post-short of cardiac surgical procedures, with regards to variation in blood pressure and volume balance (75). Also, hemodynamic changes are known to affect the occurrence of POA at some time post-cardiac surgical procedures due to an imbalance of blood pressure and fluid (76,77). In a vast community-based prospective registry, Ishii et al. showed that, in AF patients, only systolic blood pressure values beyond 150 mmHg were significantly associated with a higher risk [HR 1.74, 95% CI (1.08–2.72)] (78).

Interestingly, the study found that variables like the patient's age and other comorbidities, such as hypertension or electrolyte imbalance, were not directly related to the development of POA. This is different from several previous studies that have established elderly patients to be at higher risk of postoperative atrial fibrillation due to age-related structural and electrical changes in the myocardium. (7,54). Aging is an important predictor of POA, and the incidence of POA in patients aged 72 or older is approximately fivefold higher than that in patients aged 55 or younger. (41). In another study, AF was associated with increased age (mean difference [MD]: 9.5 years; 95% CI: 7.8–1.3) (43). The absence of a notable correlation in our population could be attributed to the moderate variation in the patients' age bracket or appropriate handling of such conditions before and after the surgeries conducted at JKCI. The source population/subject-specific demographic and clinical profile, especially the high prevalence of rheumatic heart disease, might have also influenced these findings since rheumatic heart disease is not equivalent to other forms of heart disease common in other continents (55,56).

The study also examined the management approaches utilized for these postoperative arrhythmias. It was noted that pharmacological interventions were especially employed, with common treatments including cardiac membrane stabilizers and beta-blockers. These medications are widely known for managing the rate of heartbeat as well as averting irregularity, which conforms to global norms (72,79). The use of these pharmacological therapies, such as antiarrhythmic medications and beta-blockers, underscores the importance of having robust treatment protocols in place to actively manage the occurrence of rhythm disturbances in the postoperative setting. In the study on the management approaches of POA that was undertaken

herein, it was noted that pharmacological interventions were especially used whereby the common treatments included cardiac membrane stabilizers and beta-blockers (80). Also, 23 patients received anticoagulation therapy for thromboembolic risks provoked by arrhythmias and antipain medication was prescribed for 22 patients. Reflecting a holistic approach to achieving the patient's hemodynamic goals from other studies (81,82). In one study, Oral anticoagulation was associated with a lower risk of thromboembolic events in patients with POA following cardiac surgery (83). In addition to the pharmacological therapies, procedural interventions, such as cardioversion, were utilized, studies show that cardioversion is important in the management of POA and associated complications such as thromboembolic events, delay to cardioversion of 12 hours or longer from symptom onset of AF was associated with a greater risk for thromboembolic complications (79,84). This multi-faceted approach to arrhythmia management, involving both medications and procedures, reflects the complex and individualized strategies needed to effectively address POA in the postoperative setting.

It was also ascertained from the study that in treating POA, patients are at the risk of facing post-operative related complications that may include longer stay in the hospital and bleeding which as earlier established affects nearly one-third of the patients. According to some authors, hospital length of stay after CABG surgery can be extended by 2–4 days with additional costs (14). This emphasizes the idea that perioperative management should have an ongoing process of enhancing the existing management strategies to manage the patient's arrhythmia efficiently while preventing more postoperative complications as cited in other studies (85,86). The overall mortality rate recorded in the present study was less than 1%, which was contrary to similar studies done in Tanzania that reported mortality rates of 13.3%, 14.1%, and 14.4% (22,61,87). Therefore, it can be recommended that with good management, many patients are more likely to survive despite post-management complications. However, the high incidence of postoperative hemodynamic instability and the associated increase in the length of hospital stay underscore the urgent need for improved postoperative care and early identification and management of high-risk patients. (76).

For future work, further research could be aimed at the outcomes of different POA management approaches over longer periods, as well as the costs incurred during the implementation of the strategies in the contexts of the specific resource restraints characteristic for Tanzania. Also, assessing the detailed information about specific arrhythmogenic pathways in patients with high incidences of rheumatic heart diseases may help identify local interventions to enhance the result of effective cures in the special population (88).

5.1 Study Strength

A notable strength of this study is its comprehensive analysis of postoperative arrhythmias in a specific cohort of patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute, providing valuable insights into both the incidence and management of these conditions within a Tanzanian context. The detailed examination of risk factors, treatment modalities, and outcomes, combined with a low mortality rate, offers a nuanced understanding of arrhythmia management and its implications for patient care. Furthermore, the study's integration of local data with global and regional research enhances its relevance and applicability, potentially guiding future interventions and improving clinical practices in similar settings.

5.2 Limitations and mitigations

The study had several limitations, including a short duration that may not have captured the full spectrum of postoperative arrhythmias, a single-center patient population that limits generalizability, and potential information bias in data collection. Additionally, the sample size obtained may not entirely reflect the clinical picture of patients undergoing open heart surgery. To address these, future research should extend the study duration, expand to multiple centers across Tanzania, and implement robust data quality assurance processes. Additionally, exploring genetic and procedural factors could provide deeper insights to improve risk assessment, optimize treatment plans for open-heart surgery patients, and increase the sample size. Acknowledging and addressing these limitations can strengthen the evidence and enhance the applicability of the study findings.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

In conclusion, this study identified a 54% incidence of postoperative arrhythmias among patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute, with sinus tachycardia (66.7%) and atrial fibrillation (59.2%) being the most prevalent. Key risk factors included a higher BMI, which increased the risk of arrhythmias by 1.72 times, and a history of pre-operative arrhythmias, associated with a 7.19 times higher risk. Management strategies predominantly included cardiac membrane stabilizers (the use of Magnesium sulphate injections, Calcium gluconate injections, Potassium Chlorides injection and Ringer Lactate) (69.2%), beta-blockers (61.5%), and anticoagulants (59.0%), with advanced treatments being less common. Despite a very low mortality rate of (1)1.0%, the study highlighted significant issues with hemodynamic instability (59.0%) and extended hospital stays (33.0%). These findings underscore the importance of targeted arrhythmia management and improved post-surgical care, reflecting broader trends seen in both global and regional studies while pointing to areas needing further attention.

6.2 Recommendations

Strengthen postoperative monitoring and surveillance for the prevention of postoperative new-onset cardiac arrhythmias in patients with cardiac surgery, several preoperative risk evaluations have shown branches such as BMI, history of arrhythmias, and hemodynamic stability ought to be carried out. Based on these assessment outcomes, high-risk patients ought to be given extra attention and early intervention to avoid the occurrence of POA. It might also be worth enhancing the applicability elements of anti-arrhythmic medicines together with other therapeutic procedures like beta-blockers and anticoagulants because of the consistent variation in treatment results. Education programs should be established to enable patients to report arrhythmias early and or get early treatment. Ultimately, enhancing the early identification and intervention for high-risk patients will be crucial in improving clinical outcomes and reducing

complications. Future research should continue to build on these insights, aiming to refine our understanding and treatment of postoperative arrhythmias to achieve better patient care and recovery trajectories

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APPENDICES

Appendix I: Case Report Form

JAKAYA KIKWETE CADIAC INSTITUTE

SECTION ONE

Patient ID: …… **Date:** ……. **BMS: ……**

Contact Number: …….

Sex (Gender) M…… F **Age: …….**

[ ] [ ] **Mental status: .....**

Residence: Specify street: ..... **Employment status**

District: ..... Region: ..... Government employee [ ]

Level of Education: ..... Private employee [ ]

Health of Education..... Self-employed [ ]

Health insurance coverage..... Yes No Other [ ] Specify: .....

[ ] [ ]

SEC 2: OPERATIVE VARIABLES.

Pre-operative variable

	Yes	**Yes**	**No**	**No**
Previous History of arrhythmias				
Rheumatic heart disease				
Right ventricle Hypertension				
Pre-operative arrhythmias				
Hypertension				
Smoking				
Impaired venal function				
LVEF ≤ 35%				
Diabetes Mellitus				
Obesity				
COPD				
Use of Beta-blockers				
Other medication				

Hypoxemia

Trauma and inflammation.

Hemodynamic Stress

Ischemic injury

Aortic cross crap time ≥ 90min.

Cardiopulmonary bypass time ≥ 120min.

Other variables

Types of cardio surgery

1. CABG
2. VALVE Replacement/repair
3. CABG + valve replace
4. Aortic/ ventricular septal defect repair

Electrolyte disorder	Yes	No
Na^+ level ..... K^+ level..... Ca^{2+} level..... Mg^{2+} level		

SECTION 3: POSTOPERATIVE VARIABLES

ECG Finding YES NO

Occurrence of POA [ ] [ ]

Types of Arrhythmias.....

Duration of Arrhythmias.....

Time to the occurrence of arrhythmia.....

Duration of POA.....

Use of Anti arrhythmias [ ] [ ]

Types of Anti arrhythmias

1.....

2.....

3.....

Complications of POA	**YES**	**NO**
Re- operation		
Bleeding complication		
Prolonged medical ventilation		
Return to the ICU		
Transient AV block		
Prolonged use of catecholamine		
Hospital over stay		

Doctor/Nurse/Pharmacist..... PF. No.....

Appendix II: Consent Form - English Version

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

SCHOOL OF PHARMACY.

DEPARTMENT OF CLINICAL PHARMACY & PHARMACOLOGY.

POSTOPERATIVE ARRHYTHMIAS AFTER OPEN HEART SURGERY: INCIDENCE, RISK FACTORS AND THERAPEUTIC MANAGEMENT AMONG PATIENTS AT JAKAYA KIKWETE CARDIAC INSTITUTE, DAR ES SALAAM, TANZANIA.

FORM NUMBER

Participation in this study

Purposes of the study: To assess the incidence, factors associated with arrhythmias, therapeutic management and treatment outcome among patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute in Dar es Salaam, Tanzania.

Sponsor: Self-funded.

Principle investigator: Wilson Samson Misinzo.

Procedure: There is no invasive procedure for participants.

Risk or harm: We expect no harms or risks to participants during the study.

Benefits: The finding of this study will help the Ministry of Health, the institute and other stakeholders to know the incidence, factors associated with post cardiac arrhythmia and management outcome among patients undergoing cardiac surgeries hence reducing the mortality, morbidity and over hospital stay. Also, this knowledge can lead to better management of post-operative arrhythmia risk and improved patient outcomes through more tailored treatment plans.

Confidentiality: No names or information about participants will be exposed or shared; instead, the study will use participants' identification numbers.

Participation and withdrawal rights

The participants have the right to voluntarily participate in this study or withdraw from it without payment, and there are no restrictions or outcomes for withdrawing from the study. The participants will participate in this study by responding to different open and closed-ended questions and choosing the most correct answer.

Contact person

For any question or inquiry in this study, you should contact the principal investigator, who is Wilson Samson Misinzo, Muhimbili University of Health and Allied Sciences, P.O. Box 65004, Dar es Salaam, Tanzania, phone number +255715500899, email samsonmisinzo@gmail.com. OR Core Supervisor Pharm. Leonard Buganda +255716137574, email bgleon90@hotmail.com, OR Directorate of Research and Publication, Muhimbili University of Health and Allied Sciences, P.O. Box 65001, Dar es Salaam, phone number +255222152489.

Agreement to participate

I have read the contents of this form and am satisfied with them, so I agree to participate in this study.

Participant signature..... Date ……

Researcher/Researcher Assistance Signature.....Date.....

Appendix III: Swahili consent form

CHUO KIKUU CHA FYA NA SAYANSI SHIRIKISHI MUHIMBILI

SHULE YA FAMASI

FOMU YA MAKUBALIANO

Kushiriki katika utafiti wa kukusanya takwimu za tathmini ya kiwango na mambo yanayoambatana na matatizo ya moyo baada ya upasuaji wa moyo kutokana na matumizi ya dawa za kutoa maji kabla ya upasuaji kwa wagonjwa Katika Taasisi ya Moyo ya Jakaya Kikwete, Dar Es Salaam, Tanzania:

Namba ya fomu

Utayari wa kushiriki katika utafiti huu

Lengo la utafiti:
Kuchunguza kiwango cha matukio, sababu zinazohusiana na arrhythmias, namna ya matibabu na matokeo ya matibabu kwa wagonjwa wanaofanyiwa upasuaji wa moyo katika taasisi ya moyo ya Jakaya Kikwete Dar es Salaam, Tanzania.

Mtafiti: Wilson S. Misinzo

Mfadhili: Ufadhili binafsi

Madhara/hasara: Hakuna madhara au hasara za mshiriki yeyote wa utafiti huu

Manufaa: Matokeo ya utafiti huu yatasaidia taasisi na Wizara ya Afya pamoja na wadau wengine kujua kiwango na sababu zinazohusiana na arythmia baada ya upasuaji wa moyo miongoni mwa wagonjwa, hivyo kupunguza vifo, maradhi, na muda mrefu wa kulazwa

hospitalini. Pia, ugunduzi huu utasaidia kuboresha usimamizi wa hatari za matatizo ya rythmia baada ya upasuaji, hivyo kunufaisha wagonjwa wanaofanyiwa upasuaji wa moyo katika Taasisi ya Moyo ya Jakaya Kikwete.

Usiri: Hakuna taarifa yoyote au majina ya mshiriki yatakayoandikwa au kutolewa kwa mtu yoyote asiye husika na taarifa zote za mshiriki ni siri baina ya mtafiti na mshiriki, zaidi mshiriki atatatumia namba ya utambulisho.

Haki ya kushiriki au kutokushiriki: Washiriki wana haki ya kushiriki katika utafiti huu kwa hiari au kujiondoa bila malipo, na hakuna vikwazo au matokeo kwa kujiondoa katika utafiti. Washiriki watashiriki katika utafiti huu kwa kujibu maswali tofauti kwa kuchagua amakuelezea jibu sahihi zaidi.

Mawasiliano

Kwa maswali zaidi kuhusu utafiti huu tafadhali wasiliana na mtafiti mkuu Wilson Misinzo, Chuo kikuu cha Afya na Sayansi Shirikishi Muhimbili SLP 65004 Dar es Salaam, Namba ya simu +255715500899 Barua Pepe samsonmisinzo@gmaail.com AU wasiliana na Msimamzi msaidizi Mfamasia Leonard Buganda namba ya simu +255716137574 barua pepe bgleon90@hotmail.com au wasialiana na kurugenzi ya Utafiti na Machapisho, Chuo kikuu cha Afya na Sayansi Shirikishi Muhimbili SLP 65001 Dar es Salaam, Simu namba +55222152489

Ridhaa: Nimesoma fomu hii ya makubaliano na nimeelewa yote yaliyoandikwa kwenye fomu hii na ninakubali kushiriki katika utafiti huu.

Sahihi ya Mshiriki …….. Tarehe …….……

Sahihi ya Mtafiti/Mtafiti Msa

Appendix IV: Approval for ethical clearance

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/2087 Date: 11/03/2024

MUHAS-REC-03-2024-2087
WILSON SAMSON MISINZO

MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: POSTOPERATIVE ARRHYTHMIAS AFTER OPEN HEART SURGERY: INCIDENCE, RISK FACTORS AND THERAPEUTIC MANAGEMENT AMONG PATIENTS AT JAKAYA KIKWETE CARDIAC INSTITUTE, DAR ES SALAAM, TANZANIA.

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: 11/03/2024
EXPIRATION DATE OF APPROVAL: 11/03/2025

STUDY DESCRIPTION:
Purpose:

The purpose of this prospective observational cohort study is to determine the incidence, factors associated with arrhythmias, therapeutic management and treatment outcome among patients undergoing open heart surgery at Jakaya Kikwete Cardiac Institute in Dar es Salaam, Tanzania.

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-%2014554.pdf and in the MUHAS archives.

The PI is required to:

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/.

20/03/24

Dr. Kasusu Nyamuryekung'e

Ag. Chairperson, MUHAS Research and Ethics Committee

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research, Publications & Innovations
Box 65001

Appendix V: Introduction letter

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/T.421/2022 14th March, 2024

THE EXECUTIVE DIRECTOR,
JAKAYA KIKWETE CARDIAC INSTITUTE,
P.O BOX 65141,
DAR ES SALAAM.

RE: INTRODUCTION LETTER OF WILSON SAMSON MISINZO

We would like to inform you that the carrier of this letter is Wilson Samson Misinzo with registration number HD/MUH/T.421/2022 a student in the College of Medicine at Muhimbili University of Health and Allied Science (MUHAS), pursuing Mpharm. Hospital and Clinical Pharmacy.

As part of his studies, he will be doing an elective research titled **"POST-OPERATIVE ARRHYTHMIAS AFTER OPEN HEART SURGERY: INCIDENCE, RISK FACTORS AND THERAPEUTIC MANAGEMENT AMONG PATIENTS AT JAKAYA KIKWETE CARDIAC INSTITUTE, DAR ES SALAAM, TANZANIA".**

He is being supervised by Dr. Ritah Mutagonda from MUHAS and Leonard Buganda from Jakaya Kikwete Cardiac Institute (JKCI).

The Ethical Clearance for doing the said research has been given by the University.

Kindly request your assistance and cooperation to our student.

Yours Sincerely,

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Wilson Samson Misinzo

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151373;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix VI: Permission to collect data at JKCI

UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

JAKAYA KIKWETE CARDIAC INSTITUTE (JKCI)

JAKAYA KIKWETE CARDIAC INSTITUTE

In reply please quote;
Ref No: AB.123/307/01K/22 26/03/2024

Wilson Samson Misinzo
HD/MUH/T.421/2022
Mpharm - MUHAS

RE: PERMISSION TO CONDUCT RESEARCH AT JKCI

Reference is made to your letter requesting to do a research study entitled **"POST-OPERATIVE ARRHYTHMIAS AFTER OPEN HEART SURGERY: INCIDENCE, RISK FACTORS AND THERAPEUTIC MANAGEMENT AMONG PATIENTS AT JAKAYA KIKWETE CARDIAC INSTITUTE."** here at JKCI.

This letter serves as an official document that permits you to do the above-mentioned task as requested. However, the institution also requires you to have JKCI local co-supervisor.

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 & Head of Units