SCHOOL OF MEDICINE

DEPARTMENT OF INTERNAL MEDICINE

PARTERN OF ELECTROCARDIOGRAPHIC CHANGES AMONG DIABETES MELLITUS PATIENTS ATTENDING DIABETIC CLINICS IN DAR ES SALAAM.

By

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A DISSERTATION PROPOSAL SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN INTERNAL MEDICINE AT KAIRUKI UNIVERSITY

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CERTIFICATION

It is hereby certified that the undersigned have read and hereby recommend the acceptance by Kairuki University of a Dissertation titled: **"PATTERN OF ELECTROCARDIOGRAPHIC CHANGES AMONG DIABETES MELLITUS PATIENTS ATTENDING DIABETES CLINICS IN DAR ES SALAAM."** in partial fulfillment of the requirements for the degree of Master of Medicine in Internal Medicine of Kairuki University.

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ACKNOWLEDGEMENT AND DEDICATION

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DEDICATION

This research work is lovingly dedicated to my beloved mother, Roza Tibehenderwa, my hero, my inspiration, and a true superwoman - a devoted mother of 12 children. She has been a constant source of strength, love, and faith, her tireless prayers and endless sacrifices have carried me through every challenge.

Thank you, Mama, for keeping me in your heart and in your prayers.

This achievement is as much yours as it is mine.

ABSTRACT

Background: People affected with Diabetes mellitus have two-three folds increased risk of cardiovascular disease compared to the general population. Early cardiac involvement in diabetes may be silent and can progress undetected until advanced stages of disease manifest with serious complications. Electrocardiographic changes can serve as early markers of cardiac involvement and provide insight into the progression of cardiovascular complications in diabetic patients. The increase in the burden of Diabetes mellitus in Dar es Salaam the and its known association with cardiovascular disease calls for early screening and detection of diabetes related cardiovascular complication as means to prevent and alleviate the burden of diabetes morbidity and mortality.

Objective: To determine pattern of electrocardiographic changes among diabetes mellitus patients attending Diabetes clinics in Dar es Salaam.

Methodology: A health-facility based descriptive cross-sectional study was conducted among Diabetes mellitus patients attending Diabetes clinics in Dar es Salaam, with a sample size of 206 study participants. A structured questionnaire was used for Data collection; which included socio-demographic characteristics and pertinent clinical that included general and cardiovascular factors - Blood pressure, electrocardiographic findings and laboratory tests. The Minnesota coding classification was used to interpreted the electrocardiographic findings. Data analysis was done using

Results: Among 206 Diabetes mellitus patient who were in the final data analysis mean age was 50.08 ± 22.82 years, median age of 57 years, with 50% of the population between age of 24 years and 66 years, (IQR of 42.25 years). The minimum age was 7 years and the maximum age was 101 years.

They were 74 males (5.9%) and 132 females (64.1%). Of the 206 study participants 157 (76.2%) had Type 2 Diabetes mellitus and 49 (2.8%) had Type 1 Diabetes mellitus. At least one electrocardiographic changes was noted among 126 (61%) of study participants. Ischaemic changes were the most observed ECG changes (18.9%), ST elevation, ST depression and T wave inversion being most prevalent (8.7%). There was a significant association between age and the prevalence of ECG abnormalities (χ^2 = 87.510, p-value = 0.004). Significantly higher burden of ECG change was observed in Type 2 Diabetes mellitus compared to Type 1 Diabetes mellitus patients, with a χ^2 of 18.447 and p-value = 0.010.

Conclusions: The prevalence of ECG changes among Diabetes mellitus study participants in Dar es Salaam is 61%; with ischaemic changes and conduction changes being the commonest in type 2. Moreover, Rhythm changes are more common among Type 1 Diabetes mellitus patients.

Recommendations: At baseline and regular ECG screening in Diabetes mellitus patients is needed for preventive strategies, early detection and management of cardiovascular complications. Emphasis should be for elderly patients and Type 2 Diabetes mellitus patients, to enhance risk stratification, guide therapeutic choices, inform individualized follow-up schedules to detect early ECG abnormalities and mitigate arrhythmic risk.

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ABBREVIATIONS AND ACRONYMS

ADA	American Diabetic Association
CVD	Cardiovascular Disease
DM	Diabetes Mellitus
DPP4	Dipeptidyl peptidase 4
ECG	Electrocardiogram
FBO	Faith-Based Organization
GLP	Glucagon like peptides
KU	Kairuki University
LMICs	Low and middle-income countries
T1DM	Type 1 Diabetes mellitus
T2DM	Type 2 Diabetes mellitus

DEFINITION OF TERMS

Type 1 Diabetes mellitus: Metabolic disorder characterized by hyperglycaemia with, autoimmune-mediated destruction of pancreatic beta cells which present with absolute insulin deficiency, typically diagnosed in childhood or adolescence and lifelong dependence on exogenous insulin.

Type 2 Diabetes mellitus:: Metabolic disorder characterized by hyperglycaemia as a result of progressive resistance to normal insulin and or gradual loss of capacity of the body to produce enough insulin action.

ECG Changes: Any deviation from normal pattern.

Electrocardiographic abnormalities: Refer to irregularities or changes in generation and transmission of heart's electrical impulses as recorded on electrocardiogram (ECG).

Major ECG abnormalities: Significant electrical conduction disturbances which indicate potential serious cardiac pathology, require immediate medical evaluation and suggest increased cardiovascular risk.

Minor ECG abnormalities: Subtle electrical conduction changes with limited clinical significance, do not indicate immediate cardiac risk and require monitoring but not urgent intervention.

Minnesota coding: Is a standardized system used to interpret and classify findings on electrocardiograms (ECGs or EKGs) that assigns numeric codes to specific ECG abnormalities based on standardized criteria.

ST- Depression: term that refers to the position of the ST segment in a person's ECG results. It can indicate health conditions such as hypokalemia, myocardial ischemia, or a side effect of medications.

T-wave: represents the ventricular repolarization or recovery of the heart's ventricles after they contract. A normal T wave indicates healthy heart function, while changes in its shape, such as inversion, flattening, or peaking, can point to various cardiac conditions like myocardial ischemia (lack of oxygen), electrolyte imbalances, or other heart diseases

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Diabetes mellitus (DM) is a clinical syndrome characterised by an increase in plasma blood glucose (hyperglycaemia).[1] Diabetes has many causes but is most commonly due to Type 1 or Type 2 diabetes. Type 1 diabetes is caused by autoimmune destruction of insulin-producing cells (β cells) in the pancreas resulting in absolute insulin deficiency.[1]

Whereas type 2 diabetes is characterised by resistance to the action of insulin and an inability to produce sufficient insulin to overcome this insulin resistance.[1]

Diabetes mellitus

Diabetes mellitus is an endocrinology/metabolic disorder characterized by inappropriately elevated blood glucose levels. The main sub-types of Diabetes mellitus, are Type 1 Diabetes mellitus (T1DM) and Type 2 Diabetes mellitus (T2DM), which classically result from defective insulin secretion (T1DM) and/or action (T2DM. Type 2 Diabetes mellitus is a complex condition associated with impaired glucose tolerance, insulin resistance and overall hyperglycemia.[2] Other sub-types are less common forms which include gestational Diabetes mellitus (GDM) caused by glucose intolerance diagnosed during pregnancy, Monogenic diabetes, secondary diabetes, latent autoimmune diabetes in adults and endocrinopathy-associated diabetes.[3]

In addition, WHO classifies Type 1 Diabetes as ß-cell destruction commonly immune mediated, with complete insulin deficiency and Type 2 Diabetes as ß-cell dysfunction and insulin resistance, mostly associated with overweight and obesity.

The Epidemiology of Diabetes mellitus

Global data of 2021, showed that were over 500 million people affected with Diabetes mellitus with Type 2 Diabetes mellitus accounting for over 95% of all diabetic cases.[2] Diabetes mellitus is mostly results from the interaction of number of factors such as genetic, lifestyle and environmental factors as well as abnormal basal insulin secretion and increased glucagon secretion.[4] Lifestyle of an individual such as being overweight, physical inactivity, diet, smoking and excessive alcohol consumption increases chance of developing T2DM.[4,5]

Developed countries initially used to have unmatched higher prevalence of Diabetes mellitus compared to low- and middle-income countries (LMICs).[6] However, socio-demographic shift and economic growth are responsible for rapid increase in developing countries coupled with limited access to preventive and treatment healthcare.[6,7]

In 2019 report showed that there 19 million adults aged 20-79 in Africa with diabetes, the number is projected to reach 29 million in 2030. Prevalence of DM in sub-Saharan Africa is rapidly increasing due to changes attributed to urbanization, high calorie diet consumption and sedentary lifestyles.[8] Data for DM in the region show that in 2020 there were at least 12 million people suffering from Diabetes mellitus whereas over 300,000 deaths resulted from the disease.[9]

Tanzania is among countries experiencing double-burden of diseases whereby both communicable and non-communicable diseases co-exist.[10] The prevalence of Diabetes mellitus among adults in Tanzania rose from 2.8% in 2011 to 12.8% in 2021.[11] It is estimated that the country has about 822,800 people living with Diabetes mellitus with a large portion of them from urban areas.[10]

Clinical features of Diabetes mellitus

The symptoms of DM include increased urination, thirst, hunger, weight loss, and blurred vision.[12] Severe clinical manifestations may include a non-ketotic hyperosmolar state that may result in dehydration and coma.[13] The rate at which hyperglycaemia progresses affects the severity of the symptoms a patient may exhibit at the time of diagnosis.

Diagnosis of Diabetes mellitus

According to American Diabetic Association (ADA)[14] criteria recommended for diagnosis of Type 2 Diabetes mellitus includes the following;

1. Fasting plasma glucose concentration ≥7.0mmol/L or ≥126mg/dl (without caloric intake for at least 8 hours) or
2. Two-hour plasma glucose ≥ 11.1mmol/L or ≥200 mg/dl during oral glucose tolerance test (OGTT) using a glucose load which contains equivalent of 75 gm of anhydrous glucose dissolved in water.
3. Glycated haemoglobin (HbA1c) ≥6.5% (48 mmol/mol) may be used as a follow-up test or in absence of unequivocal hyperglycaemia.
4. Random plasma glucose ≥ 11.1mmol/L or ≥ 200 mg/dl in patient with classic symptoms of hyperglycaemia or hyperglycemic crisis.
5. For T1DM, an addition test, the C-Peptide levels, quantified to evaluate endogenous insulin production, whereas low (<80 pmol/L of fasting, or <200 pmol/L 1 hour post glucose intake) or no production indicates no insulin production.

Treatment of Diabetes mellitus

The main goal of treatment of Diabetes mellitus is the reduction in blood sugar levels and lowering the chance of complications. Principles of diabetes management include pharmacological and non-pharmacological measures. The Pharmacological measures refer to use of medications for blood glucose control, such as insulin, GLP-1 agonist (exenatide) and amyline agonist (pramlintide),oral hypoglycemic agents such as biguanides (metformin), Glucosidase inhibitors (acarbose), DPP4 inhibitors (sitagliptin), and sulfonylurea[1,5] For severe obesity-related Type 2 diabetes, energy restriction through metabolic surgery to shrink the stomach is also an established and effective treatment.

Non-pharmacological measures include promotion of behavioural changes to adopt healthy lifestyle includes eating balanced diet, exercising, avoiding tobacco use and harmful alcohol consumption.[16]

Management strategies for Type 1 Diabetes mellitus involves use of lifelong insulin therapy along with continuous glucose monitoring, carbohydrate counting, and regular metabolic screening.

Cardiovascular disease in Diabetes mellitus

Diabetes mellitus has a significant effect on the functioning of the body systems including cardiovascular system. Studies show that patients with diabetes have two-three folds increased risk of cardiovascular disease (CVD) compared to the general population.[17,18] Microvascular and macrovascular damage resulting from Diabetes mellitus affect normal functioning of the heart and its associated vessels. They include thickening of myocardium, the diabetic cardiomyopathy accompanied by effects of advanced age, reduced physical activity, co-morbidities and obesity.[19] As a result patients affected by Diabetes mellitus are

prone to developing cardiovascular disease; conduction abnormalities of the heart which results in conditions like left ventricular hypertrophy, reduced left and right ventricular ejection fraction, dilated left atrium or valve disorder. These forms of the disease present with abnormal electrocardiographic changes.

Diagnosis of cardiovascular diseases and classification of ECG abnormalities

Resting electrocardiogram is one of complementary and non-invasive test examinations for diagnosis and detection of changes in cardiovascular system such arrhythmias, evidence of coronary heart disease, left ventricular hypertrophy and bundle branch blocks.[20] It allows to highlight a number of abnormalities regardless of the existence of cardiovascular risk factors and also ischemic heart disease often in silent clinical expression. From ECG readings it is possible to determine cardiovascular abnormalities related to conduction which involve disruption of electrical impulse transmission through heart's conducting system, structural or functional problems in electrical pathways. ECG changes such as ST-segment elevation or depression, T-wave inversion or presence of Q waves are indicative of myocardial infarction.[9,11] Irregular R-R intervals suggest atrial fibrillation, while wide QRS complexes and abnormal P-waves can indicate ventricular tachycardia or supraventricular arrhythmias.[6] Increased QRS voltage or left axis deviation indicate hypertrophy.[10] Diffuse ST-segment elevation and PR-segment depression indicative of pericarditis.[8] Accurate interpretation of these changes aids in early diagnosis and management of cardiac conditions.[21]

Electrocardiographic changes in Diabetes mellitus

Diabetes mellitus is known to be associated with poor prognosis particularly if there are cardiovascular complications. Cardiovascular disease is a main cause of mortality among diabetic patients accounting in approximately 70% of cases.[22] Existing studies on prevalence

and patterns of abnormalities among patients with diabetes varies largely across countries. In Netherland for example, approximately one-third of the total population of diabetic patients had minor (16.0%) or major (13.1%) ECG abnormalities.[17] In Dakar Senegal it was found that ECG abnormalities revealed that 20% of patients had rhythm disorders, 11% had right atrial hypertrophy while 25% had left ventricular hypertrophy.[23] Furthermore, 11% had a complete bundle block while primary repolarization disorders were found in 17% of patients and secondary in 18% of patients, postero-diaphragmatic necrosis in 14% of patients, real posterior necrosis in 2% of patients, extensive anterior necrosis in 15% of patients.

In Tanzania, a study done at Muhimbili National Hospital Dar es Salaam reported that prevalence of left ventricular hypertrophy (LVH) in patients was 16% by either ECG criteria; 12.2% by Sokolow-Lyon and 5.1% by Cornell product criteria.[24] Although these studies had comprehensive analysis and findings of various subtypes of abnormal ECG, they lacked an important segment of factors influencing each subtype of abnormal ECG reported for better understanding and for taking measures to address the concern revealed.

On other hand, another similar study reported that the prevalence of major and minor abnormal ECG was 9% and 34.8% respectively and successfully analyzed for associated risk factors though no significant association was found.[25] However, the study was conducted among general population of students at the University of Dar es Salaam thus could not reveal patterns of abnormal ECG among diabetic patients.

1.2 Problem statement

Cardiovascular complications are among the most significant cause of morbidity and mortality in patients with diabetes mellitus.[26] Evidence shows that, approximately 80% of diabetes-related deaths are attributed to cardiovascular complications related to prolonged

hyperglycaemia on the system (American Heart Association [AHA], 2023; International Diabetes Federation (IDF), 2023).

Early cardiac involvement in diabetes may be silent and can progress undetected until advanced stages of disease manifest with serious complications.[30,31] Electrocardiographic (ECG) changes can serve as early markers of cardiac involvement and provide insight into the progression of cardiovascular complications in diabetic patients.[32]

Urban areas in Tanzania like Dar es Salaam experiences and increased prevalence of Diabetes mellitus due to influence of urbanization, lifestyle changes and limited access to preventive healthcare services.[22] Furthermore, despite the increasing burden of diabetes mellitus in the city and its known association with cardiovascular disease[33]there is limited local data on, prevalence and patterns of ECG changes among diabetes patients attending in our setup, this lack of body of knowledge hinders bridging the gap between early detection of diabetes related complications, treatment and prevention strategies in diabetes care.

As for many other diseases, cardiovascular complications from Diabetic mellitus are largely preventable when their respective risk factors are diagnosed in early stages[34]. A standard 10s, resting 12-lead ECG is the common cardiovascular examination method for detection of abnormal ECG[17]. Despite its associated benefits; there are limited studies in Tanzania conducted on distribution of ECG changes among Diabetes mellitus patients and their associated risk factors. Currently there are few studies on the prevalence and patterns of ECG changes in both type 1 and type 2 diabetes, this lack of information on trends negatively influences the need for evidence-based practices in day-to-day diabetes care.

The absence of such data also hampers the ability to establish appropriate screening protocols and preventive strategies specific to the local population.[35] Therefore, this study aims to determine the pattern of ECG changes among diabetic patients attending diabetes clinics in Dar es Salaam, in order to bridge this knowledge gap and inform clinical practices.

1.3 Rationale of the study

The findings from this study will serve to guide clinicians on routinely screening for cardiovascular complications based on the socio-demographic, risk factors and clinical characteristics on ECG changes among these patients, keeping in at the time of diagnosis also on follow-up in diabetes care.

Given the slow, silent natural history cardiovascular disease in diabetes, there is a need for early recognition of and interventions on these complications so as to improve quality of life in patients with diabetes, to reduce health care burden and influence strategies and policies in non-communicable disease interventions.

Data from this study will help the ministry of health to develop policies and documents as well as installation of necessary infrastructure required to conduct ECG screening in diabetic clinics

The findings from this study will be useful for various National stakeholders through designing targeted prevention programs, revise policies, allocate resource and train healthcare providers to address modifiable risk factors. By informing public awareness campaigns and supporting global health goals like SDGs, the research will contribute to reducing cardiovascular diseases and advancing diabetes care by including mandatory ECG screening to diabetic patients hence early detection of cardiovascular diseases.

1.4 Research questions

1.4.1 What is the distribution of electrocardiographic changes (QT prolongation, bundle branch block, ST segment abnormalities, T wave abnormalities and left ventricular hypertrophy) by age and sex among patients with diabetic mellitus?

1.4.2 What is the distribution of ECG changes (QT prolongation, bundle branch block, ST segment abnormalities, T wave abnormalities and Left Ventricular hypertrophy) by type of diabetes?

1.4.3 What is the distribution of ECG changes (QT prolongation, bundle branch block, ST segment abnormalities, T wave abnormalities and Left Ventricular hypertrophy) by glycaemic levels among Diabetic mellitus patients?

1.4.4 What is the distribution of ECG changes (QT prolongation, bundle branch block, ST segment abnormalities, T wave abnormalities and Left Ventricular hypertrophy) by duration of Diabetes mellitus among patients?

1.4.5 What is the distribution of Electrocardiographic changes among hypertensive Diabetes mellitus patients?

1.5 Study objectives

1.5.1 Broad objective

To determine electrocardiographic changes among patients with Diabetes mellitus attending Diabetic clinics in Dar es Salaam.

1.5.2 Specific objectives

1.5.2.1 To determine the distribution of ECG changes (QT prolongation, bundle branch block, ST segment abnormalities, T wave abnormalities and left ventricular hypertrophy) by age, and sex among patients with Diabetes mellitus.

1.5.2.2 To determine distribution of ECG changes (QT prolongation, bundle branch block, ST segment abnormalities, T wave abnormalities and left ventricular hypertrophy) by type of DM (T1DM and T2DM) among Diabetic mellitus patients.

1.5.2.3 To determine the distribution of ECG changes (QT prolongation, bundle branch block, ST segment abnormalities, T wave abnormalities and left ventricular hypertrophy) by glycemic control (HbA1c) among Diabetes mellitus patients.

1.5.2.4 To determine the distribution of ECG changes (QT prolongation, bundle branch block, ST segment abnormalities, T wave abnormalities and left ventricular hypertrophy) by duration of diabetes among patients with Diabetes mellitus.

1.5.2.5 To determine the distribution of electrocardiographic changes among hypertensive Diabetes mellitus patients attending Diabetic clinics.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Empirical review

Electrocardiographic changes in patients with Diabetes mellitus show significant variations based on their socio-demographic characteristics. Available studies have presented different ECG changes which happen on each type of age-group and gender of patients. However, variables like age and gender of patients greatly influence the cardiovascular risk profiles within these groups.

A Study conducted in Kyiv, Ukraine among a population 60 children with Type 1 Diabetes mellitus revealed the following: Patients had presented with small ECG abnormalities such as incomplete left/right blockage bundle branch block in 22.5% of children, shortened PQ interval in 15%, extrasystole, tachycardia, bradycardia in 52.5% as well as T-wave amplitude decrease in 60%. The study concluded that small ECG abnormalities related to disturbances in rhythms and conduction were common in children with Type 1 Diabetes mellitus.[36]
Despite the detailed findings presented by this study, the study employed a fewer number of participants thereby having lower power for statistical analysis as well as its focus only on Type 1 Diabetes mellitus which could not be possible to make comparison with ECG changes in older age-groups whereas the current study will combine both types of diabetes patients.

A study conducted in Netherlands on Hoorn Diabetes Care system cohort determined that prevalence of ECG abnormalities in people with diabetes is that approximately one third of the population studied had minor 16% while 13.1% had major ECG abnormalities. It was noted further that men experienced a significantly higher prevalence of both major and minor abnormalities, QS patterns, QRS-axis, atrioventricular and ventricular conduction abnormalities.

When stratified by age, it was found that all ECG abnormalities were more prevalent in older people. Between groups aged below 60 years and those aged above 60 years the prevalence of major and minor ECG abnormalities increased by 15.6% points.[17] However, despite these notable findings, this study focused on European population and did not specify the duration of diabetes, which may not truly fit the African setting.

In a study conducted in UK, it was reported that the prevalence of ECG-Left Ventricular Hypertrophy was more prevalent in women than in men. Despite using a large population of participants, this study focused only on Type 1 Diabetes mellitus, thus excluded Type 2 Diabetes mellitus patients.[47]

A study done in Ethiopia on patterns and associated factors of electrocardiographic abnormality among Type 2 Diabetic mellitus patients in Amhara revealed that the overall ECG abnormality was 45% (95% CI: 39-51%). Additionally, the study revealed that the prevalence of ECG changes among Type 2 Diabetes mellitus patients were the T-wave abnormality by 21.1%, left axis deviation by 14%, sinus tachycardia by 9.3% and left anterior fascicular block by 8.5%.[37]

In the study doe in Ukraine the author added that Type 1 Diabetes mellitus patients experienced a decrease in T-wave amplitude by 60%, extrasystole, tachycardia and bradycardia in 52.5%; shortened PQ interval by 15% and incomplete left/right blockage bundle branch block 22.5%. However, limitations of these studies are that they included only one type of diabetes.[36]

In Iran, a meta-analysis on the most common electrocardiographic abnormalities in patients with Diabetes mellitus found out that patients with T1DM demonstrated longer QTc, and longer QRS. On other hand patients with Type 2 Diabetes mellitus had shown QTc interval

prolongation.[38] The limitation of this meta-analysis is that it had been conducted using secondary data which fails to comprehend extensive information; if primary data would have been used.

In South Africa, a retrospective study analysed electrocardiographic abnormalities in black South African patients with diabetes in Kwa Zulu Natal and found out that among other findings, ECG abnormalities related to left ventricular hypertrophy was 31% in T1DM while in patients with T2DM was 69%. In addition, ECG related to myocardial infarction was found to be 13.8% in T1DM and 86.2 % in T2DM respectively.[39]

A study conducted in Netherlands on prevalence of ECG abnormalities in people with Type 2 diabetes using the Hoorn Diabetes Care System cohort, findings obtained showed that unfavorable HbA1c i.e. patients who had elevated levels of glycated haemoglobin above 6.5% was associated with combined minor and major ECG abnormalities in multivariable-adjusted analyses.[17]

In Ethiopia, a multi-centre institution-based cross-sectional study on patterns and associated factors of electrocardiographic abnormality among Type 2 Diabetes mellitus patients in Amhara National Regional State Referral Hospitals, reported the following findings: Compared to those with < 7.2 mmol/L of fasting blood sugar, T2DM patients who had ≥ 7.2 mmol/L were 5 times more likely to develop ECG abnormalities.[37] The author reported that, this could be due to the fact that transport of glucose across the cell membrane is unregulated by insulin and high glucose concentration damages cells with high intracellular glucose and glucose metabolites. These metabolites activate accessory metabolic pathways, like the sorbitol and protein kinase C pathways that result in the formation of oxidative free radicals and the deposition of advanced glycation-end products.

However, despite this comprehensive report, the study did not clearly show the distribution of specific ECG change other than grouping them as minor or major. The current study expects to specific ECG changes in patients with glycaemic control or not.

In a study conducted in Iran on evaluation of electrocardiographic parameters in Type 1 Diabetes mellitus in children and adolescents. Notable findings in this study highlighted that prolonged QT, prolonged corrected QT (QTc) and QT dispersion (QTd) changed marginally in light of diabetic time terms and HbA1c results expresses that were non-noteworthy.[40]

A study was conducted in Australia to determine the effect insulin and conventional treatment in diabetic patients. In this study after 24 hours of therapies, patients who were on conventional treatment demonstrated a significant prolongation of QTc compared to their baseline ECG whereas those who were on insulin did not show any change.[41]

In one of the cross-sectional studies in USA, it was found that ECG markers such as the P-wave duration and R-peak amplitude significantly changed with increasing duration among diabetic patients.[46]

Another study, conducted among 1,314 Epidemiology of Diabetes intervention and compilation (EDIC) study participants; revealed that among Type 1 Diabetes mellitus patients it was common to develop at least one new ECG abnormality. This was observed during the 16 years of follow-up, 77.3% of participants had at least one major or minor ECG changes.[45] The limitations of this study was the lack of detailed specific ECG changes which corresponded to change in duration.

A cross-sectional study was conducted in Ethiopia to determine factors associated with electrocardiographic abnormalities. The study found out that among many other factors; having long duration of diabetes ≥ 10 years (AOR=3.36 95% CI=1.46-7.71) was statistically associated with abnormal ECG abnormalities among patients.[42]

Although hypertension can play roles as both a risk factor and confounder to ECG changes yet some studies have assessed its influence. For example, in a study conducted in Nepal on Association of Hypertension and Ischaemic ECG Changes in Type 2 Diabetes mellitus; the results showed that, hypertension was statistically associated with ECG changes in 28.61% diabetic patients with hypertension compared to 1.11% of patients without hypertension.[43]

The study of the Hoorn Diabetes Care System cohort on Prevalence of ECG abnormalities in people with Type 2 diabetes showed that, of the participants without a cardiovascular disease history, approximately one quarter had minor (14.9%) or major (9.1%) ECG abnormalities of the specific types of abnormalities, ventricular conduction defects and arrhythmias were the most prevalent. The prevalence was significantly higher in people with hypertension compared to people without hypertension for minor or major abnormalities, QS pattern, R waves, ST-segment, atrioventricular or ventricular conduction abnormalities, and arrhythmias.[17]

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This was a health-facility based descriptive cross-sectional study that was conducted among Diabetes mellitus patients attending medical clinics in selected health facilities in Dar es Salaam

3.2 Study area and population

The study was conducted in two selected Diabetic clinics at Referral Regional Hospitals in Dar es Salaam; whereas both public and private-owned facilities were given an equal chance and were randomly selected. The two study sites are Amana Regional Referral Hospital and Cardinal Rugambwa Hospital.

The target population was Diabetes mellitus patients attending Diabetic clinics in Dar es Salaam. These patients have an increased risk of developing cardiovascular complications which can be screened using an Electrocardiography.

The study population was randomly selected Diabetes mellitus patients who were attending the selected Diabetic clinics during the study period.

3.3 Sampling methods

A multistage random sampling procedure was employed to select two Regional Referral Hospitals where a total of 103 study participants were recruited. A consecutive sampling technique was used where all eligible candidates were screened for eligibility criteria and were enrolled into the study until the minimum sample size was reached. Participants were recruited from Diabetic outpatient clinics.

Stage 1: Primary sampling unit: Dar es Salaam Regional Referral Hospitals with Diabetic clinics.

Stage 2: Secondary sampling units: Random selection of two districts among five districts with Regional Referral Hospitals.

Stage 3: Tertiary sampling units: Grouping the hospitals by ownership; Public owned and Faith-Based Organization/Private hospitals then randomly selected one hospital from each arm (one public and one FBO/private Regional Hospital.)

Final units: Sample size of 206 study participants were consecutively sampled from Diabetic clinics.

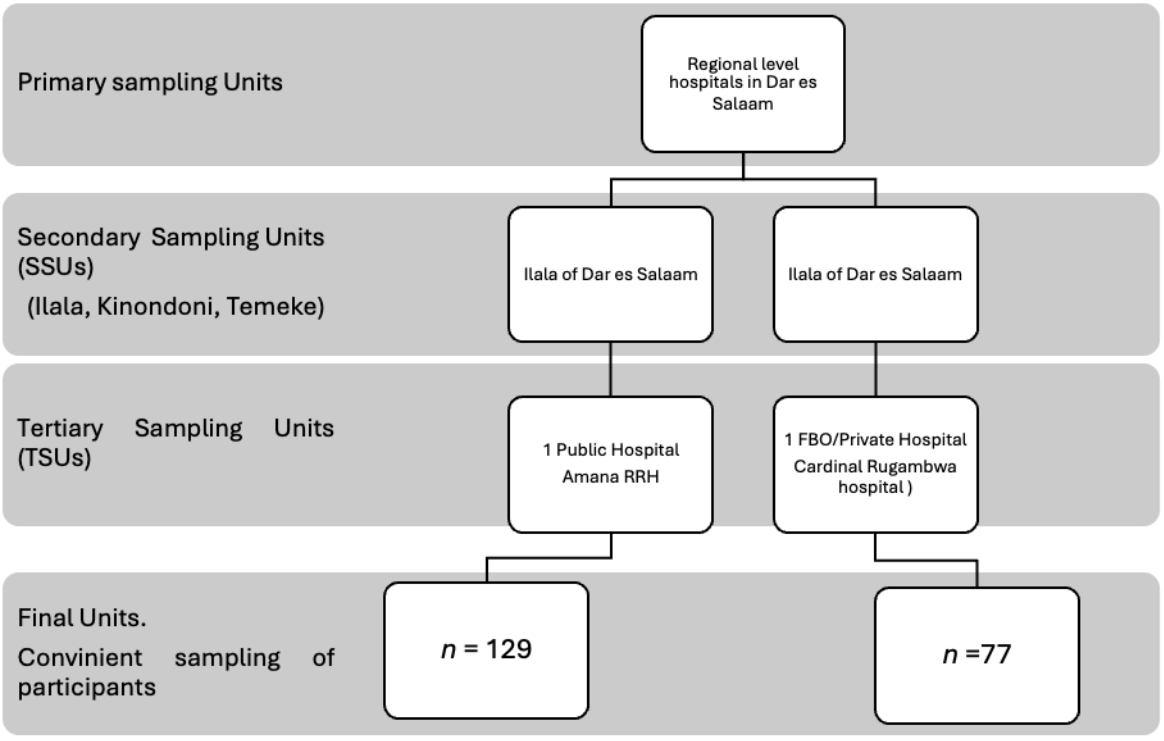

Figure 1: Multi-level sampling procedure

3.3.1 Sample size estimation

The sample size was calculated using the Kish Leslie formula used for cross-sectional studies shown below.

$$n = \frac{Z^2 P (1-P)}{\varepsilon^2}$$

Whereby: n = Minimum required sample size

Z = Percentage point of normal distribution corresponding to the level of confidence. If the level of significance is 95% then Z is 1.96

ε = Maximum likely error/ margin of error i.e. 0.05

P = Prevalence of ECG abnormalities in Type 2 Diabetes mellitus taken as 16% from previous study in Tanzania.[24]

Hence the minimum sample size is:

$$n = \frac{1.96 \times 1.96 \times 0.16 (1 - 0.16)}{0.05 \times 0.05} = 206 \text{ study participants}$$

3.4 Procedures for Data collection

3.4.1 Data collection tools

Data was collected using a structured questionnaire developed by the Principal Investigator.

3.4.2 Data collection methods

The Data collection was done by the Principal Investigator with the support of trained research assistants. The Principal Investigator and the research assistants worked hand-in-hand with the staff at Diabetic clinics at the hospital to identify the potential study participants. Health care providers approached the potential participant to screen for eligibility criteria and interest in the study before referring them to the research team. The Principal Investigator explained the aim of the study, elaborated the study procedures and obtained informed consent/assent from each participant before interviewing them for data collection. The research assistants were trained on site according to the need during the whole period of the study, training on the study procedures, administration of the study protocol and research ethics; and had supportive supervision from the Principal Investigator.

After obtaining informed consent each study participant was interviewed in privacy, guided by the structured questionnaire to collect information on pertinent aspects including data on risk factors for cardiovascular abnormalities revealed on the ECG test. The questionnaire included information on WHO identified risk factors such as socio-demographics, family history of diabetes, duration of Diabetes mellitus.

Clinical and laboratory data

The structured questionnaire was used to collect clinical and laboratory diagnostic data i.e. hypertension, ECG findings, serum HBA1c, and serum C peptide concentrations.

Electrocardiogram data

Electrocardiographic measurements for the study was performed by a certified electrophysiologist, using a standard resting 12-lead digital electrocardiographic machine with a model 12 channel electrocardiograph Bene Heart R12 manufactured by XML,PDF, Mindray. This model has the following specifications; Writer speed:5, 12.5, 25 & 50 mm/s,

Writer resolution: Horizontal 40 dots/mm @ 25 mm/s, Vertical 8 dots/m, Paper type: Thermal Z-fold A4 paper (210 mm x 295 mm) US Letter 8.5x11 in (215 x 280 mm). It uses a paper speed of 25 mm per second calibrated on 1 mv=10 mm, 0.2 s=5 mm, where each large box and the small box represent 0.2 and 0.04 s respectively. Measurement was performed after blood pressure measurement and before the venipuncture so as to prevent false readings due to changes in cardiac activity inflicted by the pain and discomfort of the venipuncture. Measurement was performed while lying in supine position of the participant with a 45-degree inclination after the participant had been asked to expose the chest region and removed any electromagnetic objects on his/her body. The participant was instructed not to speak, move and reduce breathing during ECG recording. The 10 electrodes (4 limb electrodes on both legs and arms and 6 chest electrodes, V1-V6) was placed on the participant's limbs, and chest after applying a transparent gel, yielded a total of 12 leads. The recording was done after a short period of about 10 seconds after setting connections. To ensure quality of the collected data, interpretation of the ECG recordings was done twice; first by the Principal Investigator and then by a physician using the Minnesota coding system for resting electrocardiogram.[48] Whenever discrepant results were obtained, a cardiologist was consulted to provide a clarification of the observed ECG readings.

Blood Pressure

Blood Pressure of the participants was measured using a calibrated Omron Silver Upper Arm Blood Pressure Monitor BP5255 Model number. Three blood pressure measurement was taken consecutively after participant has been resting for >5 minutes. Three blood pressure readings were taken, and the lowest was taken as the final reading. Blood pressure readings were interpreted as follows:

Table 2: Reference range for blood pressure readings

	Systolic and/or Diastolic BP	Systolic and/or Diastolic BP
Age category	<13 years	≥13 years
Normal BP	<90th percentile	<120/80 mmHg
Elevated BP	≥90th <95th percentile or ≥120 <130/<80 mmHg	≥120 <130/<80 mmHg
Hypertension Stage 1	≥95th <95th percentile +12 or ≥130 <140/≥80 <90 mmHg	≥130 <140/≥80 <90 mmHg
Hypertension Stage 2	≥95th +12 or ≥140/90 mmHg	≥140/90 mmHg

Source :(Pocolo Di Boneto, 2020)

Laboratory diagnostic tests

From each participant a request was made to take blood samples; and 3 milliliters of venous blood samples was collected in the appropriate vacutainers tube using venipuncture procedure which was done under strict aseptic techniques. Blood samples were collected in different tubes depending on the test required. EDTA tube was used to collect blood required for glycated haemoglobin (HBA1c) testing and plasma C peptide.

Collected blood samples were sent to the laboratory where they were checked for their integrity by inspecting the seal on the collection tube, the barcode label was scanned to ensure that the specimen was registered at the laboratory receiving point after passing the

standards for specimen reception. Prior to the analysis, the sample was inspected by the laboratory technologist where quantity and quality was observed and documented. The specimen that did not fulfil the quality check was regarded as void and was discarded. Blood samples was mixed well and then centrifuged at 3000 rpm for 3 minutes to separate blood cells and plasma in EDTA and gray top tubes. The HBA1c samples was measured by an Intergra 800 CTS, Roche Diagnostics, Germany) using the turbidimetric inhibition immunoassay method. Plasma glucose was estimated using Glucose oxidase enzymatic method using an automated chemistry analyzer (Cobas 8000 analyzer, Roche Diagnostics, Germany). C-peptide was quantified to evaluate endogenous insulin production, this was done using Chemiluminescence immunoassay CLIA method using an automated Chemiluminescence analyzer (Cobas e411 analyzer, Roche Diagnostics, Germany).

For external quality assurance, few blood samples were randomly taken to an independent clinical laboratory to assess the amount, state and analysis.

3.4.3 Eligibility criteria

Inclusion criteria

i) The study included all Diabetes mellitus patients attending Diabetic clinics in two selected Hospitals in Dar es Salaam and, who granted informed consent ± assent to participate in the study.

Exclusion criteria

i) Patients who were severely ill making them incapable of providing informed consent and meaningful participation.

ii) Diabetic patients who were known to have cardiovascular electrical conductivity abnormalities such as those known to have pace makers. Pacemakers set and regulate the cardiac electrophysiology thus there is a potential of getting conflicting findings.

3.4.4 Study variables

Dependent variable - ECG Changes i.e. ST segment changes, QT changes, left ventricular hypertrophy, atrial fibrillation, t wave changes,

Independent variables

Socio-demographic characteristics (age, gender), Type 1 Diabetes mellitus, Type 2 Diabetes mellitus, C-peptide levels, HbA1c levels, hypertension.

3.4.5 Ethical considerations

During data collection, the purpose of the study, its objectives and study procedures were well explained to each eligible study participants. Informed consent was then requested from each potential study participants emphasizing the voluntary nature of participation in the study and that not granting informed consent to participate in the study would not in any effect the medical care that one would get from the health care provides. If one granted consent then the process was documented by signing the informed consent form. For participants who were unable to read and write, the consent forms were read to them, and a thumbprint was used as a signature alternative.

In addition, because a sub-set of study participants were children below 18 years informed consent was obtained from parents/caretakers and where appropriate assent was also obtained. Extra care was taken to ensure children who are considered a vulnerable group were protected during the course of the study.

The study procedures did not cause any serious harm to the study participants. Participants were informed of slight pain during blood sample withdrawal, which under normal circumstances would resolve immediately after the procedure. Physical risks related to blood drawing were reduced through aseptic techniques, while psychological discomfort from participants was mitigated by creating a supportive, confidential environment. Confidentiality was maintained. Initials were used to preserve privacy. Collected data was stored confidentially in a manner that prevents unauthorized access. Data was only accessed by authorized personnel involved in this study. No participant was forced to be part of the study, and participants who wanted to discontinue were allowed to withdraw. The Principal Investigator took time to address and answer any questions raised by the study participants, ensuring that their queries were fully understood and thoughtfully responded to.

3.4.6 Ethical clearance

Ethical clearance to conduct the study was obtained from the Institutional Research and Ethics Committee of Kairuki University. Permission to conduct the study was obtained from the Administration of the respective Regional Hospitals.

3.4.7 Reliability and validity of the data

Reliability means that the results should be consistent each time the test is administered or when different investigators obtain similar responses from participants.

Validity refers to how accurately an idea is measured and whether the instrument covers all relevant content.

Structured questionnaire

The questionnaire was translated from English to Kiswahili language, and then back translated to ensure retaining of meaning by a linguistic expert. Questionnaires were corrected for errors before data entry. The Principal Investigator closely supervised all stages of the study and consulted a Biostatistician throughout the study including proposal development.

Internal validity

Internal validity in this study aimed on eliminating confounding factors, systematic errors in measurements so as to ensure the findings of this study are rigorous and reliable. The internal validity of this study was assured by: -

a) Adhering to inclusion and exclusion criteria during recruitment of the participants, orienting the clinic attending staff on the characteristics needed for a study candidate.
b) Principal investigator and the research assistant observed the use of the data collection tools that have been developed, for all of the study participants to assure reliability.
c) The Principal Investigator ensured the use of the same model and quality of the study equipment (ECG machine, Blood pressure machine), also all of the laboratory specimen analysis was conducted at one laboratory so as to ensure reliable and consistent measurements.
d) Data collected on potential confounders was subjected to further analysis on multivariable regression models.

Quality control

The internal validity of the study was ensured through adequate orientation on the study protocol to the whole research team; which was done in two phases. Phase one was orientation to the study protocol, data collection tools and the standard operating procedures (SOPs). Phase two was from day 2 and per need arise throughout all duration of the study and it was done at the study sites; this involved familiarization of the environment, practice on blood pressure measurement, sample collection technique, storage/transportation of the specimen to the laboratory for analysis.

External validity

External validity in this aimed at ensuring that the findings from this study were generalizable to the general population. The external validity of this study was assured by: -

a) Principal investigator and research assistant ensured a recruitment of representative sample by recruiting from all age range, paying attention to proportion between male and female participants,
b) The use of two Regional Referral Hospitals located at two different districts/ administrative regions reduced location specific bias thus assuring external validity.

Data safety

All data was confidentially obtained with strict observance and respect of patients' privacy by using unique study identification numbers instead of their names. The data in the computer will be secured with a password only known to the principal investigator.

3.5 Data management

3.5.1 Data coding and cleaning

Each completed questionnaire was examined for completeness by the Principal Investigator. An electronic database was created from the raw data by trained data clerks using SPSS version 25 software. Double entry was done to minimize entry errors. All collected data was backed-up on a hard drive and stored under lock and key.

3.5.2 Data analysis

Data was coded and entered into computer software SPSS version 25. Age, duration lived with diabetes mellitus, c peptide levels, HbA1c were summarized using mean and standard deviation. After being summarized, these variables were transformed into a category. Age was categorized into intervals of ten, duration lived with diabetes at interval relevant to distribution of the data and commonly used grouping in the literature studies. A standard categorization was assumed for ECG changes, HbA1c, and blood pressure were categorized in keeping with standard literature and publications.

All categorical data, such as gender, level of education, family history of diabetes mellitus, continuous variables that were transformed into categorical variables, were summarized using absolute counts and percentages. The data were presented using text, tables, and figures, depending on the volume of information aggregates required to be presented together to the objectives of this study. Proportional comparisons of the predictor variables with ECG findings were done using the chi-squared test. The predictor variables that achieved a significance level of 0.2 in the chi-square test were collectively analyzed in a multivariable logistic regression, and the results were expressed as adjusted odds ratio (aOR) with a corresponding 95% confidence interval (CI). A p-value less than 0.05 was considered

statistically significantly associated with ECG changes. Then data was analyzed for descriptive statistics which was presented in frequencies and percentages.

3.6 Dissemination of study findings

The findings of the study have been compiled into a Dissertation that has been submitted to the Department of Internal Medicine at Kairuki University in partial fulfillment of the requirements for the Degree of Master of Medicine in Internal Medicine. Copies of the dissertation will be made available at the KU Library, the two Regional Hospitals. Moreover, a manuscript has also been prepared and will be submitted to a peer-reviewed open journal for publication. Whenever possible the findings will be presented to scientific conferences.

CHAPTER FOUR

4.0 RESULTS

4.1 Enrollment log of study participants

Data collection was carried from August 2024 to July 2025 and during this period, a total of 311 patients with Diabetes mellitus attending Diabetic clinics at two Regional Hospitals were screened for eligibility criteria and asked to participate in the study. A total of 206 study participants were in the final data analysis.

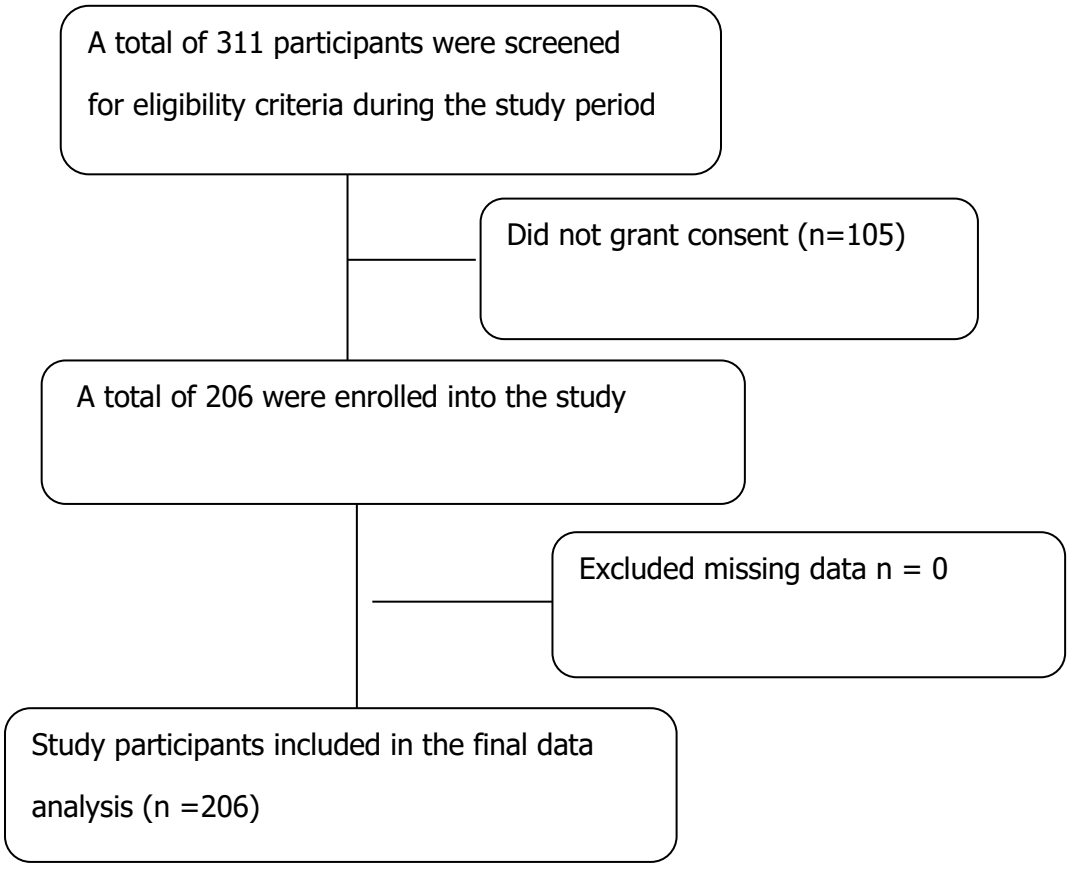

Figure 2: Enrollment flow chart of the study participants

4.2 Socio-demographic characteristics and clinical factors of study participants

Among 206 study participants in the final data analysis there is a diverse range of socio-demographic characteristics and clinical factors. The age of study participants in years showed a bimodal distribution of the participants with a mean age of 50.08 ± 22.82 years, median age of 57 years, with 50% of the population between age of 24 years and 66 years, (IQR of 42.25 years). The minimum age was 7 years and the maximum age was 101 years.

Gender distribution of the participants was unevenly distributed with 64.1% out of 206 diabetic patients being females. More than approximately 52% of the participants were married. Participants with secondary education and above were 65.9%, the majority of the participants (≈67%) were unemployed at the time of data collection. The majority of the participants (79.1%), had no familial history of Diabetes mellitus and 45.6% of the participants had diabetes for duration of one to five years, (45.6%) since diagnosis. Overall, 75.2% of participants had elevated blood pressure, more than half of the participants (58.7%) had above normal glycated haemoglobin with 38.8% having poor glycaemic control. This is shown in Tables 2 and 3 below.

Table 3: Baseline socio-demographic characteristics of study participants (n=206)

Variables		ECG changes Present (%)	ECG changes Absent (%)	Total/ (%)
Age-group in years	0-9	2 (1)	4 (1.9)	6 (2.9)
	10-19	21(10.2)	12 (5.8)	33 (16)
	20-29	7 (3.4)	10 (4.9)	17 (8.3)
	30-39	3 (1.5)	1 (0.5)	4 (1.9)
	40-49	7 (3.4)	6 (2.9)	13 (6.3)
	50-59	31 (15.0)	12 (5.8)	43 (20.9)
	60-69	29 (14.1)	22 (10.7)	51 (24.8)
	70-79	15 (7.3)	14 (6.8)	29 (14.1)
	80+	10 (4.9)	0 (0.0)	10 (4.9)
Gender	Male	45 (21.8)	29 (14.1)	74 (35.9)
	Female	80 (38.8)	52 (25.2)	132 (64.1)
	Marital status			
Marital status	Single	38 (18.4)	31 (15.0)	69 (33.5)
	Married	65 (31.6)	42 (20.4)	107 (51.9)
	Widowed	18 (8.7)	7 (3.4)	25 (12.1)
	Divorced/separated	4 (1.9)	1 (0.5)	5 (2.4)
	Non formal	10 (4.9)	8 (3.9)	18 (3.9)
Level of education	Primary level	40 (19.4)	33 (16.0)	73 (31.6)
	Secondary level	44 (21.4)	21 (10.2)	65 (31.6)
	College level	17 (8.3)	9 (4.4)	26 (12.6)
	University	14 (6.8)	10 (4.9)	24 (11.7)
Employment status	Employed	38 (18.4)	31 (15.0)	69 (33.5)
	Unemployed	87 (42.2)	50 (24.3)	137 (66.5)

Table 4: The clinical characteristics of the study participants (n=206)

Variables		ECG changes Present (%)	ECG changes Absent (%)	Total /(%)
Family history of diabetes	Yes	27 (13.1)	16 (7.8)	43 (20.9)
	No	98 (47.6)	65 (31.6)	163 (79.1)
Type of Diabetes	T1DM	24 (11.7)	25 (12.1)	49 (23.8)
	T2DM	101 (49.0)	56 (27.2)	157 (76.2)
Duration since diagnosis of Diabetes	<1 year	28 (13.6)	23 (11.2)	51 (24.8)
	1 to <5 years	61 (29.6)	33 (16.0)	94 (45.6)
	5-9 years	6 (2.9)	9 (4.4)	15 (7.3)
	10+ years	30 (14.6)	16 (7.8)	46 (22.3)
Type of medication for Diabetes	Insulin	34 (16.5)	26 (12.6)	60 (29.1)
	Oral hypoglycemics	87 (42.2)	54 (26.2)	141 (68.4)
	Oral hypoglycemics and insulin	4 (1.9)	1 (0.5)	5 (2.4)
Glycaemic control (HbA1c)	<5.7%- 6.4% (Normal to pre	48 (23.3)	37 (18.0)	85 (41.3)
	6.5% - 7.0% (target for DM)	15 (7.3)	4 (1.9)	19 (9.2)
	7.0% - 8.0% (target for DM)	14 (6.8)	8 (3.9)	22 (10.7)
	>8.0% (Poor glycaemic control)	48 (23.3)	32 (15.5)	80 (38.8)
Blood Pressure (Systolic)	Normal	22 (10.7)	17 (8.3)	39 (18.9)
	Elevated	34 (16.5)	19 (9.2)	53 (25.7)
	Hypertension Stage 1	26 (12.6)	16 (7.8)	42 (20.4)
	Hypertension Stage 2	42 (20.4)	29 (14.1)	71 (34.5)
	Hypertensive Crisis	1 (0.5)	0 (0.0)	1 (0.5)
Blood Pressure (Diastolic)	Normal	55 (26.7)	35 (17.0)	90 (43.7)
	BP (Systolic)Elevated	13 (6.3)	8 (3.9)	21 (10.2)
	Hypertension Stage 1	19 (9.2)	22 (10.7)	41 (19.9)
	Hypertension stage 2	37 (18.0)	16 (7.8)	53 (25.7)
	Hypertensive crisis	1 (0.5)	0 (0.0)	1 (0.5)

4.3 Prevalence of electrocardiographic changes

The prevalence of electrocardiographic changes among the study participants was approximately 61%. On basis of changes observed, ischaemic changes were most prevalent (18.9%), with (ST segment elevation (5.4%), ST segment depression (2.4%), T wave inversion (8.7%) of the overall electrocardiographic changes observed followed by cardiac hypertrophic changes were (17.0%); Left ventricular hypertrophy (2.4%); Poor R-wave progression (6.8%), Right ventricular hypertrophy (0.8%). Conduction abnormalities were noted in 15.5% of study participants; Axis deviation (2.9%), Bundle Branch Block (4.3%); First degree atrial-ventricular block (2.4%) and rhythm and rate disturbances accounted for 9.3%; whereby – tachycardia (4.4%) bradycardia (0.5%), premature atrial and ventricular contractions (2.9%).

This is shown in Figure 3 below.

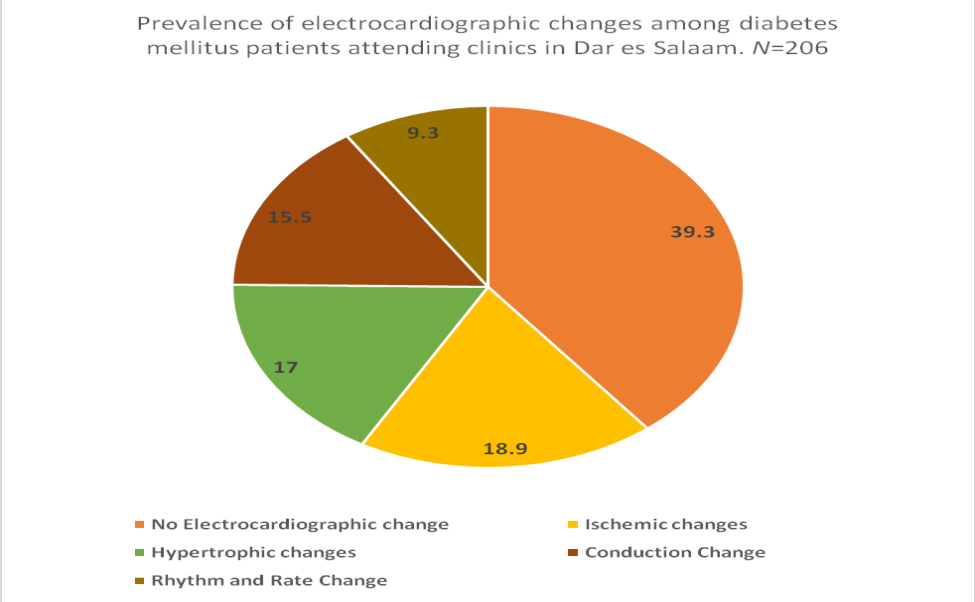

Figure 3: Prevalence of ECG changes among study participants

4.4 Classification of ECG changes according to Minnesota code

Among the 206 study participants 125 (60.7) participants had electrocardiographic changes. From the overall number of 125 – 45 (36%) study participants had major electrocardiographic changes; while 80 (64%) had /125 (64%) minor electrocardiographic changes. T-wave inversion (anterior/lateral leads (5.6%), were among major ECG changes. Poor R-wave progression (11.2%), left ventricular hypertrophy with strain pattern (9.6%) was among the most prevalent minor ECG changes. This is shown in Table 4 below. Major ECG changes highlighted with *.

Table 5: Classification of ECG changes according to Minnesota codes

Variables		Frequency (n =206)	Percentage 100%
ECG findings	ECG changes	125	60.7%
	No ECG changes	81	39.3
P-wave changes (8 – 3.9%)	P-Pulmonale	1	0.5
	P- Mitrale	7	3.4
Q-wave changes	Q waves (significant) in leads I, II, aVL, V5–V6*	2	1.0
(4 -1.9%)	Q waves in inferior leads (III, aVF) *	2	1.0
ST segment changes	ST elevation in infarction leads*	7	3.4
	ST Depression ≥ 0.5 mm (Horizontal/down-sloping) *	5	2.4
(17, 8.3%)	ST Elevation ≥1 mm in non-infarct leads	5	2.4
T-wave changes	T wave inversion in anterior/lateral leads*	7	3.4
(18, 8.7%)	T wave inversion in inferior leads*	7	3.4
	T wave flat/diphasic/notched*	4	1.9
QRS changes	Left Bundle Branch Block (LBBB)*	5	2.4
	Left Ventricular Hypertrophy	5	2.4
(22, 10.7%)	Right Ventricular Hypertrophy	1	0.5
	Left Anterior Fascicular Block	4	1.9
Conduction changes	Left Axis Deviation	5	2.4
	Right Axis Deviation	1	0.5
	Intraventricular conduction defects*	1	0.5
(36, 17.5%)	Poor R wave progression	14	6.8
	1st-degree AV Block	5	2.4
	Early repolarization*	3	1.5
	WPW Syndrome*	2	1.0
Rhythm and rate changes	Sinus bradycardia	1	0.5
	Sinus tachycardia	9	4.4
	Other arrhythmias	9	4.4
(20, 9.7%)	Premature atrial contractions	5	2.4
	Premature ventricular contractions	1	0.5

4.5 The distribution of ECG changes by age and gender among study participants

The ECG changes are observed to cut across all socio-demographic characteristics. Age seems to be statistically significant with ECG changes observed in age category 50-69 (29.1%) with p-value of 0.004. Female participants had more ECG changes (38.8%) compared to male participants (21.8%). However, this difference was not statistically significant (X^2=6.573, *p-value* = 0.475). This is shown in Table 5 below.

Table 6: Distribution of ECG changes by age and gender among study participants

Socio-demographic characteristics		ECG changes present	ECG changes absent	X^2	p- value
Age-groups in years	0-9	2 (1.0)	4 (1.9)		
	10-19	21(10.2)	12 (5.8)		
	20-29	7 (3.4)	10 (4.9)		
	30-39	3 (1.5)	1 (0.5)		
	40-49	7 (3.4)	6 (2.9)		
	50-59	31 (15.0)	12 (5.8)		
	60-69	29 (14.1)	22 (10.7)		
	70-79	15 (7.3)	14 (6.8)		
	80+	10 (4.9)	0 (0.0)	87.510	0.004
Gender	Male	45 (21.8)	29 (14.1)		
	Female	80 (38.8)	52 (25.2)	6.573	0.475

4.6 The distribution of ECG changes by type of Diabetes mellitus among study participants

The distribution of ECG changes by type of Diabetes mellitus where participants were grouped in two, Type 1 Diabetes mellitus and Type 2 Diabetes mellitus. Type 2 Diabetes mellitus was prevalent compared to Type 1 DM where percentage of distribution was 75.7% and 24.3% respectively. Between these groups Type 2 DM participants had more ECG changes (48.5%) compared to Type 1 DM group with 12.1% of the ECG changes, which is statistically significant (p-value =0.010) between the groups. This is shown in Table 6 below.

Table 7: The distribution of ECG changes among study participants according to the type of Diabetes (n=125)

ECG changes	T1DM	T2DM	X^2	p - value
None	25 (12.1)	56 (27.2)		
P-wave changes	1 (0.5)	7 (3.4)		
Q-wave changes	0 (0.0)	4 (1.9)		
ST segment changes	4 (1.9)	13 (6.3)		
T-wave changes	6 (2.9)	12 (5.8)		
QRS changes	0 (0.0)	22 (10.7)		
Conduction changes	5 (2.4)	31 (15.0)		
Rhythm changes	9 (4.4)	11 (5.3)	18.447	0.010

4.7 The distribution of electrocardiographic changes by glycaemic control

Among 125 study participants with ECG changes poor glycaemic control was in 48 (23.3%). This is shown in Table 7 below.

Table 8: The distribution of ECG changes by glycaemic control

Glycaemic control (HbA1c)	ECG changes Present	ECG changes Absent	X^2	p-value
Normal HbA1c <5.7%- 6.4% (Normal to prediabetic range)	48 (23.3)	37 (18.0)		
Target range for good control HbA1c 6.5% - 7.0%	15 (7.3)	4 (1.9)		
Target range for good control for the elderly and with co-morbidity HbA1c 7.0% - 8.0%	14 (6.8)	8 (3.9)		
Poor glycaemic control) HbA1c > 8.0%	48 (23.3)	32 (15.5)	23.863	0.300

4.8 The distribution of ECG changes by duration of Diabetes mellitus among study participants

The distribution of ECG changes by duration of Diabetes mellitus among study participants; did not show any difference. Approximately 48.1% of the study participants had duration of Diabetes mellitus from one year to five years; the difference between the distribution of the ECG changes was not statistically significant (p-value = 0.212). This is shown in Table 8 below.

Table 9: The distribution of ECG changes by duration since Diabetes mellitus diagnosis among study participants (n=206)

Duration since Diabetes mellitus diagnosis	ECG changes Present	ECG changes Absent	X^2	p-value
<1 year	28 (13.6)	23 (11.2)		
1 to <5 years	61 (29.6)	33 (16.0)		
5-9 years	6 (2.9)	9 (4.4)		
10+ years	30 (14.6)	16 (7.8)	4.499	0.212

4.9 Distribution of ECG changes among hypertensive study participants

Among the 206 study participants; 128 (62.1%) had hypertension. In this sub-set of study participants; conduction changes were most prevalent in 18%; predominantly left axis deviation. QRS complex changes (12.5%), T-wave changes (7.3%) were also observed amongst the predominant changes. The individuals with hypertension did show conduction changes more frequently compared to non-hypertensive individuals (18% versus 10.2%) while rate and rhythm changes were equally prevalent in both groups (7.8%). This is shown in Figure 4 below.

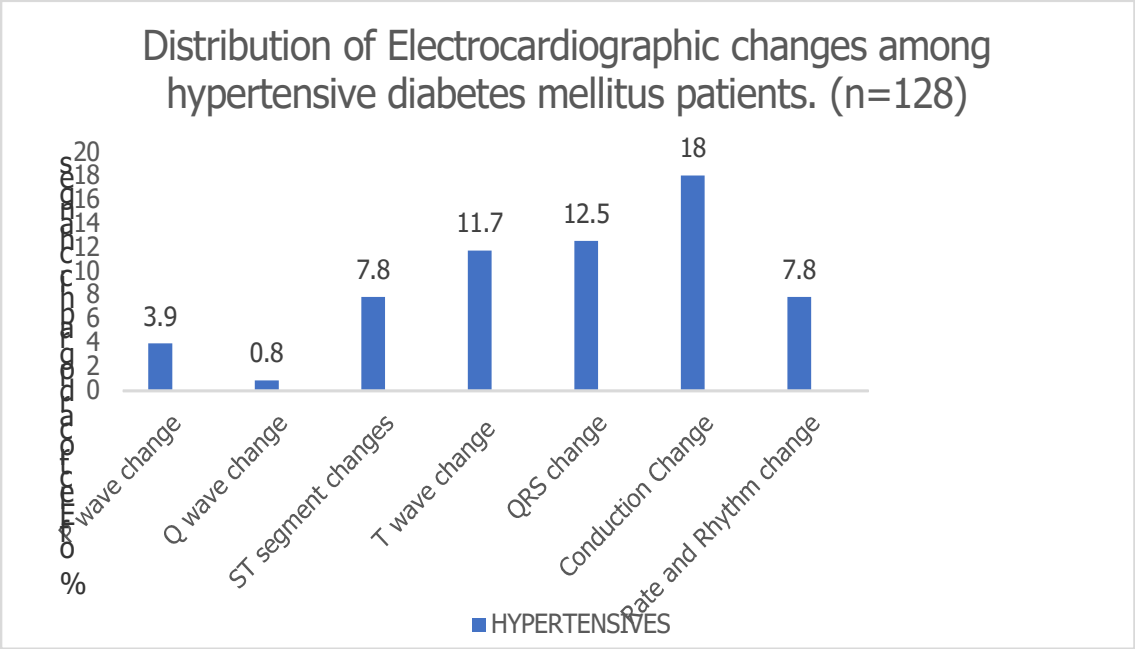

Figure 4: Chart showing ECG changes among study participants with hypertension

5.0 Multivariate logistic regression of ECG changes and factors among study participants

A multivariable logistic regression model was fitted to assess whether age, gender duration of diabetes and hypertension independently predicted the presence of ECG changes in the study participants. None of the variables reached statistical significance upon analysis.

Age of study participants had a negligible impact (Adjusted OR = 1.007; 95% CI 0.993–1.022; p-value = 0.323). G Gender was not associated with ECG changes (Adjusted OR = 0.96; 95% CI 0.53–1.73; p-value = 0.888). Duration of diabetes did not predict ECG changes (Adjusted OR = 0.997; 95% CI 0.948–1.049; p-value = 0.901). Hypertension showed no effect (Adjusted OR = 0.98; 95% CI 0.51–1.87; p-value = 0.938). These results show that when considered together age, gender, duration of diabetes and hypertension did not independently influence the odds of ECG changes in the study participants. This is shown in Table 9 below.

Table 9: Multivariate logistic regression of factors among study participants

Variables		ECG changes present (%)	ECG changes Absent (%)	aOR 95% CI (lower and upper)	p-value
Age-group in years	0-9	2 (1)	4 (1.9)		
	10-19	21(10.2)	12 (5.8)		
	20-29	7 (3.4)	10 (4.9)		
	30-39	3 (1.5)	1 (0.5)		
	40-49	7 (3.4)	6 (2.9)		
	50-59	31 (15.0)	12 (5.8)		
	60-69	29 (14.1)	22 (10.7)		
	70-79	15 (7.3)	14 (6.8)		
	80+	10 (4.9)	0 (0.0)	1.007 (0.993–1.022)	0.323
Gender	Male	45 (21.8)	29 (14.1)		
	Female	80 (38.8)	52 (25.2)	0.956 (0.532–1.727)	0.888
Duration since diagnosis of Diabetes	<1 year	28 (13.6)	23 (11.2)		
	1 to<5 yrs	61 (29.6)	33 (16.0)		
	5-9 years	6 (2.9)	9 (4.4)		
	10+ years	30 (14.6)	16 (7.8)	0.997 (0.948–1.049)	0.901
Hypertension	Yes	72 (35.0)	43 (20.9)		
	No	53(25.7)	38 (18.4)	0.975 (0.508–1.870)	0.938

CHAPTER FIVE

5.0 DISCUSSION

5.1 Electrocardiographic changes among the study participants

The study showed that fewer than half of study participants (39.3%) had entirely normal ECGs, leaving 60.7% with at least one abnormality, this in notably higher compared to 45% prevalence reported in multicentre cross-sectional study of 258 type 2 diabetes patients in the Amhara region in Ethiopia. The ischaemic changes observed in this study mirrors the findings from the Ethiopian study where the prevalence of 18.9 parallels the 21.1%of T wave abnormalities observed in the Ethiopian study. this suggests regional consistency burden of subclinical myocardial ischemia among African diabetes patients. Arrhythmias were (9.7%). Ischemic changes (ST changes (8.3%), T (8.7%) and Q waves) may reflect silent ischemia, autonomic neuropathy, or electrolyte imbalances, all of which are pathways amplified in metabolic syndrome, a hallmark of diabetes mellitus pathophysiology.

The high rate of conduction system abnormalities among the participants mirrors community cohorts in older and diabetic populations, where fibrosis and microangiopathy disrupt normal impulse propagation. Hypertrophic changes often correlate with left ventricular hypertrophy or poor R wave progression, common in patients with long-standing hypertension or diabetic cardiomyopathy. Changes in repolarization where nearly 10% rhythm and rate changes prevalence, including ectopy and rate abnormalities, underscores the need for ambulatory monitoring in at-risk patients.[52]

The significant association between age and ECG changes ($\chi^2 = 87.510$, $p = 0.004$) indicates that the prevalence of electrocardiographic changes rises sharply with advancing age. Younger participants (0–9 years) showed very low rates of ECG changes (1%), whereas those aged 50–59 years and 60–69 years had rates of 15% and 14.1%, respectively.

Notably, all individuals aged 80 years and above exhibited ECG changes. These findings mirror large cohort analyses reporting a marked increase in both major and minor ECG changes, such as bundle branch blocks and repolarization changesin older age groups.[53]

In contrast, the lack of a significant gender effect ($\chi^2 = 6.573$, $p = 0.475$) suggests that men and women experience similar overall rates of ECG changes. While previous studies have documented sex-specific differences in particular ECG parameters—men tend to have longer QRS durations and higher voltage complexes, whereas women often exhibit longer QTc intervals—these parameter variations do not necessarily translate into differences in the overall prevalence of ECG changes between sexes in population-based samples.

The study showed a significantly higher burden of ECG changes in Type 2 diabetes (T2DM) compared to Type 1 Diabetes (T1DM), with a combined χ^2 of 18.447 and p-value = 0.010. Notably, 72.8% of T2DM patients had at least one abnormality versus 87.9% in T1DM, underscoring a disproportionate clustering of repolarization, conduction, and structural electrical changes in T2DM. This mirrors the 2025 American Diabetes Association guidance, which highlights that macrovascular atherosclerosis and autonomic neuropathy in T2DM drive subclinical myocardial injury detectable as ECG changes.

ST-segment and T-wave alterations were more frequent in T2DM (6.3% and 5.8%, respectively) than in T1DM (1.9% and 2.9%). These findings reflect ischemia-related repolarization disturbances and diabetic autonomic dysfunction, both of which prolong repolarization and blunt ST-T restitution. It should be emphasized that ST- and T-wave changes are nonspecific markers of myocardial ischemia, electrolyte disturbances, or autonomic imbalance which are the processes accelerated in long-standing T2DM with coexistent coronary micro- and macroangiopathy.

Conduction defects (right or left bundle branch block, AV nodal delays) occurred in 15.0% of T2DM versus 2.4% of T1DM. The ARIC study likewise reported that T2DM patients have roughly a three- to four-fold higher prevalence of bundle branch blocks and first-degree AV block compared to non-diabetic controls, attributed to diffuse myocardial fibrosis and microvascular ischemia compromising the His-Purkinje system.[53]

Rhythm disturbances (premature beats, arrythmias) were present in 5.3% of T2DM and 4.4% of T1DM, a smaller gap but still contributing to the overall significance. A meta-analysis found that T2DM confers a 40% higher risk of atrial fibrillation than non-diabetic peers, driven by atrial remodeling and diabetic autonomic neuropathy—mechanisms more pronounced in insulin-resistant T2DM than in autoimmune-mediated T1DM, however this was not demonstrated in this study.

The cross-sectional analysis of this study assessed the presence of any ECG abnormality across four HbA1c categories:<5.7–6.4%: 48/85 (56.5%) with changes, 6.5–7.0%: 15/19 (78.9%) with changes, 7.0–8.0%: 14/22 (63.6%) with changes, 8.0%: 48/80 (60.0%) with changes.

The overall χ^2 statistic of 23.863 yielded a p-value of 0.300, indicating no statistically significant association between these HbA1c strata and the dichotomous outcome of ECG changes.

Pathophysiological link between hyperglycemia and ECG changes are: autonomic neuropathy where chronic hyperglycemia induces small-fiber nerve damage, blunting vagal tone and predisposing to QTc prolongation, heart-rate variability loss, and conduction delays, (Electrical remodeling and repolarization). Prolonged exposure to elevated glucose drives oxidative stress and myocardial fibrosis, which manifest as T-wave flattening/inversion and

QTc prolongation on surface ECG, however the output of this pathophysiological pathway was not solidified by this study. The cross-sectional nature of this study hampers the follow-up on evolution of these changes.

However, in this study the glycaemic categories did not modulate ECG changes among these participants. This observation could be attributed to; - Narrow HbA1c distribution where; most participants clustered in "normal–prediabetic" or "poor control" ranges, limiting contrast across intermediary targets, Cross-sectional design; A single HbA1c snapshot may not capture long-term glycaemic burden or variability, key drivers of autonomic and microvascular injury. In this study the unmeasured confounders e.g. pressure control, lipid profiles, and medication regimens (e.g., β-blockers) can independently influence ECG findings.

ECG changes were observed in 46.8% of patients diagnosed for <1 year, 64.8% of those with 1–<5 years' duration, 40.0% of the 5–9-year group, and 65.2% of patients with ≥10 years since diagnosis. A chi-square test yielded $\chi^2 = 4.499$ (p-value = 0.212), indicating no statistically significant trend between increasing diabetes duration and the presence of ECG changes. The highest prevalence of ECG changes occurs in the 1 to <5-year and ≥10-year groups, both around two-thirds of patients. Patients in their first year of diagnosis already show ECG changes in over half of cases (54.9%), suggesting early cardiac electrophysiological effects. On the other hand, a dip to 40.0% in the 5–9-year group bucks the overall upward trend, hinting at possible survivor bias or more intensive risk-factor management in mid-duration patients. These findings could further be explained by Early cardiac impactAcute hyperglycemia and emerging autonomic dysfunction may manifest on ECG soon after diagnosis. Peak in mid-duration: The 1–5-year window likely captures onset of microvascular complications and subclinical myocardial injury. Mid-term trough: Those

with 5–9 years' duration might represent a subset with better metabolic control or earlier interventions, lowering ECG abnormality rates. And the late-stage surge: Beyond 10 years, cumulative glycaemic burden, myocardial fibrosis, and ischemic remodeling drive the highest ECG change rates observed in this study.

A 2019 cross-sectional study at Jimma Medical Center (n = 344 T2DM patients) found that a diabetes duration ≥10 years was independently associated with ECG changes (AOR = 3.36; 95% CI 1.46–7.71), in contrast, our cohort did not demonstrate a significant elevation in ECG changes among long-standing diabetics. Possible explanations include: Sample size and distribution: Our 5–9-year subgroup was small (n = 15 total), limiting power to detect differences, heterogeneity in management: Improved glycaemic control and cardiovascular risk reduction (e.g., statins, ACE inhibitors) may blunt the cumulative injury over time, lastly the cross-sectional snapshot of this study where a single ECG was used for interpretation may have missed the intermittent or evolving conduction and repolarization changes.

A total 128 diabetes patients had hypertension (62.1%), the overallodds ratio for hypertension (yes versus no) is 0.818 with a 95% CI between 0.461 to 1.453, thislack of a statistically significant association between hypertension status and overall ECG wave changes (OR 0.818, 95% CI 0.461–1.453) contrasts with reports of high ECG abnormality prevalence among hypertensive populations. This suggests that in this cohort: Routine ECG screening may detect a similar burden of electrical changes regardless of hypertension status.

Many guideline committees highlight that hypertension over time contributes to ECG-detected left ventricular hypertrophy and strain patterns2018 Practice guidelines for the management of arterial hypertension of the European Society of Cardiology and the

European Society of Hypertension Bryan Williams.[58]Conversely, Munakata et al. reported only a modest cross-sectional difference in repolarization abnormalities between hypertensive and normotensive adults when adjusting for age and sex. Findings from this study align more closely with these latter observations, underscoring the need to account for confounders and treatment effects.

The multivariable analysis showed that gender, hypertension, age, and duration of diabetes were not independently associated with ECG changes among the participants, these finding diverges from numerous studies that have identified these factors as significant predictors of cardiac abnormalities among people with diabetes. For instance, duration of diabetes is often linked to progressive autonomic neuropathy and structural cardiac remodeling, both of which manifest on electrocardiography.[59] The lack of association may reflect the relatively narrow range of diabetes duration in this sample or effective glucose management where the participants had an acceptable glycemic control (HbA1c < 8% (61.2%)) that attenuated typical duration-related risks.

Age is traditionally regarded as a robust risk factor for ECG changes, given the cumulative exposure to metabolic derangements and subclinical atherosclerosis over time.[60]As seen in bivariate analysis, with no adjustments (Fisher's exact test, X^2 - 87.510, *p*- 0.004), age and ECG changes had significant association However, in multivariate regression analysis this association was no observed, this could be due to a modest sample size, also the effect of controlling for other variables. Gender differences in diabetic cardiac complications remain controversial.[61] Some large cohort studies report higher prevalence of ECG changes in men, attributed to differences in hormonal profiles and cardiovascular risk factor clustering. Yet, these results align with reports finding no gender disparity after adjusting for clinical

covariates, suggesting that sex-specific mechanisms may be overshadowed by other metabolic and hemodynamic influences in diabetes.

Hypertension is a well-established contributor to left ventricular hypertrophy and repolarization abnormalities detectable on ECG. The absence of a significant association in our data could be due to rigorous antihypertensive treatment among participants or to the approach used in making a diagnosis of hypertension, which may not capture blood pressure variability and cumulative burden.[62]

5.2 Strengths and limitations

The strength of the study lies in that the study followed appropriate standards of study design. From calculation of sample size, sampling procedure, recruitment of study participants, data collection and analysis of data. Not only that but also appropriate statistical tests were used in the data analysis in this study.

There were some limitations to be addressed in this study, first the cross-sectional design limits causal inference and temporal assessment of ECG evolution. Secondly, the Single ECG and HbA1c snapshots may miss intermittent or chronic patterns driven by glycaemic variability. Thirdly, the small subgroup sizes on duration lived with diabetes (e.g., 5–9 years' duration) reduce power to detect differences. Fourthly; Lack of exploration of medication regimens used in treatment of co-existing conditions (cardiac, fluid overload and hypertension have effects on serum electrolytes thus potential of altering cardiac electrophysiology, also lack of exploration of lipid levels introduces confounding effect and lastly, the absence of echocardiographic or imaging confirmation of structural heart changes. Example confirmation of Left Ventricular Hypertrophy.

Mitigation of some of the study's limitation involved; the recruitment process that was diverse and captured the true representation of the general population, also controlling of the confounders by subjecting the data to multivariate analyses.

5.3 Conclusions

The prevalence of ECG changes among Diabetes mellitus study participants in Dar es Salaam is 61%; with ischaemic changes and conduction changes being the commonest. Moreover, most ECG changes are more common among Type 2 Diabetes mellitus patients while few were observed among Type 1 Diabetes mellitus.

Age emerged as the strongest predictor of ECG abnormalities in the study population, with a clear, stepwise increase in prevalence from childhood through octogenarians and above, whereas gender had no significant influence. Type 2 diabetes was associated with a substantially higher burden of repolarization disturbances, conduction defects, and QRS abnormalities compared to type 1 diabetes which was associated with rhythm changes /, highlighting the greater subclinical myocardial injury in insulin-resistant states. In contrast, categorization by HbA1c failed to reveal significant differences in ECG change prevalence, suggesting that a single glycaemic snapshot may not adequately reflect the chronic metabolic fluctuations driving autonomic neuropathy and myocardial remodeling and potential electrophysiological risk.

Although ECG changes rates peaked in both the 1–<5-year and ≥10-year duration groups, the overall trend was non-significant, diverging from findings in an Ethiopian cohort that linked longer disease duration with more pronounced ECG changes. This discrepancy points to the influence of local treatment practices, glycaemic variability, and interventional strategies in modulating how duration translates into electrophysiological alterations.

Together, these findings underscore the primacy of chronologic aging and diabetes phenotype over short-term glycaemic control in shaping surface ECG manifestations. They support the use of routine ECG screening—especially in older adults and those with Type 2 Diabetes to detect early signs of electrical remodeling.

5.4 Recommendations

At baseline and regular ECG screening in Diabetes mellitus patients is needed for preventive strategies, early detection and management of cardiovascular complications. Emphasis should be for elderly patients and both Type 1 and 2 Diabetes mellitus patients, to enhance risk stratification, guide therapeutic choices, inform individualized follow-up schedules to detect early ECG abnormalities and mitigate arrhythmic risk.

Future studies should employ longitudinal designs, continuous monitoring, and multimodal assessments to clarify how chronic glycaemic exposure and disease duration modulate specific ECG parameters and subsequent cardiovascular outcomes.

Future research should prioritize longitudinal monitoring of glycaemic excursions (e.g., time-in-range, variability indices) and detailed treatment histories to unravel the temporal dynamics of ECG remodeling. Incorporating co-morbid conditions—particularly hypertension treatment regimens —will be essential to develop robust, individualized ECG screening protocols and to identify the mechanistic pathways by which diabetes accelerates cardiac electrical changes.

Clinical applications recommended from this study involves: Risk Stratification, therapeutic Targeting: Identifying ECG changes linked to diabetes mellitus might influence antihypertensive choices, favoring agents like ACE inhibitors or ARBs with cardioprotective effects on electrical remodeling. Follow-up planning: early detected ECG changes may guide more frequent cardiac review among diabetes patients.ECG Screening in Diabetes mellitus populations where, modest abnormalities, if present, may justify routine ECG evaluation in diabetes mellitus management guidelines especially for older adults or those with co-morbidities.

The study findings underscore the need for follow-up studies to examine how these abnormalities evolve and predict outcomes like sudden cardiac death.

CHAPTER SIX

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APPENDICES

APPENDIX I: CONSENT FORM (ENGLISH VERSION)

Title: PATTERN OF ELECTROCARDIOGRAPHIC CHANGES AMONG DIABETES MELLITUS PATIENTS ATTENDING DIABETES CLINICS IN DAR ES SALAAM

I, Dr. Sr Sarah Deogratius, a student of the Department of Internal Medicine, would like to conduct the above-mentioned research as a prerequisite for completing my postgraduate studies.

Your participation is required to obtain relevant information related to your health that will be used as data in this study.

The aim of the study is to determine the pattern of electrocardiographic changes among diabetes mellitus patients attending diabetic clinics in Dar es Salaam.The results of this study will be useful in providing recommendations for early screening of cardiovascular disease by electrocardiogram in patient with diabetes mellitus as a measure to enable early intervention before serious complications arise.

Individuals who meet the inclusion criteria for the study, will be included in this study and will be interviewed using a questionnaire that will include their socio-demographic information as well as a physical examination.

Blood tests for blood glucose, and markers of insulin levels will also be performed. There will be some pain during the needle puncture to collect the blood sample.

The results of the study will not be released to any unauthorized person.

The participant will not be required to pay any fees or money and will be free to withdraw at any time during the study.

Contact Person for Questions or Problems:

Prof. Y. Mgonda Email: ymgonda@gmail.com phone number: +255 754 277 554

Chairman, Department of Internal Medicine

Director of Postgraduate Studies and Research, KU

I, ……., have read/been briefed on the contents of this form and understand its implications. I hereby agree to participate in this study.

Signature: …… Signature: …… (Participant) Date: ……

APPENDIX II: CONSENT FORM (KISWAHILI VERSION)

Mada: MABADILIKO YA ELECTROCARDIOGRAPHIC MIONGONI MWA WAGONJWA WA KISUKARI WANAOHUDHURIA KLINIKI ZA KISUKARI JIJINI DAR ES SALAAM.

Mimi, Dk. Sr. Sarah Deogratius, mwanafunzi wa Idara ya Tiba ya Ndani, ningependa kufanya utafiti uliotajwa kama sharti la kukamilisha masomo yangu ya uzamili.

Ushiriki wako unahitajika ili kupata taarifa muhimu kuhusiana na afya yako ambayo itatumika kama data katika utafiti huu.

Madhumuni ya utafiti huo ni kubainisha mwelekeo wa mabadiliko ya kielektroniki kwa wagonjwa wa kisukari wanaohudhuria kliniki za kisukari jijini Dar es Salaam. Matokeo ya utafiti huu yatakuwa muhimu katika kutoa mapendekezo ya uchunguzi wa mapema wa ugonjwa wa moyo na mishipa kwa electrocardiogram kwa mgonjwa wa kisukari mellitus kama hatua ya kuwezesha kuingilia mapema kabla ya matatizo makubwa kutokea.

Watu ambao wanakidhi vigezo vya kujumuishwa kwa utafiti, watajumuishwa katika utafiti huu na watahojiwa kwa kutumia dodoso ambalo litajumuisha taarifa zao za kijamii pamoja na uchunguzi wa kimwili.

Vipimo vya damu kwa sukari ya damu, na alama za viwango vya insulini pia vitafanywa. Kutakuwa na maumivu wakati wa kuchomwa sindano ili kukusanya sampuli ya damu.

Matokeo ya utafiti hayatatolewa kwa mtu yeyote ambaye hajaidhinishwa.

Mshiriki hatahitajika kulipa ada au pesa yoyote na atakuwa huru kutoa wakati wowote wakati wa utafiti.

Wasiliana na mtu kwa maswali au shida:

Prof. Y. Mgonda: Barua pepe: ymgonda@gmail.com. Simu namba : +255 754 277 554

Mwenyekiti, Idara ya Magonjwa ya Ndani

Mkurugenzi wa Mafunzo ya Uzamili na Utafiti, KU

Mimi, ……..., nimesoma/nimefahamishwa kuhusu yaliyomo kwenye fomu hii na kuelewa maana yake. Ninakubali kushiriki katika utafiti huu.

Sahihi: …… Saini: …… (Mshiriki) Tarehe: ……

APPENDIX III: QUESTIONNAIRE (ENGLISH VERSION)

PATTERN OF ELECTROCARDIOGRAPHIC CHANGES AMONG DIABETES MELLITUS PATIENTS ATTENDING DIABETES CLINICS IN DAR ES SALAAM

Date _____

Study site _____

A. SOCIO-DEMOGRAPHIC INFORMATION

1. Age (Years) _____
2. Gender _____1. Male ☐ 2. Female ☐
3. Occupation: 1.Employed ☐ 2. Self-employed ☐ 3. Un-employed☐
4. Monthly Income level (Tsh) 1. Below 500,000 ☐ 2. 500,000-1,000,000 ☐

   3. above 1000,000 ☐
5. Level of Education 1. No Formal Education ☐ 2. Primary Education ☐

   3. Secondary education ☐ 3. College ☐ 4. University ☐
6. Marital status 1. Single ☐ 2. Married ☐ 3. widowed ☐ 4. Divorced ☐

B: DIABETIC INFORMATION

7. Family history of DM Yes ☐ No ☐
8. Duration lived with diabetes Mellitus……..(Years)
9. Types of Diabetes medication(s) used:

   INJECTABLES (Insulin) ☐ Oral hypoglycemics ☐

C. BLOOD PRESSURE MEASUREMENTS

10. Systolic Pressure 1…… 2……. mmHg

11. Diastolic Pressure 1…… 2……. mmHg

D. INSULIN AND GLYCEMIC CONTROL MEASUREMENTS

12. HBA1c concentration……. mmol/L and ……%

13. Plasma C-Peptide concentration……ng/ml

E. ELECTROCARDIOGRAM READINGS

14. Heart rate.....BPM

15. Rhythm 1. Regular ☐ 2. Irregular ☐

16. P Wave: Amplitude……, Duration……

17. PR Interval……. Seconds

18. QRS Complex: Duration……. Seconds, Axis 1. Normal ☐ 2. Abnormal ☐

19. QT Interval (QTc).....ms

20. ST Segment 1. Normal ☐ 2 Elevation ☐ 3. Depression ☐

21. T Wave: 1 Normal ☐ 2 Inverted ☐

22. Interpretation……..

APPENDIX IV: QUESTIONNAIRE (KISWAHILI VERSION)

MFUMO WA MABADILIKO YA ELECTROCARDIOGRAPHIC MIONGONI MWA WAGONJWA WA KISUKARI WANAOHUDHURIA KLINIKI ZA KISUKARI JIJINI DAR ES SALAAM.

Tarehe: _____

Kituo cha utafiti: _____

A. TAARIFA BINAFSI

1. Umri (Miaka) _____
2. Jinsia _____1. Me ☐ 2. Ke ☐
3. Kazi:1. Mwajiriwa ☐ 2. Amejiajiri ☐ 3. Hana ajira ☐
4. Kipato cha mwezi (Tsh) 1. Chini ya 500,000 ☐ 2. 500,000-1,000,000 ☐
   3. Juu ya 1,000,000 ☐
5. Kiwango cha elimu 1. Sina elimu ☐ 2. Elimu ya msingi ☐ 3. Elimu ya sekondari ☐
   4. Elimu ya Chuo cha kati ☐ 5. Elimu ya chuo kikuu ☐
6. Hali ya ndoa 1. Sijaoa/sijaolewa ☐ 2. Nina ndoa ☐ 3. Mjane/mgane ☐
   4. Talaka/ kutengana ☐

B: TAARIFA ZA KISUKARI

7. Historia ya Kisukari mwenye familia Ndiyo ☐ Hapana ☐
8. Muda tangu kugundulika na kisukari …….. (miaka) ☐
9. Aina ya dawa za kisukari anazotumia:

   Sindano (Insulin) Vidonge

C. TAARIFA ZA VIPIMO VYA SHINIKIZO LA DAMU NA MAABARA

10. Shinikizo la sistoli1……2…… mmHg

11. Shinikizo la diastoli 1……2 …… mmHg

D. VIPIMO VYA INSULINI NA UDHIBITI WA SUKARI MWILINI

12. Kiwango cha plasmaHBA1c …… mmol/L, na ……%

13. Kiwango cha Plasma cha C-Peptide ……ng/ml

E. MAJIBU YA ELECTROCARDIOGRAM

14. Heart rate.....BPM

15. Rhythm 1. Regular ☐ 2. Irregular ☐

16. P Wave: Amplitude……....., Duration……

17. PR Interval……. Seconds

18. QRS Complex: Duration……. Seconds, Axis 1. Normal ☐ 2. Abnormal ☐

19. QT Interval (QTc).....ms

20. ST Segment 1. Normal ☐ 2 Elevation ☐ 3. Depression ☐

21. T Wave: 1 Normal ☐ 2 Inverted ☐

22. TAFSIRI……...

APPENDIX V: STANDARD OPERATING PROCEDURES (SOPS) FOR SPECIMEN COLLECTION

Blood specimen collection

The following SOP are adopted from WHO guide to on drawing blood.

1. **Preparation**

a. Gather all necessary materials: sterile needles, collection tubes (with appropriate additives), alcohol swabs, gloves, and bandages.

b. Ensure that the environment is clean and that the health professional performing the procedure follows standard infection control practices.

2. **Patient Identification**

a. Verify the identity of the patient and explain the procedure in simple terms.

3. **Site Selection and Preparation**

a. Choose an appropriate site for venipuncture, typically the antecubital fossa.

b. Clean the site with an alcohol swab and allow it to dry completely.

4. **Collection Process**

a. Use proper techniques for venipuncture to minimize discomfort and avoid complications.

b. Fill the collection tubes in the order of the additives to avoid contamination (e.g., blood cultures first, then tubes with anticoagulants).

c. Utilize a tourniquet, if necessary, but remove it before filling the last tube.

5. **Post-Collection Care**

a. Apply pressure to the site after withdrawing the needle to minimize bleeding.

b. Bandage the puncture site appropriately.

6. **Labeling**

a. Label each blood tube immediately after collection with the patient's information, date, time, and type of test to be performed.

b. Storage and Transportation

a. Store blood specimens according to their requirements, typically at room temperature for certain tests or refrigerated for others.

b. Transport specimens to the laboratory as soon as possible, again taking care to maintain the integrity of the samples.

Additional Considerations

Safety and Waste Management

Follow safety protocols for handling and disposing of sharps and biohazard materials.

Use personal protective equipment (PPE) to minimize the risk of exposure.

Quality Assurance

Regular training and updates for staff involved in specimen collection.

Implement quality control measures to reduce variability in the collection process

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Website: www.ku.ac.tz

Ref. No. KU/PT/30.5/567

22nd April 2025

Medical Officer In-charge,
Amana Regional Referral Hospital,
Dar es Salaam.

Re: LETTER OF INTRODUCTION FOR DR. SARAH DEOGRATIUS (MMed Part II – INTERNAL MEDICINE).

The above named is a MMed postgraduate student specialising in Internal Medicine. As part of fulfilling her MMed programme, she plans to undertake a study titled, **"Pattern of Electrocardiographic Changes among Diabetes Mellitus Patients attending Diabetes Clinics in Dar es Salaam".** This study was reviewed and has been granted with an ethics approval No. **KU/IREC/27.10/559** by the KU Institutional Research Ethics Committee that will be valid for one year with effect from 16th April 2025.

This letter serves to introduce **Dr. Sarah Deogratius** who will be conducting her study in Dar es Salaam, please accord her with the needed support.

Thank you for your support and cooperation in developing human resources for health in our country.

Regards,

DIRECTOR POSTGRADUATE STUDIES * AND RESEARCH INSTITUTE * KAIRUKI UNIVERSITY P. O. Box 65300, DSM

Professor Naboth Mbembati
Ag. Director Postgraduate Studies & Research Institute

c. c. Prof. Yassin Mgonda, Head, Department of Internal Medicine, KU.
c.c. Head, Department of Internal Medicine, ARRH

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Website: www.ku.ac.tz

Ref. No. KU/IREC/27.10/559 **16 April, 2025**

Dr. Sarah Deogratius Kahumbya,
Kairuki University,
70 Chwaku Street,
Mikocheni,
P. O. Box 65300.
Dar es Salaam, Tanzania.

RE: ETHICAL CLEARANCE CERTIFICATE FOR CONDUCTING HEALTH RESEARCH

I am pleased to inform you that the research titled: **Pattern of Electrocardiographic Changes among Diabetes Mellitus Patients Attending Diabetes Clinics in Dar es Salaam (Kahumbya, S. D., 2025)** has been granted ethical approval.

This approval is in effect for one year from the above date.

- Any changes in the procedures should be reported to the Institutional Research Ethics Committee.
- Significant changes will require the submission of a revised request for ethical approval.
- You will be required to submit **a study progress report** every six months.

Permission to publish your findings should be sought from the National Institute for Medical Research (NIMR) before submission to a publisher and not concurrently.

CHAIR PERSON

Name: Prof. Frederick Kaijage

Signature:

SECRETARY

Name: Prof. Columba Mbekenga

Signature:

DIRECTOR POSTGRADUATE STUDIES AND RESEARCH INSTITUTE
KAIRUKI UNIVERSITY
P. O. Box 65300, DSM

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

AMANA REGIONAL REFERRAL HOSPITAL

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P.O. Box 25411
DAR ES SALAAM
Phone: 022—2861903

REF. NO. MoHCDGEC/ARRH/R.1/VOL IV/4

Date: 23/04/2024

Dr. Sarah Deogratius,
Kairuki University,
DAR ES SALAAM.

Re: PERMISSION FOR DATA COLLECTION

Refer to your letter dated 22th April, 2025 which requested us to allow **you** to conduct research and collect data in our institution.

We are here to acknowledge your request with the following conditions, that she must submit the results of your research after completion of analysis in order the hospital to make use of data's to solve hospital problems.

Regards.

Dr. Rose Ntambuto
FOR: MEDICAL OFFICER INCHARGE
AMANA REGIONAL REFERRAL HOSPITAL

Cardinal Rugambwa Hospital
P.o Box 40960, Dar es Salaam
Tel +255 222 843 199
Email :cardinal rugambwa @yahoo.co.uk

24/4/2024

Dr Sarah Deogratius

Re. Permission for data collection at Cardinal Rugambwa Hospital

Refer to submitted letter from Kairuki University dated 22th April 2025 which requested us allow you to collect research data from our hospital.

On behalf of **Cardinal Rugambwa Hospital**, I wish to formally **approve and allow you as you requested to collect data with the condition that you must submit the results of your study findings.**

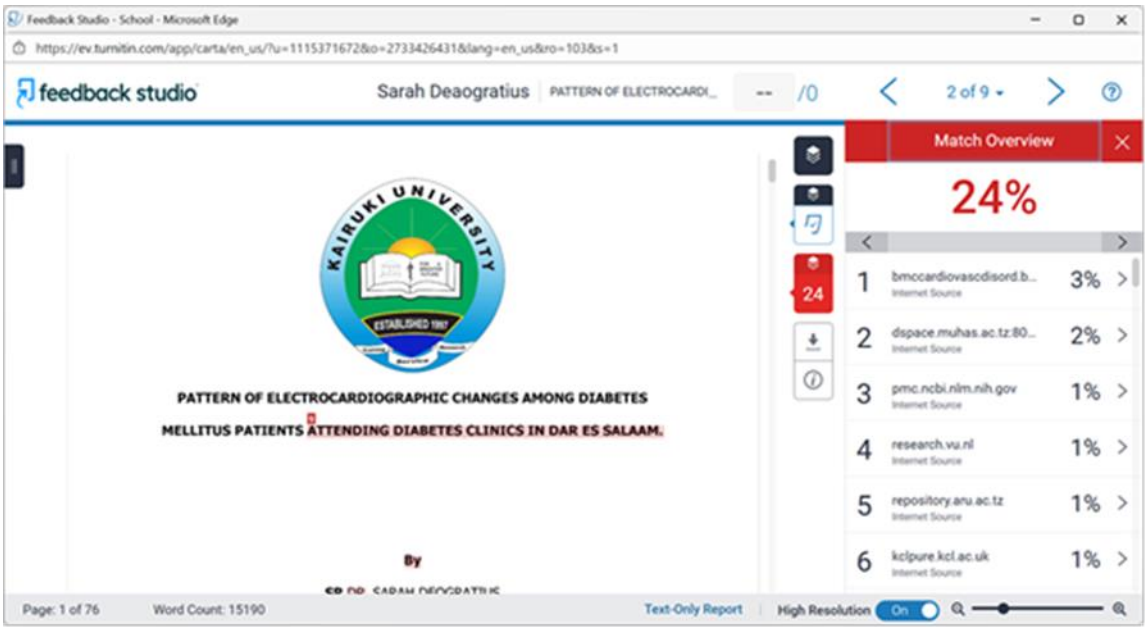
We wish you all the best.

CARDINAL RUGAMBWA HOSPITAL
P.O. Box 40960
DAR-ES-SALAAM

Yours faithfully,

Honesty

Honest Anthony
Administrator- **Cardinal Rugambwa Hospital**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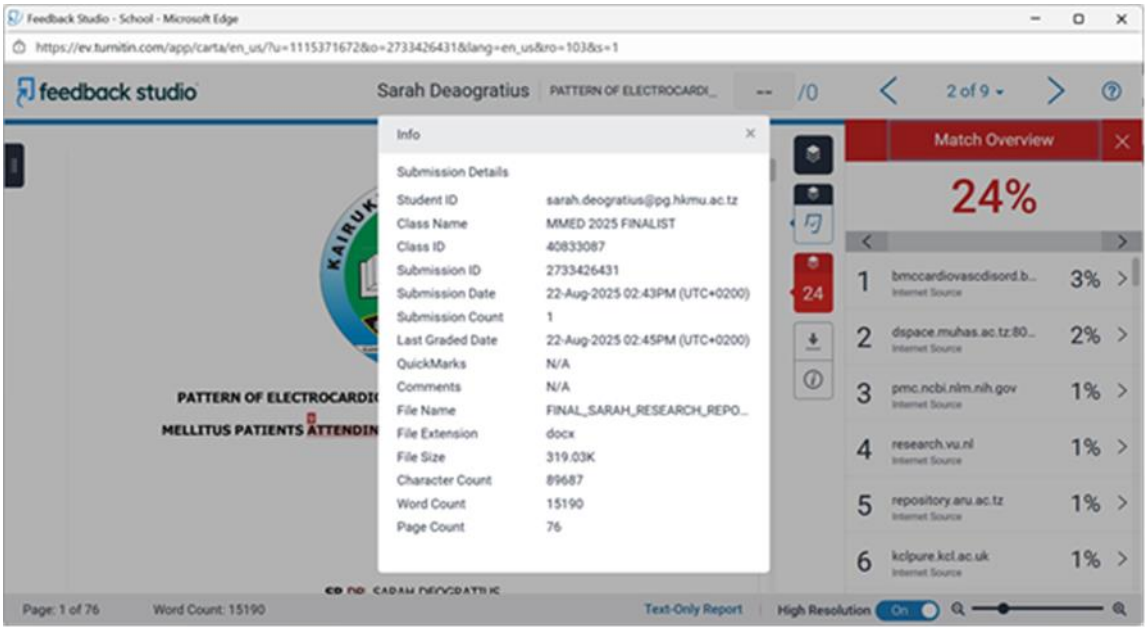
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PATTERN OF ELECTROCARDIOGRAPHIC CHANGES AMONG DIABETES MELLITUS PATIENTS ATTENDING DIABETES CLINICS IN DAR ES SALAAM.

By

DR DR. SARAH DEOGRATIUS

REG. NO: KU/PG/MC/22/0018

A Dissertation Submitted in (partial) Fulfillment of the Requirements for the Degree of Master's of Medicine (Internal Medicine) at Kahuhi University 2025.