

UNIVERSITY OF NAIROBI
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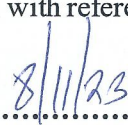
**FUNCTIONAL CAPACITY AND AEROBIC EXERCISE ACTIVITY IN
AMBULATORY PATIENTS WITH HEART FAILURE WITH REDUCED
EJECTION FRACTION AT KENYATTA NATIONAL HOSPITAL**

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**A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE
REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN
INTERNAL MEDICINE**

DECLARATION

This dissertation is my original work and is being presented as a prerequisite for a master's degree to the Department of Clinical Medicine and Therapeutics, University of Nairobi, Kenya. It has not been presented for award of a degree in any other institution. All resources and materials used or quoted have been acknowledged with reference.

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LIST OF ABBREVIATIONS AND ACRONYMS

ACEi	Angiotensin converting enzyme inhibitor
BMI	Body mass index
CPET	Cardiopulmonary exercise test
CMR	Cardiac Magnetic resonance
COPD	Chronic Obstructive Pulmonary Disease
2D ECHO	2-dimension Echocardiography
FC	Functional Capacity
HHF	Hospitalization for Heart Failure
HIV	Human Immunodeficiency Virus
HF	Heart Failure
HFmrEF	Heart Failure with mildly reduced ejection fraction
HFpEF	Heart Failure with preserved ejection fraction
HFrEF	Heart Failure with reduced ejection fraction
KNH	Kenyatta National Hospital
LVEF	Left ventricle ejection fraction
6MWT	Six minute walk test
6MWT	Six minute walk test distance
6MWT	Six minute walk test
NYHA	New York Heart association
PI	Principal investigator
RHD	Rheumatic Heart disease
SSA	Sub Saharan Africa

ABSTRACT

Background: Heart failure (HF) is associated with reduced functional capacity (FC), exercise intolerance and shortness of breath on exertion. FC provides an insight on the prognosis (morbidity and mortality) of patients with HFrEF. Six minute walk test (6MWT) is objective, easy, well tolerated and inexpensive measure of FC in patients with HFrEF. Short six minute walk test distance (6MWTD) less than 300 meters is associated with poor functional capacity, high risk of all-cause mortality, HF mortality and hospitalization for heart failure (HHF). Aerobic exercise activity done at least 150minutes every week in addition to guideline directed medical therapy improves FC, reduces mortality and HHF.

Study objectives: To determine the functional capacity of patients with HFrEF using the six minute walk test and to determine the knowledge and adequacy of aerobic exercise activity status of patients with HFrEF.

Study design: Hospital based cross sectional descriptive study.

Study location: Kenyatta National Hospital (KNH) cardiac clinic.

Study population and cases: Patients attending the cardiac outpatient clinic at KNH with HF fulfilling the Framingham diagnostic requirements and with a 2-dimension echocardiogram derived left ventricle ejection fraction (LVEF) less than 40%.

Methods: Six hundred patients were seen in the cardiac outpatient clinic in the three month study period. One hundred and ninety two patients had a diagnostic label of HFrEF and met the Framingham criteria requirements for diagnosis of HF. Fifty seven patients were excluded based on the exclusion criteria. One hundred and thirty five patients consented and were included in the study. A researcher administered study proforma was used to collect data on sociodemographic and clinical characteristics, knowledge and adequacy of aerobic exercise activity. Six minute walk test was performed based on the American Thoracic Society guideline, 2002.

Results: One hundred and thirty five patients were recruited in this study. Ninety patients (66.7%) had very low performance in the six minute walk test, 37 (27.4%) had low performance and 8 (5.9%) had middle performance. No patient had high performance. Thirty seven (27.4%) of patients had been informed of aerobic exercise activity as part of the care for HF; 33 (89.2%) were informed verbally during one-on-one interaction with a doctor during routine clinic visits. Of all recruited patients, 25 (18.5%) engaged in aerobic exercise activity. The main type of aerobic exercise activity was brisk walking in 21 (84.0%) of patients. Twelve patients (32.4%)

were informed of aerobic exercise activity but did not engage, 9 patients citing fear of exercise with a 'failing heart' as the commonest reason. Fifteen patients (60%) did not engage in aerobic exercise activity for more than 30 minutes per session, more than 5 sessions per week and more than 150 minutes per week.

Conclusion: Two thirds of patients with heart failure with reduced ejection fraction had poor functional capacity evidenced by very low performance on six minute walk test. There was inadequate knowledge and health education on the benefits of aerobic exercise activity as an adjunct to medical therapy in patients with HFrEF. Sixty percent of patients had inadequate aerobic exercise activity.

CHAPTER ONE: INTRODUCTION

Patients with HFrEF have reduced functional capacity, exercise intolerance and shortness of breath on exertion. The utility of the six minute walk test in patients with heart failure has been studied extensively. A meta analysis on the prognostic value of the 6MWD in patients with HF suggests that short six minute walk test distance is associated with high risk of all-cause mortality and HHF and advocates for its use in stratification of adverse outcomes in patients with heart failure (1).

The six minute walk test is an objective, relatively easy, well tolerated and inexpensive way of assessing functional capacity, evaluation of effectiveness of therapy and prognostic stratification of patients with chronic heart failure (2). Single measurement of the six minute walk test distance is used to determine functional capacity and for prognostic stratification of patients with HFrEF (3). Other assessment modalities of functional capacity include the New York Heart Association (NYHA) classification which is subjective and cardiopulmonary exercise test (CPET) which is expensive, requires specialized machinery and trained personnel to perform.

A 6MWD of less than 300m is associated with increased mortality, non-fatal cardiovascular events and HHF (2) (4) (5).

The American College of Cardiology/American Heart Association advocates use of the six minute walk test in assessing functional capacity in ambulatory patients with HF (6).

Aerobic exercise training is an important adjunct to optimal medical therapy in patients with HFrEF to improve functional status, reduce mortality and hospitalization for Heart Failure (HHF). The American Heart Association and the Heart Failure Society of America recommend moderate intensity aerobic exercise activity that includes brisk walking, jogging, swimming, jumping rope or cycling at least five sessions every week, at least 30 minutes every session for a total of at least 150 minutes every week to improve functional capacity, reduce mortality and HHF in patients with HFrEF (7) (8).

This study aims to determine the functional capacity and aerobic exercise activity status of patients with HFrEF in KNH.

CHAPTER TWO: LITERATURE REVIEW

2.1 Heart failure

2.1.1 Definition of Heart failure

Heart Failure (HF) is a clinical syndrome characterized by typical symptoms of breathlessness, ankle swelling and fatigue accompanied by signs of elevated jugular venous pressure, pulmonary crackles and peripheral edema caused by a structural and/or functional cardiac abnormality causing a reduced cardiac output and/or increased intra cardiac pressure at rest or during stress (9).

2.1.2 Types of HF

There are three main groups of HF based on the left ventricle ejection fraction measured by Echocardiography, radionuclide studies or cardiac magnetic resonance, namely Heart Failure with reduced ejection fraction (HFrEF) less than 40%, Heart Failure with mildly reduced ejection fraction (HFmrEF) 41 to 49% and Heart Failure with preserved ejection fraction (HFpEF) more than or equal to 50% (9).

2.1.3 Epidemiology of HF

In the year 2017, 64.3 million cases of HF were reported worldwide. Of the 64.3 million cases, 29.5 million were male and 34.8 were female. The combined male and female global age standardized prevalence rate was 831/100000. Regional differences have been observed in the age standardized prevalence rates. In the United States of America (USA), the age standardized prevalence rate was 960.4/100000, 1058.1/100000 in Europe, 870.9/100000 in South Asia and 700/100000 in Eastern Sub Saharan Africa. In Kenya, the age standardized prevalence rate of HF was 702.7/100000 (10).

In the year 2009 at KNH, the 6 month prevalence of HF in patients admitted to the medical wards was 5.7% (11).

Globally, ischemic heart disease accounts for the largest percentage (26.5%) of the age standardized prevalence rate of HF, followed by hypertensive heart disease 26.2%, COPD 23.4%, other cardiomyopathies 6.2%, non-rheumatic degenerative valve disease; mitral 2.7%, aortic 1.7%, alcohol cardiomyopathy 2.4%, rheumatic heart disease 1.8% and myocarditis 1.7% (10). In Sub Saharan Africa (SSA), the common etiologies of HF are hypertensive heart disease,

39.2%, dilated cardiomyopathy, 22.7% and rheumatic heart disease, 13.8%. Ischemic heart disease accounts for 7.2% of the HF cases (12).

Globally, the prevalence of HF increases with age with a peak of 70 to 74 years in male patients and 75 to 79 years in female patients (10). In SSA, the mean age at presentation for both sexes ranges from 36.5 to 61.5 years (12). In KNH, the mean age of patients admitted in the medical wards with acute HF in the year 2009 was 44years (11).

The THESUS-HF study evaluated gender differences in clinical profiles and outcomes of patients with HF in SSA. The study showed a 60.4% and 65.5% prevalence of HF with left ventricle ejection fraction less than 45% among male and female patients respectively. Male patients were older (54 years) compared to female patients (50.7years), had an advanced NYHA class (5.5% in NYHA IV compared to 2.9% in the same class for female patients) and were likely to be previous of current cigarette smokers (17.3% compared to 2.6% in female patients). Chronic Kidney Disease (CKD) and hypertension was more common in male patients while atrial fibrillation and anemia was more common in female patients (13).

In the USA, approximately 50% of patients with HF have a left ventricle ejection fraction less than 40% (14). In Europe, a similar prevalence of HF rEF is observed. In SSA, 53.7% of patients with HF have a LVEF less than 40% (15).

Obesity, diabetes mellitus, sedentary lifestyle and physical inactivity, cigarette smoking and dyslipidemia have been identified as cardiovascular risk factors in HF (14). Sedentary lifestyle and physical inactivity are modifiable risk factors that are the leading cause of cardiovascular disease and all-cause mortality (16) and are negatively associated with functional capacity among patients with HF (17). Hypertensive heart disease, cardiomyopathies including peripartum and alcohol cardiomyopathies and rheumatic heart disease are common etiological risk factors for HF in SSA (12).

In SSA, patients with HF have other coexisting medical conditions such as chronic kidney disease, Diabetes mellitus, HIV, Hypertension, Anemia and Atrial Fibrillation. These are associated with increased HFrEF and all-cause mortality (12) (15).

2.1.4 Decreased functional capacity and exercise intolerance in HFrEF

Decreased functional capacity refers to a diminished ability to perform activities of daily living and occupational tasks (18).

In HFrEF, there is reduced cardiac output and reduced tissue perfusion. This leads to a compensatory activation of the neurohormonal system, including the renin angiotensin aldosterone system, that negatively impacts the endothelial, skeletal and respiratory systems. Reduced production of nitric oxide and increased production of reactive oxygen species leads to vasoconstriction and tissue hypoperfusion. Hypoperfusion to skeletal muscles leads to anaerobic metabolism, reduced muscle strength and endurance and subsequent muscle atrophy. Hypoperfusion to the respiratory muscles causes exertional dyspnea that also contributes to decreased functional capacity (19).

With decreased functional capacity, exercise intolerance emerges (20). Exercise intolerance is defined as reduced ability to carry out activities that involve dynamic movement of large groups of skeletal muscles due to attendant symptoms of dyspnea and fatigue (21). During exercise, the skeletal muscles experience enhanced vasoconstriction, downregulation of endothelial vasodilatation and elevated venous pressure that impair muscle pumping function and blood flow. Intrinsic muscle abnormalities also exist in patients with HFrEF resulting in anaerobic metabolism at rest and during exercise (22). HFrEF also reduces muscle oxygen diffusion conductance (23).

The NYHA classification has been extensively used to assess FC in patients with HFrEF. It is a subjective measure of functional capacity and poorly discriminates patients across the spectrum of functional capacity (24). The CPET is the gold standard for assessment of functional capacity in these patients but is expensive and requires specialized equipment and trained personnel to perform. The six minute walk test is an objective, easy, well tolerated and inexpensive test to assess the FC of patients with HFrEF.

2.1.5 Prognosis of patients with HFrEF and decreased functional capacity

The OPTIMIZE-HF study evaluated the clinical characteristics, treatment and outcomes of patients hospitalized with HFrEF. The in hospital mortality rate for patients with HFrEF was 3.9%. HHF 60 to 90 days after discharge from hospital was 29.9%. Mortality rate 60 to 90 days after discharge from hospital was 9.8% (25). The one year mortality rate for patients with HFrEF was 37.5% and HHF rate was 30.9% (26).

The ARIC study evaluated the incidence and survival of patients with HFrEF. The thirty day, one year and five year Case Fatality Rates after HHF were 10.4%, 22% and 42.3% respectively (27).

In Europe, in hospital mortality of patients hospitalized with HFrEF was 6% (28). HHF 90 days after discharge from hospital was 21% and mortality rate 90 days after discharge from hospital was 12% (29). The one year combined all-cause mortality and HHF rate for patients with HF was 36% (30).

The INTER-CHF study evaluated the variations in mortality among patients with HFrEF in Africa, India, South East Asia, China, South America and Middle East. The overall all-cause mortality at 1 year among patients with HF in the six regions was 16.5% with variation noted in the different geographic regions. The all-cause mortality at 1 year in patients with HF in Africa was 34%, 23% in India, 15% in South East Asia, 7% in China, 9% in South America and 9% in Middle East (31).

In Sub Saharan Africa, the in hospital mortality rate among patients admitted with acute HF was 4.2%. Death or HHF rate at 60 days was 15.4%. Mortality rate at 180 days was 17.8% (32).

In KNH, mortality rate among hospitalized patients with acute HF in the medical wards was 10.7% (11).

2.1.6 Benefits of aerobic exercise activity in HFrEF

Aerobic exercise is activity performed at an intensity allowing metabolism of stored energy to occur through aerobic glycolysis and has to be structured, repetitive, purposeful and intentional (33).

Traditionally, rest was recommended for patients with HF. It has however been noted that physical deconditioning plays a role in progression of symptoms and poor outcomes. Aerobic exercise is recommended as a modality for exercise training in patients with HFrEF (34).

Aerobic exercise training in patients with HFrEF leads to reduced autonomic and neurohormonal activation, improvement of endothelial function, reduction of circulating levels of pro inflammatory cytokines, increased muscle oxidative capacity and reduced oxidative stress (35).

The net effect is an improvement in functional capacity and exercise tolerance.

Aerobic exercise reduces the risk of HHF in patients with HFrEF. The European Society of Cardiology recommends (class 1A) regular aerobic exercise to improve functional capacity and symptoms in patients with HFrEF and to reduce risk of HHF (9).

The HF-ACTION trial tested the efficacy and safety of exercise training in addition to usual care in patients with HFrEF. Among the patients on aerobic exercise training in addition to usual care, there was a 13% reduction in the combined endpoint of cardiovascular mortality and HHF compared to the patients on usual care. Exercise was well tolerated and safe (34).

In a Cochrane review by Long et al on exercise based cardiac rehabilitation for adults with HFrEF, the patients on standard therapy and aerobic exercise had reduced all-cause mortality, all cause hospitalization and HHF compared to those on standard therapy alone (17.2% versus 19.6%, 16.5 versus 23.7% and 7.1% versus 11.1% respectively) (36).

The ExTraMATCH trial assessed the effect of exercise training in patients with HFrEF. Mortality was reduced by 35% and the combined endpoint of mortality and hospitalization was reduced by 28% (37).

Aerobic exercise training improves left ventricle function and remodeling in patients with HFrEF post myocardial infarction by 12% (38).

A meta-analysis of the effect of exercise training on left ventricle remodeling in patients with HFrEF showed improvement in ejection fraction (weighted mean difference 2.59%), reduction in left ventricle end diastolic volume (-9.75ml) and reduction in left ventricle end systolic volume (-12.87ml). These effects occurred independent of the use of medications that have anti remodeling effects on the left ventricle (39).

The World Health organization (WHO) recommends that adult patients aged 18 to 64 years with HF should engage in moderate intensity aerobic physical activity that includes brisk walking, running, cycling, jumping rope or swimming for at least 30 minutes every day for five days a week, to achieve a total of at least 150 minutes of physical activity every week (40).

The American Heart Association and Heart Failure Society of America recommends moderate intensity aerobic exercise activity for at least 30 minutes per session, at least five sessions every week for a minimum of 150 minutes every week in addition to drug therapy in patients with HFrEF to improve functional capacity, reduce mortality and HHF (7) (8).

Despite these recommendations, Pozehl et al notes that 40 – 91% of patients with HFrEF have inadequate aerobic exercise activity (41) and the reasons given for inadequate aerobic exercise

uptake included lack of motivation, lack of energy, presence of physical symptoms and fear of increasing physical activity with a failing heart. In addition to patient related factors, WHO cites health system factors, social and economic factors, condition related factors and therapy related factors as barriers to long term therapies for chronic illness including HF.

Patients with HF_{rEF} and reduced FC are at increased risk of mortality and HHF. Aerobic exercise activity improves FC and exercise intolerance that results in reduced mortality and HHF.

2.2 Six minute walk test (6MWT)

2.2.1 Background

In the year 1985, Guyatt et al reported that the 6MWT was a safe and simple measure of functional exercise capacity in patients with chronic HF (42).

In the year 1987, Lipkin et al concluded that the 6MWT was an objective test for assessment of exercise capacity in patients with HF (43).

The primary outcome of the 6MWT is the six minute walk distance (44).

2.2.2 Standardization of the six minute walk test

Guyatt et al, in 1984, noted that differing encouragement statements during the six minute walk test significantly affected the distance walked and recommended its standardization.

In 2002, the American Thoracic Society published the first guideline on patient selection, indications, contraindications, step by step protocol, standard minute by minute encouragement, factors that influence results and equipment to be used in adults during the six minute walk test (45).

2.2.3 Technical aspects of the six minute walk test (45)

The six minute walk test is performed on a long, flat, straight, enclosed corridor with a hard surface. The course must be 30metres long and should be marked every 3 meters. The turnaround points are also marked. The starting point is marked using bright colored tape. The patient should have comfortable clothes and shoes. Use of usual walking aids is accepted and usual medication should be taken. The patient should not have exercised vigorously two hours prior to the test. The patient should sit near the starting point for approximately 10minutes where

the baseline characteristics are recorded according to the worksheet. The patient is then instructed to walk back and forth along the marked corridor for six minutes with rest allowed but the timer is not stopped. The technician administering the test demonstrates by walking one lap. Standard phrases of encouragement are given to the patient every minute. After completion, posttest parameters are recorded according to the work sheet, the patient is congratulated and thanked.

2.2.4 Strengths of the six minute walk test

The six minute walk test is easy to perform, reproducible and inexpensive. It reproduces the activity of daily living and has good correlation with peak oxygen uptake from cardiopulmonary exercise testing (46).

2.2.5 Determinants of the six minute walk test

Age, sex, weight, height, race, ethnicity of patients and methodology used for the 6MWT influence the six minute walk distance (44). Impaired cognitive function, acute myocardial infarction or unstable angina in the previous month and significant musculoskeletal disorders like arthritis are absolute contraindications of undertaking the test (45). Reference equations that take into consideration the named determinants have been generated and verified from healthy populations to come up with normal six minute walk test distances (44). Equations developed in Europe and the USA from healthy adults give a normal six minute walk test distance of 400 meters to 700 meters (45).

In Nigeria, reference equations for the six minute walk distance (6MWD) were developed from healthy adults without cardiovascular, pulmonary or musculoskeletal disorders aged above 21 years (47). The equations are shown below.

$$6MWD_{Male} = [153.142 \times Height_{(m)}] - [1.595 \times Age_{(years)}] + 336.585 \text{ (SEE = 61.713, } R = 0.367)$$

$$6MWD_{Female} = 1253.862 - [406.447 \times Height_{(m)}] - [1.010 \times Age_{(years)}] - [7.890 \times Weight_{(kg)}] - (23.551 \times BMI) \text{ (SEE = 50.856, } R = 0.542)$$

Figure 1 Reference equations for the 6MWD in healthy Nigerian adults

The normal six minute walk distance based on the above equation from Nigeria for healthy male participants is 481 meters to 616.8 meters and 422.6 meters to 542.4 meters for female participants (47).

The American Thoracic Society developed a standard protocol on the methodology to be followed when conducting the six minute walk test (45). This mitigates against the variability in the 6MWD that arises when different protocols are used.

2.3 Six minute walk test distance and impact on outcome in HFrEF

Mortality and morbidity increases with decreasing distance walked.

A six minute walk distance less than 300 meters is associated with increased mortality, non-fatal cardiovascular events and HHF (2).

A study carried out in Turkey in 2007 on the prognostic value of the six minute walk test in stable outpatients with heart failure with reduced ejection fraction showed increased mortality in patients who walked a distance less than 300 meters compared to those who walked more than 300 meters (79% versus 7%) (4).

A study done in Italy in 2003 on the prognostic value of the six minute walk test in patients with mild to moderate heart failure with reduced ejection fraction showed increased mortality in patients who walked less than 300 meters compared to those who walked more than 300 meters (38% versus 18%) (48).

The SOLVD Registry sub study by Bittner et al done in USA, Canada and France assessed the usefulness of the six minute walk test in patients with left ventricle systolic dysfunction as a prognostic marker of mortality and hospitalization. Patients were stratified into four groups based on the distance walked; very low performance less than 300m (level 1), low performance 300m-374.5m (level 2), middle performance 375m-449.5m (level 3) and high performance more than 450m (level 4). Patients in level 1 had a 3.7-fold increase in risk of death (10.23%) compared to patients in level 4 (2.99%). Patients in level 2 had a 2.78-fold increase in risk of death (7.88%) compared to patients in level 4. The risk of death in level 3 patients was 4.19%. Hospitalization increased as the distance walked decreased. HHF was significantly increased (22.16%) in level 1 patients, 11.2% in level 2 patients, 3.72% in level 3 patients and 1.99% in level 4 patients (49).

Our study will classify patients based on the six minute walk test distance according to the four groups by Bittner et al.

2.4 Justification of study

In Kenyatta National Hospital, the prevalence of HF is 5.7% among hospitalized patients in the medical wards with a six month mortality rate of 10.7% (11). Functional capacity is a major determinant of patients perceived quality of life and is also a predictor of morbidity and mortality among patients with HFrEF. In KNH, functional capacity is routinely assessed using the NYHA classification, a subjective measure. The six minute walk test is an objective and standardized measure of FC in patients with HFrEF. Based on the distance walked, the patients with very low, low and middle performance are considered to have poor functional capacity and at risk of mortality and HHF. Guideline recommended aerobic exercise training in addition to optimal medical therapy in patients with HFrEF improves functional capacity and quality of life and reduces HHF and mortality by 13% (34). There are no studies in Kenya on objective assessment of functional capacity using the six minute walk test and aerobic exercise activity among patients with HFrEF.

CHAPTER THREE: METHODOLOGY

3.1 Study Objectives

3.1.1 Broad objective

To assess the functional capacity and aerobic exercise activity status of ambulatory patients with HFrEF at Kenyatta National Hospital.

3.1.2 Primary Objectives

- i. To determine the functional capacity of ambulatory patients with HFrEF based on the six minute walk test performance.
- ii. To determine the knowledge and adequacy of aerobic exercise activity in ambulatory patients with HFrEF based on the American Heart Association guideline recommendations.

3.2 Study Design

This was a hospital based cross sectional descriptive study.

3.3 Study Area

KNH is a tertiary national referral hospital offering inpatient and outpatient services and specialized care. The study was conducted at the cardiac outpatient clinic that runs every Tuesday morning. Approximately 60 patients are reviewed in the clinic, totaling 240 patients every month.

3.4 Study Population

HFrEF patients attending the cardiac outpatient clinic.

3.5 Definition of Cases

Patients on follow-up in the cardiac clinic for HF, fulfilling the Framingham diagnostic requirements and with a 2D Echocardiogram derived left ventricle ejection fraction less than 40%.

3.6 Eligibility criteria

3.6.1 Inclusion Criteria

- Patients aged 18 years and above
- Patients who gave informed written consent.

3.6.2 Exclusion Criteria

- Patients with documented significant musculoskeletal disorder and/or cognitive dysfunction.
- Patients who have suffered an acute coronary syndrome in the month prior to recruitment into the study
- Patients seen in the clinic two weeks after hospitalization for acute decompensated HFrEF.

3.7 Sample Size Determination

The formula by Daniel WW (1999) was used for calculating the sample size for a prevalence study based on a simple random sample without replacement and finite population correction (50).

$$n' = \frac{NZ^2P(1-P)}{d^2(N-1)+Z^2P(1-P)}$$

Where,

n' = sample size with finite population correction

N = population size, 230 (Data from the records office)

Z = Z statistic (equal to 1.96 for a 95% confidence level)

P = 21% of patients with HFrEF had very low performance on the 6MWT. (Bittner et al)

d = precision, 0.05

Solving for the sample size equation:

$$n' = \frac{230 \times 1.96^2 \times 0.21(1-0.21)}{0.05^2 \times (230-1) + 1.96^2 \times 0.21(1-0.21)}$$

n' = 122 patients. Adjusted the sample size by 10% to cover for attrition

Final sample size = 135 patients

3.8 Sampling Procedure

Consecutive sampling technique was utilized in this study until the 12th patient was recruited on each clinic day due to logistical issues.

3.9 Recruitment and Consenting Procedure

Approximately 60 patients were reviewed in the cardiac outpatient clinic every Tuesday morning. The files of the patients who were booked for the clinic were available on the Monday afternoon preceding the clinic. The principal investigator (PI) went to the outpatient records desk every Monday afternoon and perused all the files of the patients booked for review in the clinic the following day. All patients with a diagnostic label of HF and a 2D echocardiogram report of a left ventricle ejection fraction less than 40% were identified. The PI then determined the patients who were eligible for inclusion into the study. Consecutive sampling technique was applied until the required sample size was achieved.

On the clinic day, one of the assistants briefed the potential study subjects about the study. Those willing to participate in the study were recruited upon giving written informed consent.

3.10 Outcome Variables

- Functional capacity as measured by the six minute walk test distance in meters. The normal six minute walk distance for healthy male is 481 to 616.8 meters and for healthy female is 422.6 to 542.4 meters. Categorization of distance walked was as follows; Very low performance less than 300 meters, low performance 300 to 374.5 meters, middle performance 375 to 449.5 meters, and high performance more than 450 meters.
- Knowledge of aerobic exercise activity. Awareness of benefit of aerobic exercise activity in patients with HFrEF.
- Adequacy of aerobic exercise training. Aerobic exercise training includes brisk walking, cycling, swimming, jumping rope and running undertaken by patients with HFrEF for at least thirty minutes per session at least five sessions every week. Those who exercise less than 150 minutes every week were considered to have inadequate aerobic exercise activity.

3.11 Logistics of carrying out the six minute walk test

Three research assistants were available for the study. One assistant recruited the patients in the cardiac clinic and administered the study data proforma. Another assistant escorted the recruited patients to the study site and ensured the requisite preparation for the six minute walk test in line with the American Thoracic Society recommendation was done, aided by the third assistant. The PI supervised the six minute walk test. The approximate time taken for the six minute walk test for each patient from recruitment to completion was 20 minutes. 12 patients were recruited on each clinic day between 9 am and 1 pm. The study was done over a period of 12 weeks.

3.12 Data Collection Procedures

Upon giving informed consent, demographic and clinical data, knowledge and adequacy of aerobic exercise activity was collected through the researcher administered study proforma. Patients were escorted to the site where the six minute walk test was carried out, on the first floor along a corridor beside the cardiology unit that has minimal human traffic. The requisite preparation for the test was carried out by two assistants according to the American Thoracic Society recommendations. A 30 meters walking course was marked with turnaround points. The timer was set to six minutes and the lap counter was set to zero. The principal investigator then explained to the patient the aim of the test was to walk as far as possible back and forth for six minutes without running around the marked turnaround points, pausing or resting was permitted if they got tired. The principal investigator demonstrated by walking one lap. The study subject then proceeded with the test when ready, supervised by the PI. After every minute, a standard phrase of encouragement was given, for example "you are doing well, you have 5 minutes to go". If the patient stopped to rest, the timer was not stopped. When the timer buzzed at the end of six minutes, the patient was instructed to stop walking. They were offered a seat and the distance walked was recorded. The patient was congratulated and thanked.

3.13 Training procedures

Three assistants were trained on how to recruit the patients, fill out the study proforma and prepare the patients prior to undertaking the six minute walk test.

3.14 Quality Assurance

The six minute walk test was carried out as per the protocol outlined by the American Thoracic Society.

The PI supervised the six minute walk test throughout the study.

The study proforma was translated to Kiswahili for ease of communication with patients.

3.15 Ethical Consideration

The study was conducted after approval by the Department of Clinical Medicine and Therapeutics of the University of Nairobi and the Kenyatta National Hospital ethics and research committee.

Before recruitment into the study, all eligible patients received information concerning the purpose of the study in lay terms and a signed consent was obtained.

The six minute walk test carried out in the study subjects was relevant based on the current scientific understanding of the assessment of patients with heart failure with reduced ejection fraction.

The recruited patients were free to withdraw from the study at any time during the study period without discrimination.

Patient confidentiality was maintained at all time.

Results were communicated back to the patients and their medical teams.

Patients usual care was not interrupted by this study

Health education on the benefits of aerobic exercise activity was offered to the recruited patients.

3.16 Data Management

Collection of data was done by the principal investigator and three qualified assistants. Data was entered in predesigned data collection tools. It was checked by the principal investigator for completeness, logical errors and missing data and corrections was done on site before being stored in box files strictly using patient study identification numbers. The box files were then taken to the data entry office. A data entry template designed using SPSS version 241 (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp) was used for data entry.

3.17 Statistical analysis

Data entered, deidentified and cleaned was imported into Stata Version 17 (StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC) for analysis. Descriptive analysis was done using frequencies (percentages) for categorical variables such as distance walked and exercise training activity status. Means (standard deviations) and medians (interquartile ranges) were used as appropriate for continuous variables such as age, blood pressure, oxygen saturation and resting heart rate. Descriptive statistics were presented in tables and graphs.

Functional capacity based on 6MWT distance walked; Number of patients per category (Very low performance, Low performance, Middle performance, High performance)/Total patients. Expressed as percentages, with Confidence Interval.

Knowledge of aerobic exercise activity; Number of patients informed of aerobic exercise/Total patients. Expressed as percentage.

Adequacy of aerobic exercise activity; Number of patients who exercise per category (Less than 150 minutes per week, More than 150 minutes per week)/Total patients. Expressed as percentages.

CHAPTER FOUR: RESULTS

Six hundred patients attended the cardiac outpatient clinic during the 12 week study period between 6th November 2022 and 23rd January 2023. One hundred and ninety two patients had a diagnostic label of heart failure with 2D echocardiogram derived ejection fraction less than 40 and fulfilled the Framingham criteria requirements for diagnosis of heart failure. Fifty seven patients were excluded from the study; 8 had suffered an acute myocardial infarction in the month prior, 14 had documented musculoskeletal disease, 8 had cognitive impairment and 27 had been admitted to hospital with acute decompensated heart failure two weeks prior to attending clinic. No patient declined informed written consent. One hundred and thirty five patients were recruited into the study (Figure 2).

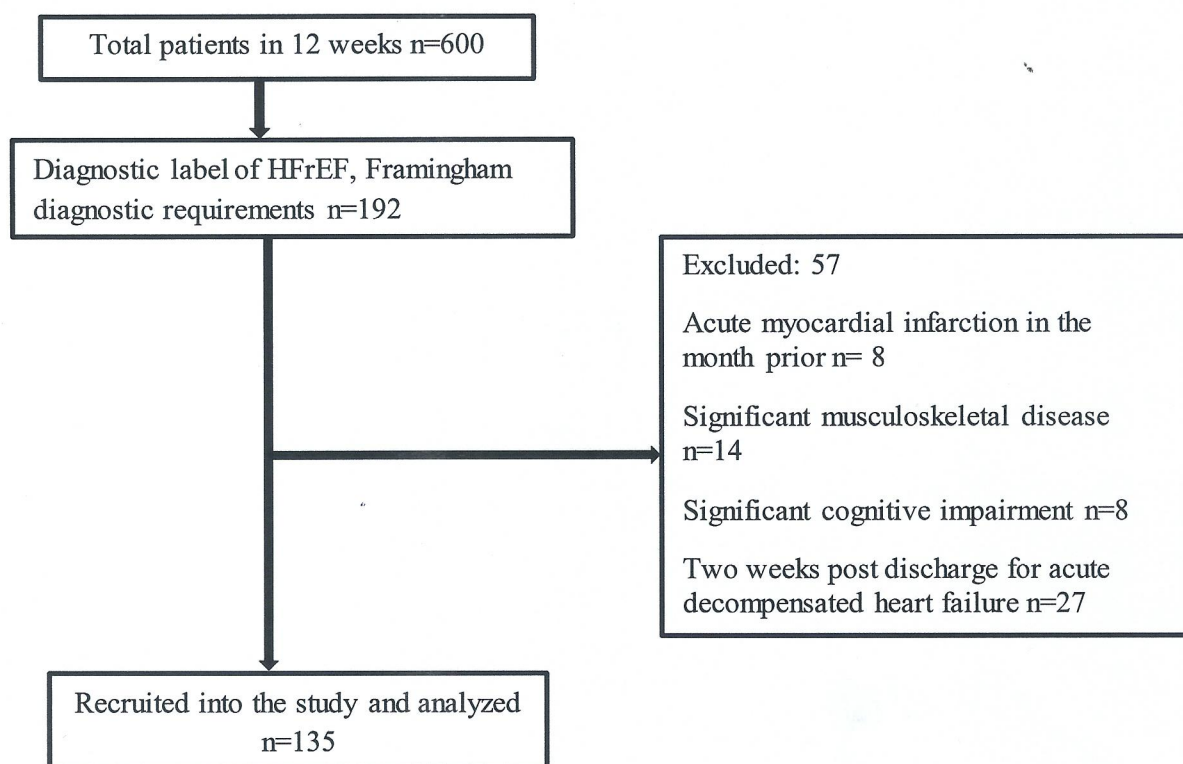


Figure 2 Study flow diagram

4.1 Sociodemographic characteristics of patients

Seventy five patients (55.6%) were female. The mean age was 49.9 years (SD 13.7) and 40 (29.6%) were aged between 40 to 49 years. Fifty six patients (41.5%) were self-employed, 68 (50.4%) had secondary level of education, 97 (71.9%) were married and 96 (71.1%) had health insurance cover as shown in table 1.

Table 1 Sociodemographic characteristics

Sociodemographic characteristics n (%)	Total 135 (100.0)
Sex, n (%)	
Male	60 (44.4)
Female	75 (55.6)
Age, mean (sd)	49.9 (13.7)
Age Category, n (%)	
<30	11 (8.1)
30- ≤40	15 (11.1)
40- ≤50	40 (29.6)
50- ≤60	27 (20.0)
60- ≤70	28 (20.7)
70- ≤80	14 (10.4)
Occupation , n (%)	
Employed	33 (24.4)
Unemployed	36 (26.7)
Self employed	56 (41.5)
Retired	10 (7.4)
Education, n (%)	
Tertiary	31 (23.0)
Secondary	68 (50.4)
Primary	33 (24.4)
None	3 (2.2)
Marital status, n (%)	
Single	20 (14.8)
Married	97 (71.9)
Divorced	6 (4.4)
Widowed	12 (8.9)
Health Insurance, n (%)	
Yes	96 (71.1)
No	39 (28.9)

sd - standard deviation

4.2 Clinical characteristics of patients

The mean resting blood pressure was 121/77mmHg, mean resting heart rate was 84/minute (sd 13.6) and mean oxygen saturation was 94% (sd 2.6) as shown in Table 2. Forty seven patients (34.8%) had a healthy weight, 50 (37%) were overweight and 38 (28.2%) were obese. Twenty patients (14.8%) smoked cigarettes. Hypertension was a documented comorbidity in 76 (56.3%) of the patients, diabetes mellitus in 19 (14.1%), chronic kidney disease in 16 (11.9%), HIV in 3 (2.2%) while 33 (24.4%) did not have any documented comorbidity. Ten patients (7.4%) had other documented comorbidities as anemia, atrial fibrillation, tuberculosis and cancer. Twenty eight patients (20.7%) were in NYHA functional class I, 91 (67.4%) were in NYHA functional class II and 16 (11.9%) were in NYHA functional class III. No patient was classified as NYHA class IV. With respect to heart failure etiological label, 42 (31.3%) had hypertensive heart disease, 62 (46.3%) had dilated cardiomyopathy, 18 (13.4%) had rheumatic heart disease and 8 (6.0%) had ischemic heart disease. Four patients (3.0%) had other documented etiologies as congenital heart disease and chemotherapy induced. The mean LVEF was 26.7% (sd 8.1); 28 (20.7%) had a LVEF less than 20%, 53 (39.3%) had a LVEF 20 to less than 30% and 54 (40.0%) had a LVEF 30 to less than 40%.

Table 2 Clinical characteristics of patients

Clinical characteristics n (%)	Total 135(100.0)
Resting systolic Blood pressure, mean (sd)	121 (21.2)
Resting diastolic Blood pressure, mean (sd)	77 (13.0)
Resting blood pressure Category, n (%)	
Normal	90 (66.6)
Elevated	45 (33.3)
Resting heart rate, mean (sd)	84 (13.6)
Oxygen saturation %, mean (sd)	94 (2.6)
BMI (kg/m ²), n (%)	
Healthy weight	47 (34.8)
Overweight	50 (37.0)
Obesity 1	36 (26.7)
Obesity 2	2 (1.5)
Cigarette smoking, n (%)	
Yes	20 (14.8)
No	115 (85.2)
Comorbidity *, n (%)	
Hypertension	76 (56.3)
Diabetes mellitus	19 (14.1)
CKD	16 (11.9)
HIV	3 (2.2)
Other	10 (7.4)
None	33 (24.4)
NYHA Class, n (%)	
I	28 (20.7)
II	91 (67.4)
III	16 (11.9)
Heart Failure etiological label, n (%)	
DCM	62 (46.3)
Hypertensive Heart Disease	42 (31.3)
Rheumatic Heart Disease	18 (13.4)
Ischemic Heart Disease	8 (6.0)
Other	4 (3.0)
Left ventricle ejection fraction, mean (sd)	26.7 (8.1)
Left ventricle ejection fraction category, n (%)	
≤20%	28 (20.7)
20-≤30%	53 (39.3)
30-≤40%	54 (40.0)

sd - standard deviation

* Percentages add up to more than 100% due to multiple response

4.3 Functional capacity based on Six minute walk test (6MWT) Performance

All one hundred and thirty five patients undertook the six minute walk test. Functional capacity based on six minute walk test performance was classified as very low performance: distance walked less than 300 meters, low performance: distance walked 300-374.5 meters, middle performance: distance walked 375-449.5 meters and high performance: distance walked more than or equal to 450 meters.

The mean six minute walk test distance was 257.3 meters (sd 76.9).

Ninety patients (66.7%) had very low performance (95% CI, 58.0%-74.5%), 37 (27.4%) had low performance (95% CI, 20.0%-35.8%) and 8 (5.9%) had middle performance (95% CI, 2.6%-11.3%) as shown in Figure 3. No patient had high performance.

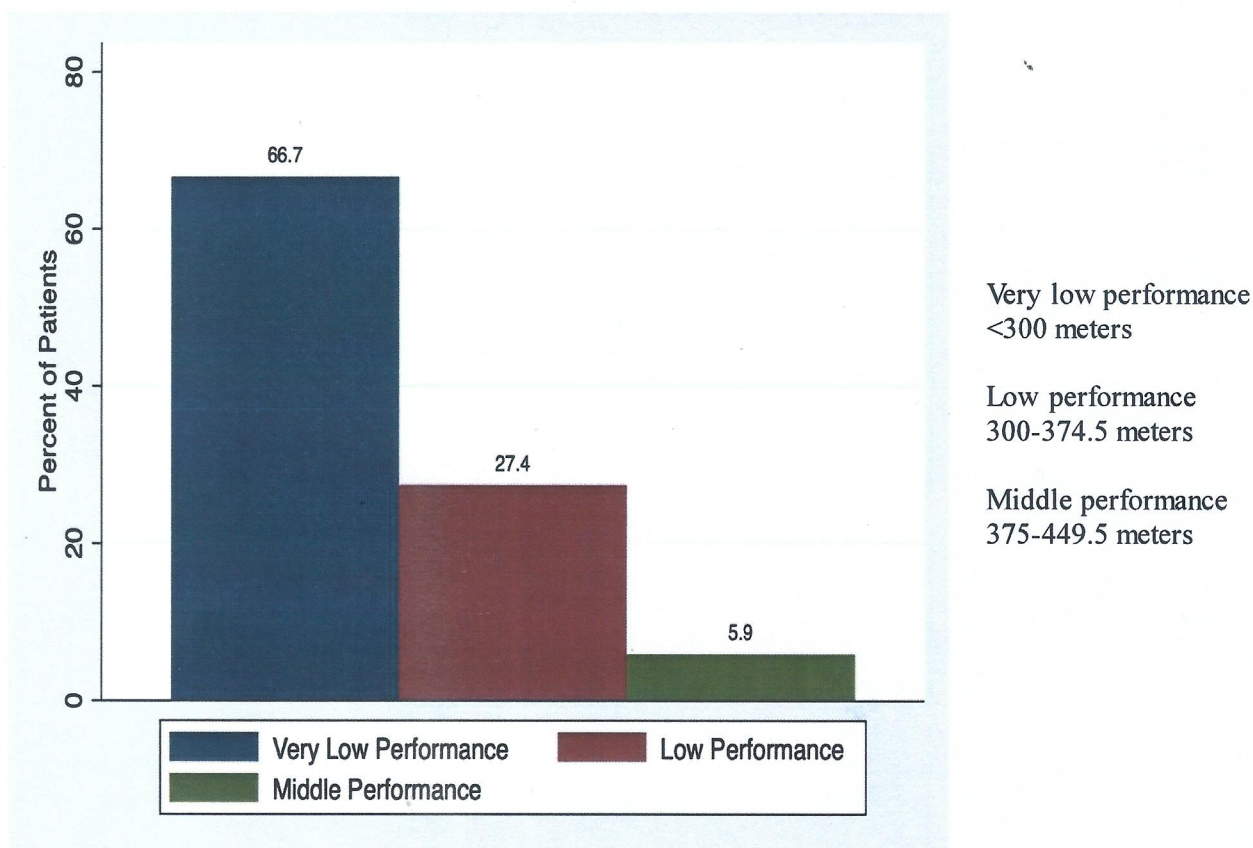


Figure 3 Six minute walk test Performance

4.4 Knowledge and adequacy of aerobic exercise activity

All one hundred and thirty five patients were assessed for knowledge and adequacy of aerobic exercise activity.

Thirty seven patients (27.4%) had been informed of the value of aerobic exercise activity as part of the care for HF_rEF and this information was given during routine outpatient clinic visits at KNH for 33 (89.2%) of the patients as shown in table 3.

Patients who were informed of aerobic exercise activity during routine clinic visits in Kenyatta National Hospital as an adjunct to care for heart failure received this information informally as verbal communication from one-on-one interaction with a doctor.

Of all the patients recruited in the study, 25 (18.5%), engaged in aerobic exercise activity.

The main type of aerobic exercise activity was brisk walking, 21 (84.0%).

Twelve patients (32.4%) were informed of aerobic exercise activity as part of care for HF_rEF but were not engaging in any exercise. The reasons cited were fear of exercise with a 'failing heart': 9, lack of motivation: 1, lack of energy: 1 and presence of physical symptoms: 1.

Fifteen patients (60.0%) engaged in aerobic exercise activity less than 30 minutes per session, less than 5 sessions per week and less than 150 minutes per week as shown in Table 3.

Table 3 Knowledge and adequacy of aerobic exercise activity

Aerobic exercise activity n (%)	Total
Informed of aerobic exercise activity as part of care for HF _r EF, n (%)	
Yes	37 (27.4)
No	98 (72.6)
Was the information given during one-on-one interaction with doctor, n (%)	
Yes	33 (89.2)
No	4 (10.8)
How was the information delivered, n (%)	
Informal, verbal	33 (100.0)
Do you engage in aerobic exercise activity, n (%)	
Yes	25 (18.5)
No	110 (81.5)
If yes, what type of aerobic exercise activity, n (%)	
Brisk walking	21 (84.0)
Cycling	4 (16.0)
Informed but does not engage in aerobic exercise training, n (%)	12 (32.4)
Lack of motivation	1
Lack of energy	1
Presence of physical symptoms	1
Fear of exercise with a 'failing heart'	9
Duration of each exercise session, n (%)	
Less than 30 minutes	15 (60.0)
More than 30 minutes	10 (40.0)
Number of exercise times per week, n (%)	
Less than 5 times a week	15 (60.0)
More than 5 times a week	10 (40.0)
Total minutes exercised a week, n (%)	
Less than 150 minutes a week	15 (60.0)
More than 150 minutes a week	10 (40.0)

CHAPTER FIVE: DISCUSSION

This study set out to determine the functional capacity of patients with HF_rEF using the six minute walk test and to determine the knowledge and adequacy of aerobic exercise activity as an adjunct to medical treatment for HF_rEF.

Two thirds of patients (66.7%) had poor functional capacity based on very low performance in the six minute walk test, walking a distance less than 300 meters.

Patients with very low performance have a 3-fold increase in risk of all cause and heart failure mortality, increased episodes of acute decompensated HF, 11-fold increased risk of heart failure hospitalizations and increased length of hospital stay (49).

A study carried out in USA, Canada and Belgium at twenty tertiary care hospitals on patients with HF_rEF found 21% of the patients had very low performance in the six minute walk test (49). Contrary to our study, the participants were predominantly white race (86%), were male (78%) and had a higher mean LVEF, 37%.

A study at 39 primary care centers in USA and Canada on patients with HF_rEF found 37% of patients had very low performance in the six minute walk test with predominant male (73.8%) and white participants (85.4%). The mean LVEF was also higher, 34.7% (51).

A study done in Italy at a tertiary health facility on patients with HF_rEF with a mean LVEF of 29.8% found 36.8% of patients had a six minute walk distance less than 300 meters (52). This study had predominant male participants, 79%.

Our study was done in Kenyatta National Hospital, a tertiary referral hospital and patients recruited may have had advanced stages of heart failure with poor functional capacity at baseline, with mean LVEF of 26.7%. The male participants were less than the female participants (44.4% versus 55.6%) and all patients were black race. Female sex and low LVEF are associated with lower six minute walk test distance (2).

One quarter of patients (27.4%) had been informed of the value of aerobic exercise activity as an adjunct to medical therapy during one-on-one interaction with a doctor at routine clinic visits. The information was delivered informally through verbal communication. Only 18.5% of

patients engaged in aerobic exercise activity, mostly brisk walking, with those not engaging citing fear of exercise with a 'failing heart' as the commonest reason. Sixty percent of patients engaged in aerobic exercise activity less than 30 minutes per session, less than 5 sessions per week, less than 150 minutes per week contrary to recommendations by the American Heart Association (AHA) guideline requirements.

Aerobic exercise activity as outlined by the AHA guideline (at least 30 minutes per session, at least 5 sessions per week, at least 150 minutes per week), in addition to guideline directed medical therapy improves functional capacity, LVEF and quality of life, reduces all cause and heart failure mortality and heart failure hospitalization. The European Society of Cardiology recommends regular aerobic exercise to improve functional capacity and symptoms and to reduce heart failure hospitalization in patients with HFrEF (9). The HF ACTION trial carried out in USA, Canada and France on patients with HFrEF showed a reduction in the combined endpoint of mortality and heart failure hospitalization by 13% when aerobic exercise was combined with medical therapy for treatment of HFrEF (34). A meta-analysis carried out in 2007 on 14 trials showed an improvement in LVEF in patients with HFrEF after aerobic exercise (weighted mean difference 2.59%) (38).

A systematic review done in 2018 on studies in the USA and Netherlands in patients with HFrEF showed 40-91% of patients did not engage in aerobic exercise activity as per the AHA guideline recommendations (41). This result is consistent with findings from our study where 60% of patients exercised less than 150 minutes per week.

There is no formal method of discussing aerobic exercise activity as adjunct to care in HFrEF or structured format of health education at the KNH cardiac outpatient clinic. Advice given to patients with HFrEF was also dependent on individual medical doctor choice. The information on aerobic exercise activity was delivered informally through verbal communication from a doctor that can lead to forgetfulness in implementation by patients with HFrEF. Poor health care literacy could also contribute to the low number of patients engaging in aerobic exercise. There is no expense associated with brisk walking as compared to others like cycling and swimming. Brisk walking can also be easily incorporated in day to day living. In addition to fear of exercise with a 'failing heart', other reasons presented for not engaging in exercise were presence of physical symptoms, lack of energy and lack of motivation.

Overall, health education in the form of structured talks and ready material like pamphlets can augment one-on-one doctor interaction in delivering information on the benefit of aerobic exercise activity and addressing some of the reasons arising as to why exercise uptake is low with the downstream effect of improving functional capacity, reducing mortality and heart failure hospitalization in the majority group of patients with very low performance in the six minute walk test.

This study had some limitations, Firstly, KNH is a tertiary referral hospital and the patients recruited in the study may have had advanced HF leading to selection bias. Secondly, an assumption was made that all patients on follow up in the cardiac clinic for HFrEF were on maximum tolerated guideline directed medical therapy. Thirdly, there is no standardized and validated tool for assessing knowledge of aerobic exercise activity as an adjunct to optimal medical therapy hence a study proforma was used.

CHAPTER SIX: CONCLUSION AND RECOMMENDATION

6.1 Conclusion

Two thirds of patients with heart failure with reduced ejection fraction have poor functional capacity evidenced by very low performance on six minute walk test therefore at increased risk for mortality and heart failure hospitalization.

There was inadequate knowledge/health education on the benefits of aerobic exercise activity as an adjunct to guideline directed medical therapy to improve functional capacity, reduce mortality and heart failure hospitalization.

Sixty percent of patients had inadequate aerobic exercise activity.

6.2 Recommendation

Six minute walk test should be adapted for objective assessment of functional capacity in patients with HFrEF.

An institutionalized health education strategy should be established to facilitate adaption of aerobic exercise activity for all patients with HFrEF without contraindications to improve functional capacity, reduce mortality and hospitalization for heart failure and address reasons for not engaging in exercise (for example fear of exercise with a 'failing heart').

Formal communication about aerobic exercise activity as an adjunct to medical therapy in treatment for HFrEF should be provided to patients for example through written material like pamphlets for ease of reference.

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APPENDICES

Appendix 1A: Patient information sheet

Introduction

I am Dr Josephine Nasieku Koikai a post graduate student in the University of Nairobi College of Health Sciences pursuing a Master's degree in Internal Medicine. I am conducting a study on the six-minute walk test in ambulatory patients with chronic heart failure with reduced ejection fraction in the cardiology outpatient clinic at Kenyatta National Hospital. The purpose of this study is to establish the exercise routine of the patients measured against the recommended standard in the guideline and to have an objective measure of functional capacity.

Procedure to be followed in the study Participation is voluntary. Should you accept to take part, the following is a summary of what the study involves:

- Obtaining your personal information and that of heart failure or any other comorbid medical condition
- Blood pressure and anthropometric measures will be recorded
- The six-minute walk test will be performed

This will take an average of 20 minutes.

Risks/cost There are minimal risks involved in the six-minute walk test. No cost will be incurred.

Your rights as a participant Your participation in this study is voluntary. If you decline to take part, your treatment will not be affected. If you agree to take part and not to answer certain questions, you are free to do so. You are free to withdraw from the study at any time. You are free to ask questions before signing the consent form.

Assurance of confidentiality All your responses will be confidential and will be stored in a locked place. I will be the only one with access to the information.

Benefits You will not incur any cost and the results will be put in your outpatient file for the cardiologist to advise further.

Compensation Participants will not receive any monetary compensation for taking part in this study.

Contacts

If you have any questions, do not hesitate to ask, clarification may be sought from

Dr Josephine Nasieku Koikai

P.O Box 10307-20100, Tel-0722559253

Or

The Secretary, KNH/UoN Ethics and Review Committee

Tel-2726300 Ext 44102

**Appendix IB: Jarida la maelezo ya mgonjwa
Utangulizi**

Jina langu ni Dr Josephine Nasieku Koikai, mwanafunzi wa uzamili, idara ya Internal Medicine katika chuo kikuu cha Nairobi. Ningependa kukuelezea madhumuni ya utafiti ninayofanya. Madhumuni ni kujua umbali ambao wagonjwa wa moyo wanaweza tembea ndani ya muda wa dakika sita.

Taratibu za kufuatwa katika utafiti

Ushiriki wako katika utafiti huu ni kwa hiari yako. Iwapo utakubali kushiriki, ifuatayo ni muhtasari wa vile utafiti utaendelezwa:

1. Maelezo yako ya binafsi, maelezo kuhusu ugonjwa wa moyo na magonjwa mengine yoyote uliyo nayo itachukuliwa.
2. Kipimo cha shinikizo la damu, urefu na uzito wako utachukuliwa.
3. Utatembea kwa dakika sita.

Utafiti huu utachukua dakika ishirini.

Hatari na Gharama Hatari ndogo yaweza kutokea wakati wa utafiti lakini madaktari watahughulikia. Hakuna gharama yoyote itaelekezwa kwako.

Haki yako kama mgonjwa Ushiriki wako katika utafiti huu ni kwa hiari na iwapo utakataa kushiriki, matibabu yako haitakutizwa. Uko na uhuru wa kutojibu maswali fulani, kusimamisha mahojiano au kujiondoa kwenye utafiti wakati wowote. Uko na haki ya kuuliza maswali kabla ya kutia saina fomu hii.

Usiri Habari yote utakayotoa na majibu yako yatahugulikiwa kisiri. Habari yote itafungiwa mahali salama na itadhibitiwa na mimi mchunguzi mkuu.

Faida Uchunguzi na taratibu zote zinafanywa bila malipo kwa mgonjwa. Majibu yako ya utafiti huu yatajulishwa kwa daktari wako wa kliniki.

Malipo Hakuna malipo ya kushiriki kwa utafiti huu.

Wawasiliani

Ukiwa na swali yoyote usiogope kuuliza. Utapata ufafanuzi kutoka kwa:

Dr Josephine Nasieku Koikai
S.L.P 10307-20100
Simu-0722559253

ama

Katibu
KNH/UoN Ethics and Review Committee
Simu-2726300, 44102

Appendix IIA: Consent form

Study Title: The six minute walk test in ambulatory patients with chronic Heart Failure with reduced ejection fraction at Kenyatta National Hospital	
Principal Investigator: Dr Josephine Nasieku Koikai	Study site: Kenyatta National Hospital

Signing this declaration does not affect your right to decline to participate in any future study

If you agree with each statement please INITIAL the box provided	
I confirm I have read or been explained to and understood the information sheet dated.....for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that participation in this study is voluntary and I am free to withdraw consent at any time without giving a reason, without any penalties.	
I understand that data collected during the study may be looked at by individuals from KNH, UoN and regulatory authorities. I give permission for these individuals to have access to my records.	
I understand that if I change my mind about taking part in this study, I can withdraw at any time and this will not have any consequences.	
I hereby declare that I have not been coerced into giving this consent.	
I agree that the data collected in this study can be stored and used in future.	
I agree that I will not receive any incentives to participate in this study	
I agree to participate in this study	

Name of participant.....Date.....Sign.....

Name of person taking consent..... Date..... Sign.....

Appendix IIB: Fomu ya idhini

Jina la utafiti: Mtihani wa dakika sita wa kutembea miongoni mwa wagonjwa wa moyo wanaohudhuria kliniki katika hospitali ya taifa ya Kenyatta	
Mpelelezi mkuu: Dr Josephine Nasieku Koikai	Eneo la utafiti: Hospitali ya taifa ya Kenyatta

Ikiwa unakubaliana na kila kauli tafadhali idhinisha kwenye sanduku	
Ninadhibitisha kuwa nimesoma au nimeelezwa na kuelewa karatasi ya habari iliyoidhinishwa.....kwa utafiti huu. Nilipata fursa ya kuzingatia habari, kuuliza maswali na kupata majibu ya kuridhisha.	
Ninaelewa kuwa kushiriki katika utafiti huu ni kwa hiari na niko huru kujiondoa wakati wowote bila kutoa sababu na bila adhabu yoyote.	
Ninaelewa kwamba data zitakazokusanywa zinaweza kuonekana na watu kutoka KNH, UoN na kutoka kwa mamlaka ya udhibiti. Ninawapa ruhusa watu hawa kuwa na upatikanaji wa rekodi zangu.	
Ninaelewa kuwa iwapo nitabadili maoni yangu kuhusu kushiriki kwenye utafiti huu, naweza kujiondoa wakati wowote bila adhabu yoyote.	
Natangaza kuwa sijalazimishwa kwa njia yoyote kutoa ridhaa hii.	
Nakubali kuwa data itakayokusanywa inaweza kuhifadhiwa kwa matumizi ya baadaye.	
Nakubali kuwa sitapokea msukumo wowote ili kushiriki kwa utafiti huu.	
Nakubali kushiriki kwa utafiti huu.	

Kutia sahihi kauli hii hakuadhiri haki yako ya kukataa kushiriki kwenye utafiti mwingine ujao.

Jina la mshiriki.....Tarehe.....Sahihi.....

Jina la anayechukua idhini.....Tarehe.....Sahihi.....

Appendix III: Study proforma (Circle appropriate response)

Study Identification number

A. Sociodemographic data

Sex (Male, Female)

Date of Birth

Occupation (Employed, Unemployed, Self employed, Retired)

Education (Tertiary, Secondary, Primary, None)

Marital status (Single, Married, Divorced, Widowed)

Health Insurance status (Yes, No)

B. Clinical Characteristics

i. Comorbidities; (Renal dysfunction, Diabetes mellitus, Hypertension, Anemia, Atrial Fibrillation, Others)

ii. BMI (kg/m²); (Healthy weight (18.5-24.9), Overweight (25-29.9) Obesity 1 (30-34.9), Obesity II (35-39.9) Obesity III (40 and above))

iii. New York Heart Association class; (NYHA I, NYHA II, NYHA III NYHA IV)

iv. Etiology of Heart Failure; (Hypertensive Heart Disease, DCM Rheumatic Heart Disease, Ischemic heart disease, Other)

v. Left ventricle ejection fraction; (<20%, 20-29%, 30-39%)

vi. Smoking status; (Yes, No)

C. Aerobic exercise activity

i. Have you been informed on aerobic exercise activity as part of your care for HFrEF? Yes, No

If Yes, Within KNH, Outside KNH

If within KNH, by whom? Doctor, Nurse, Other

How was the information delivered? Specify

Do you engage in aerobic exercise activity? Yes, No

If yes, what type of aerobic exercise activity?

Brisk walking, Cycling, Jogging

Jumping rope, Swimming, Other

If No, what are the reasons? Lack of motivation, Lack of energy,

Presence of physical symptoms, Fear of exercise with a failing heart

Other

ii. What is the duration of each exercise session?

Less than 30minutes, More than 30minutes

iii. How many times per week do you engage in the exercise?

Less than 5 times per week, More than 5 times per week

iv. Total minutes exercised per week. Less than 150 minutes, More than 150minutes

Appendix IIIB: Chombo cha kukusanya habari (Duru jibu linalofaa)

Nambari ya mgonjwa

A. Habari kuhusu mgonjwa

Jinsia (Kiume, Kike)

Tarehe ya kuzaliwa

Kazi (Kuajiriwa, Bila kazi, Kuajiri, Kustaafu)

Masomo (Elimu ya juu=1, Upili, Msingi, Hakuna elimu)

Hali ya ndoa (Ndoa, Talaka, Kufiwa)

Bima ya afya (Ndio, Hapana)

B. Sifa za kiafya

i. Magonjwa yanayoambatana

Ugonjwa wa figo, Kisukari

Shinikizo la damu, upungufu wa damu, AF

Zingine

ii. BMI (kg/m²)

Uzito sawa (18.5-24.9), Uzito kupita sawa (25-29.9)

Fetma 1 (30-34.9), Fetma 11 (35-39.9)

Fetma 111 (40 and above)

iii. NYHA

NYHA 1, NYHA 11, NYHA 111, NYHA IV

iv. Chanzo cha moyo kukosa nguvu

Ugonjwa wa moyo kutokana na shinikizo la damu,

Ugonjwa wa kupanuka kwa moyo

Ugonjwa wa moyo wa rheumatic,

Ugonjwa wa moyo wa ischemic

Zingine

v. LVEF

<20%, 20-29%, 30-39%

vi. Kuvuta sigara; Ndio, Hapana

C. Mazoezi

i Umewahi elezwa kuhusu mazoezi ya aerobic yanayosaidia matibabu yako ya ugonjwa wa moyo? Ndio, La

Kama Ndio; Ndani ya KNH, Nje ya KNH

Kama Ndani ya KNH, Nani; Daktari, Muuguzi, Mwingine

Ulipewa ujumbe huu kwa njia gani? Bainisha

Unajihusisha na mazoezi ya aerobic? Ndio, Hapana

Kama ndio, mazoezi ya aina gani? Kutembea kwa haraka, kuendesha baiskeli,

Kukimbia, Kuruka kamba, Kuogelea, Nyingine

Kama Hapana, sababu? Ukosefu wa motisha, Ukosefu wa nishati,

Dalili za mwili, Hofu kwa sababu ya shida ya moyo, Nyingine

ii. Kikao kimoja cha mazoezi huchukua muda gani?

Chini ya dakika 30, Zaidi ya dakika 30

iii. Huwa unafanya mazoezi mara ngapi kwa wiki?

Chini ya mara 5, Zaidi ya mara 5

iv. Jumla ya dakika ya mazoezi kwa wiki; Chini ya dakika 150, Zaidi ya dakika 150

Appendix IV: The six minute walk test work sheet

Unit: _____ ID: _____
 Address: _____

6-Minute Walk Test Recording Form	First name
	Last name
	Date of Birth

Supplemental Oxygen: Yes No

Flow Rate O₂ (L/min): _____ O₂ Device: _____
 Walking Limitations/other Problems: Yes No

Walking aid: Yes No

BP pre test:

Measurements	#1		#2		#3	
	Date: _____	Time: _____	Date: _____	Time: _____	Date: _____	Time: _____
• START						
• END						
• RECOVERY						
SpO ₂ , %		Rec		Rec		Rec
HR, bpm		Rec		Rec		Rec
Dyspnoea		Rec		Rec		Rec
Leg Fatigue		Rec		Rec		Rec
Number of Stops/ Total Time Stopped						
SpO ₂ nadir, %						
Limiting Factors/ Reason for Stops						
TOTAL DISTANCE						

WALKING DISTANCE				
M	#1	#2	#3	Ft
30				100
60				200
90				300
120				400
150				500
180				600
210				700
240				800
270				900
300				1000
330				1100
360				1200
390				1300
420				1400
450				1500
480				1600
510				1700
540				1800
570				1900
600				2000
630				2100
660				2200
690				2300
720				2400
750				2500

Comments:

Assessor Name _____
 Signature _____

Plagiarism screening report

SIX MINUTE WALK TEST ASSESSED FUNCTIONAL CAPACITY AND AEROBIC EXERCISE TRAINING ACTIVITY IN AMBULATORY PATIENTS WITH HEART FAILURE WITH REDUCED EJECTION FRACTION AT KENYATTA NATIONAL HOSPITAL

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LEAD SUPERVISOR AND CHAIRMAN OF DEPARTMENT APPROVAL

This dissertation has been submitted with the approval of my lead supervisor and the chairman of the Department of Clinical Medicine and Therapeutics

Prof M. D. Joshi

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Signature..... *Joshi* Date..... *8/11/23*

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Signature.....  Date..... *9/11/2023*

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