FACTORS ASSOCIATED WITH THE CLINICAL CLASS OF HEART FAILURE AMONG ADULT PATIENTS IN MOI TEACHING AND REFERRAL HOSPITAL ELDORET, KENYA.

Peter Boro Kamau

Thesis submitted in partial fulfillment for the award of Masters of Medicine, Family Medicine (MMED FM) of Moi University

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DECLARATION

This thesis is my original work and it has not been presented to any training institution as a research paper for the award of any academic degree. No part of this thesis should be reproduced without prior written permission of the author and /or Moi University.

Sign: _____ Date: _____

Peter Boro Kamau

SM/PGFM/02/13

Declaration by the Supervisors

This thesis has been submitted with our approval as university supervisors

Sign: _____ Date: _____

Dr Constantine Akwanalo

Cardiologist Moi Teaching and Referral Hospital (MTRH)

Sign: _____ Date: _____

Dr Jeremiah Laktabai

Family Medicine Moi University

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My family for their unwavering support

DEDICATION

To my wife and two boys, for all the days I have been away.

You have stuck by my side.

ABSTRACT

Background: Heart failure (HF) is a major cause of morbidity and mortality globally with the prevalence rising in Sub-Saharan Africa. Diseases such as Human Immunodeficiency Virus and diabetes have been shown to impact heart failure severity. However, clinical correlates of heart failure classes haven't been previously described in Kenya.

Objective: To assess factors associated with heart failure classes in patients at Moi Teaching and Referral Hospital (MTRH).

Methods: A cross-sectional study was done at MTRH cardiology clinic, a referral hospital for western Kenya. Participants more than 18 years of age with a diagnosis of HF who had been on follow up for more than three months were included. A pre-tested structured questionnaire was used to collect data regarding demographic information and potential correlates. Descriptive statistics such as measures of central tendency and measures of spread were used for continuous variables while frequency listings were used for categorical data. To assess for factors associated with New York Heart Association (NYHA) class, bivariate and multivariate analysis were carried out. In the multivariate analysis logistic regression model was used to determine statistically significant factors associated with NYHA class.

Results: We enrolled 228 patients with heart failure in the study with a median age of 67 years with 33% being male. At diagnosis, 46 patients (20.2%) were in classes one and two whereas 182 patients (79.8%) were in classes three and four. At enrolment, 154 (67.6%) and 74 (32.5%) were in classes one and two and classes three and four, respectively. Over the last one year of illness, 133 (58.3%) patients had no admission whereas only 29 (12.7%) had two or more admissions. In the bivariate analysis, more than one admission/year, low blood pressures, and poor adherence to drugs were associated with worse NYHA classes (P-values = 0.006, 0.008 and 0.004 respectively). After multivariate analysis, older age, poor adherence to drugs, and underweight were significantly associated with worse NYHA classes.

Conclusions: The study population had high proportions of severe heart failure who had adherence related problems. Increasing age and low body mass index were associated with the severity.

Recommendation: We recommend further studies on factors affecting adherence to drugs as this is associated with advanced heart failure classes. Larger studies to assess effects of underweight on heart failure classes are also warranted.

Contents

ABBREVIATIONS

6MWT	6 Minutes walking test
ACC	American College of Cardiology
ACE-I	Angiotensin Converting Enzyme Inhibitors
AHA	American Heart Association
BP	Blood Pressure
CCC	Chronic Care Clinic
CHARM	Candesartan in Heart failure Assessment of Mortality and Morbidity
ECG	Electrocardiogram
EF	Ejection Fraction
HB	Hemoglobin
HF	Failure
HFrEF	Heart failure with reduced ejection fraction
HFmrEF	Heart failure with mid range ejection fraction
HFpEF	Heart failure with preserved ejection fraction
HIV	Human Immunodeficiency Virus
HR	Heart Rate
HTN	Hypertension
MTRH	Moi Teaching and Referral Hospital
NYHA	New York Heart Association
SBP	Systolic Blood Pressure

Definition of terms

Unique medication This is defined as the different classes of medications the patient is currently taking e.g a person on an ACE-I, Beta blocker and a diuretic is determined to be on three unique medications

Advanced heart failure Refers to New York Heart Association classes three and four

CHAPTER ONE: INTRODUCTION

1.1 Background to the study

Heart failure is a growing public health problem on a global perspective and is one of the most common causes of hospitalization and readmission. The heart failure (HF) hospitalization rates globally are still high and in 2011 were 18 per 1000 in the USA for those over 64 years old. This makes heart failure among the leading causes of hospitalization in this age group. About a quarter of those who are hospitalized with HF get readmitted within 30 days and 30 percent within 60 to 90 days post-discharge(Krumholz, Normand, and Wang 2014)(Gheorghiade et al. 2006). The Framingham criteria are one of the clinical diagnostic tools that are globally accepted. (Jimeno Sainz et al. 2006)

In both clinical and research settings, the New York Heart Association Classification (NYHA class) criteria and/or the American College of Cardiology/ American Heart Association (ACC/ AHA) stages are used to assess severity and functional capacity of HF patients. The NYHA classes have however shown good predictive validity for functional status measured by the6 minutes walking test(6MWT) as compared to ACC/AHA stage of HF that is based on structural damage to the heart, suggesting NYHA class is a better predictor of functional ability than ACC/AHA stages of HF (Athilingam et al. 2013)

Some of the most important causes of heart failure include hypertension, valve disease, prior stroke, corpulmonale, cardiomyopathy, pericardial diseases, coronary heart disease, and metabolic problem (etiology unknown in 17% of cases).(Mair, Crowley, and Bundred 1996)

Patients with heart failure present with a variety of symptoms, most of which are non-specific. The common symptoms of congestive heart failure include fatigue, dyspnoea, swollen ankles, and exercise intolerance, or symptoms that relate to the underlying cause. (Muntwyler et al. 2002)

There is a high level of morbidity and mortality among patients with heart failure. Hospital case fatality among those with heart failure in Africa ranges from 9% to 12.5%; total in-hospital mortality rate of 17.5%, and patients with coexisting co morbidity have a significantly increased mortality.(Makule 2002).Various factors have been associated with worse outcomes in heart failure in previous studies including low blood pressure, diabetes mellitus, anemia, human immunodeficiency virus , low systolic ejection fraction, hypertension and others(Yonga G, Reriani M 2010),(Sliwa et al. 2013).

1.2 Problem Statement

As a result of progressive urbanization and changing lifestyle in Sub-Saharan Africa, the spectrum and pattern of cardiovascular diseases along with their risk factors are changing(Tantchou et al. 2011). " Heart failure (HF) is the most common cardiovascular disorder and the main driver of CVD adverse morbidity and mortality".(Cotter, Cotter-Davison, and Ogah 2013).Focus has been on communicable diseases in the past despite increasing non communicable disease burden with 9.2% of total deaths in the African region attributable to CVD (Regional commitee for Africa (WHO) 2005) with heart failure the most common CVD and driver of mortality.(Cotter, Cotter-Davison, &Ogah, 2013)

In the African population, heart failure accounts for over 30% of hospital admission in specialized cardiovascular units and 3%–7% in general internal medicine wards.(Kengne, Dzudie, and Sobngwi 2008)

Majority of the population cannot afford heart failure care, leading to poor control, high readmission rates and mortalities(Mocumbi and Olga 2012),(R Gombet et al. 2009)

The cardiac clinic at MTRH attends to many patients with advanced heart failure stages requiring recurrent inpatient care due to worsening disease states as per the NYHA classes. Our study undertook to investigate factors associated with this severe disease trend among patients attending follow up in this regional teaching and referral hospital.

1.3 Research question

What is the association between various clinical correlates, lifestyle and selected co morbidities and the clinical class of heart failure as per the NYHA of Heart failure patients?

1.4 Objectives

1.4.1 Broad

To assess factors associated with the different clinical classes of patients with heart failure on follow up at Moi Teaching and Referral Hospital.

1.4.2 Specific

1. To determine the demographic and clinical characteristics of patients with clinical diagnosis of heart failure on follow up at MTRH cardiac clinic.
2. To determine the proportion of advanced NYHA classes 3&4 of patients on follow up.

3. To determine the association between various clinical characteristics, behavior and other co morbidities on the clinical class of heart failure as given by the NYHA.

1.5 Justification of the study

Heart failure is a major and growing public health concern in terms of incidence, prevalence, morbidity, mortality and economic burden in Sub Saharan Africa with the proportion of hospitalization of patients with the principal diagnosis of heart failure having increased for the past two decades.(Yonga G, Reriani M 2010)

Research previously done in Kenya is likely to differ from the current situation at Moi Teaching and Referral Hospital(MTRH) owing to the social and economic demographics with MTRH largely serving the Western part of the country that is largely a rural population with less access to current diagnostic tools and availability of medications.

Literature review did not yield studies on heart failure outcomes done in rural Kenya over the last 20 years. However, a study done in Nairobi between year 2007 and 2009 to determine the prevalence of left ventricular dysfunction and heart failure, its causes and probable risk factors found out that left ventricular dysfunction and heart failure are significantly prevalent in this population and that the causes and risk factors were largely preventable cost effectively.(Yonga G, Reriani M 2010)

There is still a wide gap between patients with heart failure stage A (early stages) and C (advanced stages) in Kenya i.e. 26.7% and 1.9%(Yonga G, Reriani M 2010)and some of the factors we are studying may help explain this.

It is thus expected that this study will establish the proportion of heart failure patients seen at MTRH, their clinical classes and the associated factors to these classes. This information will help offer better care to these patients in a bid to prevent adverse outcomes.

CHAPTER TWO: LITERATURE REVIEW

2.1 Overview

Heart failure (HF) is a common clinical syndrome representing the end-stage of a number of different cardiac diseases.(Jessup and Brozena 2003) It is characterized by high mortality, frequent hospitalization, reduced quality of life, and a complex therapeutic regimen,(Heart Failure Society Of America 2006). It can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood. There are two mechanisms by which reduced cardiac output and HF occur: systolic dysfunction and diastolic dysfunction.

Diastolic heart failure is defined as a clinical syndrome characterized by symptoms and signs of heart failure, a preserved ejection fraction (EF) and abnormal diastolic function. Other definitions such as ‘‘heart failure with preserved systolic function’’ or ‘‘heart failure with normal or near normal ejection fraction’’ have also been used(Zile and Brutsaert 2002). In 1980, Dr. Braunwald also described systolic heart failure as ‘‘a pathophysiological state in which an abnormality of cardiac function is responsible for the failure of the heart to pump blood at a rate commensurate with the requirements of the metabolizing tissues.’’(E., Braunwald 1980).

The evaluation of patients with heart failure is based on a complete and comprehensive history, physical examination, and diagnostic studies as there is no single diagnostic test for Heart failure. The importance of the history and physical examination is supported by a meta-analysis of 22 studies of patients who presented with dyspnea to the emergency department. Wang and colleagues, showed that the overall clinical impression of the emergency room physician, based on several signs and symptoms as well as laboratory

and imaging tests, significantly increased the probability of having heart failure (positive likelihood ratio [LR], 4.4; 95% confidence interval [CI], 1.8–10). The most useful features were prior history of heart failure (positive LR, 5.8; 95% CI, 4.1–8.0), presence of paroxysmal nocturnal dyspnea (positive LR, 2.6; 95% CI, 1.5–4.5), S3 gallop on examination (positive LR,11; 95% CI, 4.9–25.0), chest radiograph showing pulmonary venous congestion (positive LR, 12.0; 95% CI, 6.8–21.0), and atrial fibrillation on electrocardiogram (positive LR, 3.8; 95% CI, 1.7–8.8)(Wang CS; FitzGerald JM; Schulzer M; Mak E; Ayas NT 2005).

The diagnosis of heart failure is often based on the Framingham criteria that looks at a series of signs and symptoms and classifies them into either major or minor with the diagnosis consisting of the concurrent presence of either 2 major criteria or 1 major and 2 minor criteria. This criterion has been shown to have high sensitivity though its specificity is low.(Jimeno Sainz et al. 2006).

The classification system that is most commonly used to quantify the degree of functional limitation imposed by HF is one first developed by the New York Heart Association (NYHA). This system assigns patients to one of four functional classes, depending on the degree of effort needed to elicit symptoms:

Class I - symptoms of HF only at activity levels that would limit normal individuals

Class II - symptoms of HF with ordinary exertion

Class III - symptoms of HF with less than ordinary exertion

Class IV - symptoms of HF at rest

A major challenge in the management of HF is the accurate identification of those patients who have a poor prognosis and who would therefore be most likely to benefit from intensive medical therapy and/or cardiac transplantation. Many univariate predictors of reduced survival have been identified in HF. Identification of these factors should be part of the initial evaluation of any patient with HF. Some of those factors include;

1. New York heart association class
2. Left ventricular ejection fraction
3. Signs of reduced tissue perfusion
4. Co morbidities such as diabetes, anemia

NYHA CLASS

The prognostic importance of NYHA functional class on outcomes in patients with heart failure has been described in various studies. In a study by Dalos D, Mascherbauer J, Zotter-Tufaro C, et al on the functional status, pulmonary artery pressure, and clinical outcomes in heart failure with preserved ejection fraction in 2016, NYHA functional class was independently associated with outcome defined as hospitalization for heart failure and/or cardiac death.(Dalos et al. 2016).

The NYHA classification has also been shown to correlate well with the 6 minutes' walk test (6MWT)with various studies supporting that worse NYHA class is associated with poor functional ability measured by 6MWT and HF readmissions.(Alahdab et al. 2009),(Athilingam et al. 2013).

In studies evaluating the use of ACE inhibitors a strong relationship has been demonstrated between the functional class and mortality whereby, asymptomatic patients (class I) have a one and four year mortality rate of 5 and 19 percent among a control of those not receiving enalapril(Investigators* 1992).Patients with NYHA class II or III HF have a 1 and 4 year mortality rate of 15 and 40 percent(Investigators* 1991)whereas those with NYHA class IV have worse outcomes with 6 and 12 month mortality rates of 44 and 64 percent in one large trial(Group* 1987).

Left ventricular ejection fraction

Clinically evident HF due to systolic dysfunction is generally not apparent until the LVEF falls below 35 to 40 percent, as determined by echocardiography.(Investigators* 1991) Patients with lower LVEFs have a shorter survival as demonstrated in a previous study where the relationship between LVEF and outcome was evaluated in 5010 patients enrolled in the valsartan heart failure trial. In this study, echocardiograms were obtained at baseline and decreasing quartiles of LVEF were associated with increasing all-cause mortality at 23 months. Patients with higher LVEF (mean LVEF 35 percent) had a significantly lower mortality rate than those with lower LVEF(mean LVEF 17 percent) (14 versus 26 percent mortality, risk ratio 0.5).(Wong et al. 2004).A recent classification of heart failure as per the SEF has been developed now to include heart failure with reduced ejection fraction (**HFrEF**), heart failure with midrange ejection fraction (**HFmrEF**) and heart failure with preserved ejection fraction (**HFpEF**).(Ponikowski et al. 2016).Heart failure with midrange ejection fraction encompasses patients with SEF between 40-49% which has always been considered a grey area.

Signs of reduced tissue perfusion

Clinical signs of reduced tissue perfusion are indicative of more severe disease and a worse prognosis. These include a low mean arterial blood pressure, renal insufficiency, an attenuated response to diuretics, and lack of hemodynamic improvement with therapy, as indicated by failure to reduce LV filling pressure, are also associated with a poorer prognosis

Low systolic, diastolic, and mean arterial blood pressures have all been associated with increased mortality in patients with HF. In the Study of Left Ventricular Dysfunction trial, each 10 mmHg decrease in baseline mean arterial pressure was associated with a 14 percent increase in total and cardiovascular mortality (Domanski et al. 1999).

Other factors that have been shown to have an impact on the prognosis of heart failure patients include Diabetes which in one retrospective study was found to be among the most powerful independent predictor of mortality and HF hospitalizations. (Pocock, Wang, Pfeffer, Yusuf, McMurray, Swedberg, Ostergren, et al. 2006).A reduced glomerular filtration rate (GFR), using serum creatinine and elevated blood urea nitrogen (BUN) are associated with increased mortality risk in patients with HF (Shlipak and Massie 2004).

Others include anemia, cardiac cachexia, atrial fibrillations and exercise variables.

2.2Heart Failure Globally and Locally

Heart failure (HF) has now been recognized as an epidemic and a major clinical and public health problem, associated with significant mortality, morbidity, and healthcare expenditures, particularly among those aged 65 and older with a prevalence of over 5.8 million in the USA, and over 23 million worldwide (Roger 2013).

A study done in the Sub Saharan Africa published in Oct2013, i.e. the THESUS-HF registry (the Sub Saharan Africa survey of heart failure) showed that patients with heart failure were mostly middle aged and with non ischemic causes. This was different from patients enrolled in North America and European registries where patients were more elderly and with ischemic related acute heart failure. This study aimed at describing prognostic factors of readmissions and death in heart failure in a developing population whereby the main predictors of a 60 day readmission or death and having excluded the geographic region were a history of malignancy, severe lung disease, admission systolic blood pressure, heart rate, signs of congestion e.g. rales, orthopnea and edema, kidney function (BUN) and echocardiography ejection fraction. Age in this case was not found to be prognostic. According to the same study, predictors of 180 day mortality were found to be in addition to the above mentioned smoking history, anemia and HIV positivity (Sliwa et al. 2013)

Between year 2007 and 2009, a study was carried out in Nairobi and its environs to determine the prevalence of left ventricular dysfunction and heart failure, its causes and probable risk factors (Yonga G, Reriani M 2010).The findings of the study were that left

ventricular dysfunction and heart failure are significantly prevalent in this population and that the causes and risk factors were largely preventable cost effectively. However limited similar studies done in MTRH were yielded in the literature review.

CHAPTER THREE: MATERIALS AND METHODOLOGY

3.1 Study site: Moi Teaching and Referral Hospital

The study was carried out at Moi Teaching and Referral Hospital located in Eldoret town in the Western region of Kenya's Uasin Gishu county, about 320km North West of Nairobi. It offers a wide range of Out-Patient and In-Patient health services.

3.2 Study Design

This was a Cross sectional study carried out from June 2016 to August 2017.

3.3 Study population

All heart failure patients on follow up at Moi Teaching and Referral Hospital who met the inclusion criteria were eligible.

3.4 Inclusion/Exclusion Criteria

3.4.1 Inclusion Criteria

Adults aged 18years and above on follow up in clinic with a diagnosis of heart failure for at least 3 months and who could give consent.

3.4.2 Exclusion Criteria

Unstable patients who needed urgent attention were excluded from the study and referred to see a doctor.

3.5 Sample Size

The sample size was calculated based on Peduzzi et al 1996 formula(Peduzzi et al. 1996)for sample size determination for a logistic regression model to assess factors associated with an outcome of interest.

I.e**. n=10k/p**

Where n is the sample size, (minimum number required to power the study adequately), k is the number of covariates (the number of independent variables under study) and p is the smallest of the proportion of positive or negative cases.

For our **K,** we considered 5 factors that had been found to be associated with worse outcomes in heart failure by more than one study during our literature review including low blood pressure, diabetes, anemia, HIV positivity and smoking.

For the **P**, we adopted the prevalence of advanced NYHA stages 3&4 from a previous study which was 0.22in the population.(Ahmed, Aronow, and Fleg 2006).

Thus n=10k/p

n=10*5/0.22

n=228

3.6. Sampling Technique

We used a consecutive sampling method in our study whereby criteria for recruitment were prepared at the beginning of the study to include participants with a diagnosis of heart failure, above 18years of age and had been in the clinic for more 3 months. A day before the data collection, the research assistant would go through all the files of the patients due for a visit next day and would note the unique identifiers for those who met the criteria. These would then be recruited in the study when they came for their clinic visit the next day. This went on until 228 participants were picked thus achieving the required sample size. In case of revisits, the patient was replaced with the next one who

met the inclusion criteria though this was avoided by tagging the previously selected files with identifiers.

3.7 Data collection instruments and procedures

Data was collected by the principal investigator assisted by an onsite research assistant that was trained beforehand by the principal investigator using an interviewer administered and structured questionnaire which was piloted before the study to ensure validity.

Patients with heart failure were further classified according to their New York Heart Association class into either class 1, 2, 3 or 4 by the principal investigator.

Social demographic data and co morbidities were obtained from the patient through a questionnaire and other medical information extracted from hospital record files. Such information included their HIV status, co morbid states such as diabetes and hypertension, most current echo reports and recent laboratory results such as hemoglobin levels within the last 3 months.

Where there were no hemoglobin results for the patient, this was done after informed consent by the principal investigator using a hemocue device calibrated in the hospital laboratory. The number of medications the patient was taking was also noted. The number of unique medications was defined as the different classes of drugs patients were on both for heart failure and other co morbidities.

Adherence to medication was assessed using the 8 point MMAS 8 scale which is a self-administered questionnaire but for purposes of our study was administered by the interviewer. Participants were graded as either having high adherence (score of 8), medium adherence,(6 to <8) and low adherence if <6 total score. This tool has been validated before in an almost similar population in Uganda(Okello et al. 2016) and was also piloted before our study. The questions on drug adherence as per the MMAS 8 tool were as follows with a score of zero for a yes and one for a no except for question seven that was scored as one for a yes and zero for a no.

1. Do you sometimes forget to take your medicines? YES NO
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking about the past two weeks, were there any days when you did not take your heart failure medicines? YES NO
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?
4. YES NO
5. When you travel or leave the house, do you sometimes forget to take your medications?
6. YES NO
7. Did you take your heart failure medicines yesterday? YES
   NO
8. When you feel like your disease condition is under control, do you sometimes stop taking your medications? YES NO

9. Have you ever felt distressed or pressured about strictly following your treatment?

   YES NO

10. How often do you have difficulty remembering to take all your medications? (Please circle the correct number)

    - Never/Rarely…….0
    - Once in a while…….1
    - Sometimes……2
    - Usually ……..3

    All the time ……..…….

The data collected from the participants was used to assess the association between duration of illness, NYHA class at diagnosis, ejection fraction, blood pressure, and selected co morbidities with current NYHA class of patients with heart failure.

3.8 Data Management and Statistical Analysis

The questionnaires were checked for completeness by the researcher and biostatistician; coded and entered in a Microsoft access database. It was later exported to STATA version 14 software for analysis. Descriptive statistics such as measures of central tendency and measures of spread were used for continuous variables while frequency listings were used for categorical data. To assess for factors associated with NYHA class bivariate and multivariate analysis was carried out. In the bivariate analysis Chi square test was used for categorical factors. In cases where the cell count was below 5 the Fishers exact test was used. For continuous variables the Kruskal Wallis test was used to test for the association between these variables and NYHA classes. Factors that were

associated with NYHA classes were included in a multiple logistic regression model to determine statistically significant factors associated with NYHA class.

Body mass index was determined as ratio of weight in kilograms to the square of height in meters. This variable was categorized using clinically acceptable limits: <18.5 kg/m2, 18.5 – 24.9, kg/m2, 25.0 – 30.0 kg/m2, and >30.0 kg/m2.

Similarly, blood pressure was categorized using clinically acceptable limits of <90/60 hypotension, >90/60-140/90, good control and >140/90 poor control. Level of adherence was also categorised into three as per the MMAS-8 scales of high adherence 8, medium adherence 6-<8 and low adherence <6.

The systolic ejection fraction was also categorised using clinically acceptable limits of >55% normal, 45-54% mildly abnormal, 30-44% moderately abnormal and <30% severely abnormal. Finally, anaemia was also categorised within clinically acceptable limits in both male and females as follows (Male normal >13g/dl, mild anaemia 11-12.9g/dl, moderate anaemia 8-10.9/dl and severe <8g/dl. For female participants, normal was >12g/dl, mild anaemia 11-11.9g/dl, moderate 8-10.9g/dl and severe as <8g/dl.

Results are presented using graphs and tables.

3.9 Study Limitations

Moi Teaching and Referral hospital is mostly a referral center thus results from this study may not fully reflect the reality in the rural areas. However, its large number of patients and the diagnostic capacity made it ideal to do the study there.

Also, our study being a cross sectional study may be prone to non response bias but this was minimized by the investigator administering the questionnaire directly to the sampled study participants.

3.10Ethical Considerations

Approval

Approval was obtained from Moi University IREC before the study commenced approval **No 0001380** attached as an appendix**.** Permission for the study was also granted from Moi Teaching and Referral Hospital.

Consent

Informed consent was obtained from participants whereby a consent form was administered by the principal investigator.

Risk

There were no invasive procedures to the participants of this study. Where the hemoglobin level was checked, it was done under aseptic technique with sterile equipment. The investigators also ensured participants were comfortable during interview and examination.

Benefits

There was no reward for participation in this study and if a patient was found to be hypertensive or anemic during this period, they were referred immediately to the doctor for further evaluation and management.

Confidentiality

Information was confidential and was not used for any other purpose other than the study. Privacy was also ensured by interviewing one subject at a time in a secluded room and filled questionnaires kept in safe custody. Names were also not used and electronic data was password protected.

CHAPTER FOUR: RESULTS

A total of 228 participants were included in the study. The median age was 67years with an IQR of (48, 77). One third of the participants were male giving a male to female ratio of 1:2. The median weight was 60.0 (IQR: 51.0, 72.0) kilograms with a median body mass index (BMI) of 22.37 (IQR: 19.15, 27.56) kg/m^2.

Table 1: Social, Demographic and Anthropometric characteristics

Variable	**Freq (%)** **Median (IQR)**
Age in years	67 (48, 77)
Gender Male Female	 77 (33.8) 151 (66.2)
NYHA Class at diagnosis 1 2 3 4	 3 (1.3) 43 (18.9) 112 (49.1) 70 (30.7)
Current NYHA Class 1 2 3 4	 30 (13.2) 124 (54.4) 70 (30.7) 4 (1.8)
Smoking Yes	23 (10.10)
Alcohol Yes	29 (12.70)

Most of the patients were in advanced heart failure at the time of diagnosis.

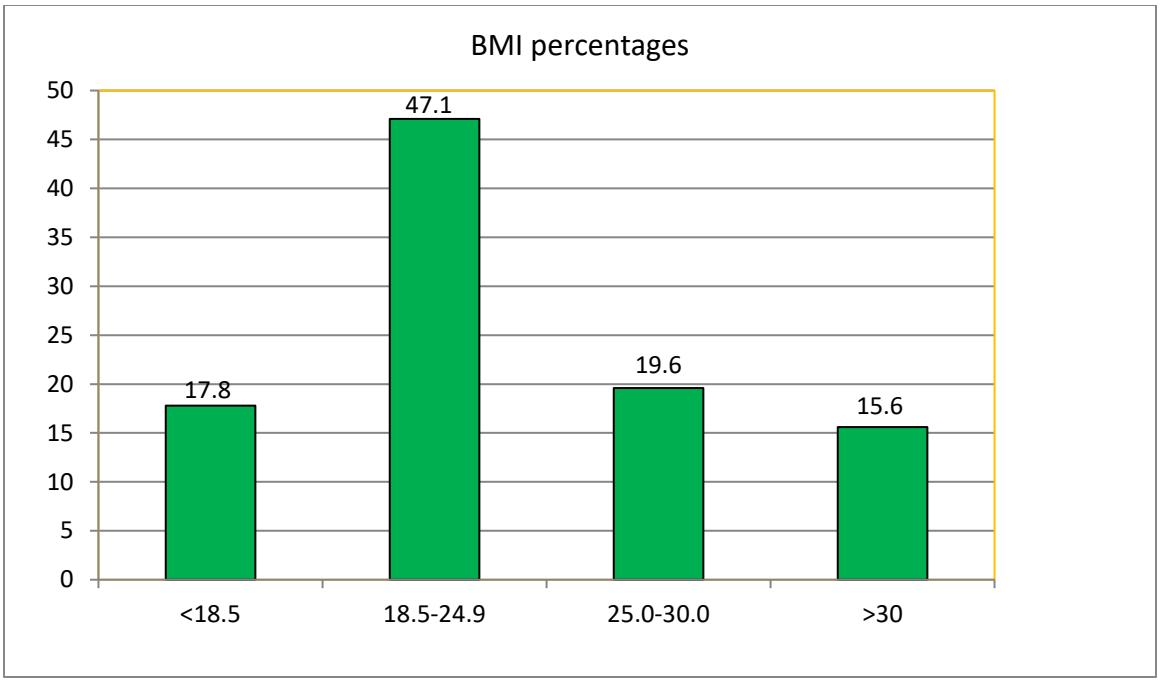

Figure 1: Distribution by BMI groups

Up to 47.1% of the participants had normal (18.5 – 24.9 kg/m^2) BMI and 35.2 % were either overweight (25.0-30.0 kg/m^2) or obese (>30.0 kg/m^2).

Table 2a: Clinical characteristics; categorical variables

Variable N=228	**n (%)**
Systolic Blood pressure (mmhg)	
<90	21(9.21%)
90-140	153(67.11%)
>140	54(23.68)
Systolic ejection fraction:	
>55%	106 (47.3%)
45-54%	18 (8%)
30-44%	60(26.8%)
<30%	40(17.9%)
Initial NYHA CLASS:	
Class 1	3(1.3%)
Class 2	43(18.9%)
Class 3	112 (49.1%)
Class 4	70(30.7)
Current NYHA CLASS:	
Class 1	30(13.2%)
Class 2	124(54.4%)
Class 3	70 (30.7%)
Class 4	4(1.8%)
No of admissions in the previous 1 year:	
None	133(58.3%)
1	66(28.9%)
2 or more	29(12.7%)

At the time of diagnosis, 20.2 % of participants were in NYHA Classes 1&2 with the remainder 79.8 in NYHA Classes 3&4 yet at the time of recruitment 67.6% were in classes 1&2 with the remainder 32.4% in classes 3&4.

Table 2b: Clinical caracteristics; continuous variables

Variable	**Median (IQR)**
Hemoglobin level (g/dl)	13.45 (12.4, 14.6)
Number of unique medications	4(4, 8)
Duration of treatment in months	36(18,120)

The median duration of time the participants had been on treatment for heart failure was 36 months with an IQR of (18,120) with the median number of unique medications they were using being 4 with an IQR of (4,8).4.

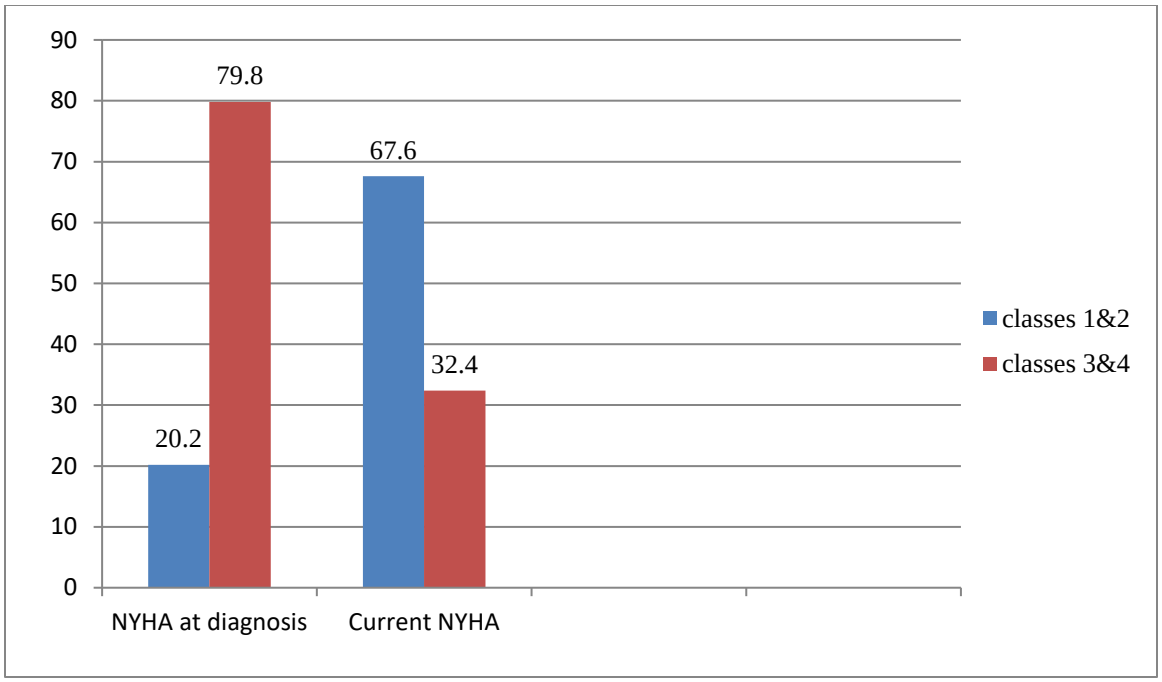

Figure 2: NYHA class at diagnosis and current

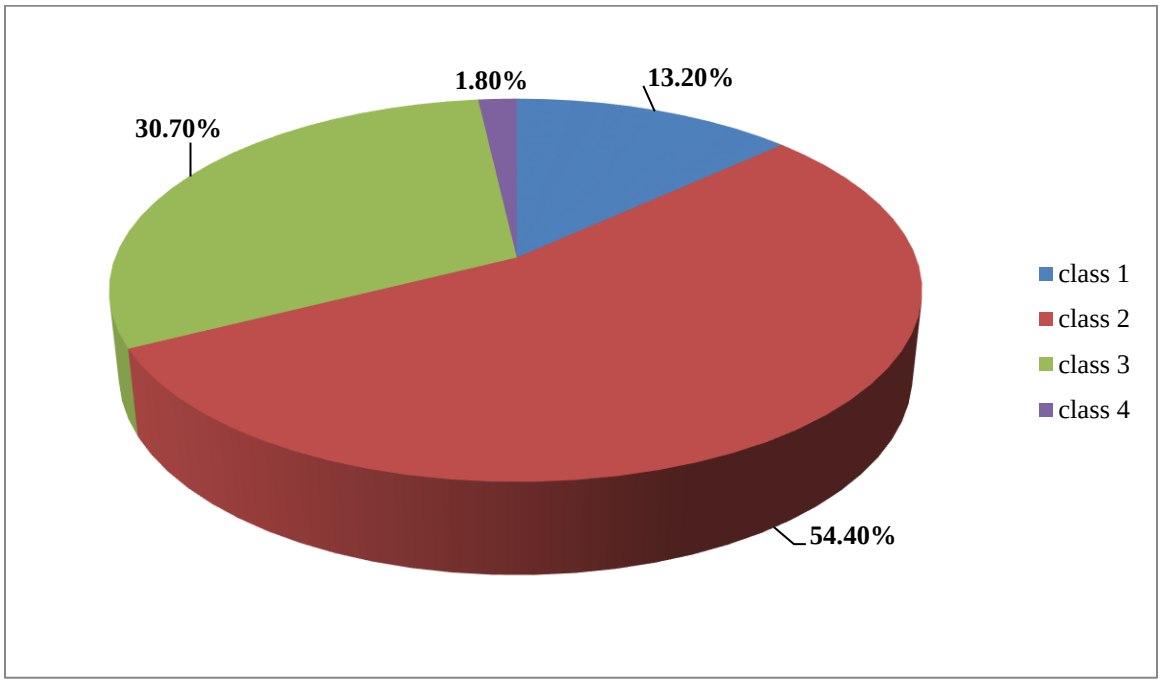

Figure 3: Current NYHA class as percentages

Drug Adherence

Of all the participants recruited, none had high drug adherence levels with 43% having low adherence and 57% having medium adherence.

Co morbidities

There were 21 participants (9.5%) who were found to have moderate or severe anemia with 164 (74.2%) having no anemia. Only seven (3.1%) of the respondents were diabetic, nine (3.9%) being HIV positive and six (2.6%) participants not knowing their HIV status. Twenty three (10.1 %) and twenty nine (12.7%) of the participants had either a current or previous history of smoking or alcohol intake respectively which was reported during the interview.

There were 97 participants (42.5%) with a positive history of hypertension and a further 54 participants (23.7%) had a prior ECG diagnosis of atrial fibrillation.

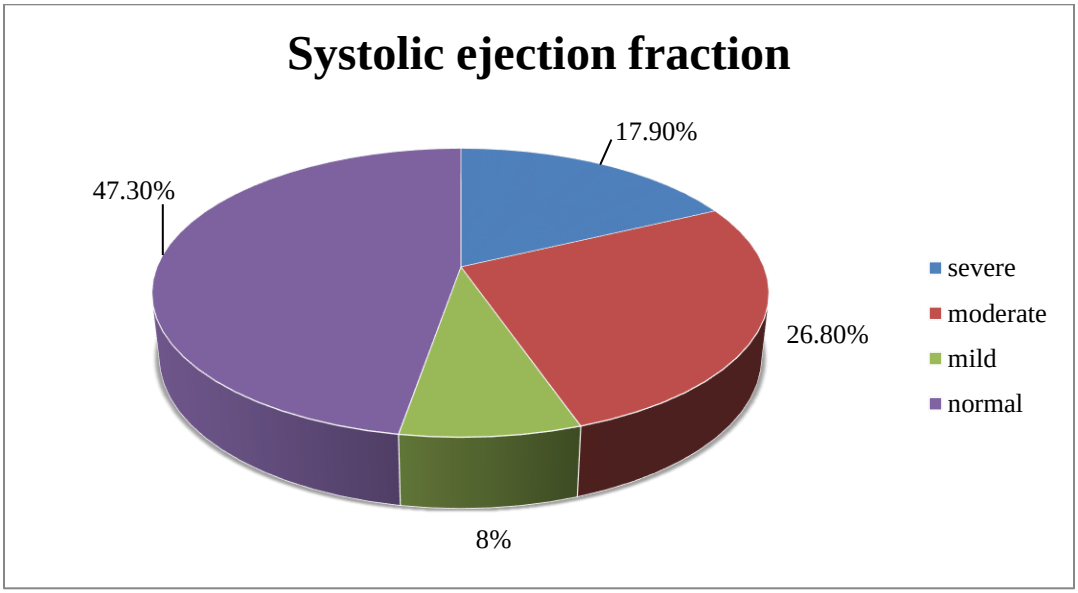

Figure 4: Systolic Ejection Fraction grades

100 participants (44.7%) had moderate to severely abnormal ejection fraction at the time of recruitment based on the most current echo done at MTRH.

Table 3: Bivariate Analysis

Variable	**Classes 1&2**	**Classes 3&4**	**P-value**
Age	63.5 (47,76)	70 (58,79)	0.050
Gender Female	100 (66.2)	51 (33.8)	0.551
Male	54 (70.1)	23 (29.9)	
BMI			
Underweight	23 (57.5)	17 (42.5)	0.13
Normal	71 (67)	35 (33)	
Overweight	29 (65.9)	15 (34.1)	
Obese	29 (82.9)	6 (17.1)	
Number of admission			
None	99 (74.4)	34 (25.6)	**0.006**
1	42 (63.6)	24 (36.4)	
2 or more	13 (44.8)	16 (55.2)	
Diabetes			
No	150 (67.9)	71 (32.1)	0.551
Yes	4 (57.1)	3 (42.9)	
HIV			
No	142 (66.7)	71 (33.3)	0.552
Unknown	5 (83.3)	1 (16.7)	
Yes	7 (77.8)	2 (22.2)	
Blood pressure			
Normal	110 (71.9)	43 (28.1)	**0.008**
High	36 (66.7)	18 (33.3)	
Hypotension	8 (38.1)	13 (61.9)	
Anemia			
Severe abnormal	1 (50)	1 (50)	0.898

Moderately abnormal	13 (68.4)	6 (31.6)	
Mild abnormal	26 (72.2)	10 (27.8)	
Normal	111 (67.7)	53 (32.3)	
Adherence			
Medium	98 (75.4)	32 (24.6)	**0.004**
Low	56 (57.1)	42 (42.9)	
Smoking			
No	141 (68.8)	64 (31.2)	0.234
Yes	13 (56.5)	10 (43.5)	
Alcohol			
No	136 (68.3)	63 (31.7)	0.5
Yes	18 (62.1)	11 (37.9)	
ECG			
Atrial fibrillation	34 (63)	20 (37)	0.111
Sinus rhythm	113 (71.1)	46 (28.9)	
Others	7 (46.7)	8 (53.3)	
SEF			
Severely Abnormal	28 (70)	12 (30)	0.769
Moderately Abnormal	43 (71.7)	17 (28.3)	
Mildly Abnormal	12 (66.7)	6 (33.3)	
Normal	68 (64.2)	38 (35.8)	
Preserved vs Reduced SEF			
<40% 40-49% >50%	62(72.1) 17(68) 72(63.7)	24(27.9) 8(32) 41(36.3)	0.457
Hypertension Yes No	66 (68.0) 88 (67.2)	31 (32.0) 43 (32.8)	0.890
NYHA at diagnosis			
1&2 3&4	34 (73.9) 120 (65.9)	12 (26.1) 62 (34.1)	0.302

Factors associated with current NYHA classes were assessed. The number of admissions in the preceding year i.e. two or more admissions was associated with severe disease (NYHA classes (3&4) with a p value of 0.006.Poor drug adherence and hypotension were also associated with NYHA classes 3&4 at P values of 0.004 and 0.008 respectively.

The variables that were significant in the bivariate analysis (Table 3) were included in a multiple logistic regression model to assess the adjusted effect. The results were as shown in Table 4.

Table 4: Multivariate Results of factors associated with advanced heart failure

Current NYHA	**Odds Ratio**	**P-value**	**95% Confidence Interval**	
Age	1.031	**0.002**	1.011	1.052
Male vs Female	0.569	0.119	0.280	1.156
BMI				
Normal vs Underweight	0.719	0.454	0.303	1.704
Overweight vs Underweight	0.658	0.425	0.236	1.839
Obese vs Underweight	0.265	**0.038**	0.076	0.928
Number of admission				
One admission vs none	1.668	0.164	0.812	3.425
Two or more admissions vs none	3.421	**0.016**	1.254	9.334
Blood pressure				
Hypotension vs Good control	1.171	0.682	0.549	2.500
Poor control vs Good control	5.974	**0.003**	1.845	19.337
Adherence				
Low vs Medium	3.139	**0.001**	1.622	6.077
ECG				
Sinus vs Atrial	0.609	0.196	0.287	1.292
Other vs Atrial	1.612	0.484	0.423	6.143

The effect of age on current NYHA class after adjusting for the other covariates was that increasing age was associated with worse NYHA classes at P value 0.002. Those in classes 1&2 had a median age of 63.5yrs (47, 76) while those in classes 3&4 had a median age of 70yrs (58, 79) meaning older participants were more likely to be at classes 3&4.

In terms of the BMI, our study showed that participants who were underweight were more likely to be in classes 3&4 as compared to the other BMI classes. The odds of being in classes 3&4 increased consistently from participants who were obese to those who were underweight with those who were obese less likely to be in classes 3&4.A multivariate analysis of the various BMI classes were significant for obese vs underweight with a P value of 0.038.

Poor adherence to drugs still remained associated with worse NYHA classes even after adjusting for the other covariates at a p value of 0.001.Those with low adherence were three times more likely to be in classes 3&4 than those with medium adherence , odds ratio 3.139 CI (1.622-6.077).

CHAPTER FIVE: DISCUSSION

5.1 Proportion of Advanced Heart failure (Classes 3&4)

Of all the sampled participants, 74 of them i.e. 32.5% had advanced heart failure at the time of the study as opposed to 79.8% at the time of diagnosis indicating significant improvement in terms of functional capacity for those who were already on follow up. However advanced heart failure classes at the time of diagnosis were not associated with advanced heart failure classes at the time of the study. Previous studies on the prevalence of various classes of heart failure as per the NYHA indicate great variability in their findings as compared to our study.

Table 5: Proportions of NYHA functional classes 3&4 from different studies

Author	Proportion	Year	Country	Sample size	Comments
Our study	32.5%	2017	Kenya	228	Outpatient setup
(Ahmed et al.	22.1%	2006	USA & Canada	988	Outpatient setup
Hebert et al.	30.8%	2011	USA	256	Outpatient setup
Kofi et al	52%	2013	Ghana	524	Outpatient setup
Oyoo et al	93.9%	1999	Kenya	91	Inpatient setup

In a large study in the United States and Canada entitled the Digitalis Investigation Group trial (DIG), the prevalence of NYHA classes 3&4 was 22.1%.This was an ancillary of the DIG trial, whereby 988 heart failure patients were recruited during a 31.5-month period between January 1991 and August 1993. NYHA class was determined at baseline by the participating investigators. Patients were recruited irrespective of their heart failure etiology or NYHA functional class. (Ahmed, Aronow, and Fleg 2006).In another study by Kathy Hebert, MD et al 2011 in USA that was comparing the ejection fractions and NYHA classes, the prevalence of advanced heart failure was 41.1% at the beginning of their study and 30.8% at the completion of the study which was almost similar to our study.(Hebert et al. 2011).

In an African population, a study done in Ghana by Isaac Kofi Owusu and Yaw Adu – Boakye et al on prevalence and etiology of heart failure in patients seen at a teaching hospital in Ghana Nov 2013, the prevalence of NYHA classes 3&4 was 52%.(Kofi Owusu 2013).524 patients were selected from the cardiac clinic in the study designed to determine the prevalence and etiology of heart failure among patients attending a cardiac clinic in the Department of Medicine, Komfo Anokye Teaching Hospital (KATH), Kumasi, Ghana.

In a study by Oyoo GO, Ogola EN et al on the clinical and social demographic aspects of congestive heart failure patients at Kenyatta National Hospital Nairobi, the prevalence of NYHA classes 3&4 was found to be 93.9%(Oyoo GO 1999).Of note though is that these were inpatients admitted with a diagnosis of heart failure whereas our study was focusing on an outpatient population**.**

The variability on the prevalence of advanced heart failure as seen in these studies was also demonstrated by Claire Raphael, et al 2006 while assessing inter operator variability in assigning the NYHA classes to heart failure patients. This study assessed limitations of the NYHA functional classification system and self-reported walking distances in chronic heart failure in the United Kingdom whereby thirty cardiologists were asked what questions they used when assessing patients with heart failure. To assess interoperator variability; two cardiologists assessed a series of 50 patients in classes II and III using the NYHA classification. 45 patients who had undergone cardiopulmonary testing were interviewed using a specially formulated questionnaire. The survey of cardiologists showed no consistent method for assessing NYHA class and also their literature survey showed that ninety nine percent of research papers do not reference or describe their methods for assigning NYHA classes. The interoperator variability study showed only 54% concordance between the two cardiologists.(Raphael et al. 2007).

5.2 Factors associated with advanced heart failure

Concerning factors associated with advanced heart failure after bivariate analysis, our study established that low drug adherence was associated with advanced heart failure. The number of admissions in the preceding one year and low blood pressures were also associated with NYHA classes 3&4.Other factors assessed were not found to be significantly associated with advanced heart failure. After multivariate analysis however, poor drug adherence, being underweight and advanced age were the only factors that remained significantly associated with advanced heart failure.

5.2.1 Poor adherence and advanced heart failure.

Poor adherence was found to be strongly associated with NYHA classes 3&4 in our study. The effect of poor adherence on NYHA classes 3&4, after adjusting for the other covariates, was more than threefold, OR: 3.139 (95% CI: 1.622, 6.077).Poor adherence to medications and worse outcomes in heart failure has been proven in previous studies. In one study on adherence to candesartan and placebo and outcomes in chronic heart failure in the Candesartan in Heart failure Assessment of Mortality and Morbidity (CHARM) program which was a double-blind, randomized, controlled clinical trial in which 7599 patients were enrolled .187 of these patients were excluded from the adherence analysis because of missing information on adherence. Patients had moderate-to severe CHF at baseline and were predominantly in NYHA functional class II or III 45% [n=3416] class II,52% [n=3985] class III, and 3% [n=194] class IV).In this study, even though adherence was not found to be significantly associated with the NYHA though this was a baseline NYHA, it was noted that in a large population with CHF, adherence to medication was independently associated with mortality and with hospital admission for heart failure with an OR of 0·52 (0·41–0·65)(Pocock, Wang, Pfeffer, Yusuf, McMurray, Swedberg, Östergren, et al. 2006a).

In our study, low adherence rates were at 43%, medium rates were at 57% with none of the participants having high adherence rates as per MMAS 8 scale.Non-adherence to medical regimens in heart failure has been shown to be a significant challenge and serves as a major reason that favorable outcomes associated with various therapies evaluated in clinical trials have not translated to the real setting and is clearly associated with poorer

outcomes(Hauptman 2008).None adherent rates globally among heart failure patients have been quoted in previous studies as between (31%–58%) (Albert 2008).This is comparable to our study at 43% for those with low adherence.

In a study by Verena ruf and Simon Stewart et al in 2006 in South Africa, the prevalence of non adherence was at 22% to the overall prescribed HF regimen using pill counts while only 16% were non compliant using self reported methods. The study had recruited 200 participants between November 2006 and April 2007 from the cardiology clinic with confirmed CHF with over 90% at classes 2&3 NYHA at the time of their diagnosis.(Ruf et al. 2010).

The average non adherence rates in patients with chronic illness generally are at 24.8%.This is according to (DiMatteo 2004). Various factors have been shown to influence adherence to medications as shown in the World Health Organization's (WHO) multidimensional adherence model(De Geest and Sabaté 2003).

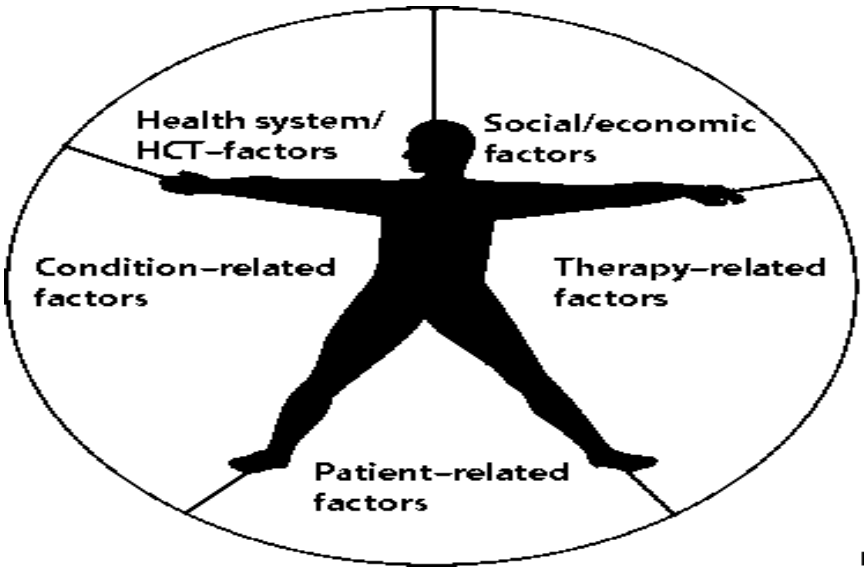

Figure 5: World Health Organization's (WHO) multidimensional adherence model

Our study however didn't look at the contribution of each of these factors to the non-adherence rates. It is however noted that in as much as non-adherence to medications is prevalent in cardiovascular populations, the variability of the methods for assessment of medication use (e.g. self-report or pharmacy refill data) makes comparisons across studies and across cardiovascular conditions difficult.(Ho, Bryson, and Rumsfeld 2009).

5.2.2 Advanced age and NYHA Classes 3&4

In our study, older participants were more likely to be in NYHA classes 3&4.Similar findings have been noted in a previous study by Ahmed et al whereby older participants (median age 71 yrs) were more likely to be in stages 3&4 than younger participants (median age 67yrs) at a P value of <0.001.(Ahmed, Aronow, and Fleg 2006).The link between advanced age and worsening heart failure stages can be explained by frailty that occurs in old age and is defined as a syndrome characterized by weakness, fatigue, and

increased vulnerability to physiologic stressors.(Deena Goldwater,MD;Natasha Lipson Altman,MD 2016)

The effect of advanced age on heart failure outcomes has not been studied widely though due in part to few participants in this particular age set.(Metra et al. 2015). However, some studies have linked advancing age to worse outcomes in heart failure as seen in our study. In the PROTECT trial that investigated 2033 patients (median age 72 years) in 2014,increased age was associated with increased risk of death at 30 days or cardiovascular/renal hospitalization, and death at 30 and 180 days.(Hazard ratio for 180-day death=1.17;95% confidence interval 1.11–1.24 for each 5-year increase).(Metra et al. 2015)

Similarly, in the EPICAL study which sought to characterize the incidence, clinical and etiologic features and outcomes of advanced congestive heart failure, mortality was independently affected by age whereby patients aged 70 to 80 years had a 50% higher risk of death than those aged less than 70years.(Zannad et al. 1999)

While evaluating data from 7599 patients in the CHARM program with CHF with and without left ventricular systolic dysfunction in 2006,Stuart J. Pocock et al also showed older age >60 yrs to be a powerful predictor of death or HF hospitalization. They estimated a 46% increase in hazard for every 10years of age above 60, with 95% CI 38–54%.(Pocock, Wang, Pfeffer, Yusuf, McMurray, Swedberg, Östergren, et al. 2006b)

5.2.3 Body Mass Index (BMI) and Advanced NYHA Classes.

According to our study, the lower the BMI the more likely it was for a participant to be in advanced NYHA classes of heart failure. Underweight participants were more likely to be in classes 3&4 than obese participants (P value 0.038).Association between low BMI and worse outcomes in heart failure has been demonstrated in previous studies. In their study in 2007 on BMI and prognosis in patients with chronic heart failure, Satish et al found that in patients with symptomatic and chronic HF, underweight status or low BMI were associated with a greater risk of all-cause death, with mild to moderate overweight status being associated with the lowest risk. In this study, 1831 patients died during a median follow-up of 37.7 months.“After adjustment for potential confounders, compared with patients with BMI between 30 and 34.9, patients in lower BMI categories had a graded increase in the risk of death. The hazard ratios (95% confidence intervals) were 1.22 (1.06 to 1.41), 1.46 (1.24 to 1.71), and 1.69 (1.43 to 2.01) among those with BMI of 25 to 29.9, 22.5 to 24.9, and <22.5, respectively.”(Satish Kenchaiah, Stuart J. Pocock, Duolao Wang, Peter V. Finn, Leonardo A.M. Zornoff and and for the CHARM Investigators 2007).A meta-analysis on the impact of body mass index and mortality in heart failure in 2008 that included nine observational studies with 28,209 participants had similar findings. In this study, Oreopoulos et al found that overweight and obesity were associated with lower all-cause and cardiovascular mortality rates in patients with CHF and were not associated with increased mortality in any study.“The potentially protective effect of increased BMI in CHF has been termed the obesity paradox or reverse epidemiology”.(Oreopoulos et al. 2008).This has also been described in another study by Guder et al while looking at the impact of cardiovascular risk factors including BMI, total

cholesterol and systolic blood pressure where their study suggested that presence of these risk factors predicted better survival in clinically symptomatic patients as per the NYHA classes and ACC/ AHA stages. (Güder et al. 2015)

5.2.4Systolic Ejection Fraction (SEF) and Advanced NYHA Classes

In our study, 38.4% of the participants had HFrEF, 11.2% had HFmrEF with the remaining 50.4% having HFpEF. There was however no association between the SEF and the NYHA functional classes. This finding of lack of association between SEF and NYHA is not unique to our study having been described before in other studies. Kathy Hebert, MD et al 2011, in their study comparing changes in the SEF and the NYHA classes suggested that EF and NYHA changes did not classify the patients in the same way. In their study, only 86 of 256(33.5%) patients were correctly classified by NYHA class as showing improvement, no change, or deterioration between echocardiographic assessments.(Hebert et al. 2011).

In a more recent study by Mahmoud et al in 2017 on echocardiographic predictors of outcome in acute heart failure patients in Sub Saharan Africa from the THESUS-HF study, the LVEF was not associated with outcomes which included 60days death or readmission. In this study, the SEF was classified as either preserved at >50% or reduced at <50%.The prevalence of those with reduced systolic ejection fraction as per this study was 73%.(Sani et al. 2017).Whereas this study did not directly compare the SEF and the NYHA classes, the outcomes that included readmission and death are usually associated with advanced NYHA class.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

1. Our study population had a higher proportion of patients with advanced heart failure classes.
2. Poor adherence to drugs is independently associated with advanced NYHA functional classes 3&4.
3. Lower BMI and increasing age are also associated with advanced NYHA classes 3&4

6.2 Recommendations

1. Since poor adherence was independently associated with worse NYHA association stages 3&4, we recommend further studies on factors affecting adherence and ways to improve it in the clinic.
2. We recommend a more robust study to assess the effect of low BMI on heart failure and nutrition support for patients attending HF clinic
3. For advancing there is need to sensitize the clinicians and care givers on this group of patients and for closer and more individualized follow up.

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APPENDICES

1. Informed Consent Form

Study No……

"**Factors associated with the clinical class of adult patients with heart failure seen at MTRH cardiac clinic**"

Invitation to participate

You are invited to participate in this research study investigating the outcomes of adult patients diagnosed with heart failure seen at MTRH cardiac clinic.

Basis for selection

You are eligible to participate in this study as you are being followed up for heart failure here at MTRH cardiac clinic.

Purpose of the study

The main aim of this study is to determine factors associated with the different clinical class of patients with heart failure on follow up at Moi Teaching and Referral Hospital.

Procedures

You will be asked some questions about the date you were first diagnosed with heart failure, your past health and social life and the type of drugs you are currently taking.

A brief clinical exam and echo will be performed. If you have not had your hemoglobin level checked over the last six months, this will be done as part of your routine care at the usual hospital rates.

Potential benefits

There is no reward for participation in this study. Patients will be booked to the physician's clinic for follow up. Knowledge on the factors associated with different clinical stages may potentially improve the knowledge on management of this condition.

Potential risks

There are no risks in this study as no invasive procedures will be used. If the hemoglobin level has to be checked, this will be done at the lab under sterile procedures.

Guarantee of confidentiality

To ensure confidentiality, at no time will your name appear on any materials or reports of the research findings (including web site postings of the results, conference presentations or publications).Materials associated with this study will be kept under lock and key in a cabinet .Your signed consent form will be stored separately from your data to ensure complete confidentiality and at the end of this study, all materials will be destroyed.

Withdrawal from participation

Participation in this study is voluntary and your decision to or not to participate will not affect your management at MTRH. If you decide to participate, you are free to withdraw your consent and to discontinue your participation at any time.

Offer to answer any questions

If you have any questions about the procedures at any time, please do not hesitate to ask. All questions about the procedures and the study in general will be answered .However; some questions may not be answered until after you have completed the procedures to ensure that the answers will not affect your responses.

Participant's statement

I am voluntarily making the decision to participate and my signature certifies that I have heard and understand the aforementioned information. Also my questions have all been answered to my satisfaction and signing this document doesn't mean I waive any legal rights.

Participant's signature _____Date_____

Research Investigator's Statement

In my judgment, the aforementioned participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to do so.

Research Investigator's Name_____

Signature_____ Date_____

0715539080, P.O BOX 3 Eldoret Kenya 30100

.Email:boro_c84@yahoo.com

2. Fomu ya Idhini

NambariyaUtafiti ……

Matokeo ya matibabu kwa watu wazima wenye ugonjwa wa moyo wanaotibiwa katika Hospitaliya MTRH.

MwalikowaKushiriki

Unaalikwa kushiriki katika utafiti wakuchunguza matokeo ya matibabu kwa watu wazima waliopimwa na kupatikana na ugonjwa wa moyo katika hospitali ya MTRH

Msingi wa kuteuliwa

Unafuzu kuwa mshiriki katika utafiti huu kwa sababu unapokea matibabu hapa hospitali ya MTRH

SababuyaUtafiti

Sababu kuu ya utafiti huu nikujua matokeo ya matibabu kwa watu wazima walio na ugojwa wa moyo wanaotibiwa katika Hospitali ya MTRH.

Utaratibu

Utaulizwa maswali kadhaa kuhusu siku ulipotambuliwa kuwa na ugonjwa wa moyo pamoja na historia ya afya yako, maisha yako ya kijamii na aina ya dawa unayotumia kwa sasa. Pia uchunguzi wako wa kiafya na uchunguzi wa moyo kufanywa. Pia kama hujachunguzwa kiwango chako cha damu kwa muda wa miezi tatu iliyopita, utapata kuchunguzwa katika.

Uwezekano wa faida

Hakuna malipo ya kushiriki kwa utafiti huu. Wagonjwa wenye ugonjwa wa moyo watasajiliwa kwenye cliniki ili daktari awafuatilie. Kujua matokeo ya wagojwa itasaidia kuzidisha jinsi wagonjwa wenye ugonjwa huu wanahudumiwa.

Uwezekano wa Adhari

Hakuna adhari wakati wautafiti huu kwani kuna utaratibu maalumu utakaotumika kuzuia adhari zozote.

Kudumishwa kwa siri

Jina lako haliwezi kuwekwa kwenye vifaa au kwenye ripoti ya matokeo ya utafiti (zikiwemo, matokeo kuwekwa kwenye mtandao, maonyesho kwenye mikutano au machapisho) ilikudumisha siri. Vifaa vya utafiti vitawekwa mahali pa siri. Fomu ya idhini ulioweka sahihi itawekwa sehemu tofauti na data yako ilikuwek asiri. Baada ya utafiti, vifaa vyote vitaharibiwa.

Kujitoa kutoka Utafitini

Kushiriki katika utafiti ni kwa hiari na sababu ya kujitoa haiwezi kua dhiri au kukuzuia kupata matibabu hospitali ya MTRH. Ukiamua kushiriki una uhuru pia wa kujitoa katika utafiti wakati wowote.

Kujibu swali lolote

Kama una swali lolote kuhusu utafiti wakati wowote, tafadhali usiogope kuuliza.Maswali yote kuhusu utaratibu au utafiti yatajibiwa,lakini maswali mengine yanaweza kutojibiwa hadi baada ya kumaliza utafiti ili kuthibitisha kuwa majibu hayawezi kuadhiri matokeo.

Taarifa ya Mshiriki

Ninafanya uamuzi kushiriki kwa hiari na sahihi yangu ni dhibitisho kuwa nimesikia na kuelezwa masharti hayo. Pia maswali yangu yamejibiwa nanimetosheka kuweka sahihi katika cheti hikimaanishi nimetoa hakisho zote za kisheria.

Sahihi _____ Tarehe_____

Taarifa ya Mtafiti

Kwa uamuzi wangu, mshiriki huyu ametoa ushiriki wake kwa hiari, na kwa kujua ametoa idhini na anauwezo wa kufanya hivyo kisheria.

Jina la Mtafiti_____

Sahihi ya Mtafiti _____Tarehe _____

3. Study Questionnaire

Demographic Data.

Date…….

Age…… Gender/sex Male ☐ Female ☐

Weight…….. Height…….. BMI…… HB……..

Clinical Data.

Year diagnosed with HF…….

No of admissions due to HF in the last 1 yr……..

NYHA staging at time of diagnosis…… Current NYHA staging……

Type of medication currently taking

1. …… Duration (months)……

2. ……... Duration (months)……

3. ……. Duration (months)……

4. …….. Duration (months)……

Do you sometimes forget to take your medicines? YES ☐ NO ☐

People sometimes miss taking their medications for reasons other than forgetting. Thinking about the past two weeks, were there any days when you did not take your heart failure medicines? YES ☐ NO ☐

Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it? YES ☐ NO ☐

When you travel or leave the house, do you sometimes forget to take your medications?

YES ☐ NO ☐

Did you take your heart failure medicines yesterday? YES ☐ NO ☐

When you feel like your disease condition is under control, do you sometimes stop taking your medications?

YES ☐ NO ☐

Have you ever felt distressed or pressured about strictly following your treatment?

YES ☐ NO ☐

How often do you have difficulty remembering to take all your medications? (Please circle the correct number)

Never/Rarely…….0

Once in a while…….1

Sometimes……2

Usually ……..3

All the time ……..…….4

Co morbidities: Hypertension: YES ☐ NO ☐……

Diabetes: YES ☐ NO ☐……..

HIV: YES ☐ NO ☐ Unknown

Others……

……

Smoking: YES ☐ NO ☐ yrs…….

Alcohol: YES ☐ NO ☐ yrs……

Blood pressure: Systolic…… Diastolic…… Pulse rate ……..

Systolic ejection fraction…….

ECG rhythm report…….

4. Heart Failure Criteria

The Framingham criteria for the diagnosis of heart failure consist of the concurrent presence of either 2 major criteria or 1 major and 2 minor criteria.

Major criteria include the following:

- Paroxysmal nocturnal dyspnea
- Weight loss of 4.5 kg in 5 days in response to treatment
- Neck vein distention
- Rales
- Acute pulmonary edema
- Hepatojugular reflux
- S3 gallop
- Central venous pressure greater than 16 cm water
- Circulation time of 25 seconds
- Radiographic cardiomegaly
- Pulmonary edema, visceral congestion, or cardiomegaly at autopsy

Minor criteria are as follows:

- Nocturnal cough
- Dyspnea on ordinary exertion
- A decrease in vital capacity by one third the maximal value recorded
- Pleural effusion
- Tachycardia (rate of 120 bpm)
- Bilateral ankle edema

5. Procedure for Blood Pressure measurements

Equipment

- Quiet room
- Comfortable seat
- Automated Blood Pressure Machine

Procedure

1. Patient was seated in a comfortable chair with both legs on the floor uncrossed

2. Procedure was explained to the subject.

3. A properly sized BP cuff length of which is at least equal to 80percent of the circumference of the upper arm was used with the elbow at the level of the heart.

4. Cuff was placed around the upper arm with the lower edge at least 1 inch above the antecubital fossa and then rapidly inflated.

5. The blood pressure reading was noted and recorded.

6. If pressure was elevated, measurement was repeated after 15minutes.

6. Procedure for HB check.

1. Patient was seated in a comfortable chair

2. Procedure was explained to the subject and informed consent acquired.

3. Left hand was used for Right handed people and vice versa.

4. Area cleaned with an alcohol swab.

5. A sterile needle was used and blood collected with a capillary and transferred to the hemocue for reading

6. Pressure on the puncture wound applied for a few seconds to allow hemostasis.

7. Results were communicated to the patient.

7. NYHA functional class sample questions

NYHA functional class sample questions	CLASS
Are you dyspneic at rest or can't finish a sentence	iv
Are you able to perform minor house cores but still dyspneic	iii
Can you walk long distances on flat surface or slightly elevated ground without taking rest	ii
Can you climb stairs with some minimal limitations	i