HEALTH-RELATED QUALITY OF LIFE AND ITS DETERMINANTS AMONG HEART FAILURE PATIENTS ON TREATMENT AT KENYATTA NATIONAL HOSPITAL

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DEDICATION

This work is dedicated to my daughter, Carren Kende Murikinyi for her patience and giving my life a meaning.

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ABBREVIATIONS AND ACRONYMS

ACEIs	Angiotensin Converting Enzyme Inhibitors
ARA	Aldosterone Receptor Antagonist
ARBs	Angiotensin Receptor Blockers
CAD	Coronary Artery Disease
CARE-HF	Cardiac Resynchronization in Heart Failure
CHARM	Candesartan in Heart Failure-Assessment of Reduction in Mortality and Morbidity
CHF	Congestive Heart Failure
CIBIS-2	Cardiac Insufficiency Bisoprolol Study 2
COPD	Chronic Obstructive Pulmonary Disease
COPERNICUS	Carvedilol Prospective Randomized Cumulative Survival
CORNFIRM-HF	Ferric CarboxymaltOse evaluation on performance in patients with Iron deficiency in combination with chronic Heart Failure
DM	Diabetes Mellitus
EMPHASIS-HF	Eplerenone in Mild Patients Hospitalization and Survival Study in Heart Failure
ERC	Ethics and Research Committee
FAIR-HF	Ferinject Assessment in patients with IRon deficiency and chronic Heart Failure
HF	Heart Failure
HFpEF	Heart Failure with preserved Ejection Fraction
HFrEF	Heart Failure with reduced Ejection Fraction
H-ISDN	Hydralazine-Isosorbide Dinitrate
HIV	Human Immunodeficiency Virus
HRQoL	Health Related Quality of Life
ID	Iron Deficiency
KNH	Kenyatta National Hospital
KNH/UON-ERC	Kenyatta National Hospital/University of Nairobi- Ethics and Research Committee
LVEF	Left Ventricular Ejection Fraction

MERIT-HF	Metoprolol CR/XL Randomized Intervention Trial in Congestive Heart Failure
MRA	Mineralocorticoid Receptor Antagonist
NYHA	New York Heart Association
OPTIMIZE-HF	Organized Program To Initiate life-saving treatment In hospitalized patients with Heart Failure
PI	Principal Investigator
QoL	Quality of life
RALES	Randomized Aldactone Evaluation Study
SOLVD	Studies Of Left Ventricular Dysfunction
THESUS-HF	The Sub-Saharan Africa Survey of Heart Failure
TOPCAT	Treatment Of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist Trial
Val-HeFT	Valsartan Heart Failure Trial
WHO	World Health Organization
WHOQOL-BREF	World health organization quality of the life-short version
βB	Beta Blockers

OPERATIONAL DEFINITION OF TERMS

HRQoL	Multi-dimensional construct that includes domains related to physical, mental, emotional and social functioning, that are affected by one's disease and/or treatment.
Quality of Life	The general well-being of individuals and societies, outlining negative and positive features of life. It measures life satisfaction, including physical health, family, education, employment, wealth, religious beliefs, finance and the environment.
Physical health	A state of well-being when all internal and external body parts, organs, tissues, and cells can function properly as they are supposed to function. It has effects on the following components; activities of daily living, dependence on medicinal substances and medical aids, energy and fatigue, mobility, pain, and discomfort, sleep and rest and work capacity.
Environmental health	The ability to interact with the surrounding effectively. The components include; availability of financial resources, health and social care, free, physical safety & security, accessibility and quality home environment, opportunities for acquiring new information and skills, participation in opportunities for recreation, leisure activities, physical environment (pollution, noise, traffic) and mode of transport.
Comorbidity	Presence of one or more additional illnesses occurring concurrently with the heart failure
Single	Never married, separated, divorced, or widowed
Living with someone	Residing with another person in the same dwelling place

Employed	With any form of a gainful source of income, includes, skilled/unskilled laborers, professionals, self-employed
Unemployed	Not engaged in any income generating activity
Etiology	The underlying cause of the heart failure
Smoking	Cigarette, shisha, tobacco

ABSTRACT

Background: Heart failure (HF) is a debilitating chronic condition that adversely affects the Health- related quality of life (HRQoL), an important outcome in HF management. HRQoL is a multidimensional construct of well-being affected by the physical, mental, emotional, and social status of the patients. The ability to identify the predictors of HRQoL among patients with HF is crucial in improving clinical care and determining targets of intervention for the prevention and treatment of the condition.

Objective: The aim of this study was to determine the HRQoL and identify its determinants among heart failure patients attending the Cardiac clinic at the Kenyatta National Hospital (KNH).

Methods: A cross-sectional study was conducted to determine HRQoL of patients with HF. A total of 109 patients were recruited into the study via a consecutive sampling. The HRQoL was measured using the generic tool, WHOQOL-BREF. Both descriptive and inferential statistics were employed. Socio-demographic and clinical variables were used as explanatory variables in both the Bivariate and Multivariate linear regression analysis to identify the predictors with the level of significance set at $p = < 0.05$.

Results: Patients were predominantly females (66.1%), had a mean age of 55.3 ± 17.0 years. The etiologies of HF were identified as hypertension (40.4%), cardiomyopathy (39.5%), and Rheumatic heart disease (23.9%) among others. The major comorbidities were hypertension (48.6%), valvular heart disease (45.0%) and atrial fibrillation (12.8%). The common classes of drugs used were ACEIs/ARBs, β-blockers, diuretics, Aldosterone Receptor Antagonists (ARAs), and cardiac glycosides. In linear regression analysis, higher NYHA grading, lower education level, lower age and no Beta-blocker prescription were identified as significant factors associated with poor HRQoL.

Conclusion: NYHA functional class was the most important predictor of HRQoL. Interventions targeted to improve the physical symptoms would therefore improve HRQoL.

Recommendations: For early diagnosis and treatment of HF and the primary cardiac conditions as well as the assessment of the prevalence and causes of cardiomyopathy among the heart failure patients at Kenyatta National Hospital

CHAPTER ONE: INTRODUCTION

1.1 Background to the study

Health-related quality of life (HRQoL) refers to a multidimensional concept that explains how a health condition influences the whole well-being of a patient by affecting the physical, psychological, environmental, and social relationships (1,2). According to the World Health Organization, the quality of life is "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment" (2). In a clinical set up, the assessment of the quality of life focuses on the health-related quality of life.

In patients with heart failure (HF), the HRQoL is usually poorer than that in the age-matched general population without the HF, because of the typically high burden of comorbidity and complications of the illness (3). Among the patients suffering from heart failure, HRQoL has been identified as an important predictor of morbidity and mortality and therefore valued as a subjective and patient-centered important outcome (4,5). Understanding the importance of the HF on the patient's HRQoL can provide vital knowledge that can inform the clinical process in decision making.

Heart failure is a complex clinical syndrome resulting from the structural and functional impairment of the heart hence affecting the diastolic or systolic function which in turn impairs ventricular filling and/or ejection of the blood (6). This makes the patients experience a chronic and life-threatening disease trajectory that is characterized by a triad of physical symptoms that includes easy fatigability, shortness of breath or exertion dyspnoea and the edema. These are followed by the deterioration of functional status, episodes of adverse cardiac events and hospital re-admissions (7,8). As a result, there is exercise intolerance and fluid retention, causing pulmonary or splanchnic congestion and/or peripheral edema. The diagnosis of heart failure is majorly a clinical diagnosis through a careful and thorough history taking combined with physical examination (6).

Due to the debilitating impact of these complications on heart failure patients, there has been a need to recognize the importance of the health-related quality of life and how such could be improved.

HF has a high prevalence particularly among populations aged 65 years and older causing significant mortality, morbidity and medical care related expenses. Currently, it has a prevalence of more than 26 million people worldwide and 5.8 million in USA making it a global pandemic with a 25% projected prevalence increase by the year 2030 (9,10). In the African countries, cardiovascular diseases are often recognized as the cause of morbidity and mortality. This is attributed to the urbanization with the adoption of sedentary lifestyles as well as improvement in malnutrition. Currently, 7% - 10% of all medical hospitalizations in Africa are attributable to the cardiovascular diseases with the HF forming the bulky of the primary diagnosis at 3% - 7% for the suspected cases (11,12).

In terms of the etiology, among the developed countries, the coronary artery disease is the major etiological factor (13). Alternatively, in Sub-Saharan Africa, hypertension, cardiomyopathy, and rheumatic heart disease are the predominant causes of HF accounting for more than two-thirds of the cases (14,15), while the Ischemic heart disease is rare at 8%. The remaining is attributed to the Cor Pulmonale and pericarditis, reflecting an important role played by the infections that include mycobacterium tuberculosis and the Human Immunodeficiency Virus (HIV).

1.2 Problem Statement

Heart failure (HF) is a common pathway for various clinical conditions affecting the heart, with an incidence increasing with advancing age. The condition generally runs a poor prognostic course and it is associated with high hospital readmission rates as well as poor QoL (13). A study carried out at the Kenyatta National Hospital (KNH) revealed 4 - 6 months mortality of 25 - 38% and re-hospitalization rates of 38%. These were attributed to poor NYHA score, shorter duration of HF prior to admission and hyperuricemia on admission (16).

Goals of therapy in HF encompass a triad of strategies that includes; halting the disease progression in order to reduce the mortality risk and requirement for hospitalization,

symptoms improvement to allow patients to feel comfortable for the remaining duration of life, and finally to enhance the overall QoL among these patients. This holistic approach is important for therapy optimization. However, over the years, the clinicians have extensively applied the first two strategies with little if any attention accorded to the influence of the disease on QoL despite the evidence that the heart failure has a poor HRQoL score and this ultimately has an impact on the patients' clinical outcomes.

This study aims to evaluate the HRQoL and its determinants among patients suffering HF. By using measurable aspects of HRQoL, it will be demonstrated how HF affects the QoL and the patients will stand to benefit substantially from several interventions directed at the modifiable factors in order to improve the overall well-being and QoL of the patients. This will enable the patient to maximize their physical, psychological, and social functioning with reference to their supportive environment that shall enable them live a full, gratifying and constructive life.

1.3 Study Justification

The goals of treatment in heart failure includes; life expectancy maximization, improvement of HRQoL and the prevention of the disease progression and admissions. These are achievable with optimal treatment in accordance with clinical practice guidelines and patient's adherence (6).

The recognition of the HRQOL as a vital clinical indicator can be relied upon in predicting the morbidity and mortality among the HF patients. Determining the HRQoL allows for objective evaluation of how and to what extent does the illness influences the patient's quality of life and how they effectively deal with it. These assessments can be used as basis for measurements of outcomes that provide a framework to determine the impacts of any intervention in the patient's QoL.

Therefore, the knowledge of these factors affecting HRQoL among HF patients, can help in the provision of effective interventions that improves the debilitating impact associated with the illness (7). Due to the poor prognostic course of HF, studies have established that many patients would prefer improved health related quality of life more than the survival and hence the importance in maximizing the HRQoL (13).

1.4 Objectives

1.4.1 Main Objective

To evaluate the health-related quality of life and its determinants among patients with HF at KNH.

1.4.2 Specific Objectives

1. To identify of HF at KNH.
2. To determine the comorbidities associated with HF at KNH.
3. To evaluate the drugs used to manage HF at KNH.
4. To determine the health related quality of life of patients with HF at KNH.

1.5 Research Questions

1. What is the etiology of HF at KNH?
2. What comorbidities are associated with the HF at KNH?
3. Which drugs are used to manage patients with HF at KNH?
4. What is the health-related quality of life of patients with HF at KNH?

1.6 Significance of the study

The knowledge about the HRQoL among the patients with heart failure and its determinants will help in providing individually tailored interventions. This is by addressing various aspects influencing the individual patient's quality of life. The study further will inform the medical decision-making process that will guide in the development of effective interventional strategies that will reduce the negative impact of the illness and improve the HF patient's overall quality of life. With the improved QoL among these patients, mortality and hospitalization rates will reduce.

1.7 Delimitations

The study will be carried out within the cardiology clinic of the KNH, with all the participants meeting the inclusion criteria being selected through a consecutive sampling technique.

1.8 Limitations

The consecutive sampling procedure whereby; every subject meeting the inclusion criteria is selected until the required sample size is achieved, is likely to produce a non-representative sample that can introduce a sampling error as the selected participants may share some common similarities.

Being a cross-sectional design, the causal effect relationship cannot be defined explicitly between the variables.

The study will be conducted in a national teaching and referral hospital with a wide range and accessibility to HF medications, cardiologists' consultation and reviews and the study population represent the most severe cases of HF. As such, the results cannot be generalized to other hospitals in the country.

Patients may not willingly volunteer accurate information; tending rather to give information based on what they think the investigator would like to hear.

1.9 Conceptual/Theoretical Framework

Independent Variables **Dependent Variables** **Outcome**

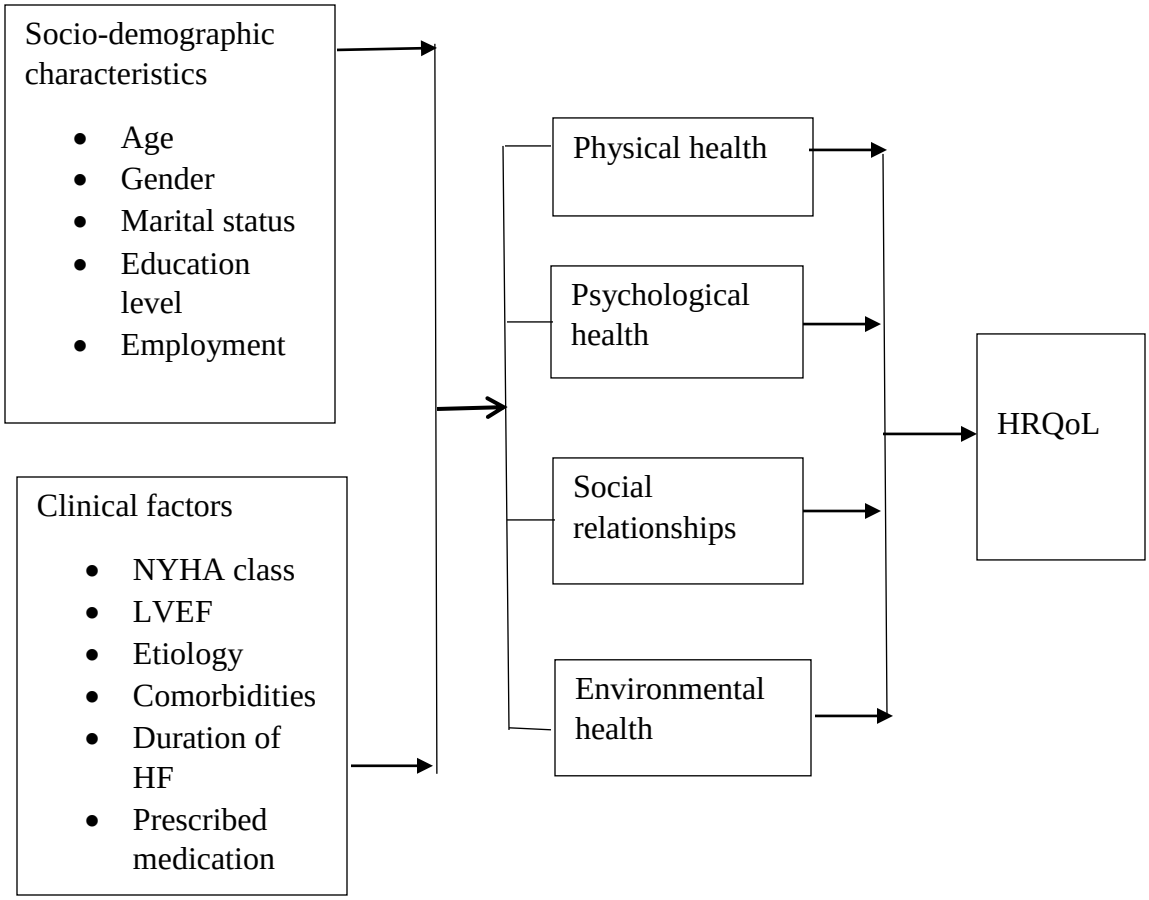


Figure 1.1: Conceptual framework **(Author; *Mutiga, 2018*)**

Quality of life (QoL) is impaired among the patients with HF in a variety of ways. Several variables including the socio-demographic factors, clinical and psychosocial variables may act directly or through complex interactions to produce the patient's own perception of the sensations. This may result from derangement in physical condition and its effects on the daily life. These variables influence the manner in which the patients perceive their physical symptom condition in relation to heart failure and this in turn, affects their QoL.

Socio-demographic factors can influence the perceived QoL by their effects on physical health by influencing the level of fatigue, mobility, and bodily discomfort or ability to afford the medical assistive devices. This may too affect the psychological health via the perceived bodily appearance, self-esteem, and personal beliefs. Marital status, level of education and the employment are likely to guarantee social relationships while the environment factors are likely to be influenced by the employment status.

The clinical variables related to the disease severity in HF, for instance, higher NYHA functional class, reduced LVEF, the presence of comorbidities and the long-standing HF are likely to be related with the reduced QoL. The optimal usage of medications with minimal adverse drug effects would improve the HRQoL.

Presence of depression and anxiety disorders due to the perceived mortality associated with the HF and the impaired physical activity is likely to impact negatively on the HRQoL while the presence of social support among these patients and the good perceived level of control would improve the HRQoL.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter acknowledges the importance of the assessment of the QoL among the patients with the heart failure as well as depicts various factors that affect their QoL. Studying and analyzing the various domains of the QoL as set out by the WHO would permit a better comprehension of how the quality of life is influenced by the derangement in health status observed in HF, that in turn would inform the development of suitable and relevant standards to assess the changes in the quality of life (2).

In the management of the patients with heart failure, the importance of the QoL is underscored, with current studies indicating the HF patients' preference for the improved HRQoL over the survival (17). QoL is a component of two aspects, i.e. the health-related quality of life (HRQoL) and the non-health related QoL. HRQoL is an important measure to evaluate the impact of a disease and the effects of medical intervention as perceived by the patient through the effects on the domains of life (18). Measuring HRQoL is, therefore, a standard way of describing the domains that include; physical, psychological and social effects of the HF and its treatment.

This chapter highlights the concept of QoL in relationship to HF in view of physical health, psychological health, social relationships and environment. It also discusses the effects of socio-demographic characteristics among HF patients on their QoL. In addition, the clinical characteristics of the patients that include the etiology of the HF, comorbidities associated with HF, duration of the illness, NYHA functional class, LVEF, cardiovascular interventions, physical symptoms and the prescribed medications used to manage the HF are discussed in relation to their influence on the QoL.

2.2 Health-Related Quality of Life

The HRQoL is a double-sided concept based on health and QoL that encompasses the subjective assessment of both desirable and negative aspects of health. The negative aspect includes disease and dysfunctions, whereas the desirable aspect encompasses feelings of mental and physical well-being, full functioning, physical fitness, and

efficiency of the mind and body. The HRQoL is influenced by the patient's experiences, belief systems, expectations, and perceptions.

HRQoL is a multidimensional and a dynamic concept with multiple domains that affect the patient's physical and/or mental health. These domains include individual's physical health, psychological state, social relationships, and their relationships to the salient features of their environment. They are health related to the extent they are influenced by illness, injury, and treatment. In addition, HRQoL is a dynamic concept resulting from past experience, present circumstances, and future expectations.

2.2.1 Physical Health

The physical health or well-being refers to the extent to which HF and its treatment induce physical changes that cause hindrance in the capacity to perform daily physical tasks. It's a patients' self opinion about their QoL in which they rate their perceptions about the effect of their illness or the treatment on their health status. HF affects patient's QoL through physical symptoms, namely, sleep disturbance, fatigue, shortness of breath, and changes in appetite. Decreased physical activity caused by exercise intolerance due to the debilitating symptoms of HF (dyspnoea and fatigue) negatively affects the individual's ability to adequately perform activities required for normal daily life and therefore affecting their independence and QoL (2). This is in consistency with the findings of Hwang *et al* in Taiwanese study that established the burden of physical symptoms as a strong predictor of physical health and overall QoL (19). Similar findings by Pelegrino *et al* have echoed this by showing that the severity of HF symptom, vigor, and psychological health explained 54% of HRQoL measured among 130 patients with HF diagnosis (20).

2.2.2 Psychological Health

This is a subjective domain of the QoL that determines the status of the mental health as reported by the patient. It assesses the patient's bodily image and figure, self-esteem, positive and negative emotional feelings, individual's belief system as well as thought process, learning, memory, and mental focus (2). The debilitating physical symptoms of

HF are associated with anxiety and depression that affect the psychological well-being of the patient. The emotional distress among the patients with HF greatly affects their well-being leading to a poor HRQoL. This is attributable to the poor prognostic process of the disease, recurrent hospital admissions, debilitating physical symptoms and the loss of self control associated with the complex treatment regimen that causes the feelings of helplessness.

The psychological variables have a strong impact on the HRQoL and they should be routinely assessed and addressed in HF patients (21). Study by Quinn *et al*, reported that HF patients possessed more spiritual well-being than their non-HF counterparts (22). Spiritual care among HF patients accounts for variance in their HRQoL. Due to the physical debilitating nature of the disease, patients (especially those with advanced disease) may take matters of divinity seriously and may be their only hope for continued existence.

Studies carried out by Zuccala *et al,* and Joanna *et al,* singled out depression and anxiety as major comorbidities among HF patients and which significantly affected the HRQoL. The two conditions negatively impacts on the patient's adherence to the prescribed medications, diet and the exercise program among the HF patients (23,24).

2.2.3 Social Health

The social health as a domain of the HRQoL is also referred to as the individual's social relationships. It is concerned with an individual's interaction and relationship with other people in the community as well as the social institutions. This domain assesses the availability of social support, personal relationships and sexual activities among the patients (2,25). The social support is derived from the individual's social networks involving the family members as well as the peers who provide the critically needed emotional, physical and informational support. Social support enables the patients to maintain self-care by offering proper management of the disease symptoms as well as keeping the physical and emotional stability. This improves the patient's well-being and health which in turn enhances the QoL. Graven *et al,* did an integrative review of thirteen studies which asserted that social support greatly enhances the HRQoL. Social support

influences the HF self-care maintenance and management related behaviors (26). In support of this finding are other studies that have shown how lack of social support and isolation negatively impacts on the HRQoL among HF patients (27,28). The poor HRQoL associated with social isolation may also be mediated by the depressive symptoms experienced by the patients with HF. The level of social support experienced by these patients directly mediates the impact of depression and anxiety. On several occasions, social support has shown a protective influence against these adverse events (29).

Patient-encounters with the healthcare professionals as well as the social insurance officials have been shown to improve the HRQoL. This is likely to be due to the reassurance on the improvement of their conditions and the insurance cover for their medical bills respectively (30).

Therefore, the lack of social support can lead to poor compliance to the prescribed self-care and medical regimens. This is ultimately associated with poor treatment outcomes, hence the observed poor HRQoL.

2.2.4 Environmental Health

The environmental health domain encompasses facets of financial resources, freedom, physical safety, and security of the patient. It also includes the quality and accessibility to health and social care enjoyed by the patient, the status of the home environment that can provide favorable setting for the acquisition of new information and skills. It also covers the aspect of the physical environment, recreation activities and the mode of transport (2,31).

In a study among Korean patients with CHF, Chu *et al*, identified the perceived economic status of the patient as a significant factor associated with the HRQoL. The patients with the low family income and perceived their economic status as below the mid-level had poor HRQoL (32). This was in accordance with the Gott *et al*, study in the UK that reported lower socioeconomic status to have negatively impacted on the overall QoL of patients with HF (33). Patients with HF undergo financial hardships associated with job loss and increases in medication costs. Alternatively, patients may fail to honor doctor's

appointments/visits as well as compliance to medications occasioned by the financial burden.

2.3 Effects of Socio-Demographic Profiles on QoL

Quality of life among the patients suffering Heart Failure can be affected by the individual patient's socio-demographic characteristics. A study conducted in Brazil on outpatients established a weak association between HRQoL and the age. The younger and female patients indicated perception of more negative HF effects on HRQoL than older and male patients. Furthermore, the study neither found an association with the educational background nor the marital status (20). In harmony with this is the study conducted by Seongkum *et al,* in USA among discharged patients with the HF that established that sex, marital status, education and smoking were not associated with the physical symptom status that was the most significant predictor of HRQoL. However, the study also concluded that the patients who were older, worked full-time or part-time inside or outside their homes, had better physical symptom status and less anxiety reported better HRQoL (8). In contrast, the study "CARE-HF" found out that, female patients with HF experienced greater physical and decreased HRQoL compared to men that are consistent with other studies (34,35). A study in Greece on hospitalized patients revealed a worse QoL associated with the age above 60 years, secondary education, residency in county capital and working in the civil service (36). The poor QoL among civil servants as compared to householders could be explained by the physical limitations of the illness coupled with the employer's demand for the services, while the capital residence is associated with daily stress like traffic jams. Another study in Taiwan reported age as a predictor of HRQoL among patients with HF, whereby the young age exhibited poorer HRQoL (19). This is in contrast to another study that established old age association with worse HRQoL among HF patients. This was explained by the fact that the age itself is an important risk factor for cardiac diseases, with the older patients more prone to comorbidities that are contributory factors in the poor HRQoL (37).

2.4 Effects of Clinical Characteristics on the QoL

These includes the etiology of the HF, comorbidities associated with HF, duration of the illness, NYHA classification of the HF, LVEF, cardiovascular interventions, physical symptoms, and the prescribed medications used to manage the HF.

2.4.1 Prescribed medications used to manage HF

In chronic medical conditions, various therapeutic interventions produce comparable benefits and risks. Therefore, therapies may add survival benefits, new value or adverse effects. This warrants for the evaluation of these therapies, amongst being their effects on the QoL. This provides the basis for the selection of the optimal drug regimen. Therapeutic goals in patients diagnosed with heart failure are; alleviation of symptoms and signs, prevention of the hospitalizations, and improvement on the survival which in turn improves the overall QoL of the patients (38,39). The pharmacological treatment is chosen based on the severity of the condition and the associated comorbidities. Patients with advanced HF experience a high symptom burden comparable to patients with advanced cancer. In such situations, palliative care should be utilized to address the distressing symptoms (40).

The major pharmacological classes of drugs used for the treatment of HF include Angiotensin Converting Enzyme Inhibitors (ACEIs), Angiotensin Receptor Blockers (ARBs), β-blockers (βB), Vasodilators, Diuretics, Aldosterone Receptor Antagonist (ARA), and the Cardiac glycosides (38,39). The three neurohumoral antagonists – an ACEI (or ARB), a βB, and a ARA are fundamental in modifying the progression of systolic HF and must be considered for all patients. These disease-modifying agents are administered with the diuretics to alleviate the signs and symptoms resulting from the congestion (38).

ACE-inhibitors are indicated as the first line therapy in patients with reduced left ventricular dysfunction. They reduce both preload and afterload through inhibition of Angiotensin I activation to the highly vaso-constrictive Angiotensin II and blockade of Angiotensin II mediated aldosterone release respectively. They significantly decrease the cardiovascular related mortality, myocardial infarction, and hospital admissions among

the heart failure patients with asymptomatic or symptomatic left ventricular dysfunction (38,39,41). ACE-inhibitors and β-blockers are started together as soon as viable on the diagnosis of HF with a reduced ejection fraction (HF*r*EF). Their roles are complementary in that the ACE-inhibitors prevent the LV remodeling whereas β-blockers improve the EF. In addition, β-blockers are anti-ischemic and thus reduce the risk of sudden myocardial death. This confers benefit in reducing early overall mortality as strongly evidenced in the studies of CIBIS-2, COPERNICUS, and MERIT-HF trials (42–44). The use of ACE inhibitors significantly reduced mortality and number of hospital admissions among HF patients with consistent effects in a broad range of patients. This was an outcome of the benefits of ACE-inhibitors in improving the symptoms, exercise tolerance, quality of life, and exercise performance (38,39,45).

ACEIs are associated with angioedema and therefore, caution should be exercised in patients with low systemic blood pressure, reduced renal blood supply, or elevated potassium in serum. ACE inhibitors do block kinase and thus cause increase in blood levels of bradykinin, which can induce a dry and irritating cough (39,46).

ARBs remains the recommended alternative in patients intolerant to the side effects of ACE inhibitors (47,48). CHARM-Added and Val-HeFT trials did recommend for a combination of ARBs with ACE inhibitors for the improved clinical signs and symptoms with a concomitant important reduction in relevant cardiovascular events and overall improved QoL (49,50). However, the RALES and EMPHASIS-HF studies established the superiority of the aldactone and eplerenone respectively in reducing the all-cause mortality as opposed to ARB “add-on” treatment (51–53).

MRAs inhibit aldosterone and other corticosteroids binding receptors. The RALES and the EMPHASIS-HF studies have given MRAs considerable evidence for their therapeutic usage in heart failure (51–53). In the TOPCAT trial, the spironolactone did show a reduction in hospitalization without influence on the combined endpoint of death with the known adverse effects of rising creatinine and hyperkalemia being observed with the treatment group (54).

Diuretic therapy is important for symptomatic management of CHF. They are essential in fluid overload to alleviate the signs and symptoms associated with congestion which can

manifest as peripheral edema, pulmonary congestion and/or splanchnic congestion (38). Loop diuretics have rapid and shorter diuresis in comparison to thiazides which produce a gradual and prolonged diuresis (55). The preference is accorded to loop diuretics compared to thiazides in HFrEF though their actions are synergistic when combined in resistant edema. On restoration of the dry body weight, their doses should be titrated accordingly to prevent dehydration that can lead to hypotension and renal insufficiency/ischemia (56). For patients with preserved ejection fraction (HFpEF), diuretics may negate the use of other disease-modifying therapies or achievement of their target dose.

Cardiac glycoside (digoxin) is used in symptomatic management among patients with atrial fibrillation (AF). It can also be used in patients in sinus rhythm with symptomatic HF and an LVEF $\leq$ 40%. It does not offer mortality benefit but shows a reduced rate of hospitalization both overall and for worsening HF (57,58).

Combination of hydralazine and isosorbide dinitrate (H-ISDN) has shown reduced morbidity and mortality when added to the conventional therapy, and it's the therapy of choice for patients who cannot tolerate the ACEIs or ARBs. This was shown to increase exercise capacity and LVEF (38,59,60).

2.4.2 Comorbidities associated with HF

Patients with heart failure often have several other concomitant diseases that adversely complicate the management and affect the treatment outcomes. There are cardiac and non-cardiac comorbidities with the former including atrial fibrillation, coronary artery disease (CAD), and hypertension as the latter includes kidney disease, anemia, diabetes mellitus (DM), sleep-disordered breathing (SDB), obesity, and depression (61). All these increase the morbidity and mortality among the HF patients and they need a multidisciplinary medical team for accurate diagnosis and treatment (62,63).

In a multicenter European study on iron deficiency (ID) and HRQoL in CHF, it was reported that ID independent of anemia status impacted negatively on the HRQoL (64). Further studies, i.e. FAIR-HF 1 and CONFIRM-HF trials did support the role of ID in the

QoL. The trials demonstrated significant improvements in functional capacity, NYHA class, and LVEF (65,66), with the treatment of the ID.

Findings from the OPTIMIZE-HF revealed that the presence of COPD among HF patients is related with the increased burden of co-morbidities, lower use of evidence-based HF medications, longer hospital admissions, and increased in-hospital non-cardiovascular mortality (67).

Patients with HF commonly experience depression with morbid and mortal consequences (68). In CARE-HF study, 50% of patients reported anxiety/depression with the severe anxiety predicting the readmission (21,35). A study carried in Taiwan acknowledged the depression as well as the physical symptoms of easy fatigability and shortness of breath as the predictors of QoL among HF patients (19). Other studies by Zuccla *et al*, Show-Li *et al*, and Staniute *et al*, have reported similar findings that related anxiety disorders, social support and depressive symptoms with poorer HRQoL, without effect on the LVEF (19,23,29,69). In contrast, studies have shown that, higher BMI has a protection against the adverse effect of depression symptoms among the patients with HF (70). The psychological variables have a strong impact on the HRQoL and should be routinely assessed for patient's treatment. Depressive symptoms impair the physiological well-being as well as the self-care thus affecting the patient's QoL.

CHF is increasing in prevalence among diabetes mellitus (DM) patients. Several mechanisms are postulated as responsible for this, including diabetic cardiomyopathy, autonomic dysfunction, metabolic aspects and myocardial blood flow dysfunction (71). The presence of DM in HF is associated with poorer HRQoL and poor long-term survival in particular (72).

2.4.3 Etiology of the heart failure

The etiology of heart failure varies among different countries. In the developed countries, coronary artery disease is the major etiological factor. However, in Sub-Saharan Africa, hypertension, cardiomyopathy, and rheumatic heart disease are the predominant causes accounting for more than two-thirds of the cases, while the Ischemic

heart disease is rare at 8% (12–15). The remaining cases can be attributed to the Cor Pulmonale and pericarditis. This underscores the considerable role played by the infections for instance mycobacterium tuberculosis and the Human Immunodeficiency Virus (HIV). Studies among the Korean and German populations established the ischemic heart disease to be the most common etiology among their populations (13,32).

Among the Ghanaians, Amoah *et al*, established the main etiologies of HF to be hypertension, rheumatic heart disease, and cardiomyopathies at 21.3%, 20.1% and 16.8% respectively (73). Studies in Kenya reveal consistency with other countries in Sub-Saharan Africa, whereby the non-ischemic causes predominates (14). The study by Ogeng'o *et al*, revealed that 9.5% of the HF cases were ischemic, compared to 1999, where only 2.2% were ischemic. This study further found out that the most frequent causes of HF were cardiomyopathies (18.1%), hypertension (15.5%), diabetes mellitus (14.7%), valvular heart disease (12.9%) and myocardial infarction (9.5%) (74,75).

2.4.4 Quality of life and somatic variables

Somatic variables are measures of disease severity, namely, NYHA functional class, LVEF, and duration of HF diagnosis. According to Juenger *et al*, worsening NYHA functional class reduces the QoL. In contrast, LVEF and duration of HF showed no association with quality of life (76). This is in consistency with the SOLVD trial quality of life sub-study and recent studies in Japan by Show-Li *et al*, that reported that the depressive symptoms and NYHA functional class were significantly predictive of the physical domain of QoL (19,77)

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter highlights the methodological details appropriate for this study. The chapter describes the research design, study site, target population, sampling technique, data collection, data analysis, as well as the logical and ethical considerations.

3.2 Study design

The study design was cross-sectional. Cross-sectional studies are normally conducted at one point in time or within a short period. These studies are often used to estimate the prevalence of an outcome of interest in the population or a sub-group of interest, but cannot be used to answer the questions about the causes of disease or the results of the intervention. The temporality is not known and therefore the data cannot be used to infer causality. The studies also allow for assessment of many different variables (outcomes and risk factors) at the same time and are useful for generation of hypothesis for future studies. The purpose of this study was to shed light on the HRQoL and its determinants among the HF patients attending the cardiac clinic.

3.3 Study site

The study was carried out at the Cardiac clinic of the Kenyatta National Hospital. The hospital is located in the Upper Hill area of Nairobi, the administrative capital city of Kenya. Kenyatta National Hospital is a Teaching facility and hosts the College of Health Sciences of the University of Nairobi, and Kenya Medical Training College, Nairobi Campus. The facility is one of the best equipped public hospitals and serves as a referral center for patients from the entire country. Its choice was informed by the availability of a sizeable number of patients presenting with HF. The Cardiac clinic is one of the medical outpatient's clinics (MOPC), known as the clinic number 17 and it is located on the ground floor of the KNH, directly opposite the Pediatric clinic. The clinic is conducted once weekly (on Tuesdays) with approximately 20 - 25 patients per week seen. The patients who visit the clinic suffer from cardiovascular diseases including

arrhythmias, hypertension, heart failure, valvular heart diseases (i.e. infective endocarditis, mitral regurgitation, and rheumatic fever), coronary artery diseases (i.e. myocardial infarction, angina pectoris, acute coronary syndrome e.g. deep venous thrombosis, and heart attack), and complications of prosthetic valves among others. The clinic is run by a team of six cardiologists who conducts the clinical review of the patients that includes; physical assessment, laboratory and radiological investigations, health education, writing of the prescription, appointments/admission, referral to other clinics and hospitals as well as discharges.

3.4 Target and study population

The target population was patients aged 18 years and above presenting with a medical diagnosis of heart failure attending the cardiology clinic at KNH, while a study population was the patients who met the set inclusion criteria.

3.4.1 Inclusion criteria

1. Patients diagnosed with HF
2. Patients aged 18 years and above
3. Patients who consented to participate in the study.

3.4.2 Exclusion criteria

1. Patients with cognitive impairment e.g. dementia or psychosis (who were not likely to recall their conditions well enough)
2. Patients with concomitant acute illnesses (that would have acutely influenced their QoL)
3. Patients with coexisting terminal illnesses
4. Patients who failed to consent.

The study participation was completely voluntary and the participants had to confirm their acceptance for participation by way of signing the consent after explanation.

3.5 Sampling

3.5.1 Sample size determination

The sample size was calculated using the Cochran formula for the prevalence study (78).

$$n_{\circ} = \frac{Z^2\ P\ (1-P)}{d^2}$$

Where:

$n_{\circ}$ = Calculated sample size required for the study

Z = Standard normal deviate (at 95% Cl, Z = 1.96)

d = Precision or the margin of error, set at 5% = 0.05

P = Estimated prevalence of HF was determined from the etiologies of heart failure which was one of the outcomes of interest in the study. From a previous study done at the KNH, the most frequent cause of HF was found to be cardiomyopathy responsible for 18.1% of the cases(74).

(1 - P) = 1 - 0.181 = 0.819

Therefore, substituting for the values,

Sample size, $n_{\circ} = \frac{1.96^2 \times 0.181(1-0.181)}{0.05^2}$ = 228 Patients

By applying the Cochran correction for the finite population,

$$n = \frac{n_{\circ}}{1 + \frac{n_{\circ}}{N}}$$

Where, n = Minimum sample size required

$n_{\circ}$ = Calculated sample size (= 228 patients)

N = Total number of heart failure patients who attends the Cardiac clinic for a two months period (when data was to be collected) was 160 patients.

Substituting for the values,

n = (228)/ (1+ (228)/160) = 94 Patients.

To cater for the non-response and inaccurate records, additional 15% was included,

Final sample size, $N_{\circ} = n + (\frac{15}{100} \times 94)$ = 94 + 14 = 108 Participants

3.5.2 Sampling technique

Consecutive sampling technique was used, whereby; every subject meeting the inclusion criteria was selected until the required sample size was achieved. Prior to the clinic day, the patient files were usually obtained from Central Health Records and Information office of KNH and taken to the Cardiac clinic records office.

The principal investigator (PI) and the research assistants perused the medical files for the patients expected to attend the clinic the following day. They then identified all the patients who met the inclusion criteria using the eligibility screening form *(Appendix 1)*. A list of the outpatient file numbers that met the inclusion criteria was made. A tag was stapled onto these files for ease of identification.

3.5.3 Participant recruitment

During the clinic day, the identified patients were comprehensively informed of the study as they waited to be attended to by their physicians. Thereafter, those eligible and willing to volunteer in the study were taken through the consenting process and signed the consent form *(Appendix 2A –English Version or Appendix 2B – Kiswahili version).* They were thereafter issued with the questionnaires *(Appendix 3 & 4),* taken through and helped to fill with the support of the PI and research assistants. This procedure was repeated on other clinic days until the desired sample size was attained.

To avoid duplicate sampling of the same patient, tags were used after the first encounter. The tags were stapled to the patient files and the date of interview indicated to ensure they remained in place to the end of the study. No participant was interviewed more than once.

3.5.4 Training of research assistants

The principal investigator (PI) identified one willing and capable research assistant (Clinical officer) and trained him before the commencement of the research. The training entailed an explanation of the nature of the study, its objectives and importance. Intensive training and demonstration of use of the data collection tools was done. Ethical considerations and overall conduct expected of a scientific research was explained. The competence of the research assistant was assessed by the PI before the study commenced. The PI thereafter supervised the whole research process.

3.6 Research Instruments

3.6.1 Questionnaires

WHOQOL-BREF (*Appendix 4*), which is a short version of WHOQOL-100 and a generic tool was used to assess the overall QoL as well as the specific scores for the four major domains, namely; physical health, psychological health, social relationships and environment health. The tool was used in its standard form as provided for by the WHO without alterations.

The tool was supplemented with a well-structured questionnaire *(Appendix 3),* developed by the principal investigator to capture the details pertaining to the patient's bio-data, socio-demographic, and clinical information that was to aid in the final analysis of results. Clinical data was abstracted from the patient's medical file and filled into the structured questionnaire by the PI and research assistant.

3.6.2 Eligibility screening form

This form was used to guide the selection of patients who met the inclusion criteria *(Appendix 1).*

3.6.3 Informed consent form

This form was used to obtain voluntary consent from those who met the inclusion criteria. It was in English and Kiswahili languages and was read in the language most

appropriate for the respondent (*Appendix 2A & 2B).* The patient was also allowed to give consent through his/her proxy.

3.7 Pilot study or Pre-Testing

3.7.1 Pre-testing

A few copies of the questionnaires were administered to about 10% of the target population (approximately 10 patients) at the cardiac clinic (79). Modification of the questionnaires was done based on the results obtained.

3.7.2 Pilot study

The modified questionnaires were administered to another 10 patients of the target group to ensure they were flawless and capable of collecting the kind of information that was required. Thereafter, questionnaires were revised in accordance to the weaknesses observed during the piloting. Enough copies of the questionnaires were thereafter printed and data collection commenced.

3.8 Validity

The validity of the study was maintained by ensuring that the questionnaires were well laid out and relevant with regard to objectives of the study. The questions were arranged sequentially using simple, clear, concise and acceptable language. A research assistant was chosen from among the registered clinical officers who had worked in the cardiac clinic. He was thoroughly trained by the PI before the actual study commenced. The study site chosen gave a good representation of the general population since KNH attends to patients from all parts of the country. In addition, the sample size used in the study was adequate based on the scientific requirements.

3.9 Reliability

Data collection tools were pre-tested as described under the pilot study for reproducibility before the actual study was carried out to ensure there were no ambiguities in responses. Amendments were done on the instruments where necessary in order to improve their efficiency and effectiveness before rolling them out.

3.10 Data Collection Techniques

Field data was collected by the use of questionnaires *(Appendix 3 & 4).* After the participant's voluntary consent, they were invited individually for a face to face interview and assisted to complete the questionnaire. This was done within the hospital and only the researcher and participant were present to ensure confidentiality. In addition, treatment charts, prescription, and medical records belonging to each study participant were reviewed by the PI or research assistant to abstract data on clinical profile aspects, namely, LVEF, etiology of the HF, and the prescribed medications, which was not obtained directly from the participants. The PI or research assistant assessed the patients and allocated the NYHA functional class to each of the participants based on the NYHA classification criterion (*Table 3.1*).

The structured questionnaire (*Appendix 3*) had two main sections, namely; socio-demographic characteristics and the patient's clinical profile, and each response had a code that was used during data entry into excel sheet.

The data for the quality of life (*Appendix 4*) was grouped into five domains, namely; physical, psychological, environmental, social relationships and overall QoL. Each domain had specific responses which were obtained from the participant's self-reporting.

Table 3.1: Guide for the NYHA classification

Class	Patient symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnoea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

3.11 Data management

3.11.1 Data Processing

The participants' questionnaires each bore a unique serial number for identification purposes. These numbers were entered into individual participant's details in the Excel sheet. Raw data collected was coded and entered into Excel sheet. Data entries were done on a daily basis and were checked routinely for accuracy and completeness. Any inconsistencies and ambiguities were rectified immediately. Data was backed up daily into a hard drive. On completion of the data entry process, data was cleaned and exported onto the STATA® Software for analysis.

3.11.2 Data Quality Control

A pilot study was carried out before the actual study to test for the relevance and ease of data collection of the instruments and necessary amendments were done. Research assistant was trained prior to the study with regard to the study objectives and the data collection instruments. All data entries were password-protected and were entered by the

PI. Data was backed up in a hard drive and kept in a separate location where only the PI had access. Data cleaning was done to correct any errors that occurred during entry.

3.11.3 Study Variables

The quality of life was the dependent variable and the independent variables were socio demographic characteristics and the clinical profiles of the patient. The QoL domains investigated include; physical health, psychological health, social relationships, and environmental health.

The facets incorporated in the physical health were; activities of daily living, dependence on medicinal substances and medical aids, energy, and fatigue, mobility, pain and discomfort, sleep, rest and work capacity. Psychological health had bodily image and appearance, negative feelings, positive feelings, self-esteem, spirituality/religion/personal beliefs, thinking, learning, memory, and concentration. The aspects evaluated in the social relationships were; personal relationships, social support, and sexual activity. The environmental health was assessed using; financial resources, freedom, physical safety and security, health and social care: accessibility and quality, home environment, opportunities for acquiring new information and skills, participation and opportunities for recreation/leisure activities, physical environment (pollution / noise /traffic / climate) and transport.

The socio demographic characteristics assessed include; age, sex, marital status, living arrangement, level of formal education, employment status, use of alcohol, and tobacco smoking. The clinical data collected include; duration of the HF, hospitalizations, comorbidities, NYHA functional class, LVEF, etiology, and the prescribed medications.

3.11.4 Data Analysis

All the 26 items in the WHOQOL-BREF were assessed for completion and the respective score recorded (Table 3.14). Calculation of the respective domain score was determined by considering the relevant questions according to the tool. The overall QoL and general health was computed from questions 1 and 2. Physical health score was obtained from questions; 10, 15, 16, 17, 18 and a reversal score of question 3 and 4. Psychological health was calculated from questions; 5, 6, 7, 11, 19 and reversal of question 26. Social

relationships score was calculated from questions; 20, 21, and 22. Finally, environmental health score was derived from questions; 8, 9, 12, 13, 14, 23, 24 and 25. The raw scores were computed by a simple algebraic sum of each item in each of the four domains. Then, each raw scale was transformed to get a transformed score using the below equation;

$$\text{Transformed Score} = \{\frac{(Actual\ raw\ score - Lowest\ possible\ raw\ score)}{Possible\ raw\ score\ range}\} \times 100$$

Where, "Actual raw score" was the values achieved through summation, ''lowest possible raw score'' was the lowest possible value that could occur through summation, and ''Possible raw score range" was the difference between the maximum possible raw score and the lowest possible raw score. Descriptive and inferential statistics were computed for socio-demographic and clinical data.

The overall QoL and individual domains' score were taken as the outcome variables while the patient's sociodemographic and clinical data was taken as the explanatory (independent) variables. Data was analyzed using STATA® Software by performing a Bivariate and Multivariate linear regression to determine associations between the various predictive variables and the HRQoL, and individual domain's score. *P*-values of < 0.05 were considered to be statistically significant.

The results were presented in form of frequency distribution tables, percentages and graphs.

3.12 Logistical and Ethical Considerations

Before the data collection commencement, ethical clearance was sought from the ethical review committee of KNH/UON. Institutional approval was also sought from KNH once the KNH/UON-ERC had sanctioned the study. Respondents were informed of the purpose of the study and their signed consent was obtained before participation in the study (*Appendix 2A & 2B*). The participant's right to refuse or withdraw from the study was fully maintained and the information provided by each respondent was kept strictly confidential. An approval to use the "WHOQOL-BREF" questionnaire for the study was obtained from World Health Organization.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter describes the results obtained after descriptive and inferential analysis of the data. It includes the socio-demographic and clinical characteristics of the study participants and the linear regression analysis of the determinants of the healthy related quality of life.

4.2 Socio-Demographic Characteristics

A total of 109 study participants were interviewed using a structured questionnaire where 37 (33.9%) were males and 72 (66.1%) were females as shown in **table 4.1**

Table 4.1: Sociodemographic Characteristics of the Study Participants

Variable	n (%)	M ± SD
Gender		
Male	37 (33.9)	
Female	72 (66.1)	
Age (years)		55.3 ± 17.0
18-30	10 (9.2)	
31-40	14 (12.8)	
Over 41	85 (78.0)	
Body Mass Index		27.8 ± 7.3
Underweight	4 (3.7)	
Normal	42 (38.5)	
Overweight	22 (20.2)	
Obese	41 (37.6)	
Marital Status		
Single	18 (16.5)	
Married	91 (83.5)	
Living Arrangement		
With someone	94 (86.2)	
Alone	15 (13.8)	
Level of formal education		
None	18 (16.5)	
Primary	42 (38.5)	
Secondary	40 (36.7)	
Tertiary	9 (8.3)	
Employment Status		
Unemployed	70 (64.2)	
Employed	39 (35.8)	
Alcohol Intake		
Yes	26 (23.8)	
No	83 (76.2)	
Smoking History		
Yes	20 (18.4)	
No	89 (81.6)	

The mean age was 55.3 years (SD ±17.0) and ranged 18 to 94 years old. Most of the participants were above 41 years old while those aged between 18 and 40 years old were 24 (21.0%). Forty-one (37.6%) respondents were obese while 22 (20.2%) and 42 (38.5%) of them were overweight and of normal BMI respectively. The participants had a mean BMI of 27.8 ± 7.3 kg/m^2. Stratifying for the gender, majority of females were above overweight (63, 63.89%) as compared to males (17, 46.95%). Regarding their marital status, 91 (83.5%) were married and 18 (16.5%) were single. Majority (94, 86.2%) were living with someone, while fifteen (13.8%) were living alone. Only 9 (8.3%) respondents

had attained a tertiary level of education while 42 (38.5%) and 40 (36.7%) of them had attained the primary and secondary level respectively.

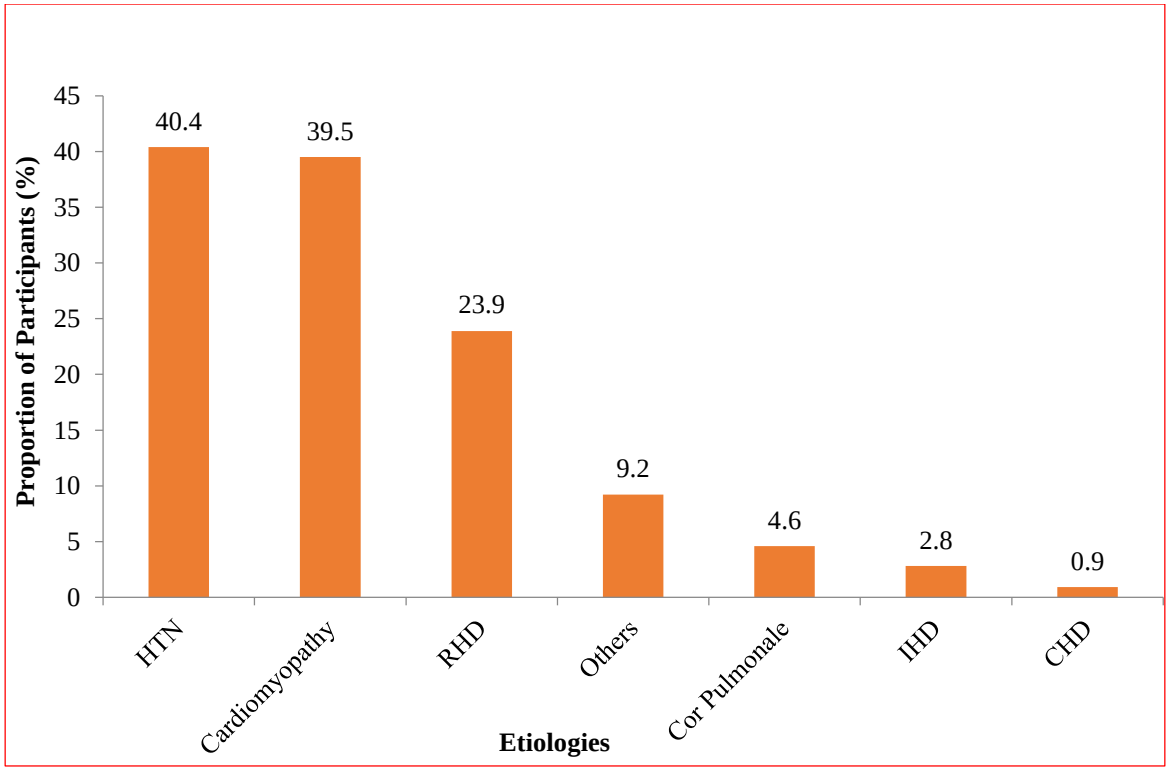
4.3 Clinical Characteristics

Forty-eight (44.0%) participants had suffered from heart failure for over four years. Majority (74, 67.9%) had never been hospitalized. There was an almost equal representation of participants with preserved and reduced ejection fraction at 56 (51.4%) and 53 (48.6%) respectively (**Table 4.2**).

Table 4.2: Clinical Characteristics of the Study Participants

Variable	n (%)
Duration of Heart Failure (years)	
Below 1	15 (13.8)
1-2	25 (22.9)
2-3	9 (8.3)
3-4	12 (11.0)
Over 4	48 (44.0)
Hospital Admission	
Yes	35 (32.1)
No	74 (67.9)
LVEF	
< 40	53 (48.6)
≥ 40	56 (51.4)

The most common etiology was hypertension (44, 40.4%) followed closely by Cardiomyopathy (43, 39.5%) as shown in **figure 4.1**.



HTN- Hypertension, IHD- Ischemic heart disease, RHD- Rheumatic heart disease, CHD- Congenital heart disease

Figure 4.1: Etiology of Heart Failure

The majority of the subjects were symptomatic in NYHA-Functional class II-IV (102, 93.6%) as shown in **figure 4.2.**

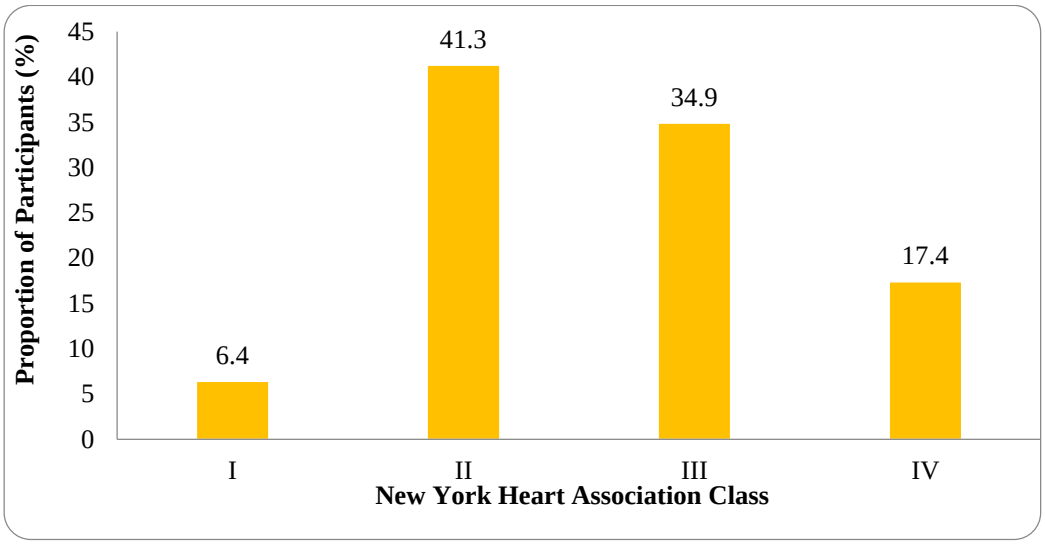
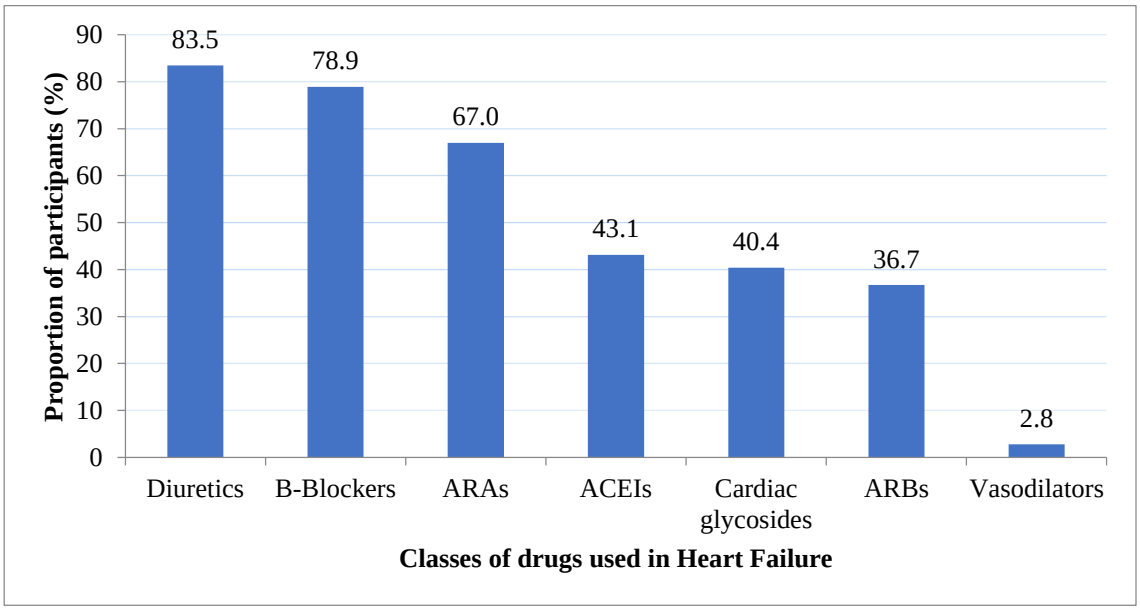


Figure 4.2: NYHA Classification of Heart Failure

The mean number of medications was 4.9 (± 1.3). The most used classes were diuretics (91, 83.5%), followed by beta-blockers (86, 78.9%) and ARAs (73, 67.0%) as shown in **figure 4.3**.



ACEIs- Angiotensin converting enzyme inhibitors, ARBs- Angiotensin II receptor blockers, ARAs- Aldosterone receptor antagonists

Figure 4.3: Classes of drugs used in Heart Failure

Specifically, the most common drugs prescribed were carvedilol (75, 68.8%) followed by spironolactone, furosemide, enalapril, digoxin and losartan among others (**Table 4.3**).

Table 4.3: Types of drugs used

Medications	n (%)	M ± SD
Carvedilol	75 (68.8)	
Spironolactone	73 (67.0)	
Furosemide	72 (66.1)	
Enalapril	49 (45.0)	
Digoxin	37 (34.0)	
Losartan	29 (26.6)	
HCTZ	13 (12.0)	
Telmisartan	8 (7.3)	
Nebivolol	6 (5.5)	
Ivabradine	6 (5.5)	
Metolazone	5 (4.6)	
Atenolol	4 (3.7)	
Hydralazine	3 (2.8)	
Candesartan	1 (0.9)	
Metoprolol	1 (0.9)	
Eplerenone	1 (0.9)	
Pill Burden		4.9 ± 1.3
1-4	45 (41.3)	
5-8	64 (58.7)	

Some of the participants had several Comorbidities. Majority had one followed by two and three respectively as shown in **figure 4.4**

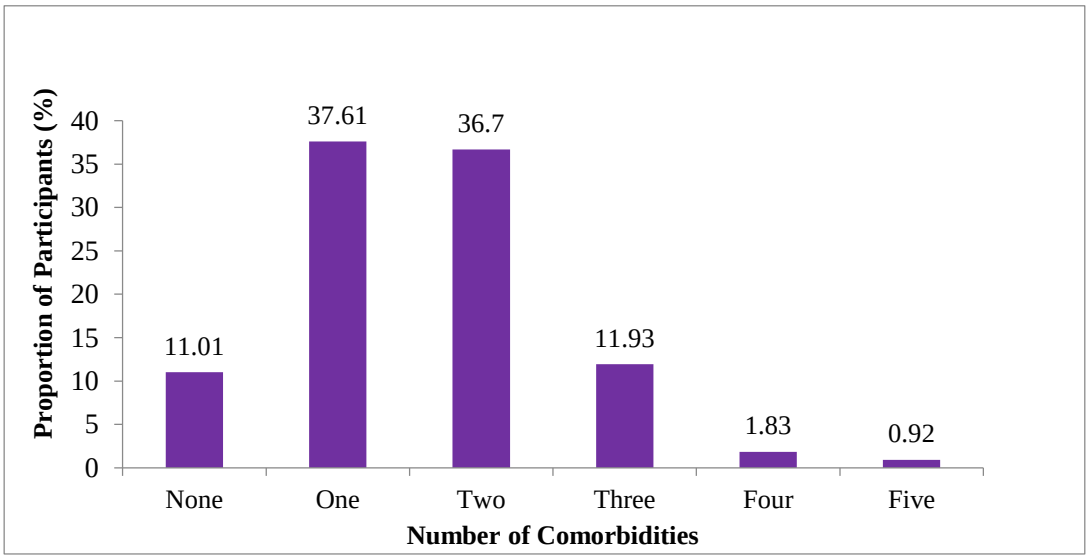


Figure 4.4: Number of Comorbidities per participants

The Comorbidities included hypertension (56, 48.6%), valvular heart disease (49, 45%), atrial fibrillation (14, 12.8%), diabetes mellitus (8, 7.3%), and chronic obstructive pulmonary disease, (7, 6.4%) among others as shown in **table 4.4**.

Table 4.4: Prevalence of Comorbidities

Type of Comorbidity	n (%)
HTN	56 (48.6)
VHD	49 (45.0)
AFIB	14 (12.8)
DM	8 (7.3)
COPD	7 (6.4)
CKD	6 (5.5)
IHD	5 (4.6)
Breast Ca	4 (3.7)
Anaemia	1 (0.9)
Acute Coronary Syndrome	1 (0.9)
Others	34 (31.2)

4.4 Quality of life Measurements

The chart in figure 4.5 shows the means of the health related quality of life scores. The social domain had the highest overall mean score (61.1 ± 16.9) while the physical domain had the lowest score (45.1 ± 21.1). The overall quality of life among the participants was 48.6 ± 20.5.

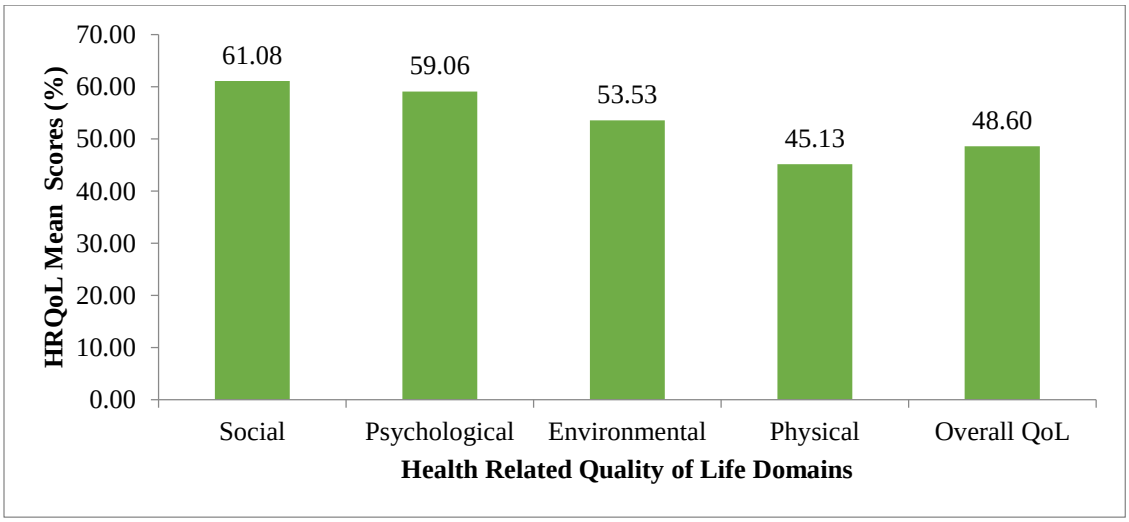


Figure 4.5: Means of Health Related Quality of Life Domain Scores

4.4 Determinants of health related quality of life

4.4.1 Determinants of physical health

Linear regression analysis was carried out with physical health (PH) as the dependent

Table 4.5: Determinants of physical health

Variable	Bivariate analysis		Multivariate analysis	
	β (95% CI)	***P*-value**	**β (95% CI)**	***P*-value**
Age category	1.6 (-4.8, 8.0)	0.617	4.3 (-2.8,11.4)	0.237
BMI	0.1 (-0.4, 0.7)	0.665	0.2 (-0.4, 0.7)	0.560
Gender	-1.7 (-10.2, 6.8)	0.697	0.2 (-9.7, 10.2)	0.963
Marital status	-1.8 (-12.6, 9.0)	0.743	-2.3 (-12.8, 8.2)	0.665
Living arrangement	3.7 (-7.9, 15.4)	0.529	2.9 (-7.9, 13.7)	0.597
Level of education	6.1 (1.5, 10.7)	**0.010***	4.1 (-0.5, 8.6)	0.079
Employment status	6.7 (-1.6, 15.0)	0.111	2.6 (-5.1, 10.4)	0.498
Alcohol intake	-1.4 (-10.8, 8.1)	0.776	3.8 (-8.9, 16.5)	0.554
Smoking	-6.7 (-17.0, 3.6)	0.200	-8.3 (-23.1, 6.5)	0.270
Duration of HF	0.4 (-2.2, 3.0)	0.741	-0.2 (-2.5, 2.0)	0.836
Hospital admission	-9.7 (-18.1, -1.3)	**0.024***	-2.7 (-11.0, 5.5)	0.514
Comorbidities	-7.8 (-16.8, 1.2)	0.088	-8.5 (-17.2, 0.2)	0.056
NYHA Class	-131 (-17.1, -9.0)	**< 0.001**	-11.7 (-16.1, -7.2)	**< 0.001**
LVEF	3.1 (-4.9, 11.1)	0.445	-0.4 (-7.6, 8.4)	0.926
No. of Comorbidities	0.1 (-4.1, 4.3)	0.952	-0.5 (-3.5, 4.5)	0.793
Pill burden	0.3 (-2.8, 3.4)	0.848	0.7 (-2.3, 3.6)	0.661

variable and sociodemographic characteristics the independent variables with positive coefficients indicating a percentage increase in PH score and vice versa. The results are summarized in **table 4.5**.

An increase in NYHA class from I to IV significantly reduced PH score by 131% (p = < 0.001) in a bivariable model and 11.7% (p = < 0.001) in a multivariable model. The NYHA class was an independent predictor of the PH score. As the participants' level of education improved from primary to secondary and above, PH score improved by 6.1% (p = 0.010) in bivariable and 4.1% (p = 0.079) in multivariable models, respectively. This implied the participants with informal and primary education had lower PH score than those who attained secondary and tertiary levels respectively. Although the significance was lost in the Multivariable model, the coefficient remained positive. The other sociodemographic characteristics that enhanced the PH score though not statistically significant were; age, employment, body mass index, and employment.

Hospitalizations related with complications of heart failure significantly reduced the PH score among the participants by 9.7% (p = 0.024) in the bivariable model but the significance was lost in the multivariable model with the coefficient remaining negative 2.7% (p = 0.514). Other sociodemographic factors that reduced the PH score though not statistically significant included; smoking and presence of comorbidities.

4.4.2 Determinants of psychological health

Linear regression analysis was carried out with psychological health (PS) as the outcome variable and sociodemographic characteristics as the explanatory variables and the results summarized in **table 4.6**. Psychological health score improved by increase with age from 18 years by 2.9% (p = 0.122), and 1.7% (p = 0.039) in bivariable and multivariable linear regression models respectively. Though the age didn't have statistical significance in the bivariable model, the significance was achieved in the multivariable model. An increase in NYHA class from I to IV reduced PS score by 8.4% (p = < 0.001) in a bivariable model and 8.5% (p = < 0.001) in a multivariable model. The association was statistically significant with a negative association.

Table 4.6: Determinants of psychological health

Variable	Bivariate analysis		Multivariate analysis	
	β (95% CI)	***P*-value**	**β (95% CI)**	***P*-value**
Age category	0.1 (-0.03, 0.3)	0.122	0.2 (0.01, 0.4)	**0.039 ***
Crude BMI	-0.0007 (-0.4, 0.4)	0.997	-0.1 (-0.5, 0.3)	0.604
Gender	-2.5 (-8.6, 3.7)	0.424	2.1 (-5.6, 9.8)	0.586
Marital status	2.0 (-5.9, 9.8)	0.618	0.5 (-7.6, 8.6)	0.907
Living arrangement	-2.1 (-10.6, 6.3)	0.618	-1.9 (-10.1, 6.2)	0.642
Level of education	0.8 (-2.6, 4.2)	0.647	-0.4 (-3.2, 4.1)	0.812
Employment status	2.9 (-3.2, 8.9)	0.350	1.7 (-4.2, 7.6)	0.570
Alcohol intake	0.5 (-6.3, 7.4)	0.881	-3.4 (-13.1, 6.4)	0.495
Smoking	1.4 (-6.1, 8.9)	0.712	6.1 (-5.3, 17.4)	0.293
Duration of HF	0.6 (-1.3, 2.5)	0.539	0.2 (-1.6, 1.9)	0.824
Hospital admission	-3.7 (-12.1, 0.2)	0.057	-2.8 (-9.0, 3.4)	0.370
Comorbidities	-2.5 (-9.1, 4.0)	0.446	-4.5 (-11.0, 2.0)	0.171
NYHA Class	-8.4 (-11.4, -5.3)	**< 0.001**	-8.5 (-12.0, -5.1)	**< 0.001**
LVEF	2.0 (-3.8, 7.8)	0.491	-1.0 (-6.9, 5.0)	0.752
No. of Comorbidities	1.2 (-1.8, 4.3)	0.419	0.5 (-2.6, 3.6)	0.736
Pill burden	0.2 (-2.0, 2.4)	0.864	0.1 (-2.2, 2.3)	0.959

The other sociodemographic characteristics which reduced the PS score were BMI and hospitalizations despite that, the associations were not statistically significant. Employment status and marital status enhanced the PS score although the increase was not statistically significant.

4.4.3 Determinants of social health

The association between social health score and sociodemographic characteristics were investigated whereby the social health (SH) score was the dependent variable and sociodemographic characteristics were the independent variables. The results are summarized in **table 4.7**. There was a statistically significant relationship between social health score and the worsening in NYHA class from I to IV with a reduction in SH score by 3.7% (p = 0.051) in the bivariable model. However this significance was lost in the multivariable model with a reduction in SH score by 3.0% (p = 0.146) but the coefficients remained negative. Presence of a morbidity among the participants reduced the SH score by 6.1% (p = 0.100) and 8.2% (p = 0.045) in bivariate and multivariate analysis respectively. The reduction was statistically significant in the multivariable model (p = 0.045) while in bivariate analysis, the association was not significant but remained negative. Other sociodemographic factors that indicated a negative relationship with the SH score included; body mass index, living arrangement, alcoholism, hospital admission, and LVEF. Other factors did show a positive relationship but not statistically significant included; age, marital status, level of education, and employment status.

Table 4.7: Association between sociodemographic characteristics and Social Health

Variable	Bivariate analysis		Multivariate analysis	
	β (95% CI)	***P*-value**	**β (95% CI)**	***P*-value**
Age category	0.6 (-4.5, 5.7)	0.811	2.7 (-3.8, 9.2)	0.413
Crude BMI	-0.2 (-0.7, 0.2)	0.311	-0.3 (-0.8, 0.2)	0.273
Gender	-3.7 (-10.5, 3.1)	0.285	0.2 (-9.0, 9.4)	0.965
Marital status	3.9 (-4.8, 12.5)	0.381	4.7 (-5.0, 14.3)	0.341
Living arrangement	-4.5 (-13.8, 4.9)	0.344	-7.7 (-17.7, 2.2)	0.127
Level of education	3.4 (-0.3, 7.2)	0.070	3.0 (-1.2, 7.2)	0.154
Employment status	2.0 (-4.7, 8.8)	0.550	0.9 (-6.2, 8.0)	0.796
Alcohol intake	-1.5 (-9.1, 6.1)	0.694	-9.6 (-21.3, 2.1)	0.106
Smoking	1.7 (-6.6, 10.1)	0.681	9.8 (-3.8, 23.4)	0.158
Duration of HF	0.4 (-1.7, 2.5)	0.684	0.6 (-1.5, 2.7)	0.595
Hospital admission	-3.7 (-10.5, 3.2)	0.294	-2.5 (-10.1, 5.1)	0.514
Comorbidities	-6.1 (-13.3, 1.2)	0.100	-8.2 (-16.2, -0.2)	**0.045***
NYHA Class	-3.7 (-7.5, 0.02)	**0.051***	-3.0 (-7.1, 1.1)	0.146
LVEF	-2.0 (-8.4, 4.5)	0.543	-2.3 (-9.7, 5.0)	0.531
No. of Comorbidities	1.6 (-2.3, 4.4)	0.530	2.1 (-1.6, 5.7)	0.267
Pill burden	-0.2 (-2.7, 2.2)	0.857	-0.4 (-3.1, 2.3)	0.777

4.4.4 Determinants of Environmental Health

The relationship between environmental health (EH) score and sociodemographic characteristics were investigated with the environment score as the dependent variable and sociodemographic characteristics the independent variables. The results are summarized in **table 4.8**.

The worsening in the NYHA class of heart failure reduced the EH score by 4.4% (p = 0.007) and 4.2% (p = 0.014) in bivariable and multivariable models respectively. Participants with a prescription containing a β-blocker had a statistically significant EN score improved by 8.1% (p = 0.016) and 8.4% (p = 0.019) in bivariable and multivariable linear regression models respectively.

Increase in age, being married, having a higher education, or a paying job and never being admitted in hospital had an improvement on the EH score but the associations were not statistically significant. Living alone and a female gender showed a reduced EH score but the association was not statistically significant.

Table 4.8: Association between sociodemographic characteristics and environment

Variable	Bivariate analysis		Multivariate analysis	
	β (95% CI)	***P*-value**	**β (95% CI)**	***P*-value**
Age category	4.1 (-0.1, 8.4)	0.058	3.5 (-1.8, 8.8)	0.194
Crude BMI	0.2 (-0.2, 0.6)	0.244	0.2 (-0.2, 0.6)	0.313
Gender	-5.3 (-11.0, 0.4)	0.069	-2.9 (-10.3, 4.5)	0.435
Marital status	1.7 (-5.6, 9.1)	0.643	0.8 (-7.0, 8.5)	0.844
Living arrangement	-1.7 (-9.6, 6.3)	0.677	-0.6 (-8.6, 7.4)	0.880
Level of education	2.9 (-0.3, 6.0)	0.075	2.7 (-0.7, 6.1)	0.116
Employment status	2.5 (-3.2, 8.2)	0.387	1.4 (-4.4, 7.1)	0.638
Alcohol intake	1.7 (-4.7, 8.1)	0.604	-4.7 (-14.1, 4.7)	0.323
Smoking	4.7 (-2.3, 11.7)	0.190	6.3 (-4.6, 17.2)	0.256
Duration of HF	0.4 (-1.4, 2.1)	0.678	0.5 (-1.2, 2.1)	0.584
Hospital admission	1.8 (-4.1, 7.6)	0.549	3.2 (-2.9, 9.3)	0.300
Comorbidities	0.4 (-5.8, 6.6)	0.898	-2.4 (-8.9, 4.1)	0.463
NYHA Class	-4.4 (-7.5, -1.2)	**0.007***	-4.2 (-7.5, -0.9)	**0.014***
LVEF	-0.2 (-5.7, 5.2)	0.928	1.2 (-4.8, 7.3)	0.689
No. of Comorbidities	2.3 (-0.5, 5.1)	0.109	2.3 (-0.7, 5.3)	0.125
Pill burden	1.8 (-0.3, 3.8)	0.092	0.7 (-1.5, 2.9)	0.538
β- blockers	8.1 (1.6, 14.6)	**0.016***	8.4 (1.4, 15.4)	**0.019***

4.4.5 Determinants of the Overall Health-Related Quality of Life score

The sociodemographic predictors of the overall quality of life were determined and the results summarized in **table 4.9**.

Table 4.9: Sociodemographic characteristics predictors of the overall HRQoL

Variable	Bivariate analysis		Multivariate analysis	
	β (95% CI)	***P*-value**	**β (95% CI)**	***P*-value**
Age category	-2.0 (-8.2, 4.2)	0.532	2.7 (-4.5, 9.8)	0.459
Crude BMI	-0.02 (-0.6, 0.5)	0.947	0.09 (-0.5, 0.6)	0.747
Gender	-4.6 (-12.8, 3.6)	0.273	-0.7 (-10.7, 9.4)	0.896
Marital status	-7.5 (-17.9, 2.9)	0.158	-3.9 (-14.5, 6.7)	0.466
Living arrangement	1.6 (-9.7, 13.0)	0.778	1.0 (-9.9, 12.0)	0.852
Level of education	6.5 (2.1, 11.0)	**0.004***	5.9 (0.9, 10.8)	**0.021***
Employment status	4.6 (-3.5, 12.7)	0.267	1.2 (-6.5, 9.0)	0.754
Alcohol intake	1.1 (-8.1, 10.3)	0.816	-1.8 (-14.6, 11.1)	0.785
Smoking	1.7 (-8.4, 11.8)	0.738	1.6 (-13.3, 16.4)	0.834
Duration of HF	0.05 (-2.5, 2.6)	0.966	-1.0 (-3.3, 1.3)	0.406
Hospital admission	1.6 (-6.8, 10.0)	0.702	7.6 (-0.7, 15.9)	0.073
Comorbidities	-6.6 (-15.4, 2.2)	0.138	-7.3 (-16.1, 1.5)	0.104
COPD	-21.4 (-36.8, -6.0)	**0.007***	-13.4 (-29.2, 2.3)	0.093
NYHA Class	-10.6 (-14.8, -6.4)	**0.000***	-9.6 (-14.2, -5.0)	**0.001***
LVEF	4.3 (-3.5, 12.0)	0.281	5.4 (-2.8, 13.5)	0.194
No. of Comorbidities	-0.6 (-4.7, 3.5)	0.770	-1.1 (-5.1, 2.9)	0.596
Pill burden	1.7 (-1.3, 4.7)	0.261	2.5 (-0.5, 5.5)	0.098

The attainment of higher levels of education improved the overall health-related quality of life (HRQoL) score by 6.5% (p = 0.004) and 5.9% (p = 0.021) in bivariable and multivariable models respectively. The progression of the heart failure from NYHA class I to advanced stages, NYHA IV, impacted negatively to the overall HRQoL score with a reduction of 10.6% (p = < 0.001) and 9.6% (p = < 0.00) in bivariable and multivariable models respectively. Therefore, the level of education and the NYHA class were strong independent predictors of the HRQoL score. Participants who had COPD as a comorbidity had a HRQoL score reduced by 21.4 percent (p = 0.007). Other factors that improved the QOL but not statistically significant included: being employed, not smoking, not previously hospitalized and having a preserved LVEF. Higher burden of Comorbidities, being married and the female gender reduced the HRQoL.

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter contains the discussion of the research findings. The conclusions and recommendations are also included.

5.2 Discussion

The participants in this study were predominantly over 41 years old, females, married, with primary level of education, without a gainful employment and had lived with the disease for over four years. The prevalence of heart failure was twice among females than males in the study population. This contradicts an earlier study by Ogeng'o *et al,* which reported a male to female ratio of 1:1 in a sample size of 116 (74). HF is a complication for a number of conditions affecting the heart. The progression of these heart conditions if not adequately managed causes heart failure with an advancing age. Other studies done among the adult Kenyan population did show a mean age of 52.2 years (74). When compared to Europeans with the mean age of 65 ± 10 years, there is an early onset of heart failure among the African populations and this negatively impacts on the economically productive age group in the society (35). This is probably due to delayed diagnosis or inadequate management of the underlying heart conditions with an early progression to heart failure.

The majority of the patients were symptomatic NYHA-Functional class II-IV and this concurs with findings from other local studies (74,75). Hypertension and cardiomyopathy emerged as the major causes of heart failure among the participants. This is in support of other studies by Ogeng'o *et al,* and the Sub-Saharan Africa study of heart failure among 9 countries by Albertino *et al,* (74,80). However, this disagrees with Oyoo *et al,* study that identified rheumatic heart disease as the major cause of heart failure, followed closely by cardiomyopathy (12).

Comorbidities are common in heart failure. They could be diseases of the cardiovascular system or not. For instance, the untreated underlying causes of HF remain as

comorbidities. Other diseases could be in coexistence without a relationship to the HF. In the current study, most of the participants reported at least one comorbidity. This was higher compared to a study by Viviane *et al*, study that was done at a Brazilian hospital (20). The major comorbidities reported were hypertension, valvular heart disease and atrial fibrillation. The VHD is predominantly caused by rheumatic fever and infective endocarditis. This concurs with Kimani *et al,* study that established Valvular heart disease as the most common comorbidity followed by hypertension, and diabetes mellitus (81). However, it does not fully concur with the findings of a study by Ogeng'o *et al,* that reported the major causes/comorbidities of HF as cardiomyopathy, hypertension, diabetes and valvular heart disease (74).

A large variation of prescribed medications was reported, ranging from two to eight classes of drugs. Majority of the patients were on a loop diuretic or a combination of diuretics, with the most frequently prescribed being furosemide alone or in combination with spironolactone. Other studies done in Korea by Sang Hui *et al,* have posted similar results (32). The second most prescribed drugs were beta-blockers with the carvedilol topping the list. B-blockers are normally used in stable patients. The other classes of prescribed drugs included ACEIs, digitalis, ARBs, vasodilators, anticoagulants and lipids lowering drugs among the overweight patients. ACEIs are indicated as first line therapy in NYHA class I of HF and for the patients suffering left ventricular dysfunction and a reduced ejection fraction as they reduce preload and afterload without causing a reflex sympathetic activation. ARBs are alternatives for the patients who cannot tolerate the ACEIs. Beta blockers are introduced for patient at NYHA class II of HF with structural heart disease with no clinical symptoms of HF. This is meant to minimize further cardiac injury by preventing or slowing the remodeling process. Beta-blockers are therefore key in the management of HF as adjuvant therapy. Diuretics are essential in symptomatic management of CHF especially in the setting of pulmonary congestion. Other therapies are introduced for NYHA class III of HF for the patients who remain symptomatic, these includes: vasodilators, digoxin or cardiac assistive devices (6,38,39,82).

The overall HRQoL score among the participant was below average. Social health domain scored the best. This is an indication that personal relationships and social

support among the participants were good. However, the physical domain scored the lowest, an indication of the detrimental effects of the hallmark symptoms (dyspnoea, fatigue and edema) of the HF on this domain. These symptoms affect mobility, work capacity and cause dependence on medicinal substances and medical aids (7,8). Studies have shown that physical symptom is one major predictor of QoL in HF patients. These symptoms commonly affect various aspects of the patient's lives hence giving a profound adverse impact on the HRQoL (8,32).

The current study identified NYHA functional class, level of education, age, and use of Beta-blockers as the significant factors associated with HRQoL in HF patients. It also identified other predictors including being married, having a source of income, duration of heart failure, good LVEF and living with someone as positively impacting on the HRQoL. However other factors influenced the HRQoL negatively and these includes high BMI, presence of comorbidities, and COPD.

The NYHA categorizes HF into four classes based on the intensity of the physical symptoms. These classes stratify the degree of limitation imposed by the disease on the individual's daily activities. The present study showed that the advanced functional class compromises the HRQoL. This is similar to the findings of other studies by Mailson *et al,* and Viviane *et al,* (20,83). The disease severity impacted on all the health domains.

Improvement in the level of education significantly improved the HRQoL. This is probably due to access to gainful employment thus better financial resources. This would directly enhance the patient's access for healthcare. Also, this would encourage better understanding of the disease process thus improved self-care management by the patient as well as better drug compliance and good health-seeking behavior for health checkups. According to Peters-Klimm *et al,* educated people have lower levels of emotional and physical distress reduced as a result of paid work and economic resources (13). However, other studies have found no association between education background and the HRQoL in HF patients (8,20).

Increase in participant's age was associated with better HRQoL. This was significantly manifested in the psychological health domain. This is probably due to mental maturity

associated with age and therefore better acceptance of one's bodily image and appearance, self-esteem and spiritual inclination. Further, young patients are likely to undergo severe psychological pain, stress and depression due to the debilitating and chronic nature of the disease. Contrary to the current study, Viviane *et al*, found a negative and weak association between the HRQoL and age (20).

Uniquely, this study found out a significant association between the prescription of a beta-blocker and the HRQoL via the positive influence on the environmental health domain. This is probably due to the beneficial effects of the drug in slowing the cardiac remodeling hence delaying the eventual cardiac failure. This offers the patients vitality and health for many years of survival hence participating in finance-generating ventures, maintaining their jobs, and able to participate in recreation/leisure activities.

Being married, living with someone, being employed, and having a higher LVEF improved the HRQoL, although not significant. The presence of comorbidities, especially the COPD, was associated with poor HRQoL (13). Higher BMI too was associated with a poor HRQoL. This is probably due to its negative effect on the physical and psychological health to low self-esteem and dissatisfaction with the bodily image and appearance.

5.3 Conclusion

The most common possible underlying causes in heart failure are hypertension and cardiomyopathy. The majority of the study participants had clinical NYHA functional class II-IV of HF. Their pharmacological therapies predominantly included ACEI/ARB, Beta-blockers, diuretics, ARAs, and cardiac glycosides.

The results indicated that, the HRQoL among heart failure patients was still suboptimal. NYHA functional class, education, age and use of Beta-blockers had positive effect on HRQoL in HF patients. The NYHA class was the single most important predictor on all the health domains. Other modifiable predictors of HRQoL although not found to be significant included BMI, employment, living arrangement, LVEF, and comorbidities.

5.4 Recommendations

5.4.1 Recommendations for policy and practice

1. The finding of the study indicates that, many cases of heart failure are as a result of the complications of the underlying medical conditions such as hypertension and cardiomyopathies. Therefore, strategies to contain the primary conditions should be considered.
2. The severity of the heart failure has a profound outcome on the HRQoL of heart failure patients. Therefore, early diagnosis and treatment of HF should be considered in order to improve their HRQoL.
3. Use of evidence based guidelines for HF treatment on its impact on patient outcomes including HRQoL.

5.4.2 Recommendations for further research

1. Further research to assess the prevalence and etiologies of cardiomyopathy (CMP) among the patients should be done. The CMP was identified as a major etiology in heart failure.
2. Use of a more robust design to address the uncertainties identified in this study.

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APPENDICES

APPENDIX 1: ELIGIBILITY SCREENING FORM

All the subjects to be enrolled must meet eligibility criteria based on the inclusion/exclusion criteria detailed in this form.

(I) Study Information:

Title:	**Health related quality of life and its determinants among heart failure patients on treatment at Kenyatta National Hospital**
KNH/UoN/ERC Protocol Number:	
Principal Investigator:	DR. MARTIN M. MUTIGA

(II) Subject Information:

Subject Name/ID:
Gender: ☐ Male ☐ Female

(III) Inclusion/Exclusion Criteria

Inclusion Criteria	**Yes**	**No**
1. Has the patient been diagnosed with heart failure?	☐	☐
2. Is the patient aged 18 years and above?	☐	☐
3. Is the patient on treatment for heart failure?	☐	☐

4. Is the patient enrolled at KNH cardiac clinic?	☐	☐
5. Has the patient consented to participate in the study?	☐	☐
Exclusion Criteria	**Yes**	**No**
1. Does the patient have any cognitive impairment e.g. dementia, psychosis?		
2. Does the patient have any severe acute illness?		
3. Does the patient have any coexisting terminal illness?		
4. Does the patient fail to meet the inclusion procedure?		

All participants' files must include supporting documentation to confirm subject's eligibility. The method of confirmation can include, but not limited to, radiological results, laboratory test results, subject self-report, and medical record review.

(IV) Statement of Eligibility

This subject is ☐**eligible** / ☐**not eligible** for participation in the study.

Signature:	Date:
Name:	

APPENDIX 2A: CONSENT FORM – *ENGLISH VERSION*

To be read in a language that the respondent understands.

Introduction

I am Dr. Martin Murikinyi Mutiga, from the University of Nairobi. I am currently undertaking my postgraduate studies in Clinical Pharmacy. As part of my postgraduate studies, I am taking a study on health related quality of life and its determinants among heart failure patients on treatment at the Kenyatta National Hospital.

I will be specifically concerned with finding out your prescribed medications, the cause of your heart failure, comorbidities you're suffering from, and I shall assess your quality of life using a questionnaire. This study will enable a comprehensive assessment of your well-being and the impact of heart failure on your quality of life that cannot be adequately assessed by medical outcomes alone.

Procedures involved

If you agree to participate, I will access your medical file and get information on the cause of your heart failure and other clinical parameters related to your condition. I will also administer questionnaires seeking to find out your socio-demographic information and your perception of well-being. All information obtained will be handled confidentially. This will take about 30 minutes.

Your rights as a participant

Your participation in this study is voluntary.

Whether you choose to participate or not will not affect your medical care.

You are free to terminate the interview and withdraw from the study at any time.

You are free to ask questions before signing the consent form and during the study.

None of the information collected will be attributable to you or be traced to you nor shared with any other party. Information gathered will only be used for the purposes of this study.

Risks of participation

There are no risks that you will experience.

There will be no costs incurred by you as the patient should you choose to participate in this study.

Benefits of participation

There will be no direct benefits to you, but all useful information that will improve the quality of care will be shared with your doctor.

Confidentiality

All the information gathered during the study will be kept confidential. Only researchers have access to personal information. Information gathered will be documented and analyzed anonymously.

If you have any question during the course of the study, you may contact the following:

1. Dr. Martin Murikinyi Mutiga,
   Department of Pharmaceutics & Pharmacy Practice,
   School of Pharmacy, University of Nairobi,
   Mobile: 0723313265. ***OR***

2. Dr. P.N. Karimi PhD,
   Department of Pharmaceutics and Pharmacy practice,
   School of Pharmacy, University of Nairobi,
   P.O BOX 19676-00202, Nairobi. ***OR***

3. Chairperson, KNH/UON Ethics and Research Committee,
   Tel: 020-2726300/2716450 Ext 44102,
   Email: uonknh-erc@uonbi.ac.ke
   P.O BOX 20723-00100, Nairobi.

Before I involve you in my study, I request you sign the consent form below.

CONSENT TO PARTICIPATE IN THE STUDY

STUDY NO…… DATE……..…….. TIME……..

I hereby give my written and informed consent to participate in this study on health related quality of life and its determinants among heart failure patients on treatment at the Kenyatta National Hospital. I have been adequately explained to about the study by Dr. Martin Murikinyi Mutiga/his assistant. I do this with the full understanding of the purpose of the study procedures involved which include review of my file records and answering to a study proforma and a questionnaire which have been explained to me. I understand that my rights will be respected, and confidentiality maintained at all times.

I also understand that the consent is voluntary, and I am at liberty to withdraw from the study without my care being affected.

Patient's signature……..

Patient's Name…….……

Investigator's Statement

I, the Principal Investigator/assistant, have fully educated the research participant on the purpose and implication of this study.

Signed…… Date…….

APPENDIX 2B: FOMU YA IDHINI – *TOLEA LA KISWAHILI*

Utangulizi

Mimi ni Dkt. Martin Murikinyi Mutiga kutoka Chuo Kikuu cha Nairobi. Kwa sasa nasomea uzamili katika Famasia ya Kimatibabu. Kama sehemu ya masomo yangu ya uzamifu, ninafanya utathimini wa Ubora wa Maisha na Vigezo vyake baina ya wagonjwa wanaougua Ugonjwa wa Moyo kupungua nguvu katika Hospitali Kuu ya Kenyatta.

Nitajihusisha hasa na utadhimini wa dawa ulizoagizwa kutumia, kinachosababisha moyo wako kupungua nguvu, magonjwa mengine unayougua, na nitatathimini ubora wa maisha kwa kutumia dodoso. Utafiti huu utawezesha tathmini ya kina ya ustawi wako na athari ya kushindwa kwa moyo juu ya ubora wa maisha yako ambayo haiwezi kutosha tathminiwa na matokeo ya matibabu pekee.

Utaratibu

Ukikubali kushiriki, nitapata faili yako ya matibabu na kupata taarifa juu ya chanzo cha kushindwa kwa moyo wako na vigezo vingine vya afya kuhusiana na hali yako. Pia, nitakupea dodoso kwa madhumuni ya kujua habari yako ya kijamii na mtazamo wa ustawi wako. Habari zote zitakazokusanywa zitahifadhiwa kwa siri. Upimio huu utachukua takribani dakika 30.

Haki yako kama mshiriki katika utafiti huu

Ushiriki wako katika utafiti huu ni wa kujitolea.

Hata ukichagua kushiriki au ukatae kushiriki haitaathiri matibabu yako.

Una uhuru wa kujiondoa katika mahojiano na katika utafiti huu wakati wowote.

Una uhuru wa kuuliza maswali kabla ya kutia sahihi katika fomu ya idhini na wakati wa utafiti.

Habari zitakazokusanywa zitawekwa siri na hazitajulikana zimetokana na wewe wala kuwa chanzo chake ni wewe wala hazitapewa mtu mwingine. Habari zitakazokusanywa zitatumika tu kwa madhumuni ya utafiti huu.

Hasara za ushiriki

Hakuna hasara yoyote utakayopitia au kupata.

Hakutakuwa na gharama zitakazotumika na wewe kama mgonjwa iwapo utaamua kujiunga na utafiti huu.

Manufaa ya kushiriki

Hakutakuwa na faida ya moja kwa moja kwako, lakini taarifa zote muhimu zinazoweza kuboresha ubora wa huduma zitakabidhiwa daktari wako.

Siri

Habari zote zitakazokusanywa wakati wa utafiti zitahifadhiwa kwa siri. Ni watafiti pekee ndio wanaoweza kufikia habari za kibinafsi. Habari zitakazokusanywa zitaandikwa na kuainishwa bila kutaja washiriki.

Ikiwa una swali lolote wakati wa utafiti, unaweza kuwasiliana na wafuatao:

1. Dkt. Martin Murikinyi Mutiga,
   Idara ya Dawa na Tiba ya vitendo,
   Shule ya Famasia, Chuo Kikuu cha Nairobi,
   Simu ya mkono: 0723313265. ***AU***

2. Dkt. P.N. Karimi PhD,
   Idara ya Dawa na Tiba ya vitendo,
   Shule ya Famasia, Chuo Kikuu cha Nairobi,
   S.L.P 19676-00202, Nairobi. ***AU***

3. Mwenyekiti, KNH/UON Kamati ya Maadili na Utafiti,
   Nambari ya Simu: 020-2726300/2716450 Ext 44102,
   Barua pepe: uonknh-erc@uonbi.ac.ke
   S.L.P 20723-00100, Nairobi.

Kabla nikuhusishe katika utafiti wangu, nakuomba utie sahihi katika fomu ya idhini ifuatayo:

IDHINI YA KUSHIRIKI KATIKA UTAFITI

NAMBARI YA UCHUNGUZI…….TAREHE……..…..WAKATI…….

Natoa idhini andishi na ninayoifahamu ili kuniruhusu kushiriki katika utafiti huu ambao utatathimini Ubora wa Maisha na Vigezo Vyake baina ya wagonjwa wanaougua Ugonjwa wa Moyo kupungua nguvu katika Hospitali Kuu ya Kenyatta.

Nimepewa maelezo yanayofaa kuhusu utafiti wa Dkt. Martin Murikinyi Mutiga/msaidizi wake. Ninafanya hivi kwa vile naelewa lengo kuu la utafiti huu na taratibu zitakazohusishwa kama vile kuangaliwa kwa maagizo ya daktari na kujibu maswali katika fomu ambayo nimepewa maelezo yake.

Ninaelewa kuwa haki zangu zitaheshimiwa, na suala la kuhifadhi utambuzi wangu utadumishwa wakati wowote.

Pia ninaelewa kuwa idhini ya kushiriki ni ya kujitolea, na nina uhuru wa kujiondoa katika utafiti huu bila kuadhiriwa kwa huduma kwangu.

Sahihi ya Mgonjwa……

Jina la Mgonjwa……..

<u>Kauli Ya Mchunguzi</u>

Mimi, Mchunguzi Mkuu/msaidizi, nimemuelimisha mshiriki wa utafiti kuhusu lengo kuu la utafiti na kinachodokezwa na utafiti huu.

Sahihi ……. Tarehe …….

APPENDIX 3: QUESTIONNAIRE

A. BIODATA

1. Patient code…….
2. Name/Initials……..…..
3. Physical address/Contact…….
4. Date of the study…….

B. SOCIO-DEMOGRAPHIC PROFILES

1. Age {*in year*} ……..
2. Age category (*please tick one)*

Age category (years)	**Code**
18 – 30 **[ ]**	1
31 – 40 **[ ]**	2
Above 41 **[ ]**	3

3. Weight ……..kg. Height……cm
4. BMI

BMI	<18.5	18.5-24.9	25 – 29.9	≥ 30
Code	1	2	3	4

5. Gender { *please tick one* }

Male **[ ]**	Female **[ ]**
0	1

6. Marital status { *please tick one* }

Single **[ ]**	Married **[ ]**
0	1

7. Living arrangement { *please tick one* }

Living with someone **[ ]**	Living alone **[ ]**
0	1

8. Level of formal education { *please tick one* }

	None [ ]	Primary [ ]	Secondary [ ]	Tertiary [ ]
Code	1	2	3	4

9. Employment status { *please tick one* }

	Unemployed [ ]	Employed [ ]
Code	0	1

10. County of permanent residence ……..

11. Do you take alcohol? **Yes [ ] (1) No [ ] (0**)

12. If yes, for how long have you taken alcohol? **…….years**

13. Do you smoke? …… **Yes [ ] (1) No [ ] (0)**

14. If yes, how many years have you smoked?**……..years**

C. CLINICAL PROFILES

15. When were you first diagnosed with this condition?{*please tick one*}

Duration	< 1year [ ]	1-2 years [ ]	2-3 years [ ]	3-4 years [ ]	> 4 years [ ]
Code	1	2	3	4	5

16. Have you been admitted to a hospital for this condition before?{*please tick one*}

	Yes [ ]	No [ ]
Code	1	0

17. Do you have any other illnesses (Comorbidities)?{*please tick one*}

	Yes [ ]	No [ ]
Code	1	0

List of comorbidities (*If response in question 3 is yes*)

S/No	Comorbidity	Present	Absent
18.	Hypertension	1	0
19.	Anaemia	1	0
20.	Sleep disordered breathing	1	0
21.	Chronic kidney disease	1	0
22.	Diabetes mellitus	1	0
23.	COPD	1	0
24.	Breast cancer	1	0
25.	Ischemic heart disease	1	0
26.	Atrial fibrillation or Flutter	1	0
27.	Peripheral artery disease	1	0
28.	Acute coronary syndrome	1	0
29.	Valvular heart disease	1	0
30.	Hyperthyroidism	1	0
31.	Others (Specify)	1	0

If yes, for how long have you suffered from these other illnesses?

S/No	Comorbidity	Duration (years)
32.	Hypertension	
33.	Anaemia	
34.	Sleep disordered breathing	

35.	Chronic kidney disease	
36.	Diabetes mellitus	
37.	COPD	
38.	Breast cancer	
39.	Ischemic heart disease	
40.	Atrial fibrillation or Flutter	
41.	Peripheral artery disease	
42.	Acute coronary syndrome	
43.	Valvular heart disease	
44.	Hyperthyroidism	
45.	Others (Specify)	

D. **CLINICAL PROFILES** {*to be filled by investigator with data from the file*}

S/No		**Please tick one**	**Code**
46.	NYHA Functional Classification	I	1
		II	2
		III	3
		IV	4

S/No		Please tick one	Code
47.	LVEF	< 40%	0
		≥ 40%	1

Etiologies in heart failure {Tick appropriately}

S/No		Present	Absent
48.	Rheumatic Heart Disease	1	0
49.	Hypertension	1	0
50.	Cardiomyopathy	1	0
51.	Pericardial disease	1	0
52.	Cor Pulmonale	1	0
53.	Ischemic Heart Disease	1	0
54.	Congenital Heart Disease	1	0
55.	Other (specify)…….	1	0

56. Number of comorbidities……..

Medications prescribed in heart failure {*Tick and fill appropriately*}

S/No.	**Class**	**Specific drug**	**Code**	**Absent**
57.	ACEIs	Enalapril	1	0
		Captopril	2	0
		Ramipril	3	0
		Lisinopril	4	0
		Fosinopril	5	0
58.	ARBs	Losartan	6	0
		Irbesartan	7	0
		Valsartan	8	0

		Candesartan	10	0
		Telmisartan	11	0
59.	β- Blockers	Carvedilol	12	0
		Atenolol	13	0
		Metoprolol	14	0
		Nebivolol	15	0
		Bisoprolol	16	0
60.	Diuretics	Furosemide	17	0
		Metolazone	18	0
		Chlorthiazide	19	0
		Chlorthalidone	20	0
61.	ARAs	Spironolactone	21	0
		Eplerenone	22	0
		Triamterene	23	0
62.	Vasodilators	Hydralazine	24	0
63.	Nitrates	Isosorbide Dinitrate	25	0
64.	Cardiac glycosides/ Cardiotonic	Digoxin	26	0
		Ivabradine	27	0

65. Number of drugs used……

Classes of drugs

	Class of drug	Present	Absent
66.	ACEIs	1	0
67.	ARBs	1	0
68.	b-Blockers	1	0
69.	Diuretics	1	0
70.	ARAs	1	0
71.	Vasodilators	1	0
72.	Nitrates	1	0
73.	Cardiac glycosides/Cardiotonic	1	0

Domain Scores

	Domain	Score	Code
74.	Physical		0
75.	Psychological		1
76.	Social		2
77.	Environmental		3
78.	Overall QoL		4

APPENDIX 4: Quality of life (WHOQOL-BREF)

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

1. How would you rate your quality of life?

Please circle the number				
Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very Good**
1	**2**	**3**	**4**	**5**

2. How satisfied are you with your health

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

The following questions ask about **how much** you have experienced certain things in the last two weeks.

3. To what extent do you feel that physical pain prevents you from doing what you need to do?

Please circle the number				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

	Please circle the number					
		Not at all	A little	A moderate amount	Very much	An extreme amount
4.	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Please circle the number				
		Not at all	Slightly	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

		Please circle the number				
		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

15. How well are you able to get around?

Please circle the number				
Very poor	**Poor**	**Neither poor nor well**	**Well**	**Very well**
1	**2**	**3**	**4**	**5**

The following questions ask you to say how **good** or **satisfied** you have felt about various aspects of your life over the last two weeks.

		Please circle the number				
		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5
20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5

		Please circle the number				
		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transportation?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

		Please circle the number				
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression**?**	Never	Seldom	Quite often	Very often	Always
		1	2	3	4	5

Did someone help you fill out this form? *(Please circle Yes or No*)

Yes No

How long did it take to fill this form? ……

<u>THANK YOU FOR YOUR HELP</u>

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Table 3.14 Summary of scores

Domains	**Equations for domain scores**	**Actual Raw Score**	**Lowest Possible Score**	**Possible Raw Score Range**	**Transformed Score (%)**
Physical health	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18	=	7	28	=
Psychological health	(6-Q26) + Q5 + Q6 + Q7 + Q11 + Q19	=	6	24	=
Social health	Q20 + Q21 + Q22	=	3	12	=
Environment health	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25	=	8	32	=
Overall QoL	Q1 + Q2	=	2	8	=