THE UNIVERSITY OF NAIROBI, COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS

THE PREVALENCE OF SEXUAL DYSFUNCTION AND ASSOCIATED FACTORS AMONG AMBULANT HEART FAILURE PATIENTS ATTENDING KENYATTA NATIONAL HOSPITAL

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DEDICATION

Dedicated to my late Mum; in your memory we find the strength and the resilience to press on. Your values and teachings still live with us. May you forever rest in an eternal peace.

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To the Almighty God, for always being my guiding light without whom none of this would be possible.

My sincere gratitude goes to my family, friends, and the faculty members at department of clinical medicine and therapeutics for the undying support and encouragement through-out this journey.

Finally, my supervisors and the statistician for their guidance and time.

TABLE OF CONTENTS

TABLES

LIST OF ABBREVIATIONS AND ACRONYMS

ACE	Angiotensin-Converting Enzyme
AHA	American Heart Association
ARB	Angiotensin II Receptor Blockers
cGMP/cAMP	Cyclic Guanosine Monophosphate/Cyclic Adenosine Monophosphate
DSM-V	Diagnostic and Statistical Manual of Mental Disorders
ED	Erectile Dysfunction
eNOS	Endothelium-Derived Nitric Oxide
ESC	European Society of Cardiology
FSFI-6	Female Sexual Functional Index-6
GDMT	Guideline Directed Medical Therapy
HF	Heart Failure
ICD-10	International Classification of Diseases
ICF	Informed Consent Form
IIEF-5	International Index of Erectile Function-5
KNH	Kenyatta National Hospital
LVEF	Left Ventricular Ejection Fraction
NYHA	New York Heart Association
MMAS	Massachusetts Male Aging Study
QoL	Quality of Life
SD	Sexual Dysfunction
SPSS	Statistical Package for Social Science
SSA	Sub Sahara Africa
UON	University of Nairobi

DEFINITION OF TERMS

Heart Failure: According to Universal HF Definition, HF is defined as a clinical syndrome with current or prior symptoms and or signs caused by a structural and/or functional cardiac abnormality (as determined by an EF of <50%, moderate/severe ventricular hypertrophy or moderate/severe valvular obstructive or regurgitant lesion) & and corroborated by at least either Elevated natriuretic peptide levels or objective evidence of cardiogenic pulmonary or systemic congestion by diagnostic modalities, such as imaging or hemodynamic measurement at rest or with provocation (e.g. exercise)(1).

Sexual Dysfunction: Sexual dysfunction refers to a difficulty experienced by an individual or a couple during any phase of the sexual response cycle (2,3)which traditionally includes excitement, plateau, orgasm, and resolution(4).

Erectile Dysfunction: Is the persistent inability to attain and maintain a penile erection to sufficiently perform a satisfactory sexual function(5,6).

ABSTRACT

Background: Sexual activity is an important determinant of quality of life among chronic heart failure patients. Globally, Heart failure poses major public health burden with high morbidity and mortality. Despite numerous studies in other part of the world, sexual dysfunction is under-recognized and not sufficiently reported in Africa. This study has therefore clinical and epidemiological relevance

Objective: To determine the prevalence of sexual dysfunction and related factors among ambulatory Heart failure patients attending the adult cardiology clinic at Kenyatta National Hospital.

Method: A descriptive cross-sectional study design carried out at the KNH adult cardiology clinic. Ambulatory patients over the age of 18 years with a documented diagnosis of HF based on Framingham's criteria on follow up at the KNH cardiology clinic for three months were randomly sampled. The presence of female sexual dysfunction and male erectile dysfunction were assessed using Female Sexual Function Index (FSFI-6) and male Erectile dysfunction International Index of Erectile Function (IIEF-5) version respectively.

Analysis: Prevalence of erectile dysfunction or female sexual dysfunction among heart failure patients was determined as a proportion of men with ED or women with FSD and reported as a percentage.

The association between sexual dysfunctions with some selected socio-demographic and clinical characteristics was analyzed using the Pearson chi-square for categorical data, and independent t-tests for continuous data. The odds ratio, as well as the 95% confidence interval, was calculated. The p-value was set at < 0.05

Results: A total of 306 heart failure patients were recruited for the study. 164 (53.6%) were male with mean age of 52.1 ± 17.2 years, and 142 (46.4%) were female with mean age of 53.1 ± 15.2years. The prevalence of ED in heart failure is **71.3%,** with 45.7% of male patients experiencing mild, 12.2% moderate, and 13.4% severe erectile dysfunction. The prevalence of Female sexual dysfunction in Heart failure is **81.0%** with 44.4%,12.0% and 24.6% reporting mild, moderate and severe FSD respectively. Increasing age, advanced NYHA class and presence of comorbities such as diabetes, hypertension as reported in our study was associated with increased erectile dysfunction.

Conclusions: This study demonstrated that majority of heart failure patients have sexual dysfunction with majority of those having mild sexual dysfunction.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background

Globally, Heart failure (HF) poses significant burden with high rates of morbidity and mortality. In the year 2017, the global burden of diseases, estimates cases of heart failure to be over 64.3 million worldwide with epidemiology varying within and between countries and continents (7,8), and this figure is expected to increase in the next few decades (9). Despite advancement in medical therapy and device assistance, likely outcomes from heart failure are still poor. According to a population based cohort study in united kingdom, Survival after diagnosis of HF has shown only modest improvement in the 21st century and lags behind other serious conditions such as cancer (10).

While comparable estimates are currently unavailable for Sub Saharan Africa (SSA), Hospital-based studies shows that heart failure is the commonest primary diagnosis of people admitted with cardiovascular disease accounting for up to 9 to 15% percent of hospital admissions (11). Survival rates are poorer in SSA with estimated 6 months mortality rates approaching 20% (12). With improved survival from communicable diseases due to improved medical care and vaccination, and due to expanding urbanization, and changes in nutrition and lifestyle, the burden of heart failure is predicted to increase (9). In the SSA, The burden of CVDs and their risk factors is increasing with available projections suggesting that in a few decades from now, CVDs and other NCDs will overtake communicable diseases as the most frequent cause of death in this region (13).

Sexual activity is an important determinant of life quality among heart failure patients. The prevalence and burden of erectile dysfunction of over 97,000 male respondents over the age of 18 years across 8 different countries was 40.5% (37.2-48.6%) and the prevalence varied across geographies, age, smoking and alcohol use, regular exercise and presence of comorbidities (14). By 2025, it is estimated that 322 million men globally shall be affected by erectile dysfunction, an increase from 152 million men in 1995 (15). In addition, erectile dysfunction considerably affects the quality of life of men's partners. Partners of men with erectile dysfunction experiences lower sexual satisfaction, corresponding to the degree of erectile dysfunction in their partner (16).

The American Heart Association (AHA) approximates that sixty to eighty-seven percent of all heart failure patients suffer from sexual dysfunction including a decline in sexual interest and activity. (17). Despite its impact, the psychosocial aspect of the management of patients is sometimes overlooked in our practice which contributes to high disease burden.

Sexual dysfunction is under-recognized and under-reported with the prevalence of sexual dysfunction and its related factors poorly described in Africa. This resulted in a scarcity of evidence-based research on sexual dysfunction among heart failure patients.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Definition of Heart Failure

HF is defined as a clinical syndrome with current or previous symptoms and signs due to a structural and/or functional cardiac abnormality (as determined by an EF of <50%, moderate/severe valvular obstructive or moderate/severe ventricular hypertrophy or regurgitant lesion) and supported by at least either high natriuretic peptide levels or objective evidence of cardiogenic, pulmonary or systemic congestion by diagnostic modalities, like imaging or hemodynamic measurement at rest or with exacerbation such as exercise(1).

2.2 Epidemiology of Heart Failure

Heart failure is a growing public health concern with a global prevalence of about 64.3 million, and its epidemiology varies widely within and between countries (7). HF is associated with high morbidity and mortality and presents substantial challenge to the healthcare system. Currently, in high-income countries, HF is the most common diagnosis in hospitalized elderly patients aged >65 years (18).

The international congestive heart failure studies (INTER-CHF), a multicenter cohort study was carried out in sixteen African countries, South America, the Middle East and Asia with 6 months and one-year follow-ups (19,20). It was the first major study to methodically obtain data from hospitalized and out-patients with HF in these regions, that up until then was under-represented in previous global HF studies. Mortality rates was reported highest in Africa with (34%), in Southeast Asia (15%), and the lowest in China (7%), South America (9%), and the Middle East (9%), and the regional differences persisted after multivariable adjustment (21). Marked regional variation in mortality existed among heart failure patients after multivariable adjustment perhaps due to interplay between health-care infrastructure, quality and access, or genetic and environmental factors (21).

Before the INTER-CHF study, data from the Sub-Saharan Africa Survey of Heart Failure (THESUS–HF) a prospective, observational survey of 1006 acute HF people from 9 African nations, to characterize the cause, treatment, and outcomes during 6 months of follow-up, revealed acute Heart failure has predominately non-ischemic causes. Hypertension was reported as the rising cause of heart failure (35.4%), significant increase in cardiomyopathies (29 %), and a decline in rheumatic heart disease (7%) compared to previous studies. Ischemic heart disease contributing 20% of cases of heart failure. The condition was noted in middle-aged adults, equally in women and men and is associated with high mortality (22).

Besides the clinical burden, heart failure imposes a huge economic burden. In 2012 global expenditure on heart failure was estimated at around US$108 billion. The expenditure on heart failure varies extensively between middle and low-income countries and high-income countries. The total cost of medications for patients with HF in the USA is likely to increase from US$20.9 billion in 2012 to $53.1 billion by 2030 (7,23).

HF has become the leading form of cardiovascular disease in Africa with a great socio-economic burden owing to its high level of prevalence, mortality, and impact on the growing population. Although no information is available on the prevalence of heart failure in the general population, indirect estimates can be derived from epidemiology documented from high income, developed nations. For instance, roughly 3-7% of patients hospitalized in Africa are due to heart failure(11). However, it is conceivable, that HF has the similar relative economic burden on African health resources just like in high income countries and approximately 1% of the health budget is spent on managing patients with heart failure (24).

Furthermore, the presentation of HF in younger age groups in SSA has put an additional economic burden due to the number of active life years lost in this productive group of people which in turn undermines the productivity of the continent.

2.3 Pathophysiology of Heart Failure

Heart failure is a syndrome that can present as multiple organ dysfunctions. (25) Following initial cardiac injury which may occur acutely such as myocardial infarction, or chronically like in hypertension which results in a reduced cardiac output. cellular, structural, neurohumoral and molecular (sub-cellular structure) mechanisms are activated and act as a network to maintain physiological functioning. These processes influence the function among intra as well as intercellular behavior. (25,26)

As a consequence, the activation of the renin-angiotensin-aldosterone (RAAS), the sympatho-adrenergic (SNS) and cytokine system takes place leading to adaptive mechanisms that stabilize cardiac output temporarily through increased salt and water retention, peripheral arterial vasoconstriction, increased contractility, and release of inflammatory mediators. (25,27)

However, sustained activation has deleterious effects which ultimately result in pathological ventricular remodeling, myocardial fibrosis, and apoptosis, altered gene expression and inflammation. This perpetuates the deterioration of cellular function in a vicious cycle that subsequently leads to cardiac decompensation.(26,28) These maladaptation mechanisms are the initiators for the observed heart failure practical clinical findings like dyspnea, fluid

retention, malabsorption, reflex tachycardia, arrhythmias, and ultimately multi-organ dysfunction leading to death (25).

2.4 Sexual Dysfunction

According to the 10th edition of the *International Classification of Mental and Behavioral Disorders* (ICD-10), sexual dysfunction is difficulties experienced by individual or a couple during any phase of the sexual response cycle (2). A similar definition was proposed by a Consensus Statement from the Fourth International Consultation on Sexual Medicine of 2015 (3). Sexual dysfunction prevents a person from experiencing satisfaction from sexual activity. Traditionally, sexual response cycle includes excitement, plateau, orgasm, and resolution. Desire and arousal are parts of the excitement phase of the sexual cycle (2,4,29). It is important to know that both women and men experience these phases, even though the timing usually differs. For instance, it is unlikely for both partners to reach orgasm at the same time. Additionally, the intensity of response and the time spent in each phase varies from person to person (30).

Erectile dysfunction is the persistent failure to achieve and/or maintain a penile erection suitable for sexual intercourse (5,6). Other disorders of sex in males are delayed ejaculation despite enough sexual stimulation (retarded ejaculation) or early, or premature ejaculation, lack of desire for sex and failure of detumescence (31).

In females, however, sexual dysfunction definition is more difficult as women's sexual perception is more complex and lacks objective assessment. Several definitions of sexual dysfunction for women exist but the most descriptive of them define it as decrease in sexual desire or arousal or failure to achieve orgasm or insufficient vaginal lubrication before and during intercourse or incapacity to relax the vaginal muscles sufficiently leading to painful intercourse (32).

2.5 Epidemiology of Sexual Dysfunction

2.5.1 Male Erectile Dysfunction

Existing reports indicates over 150 million men globally have some level of ED. The projected prevalence of ED in 2025 is 322 million men worldwide with the highest numbers to be recorded in developing nations due to increased life expectancies and expanding populations (15).

The Massachusetts Male Aging Study (MMAS) reported the results of 1709 men aged 40-69 with an unexpectedly high rate of 52% ED prevalence. Furthermore, it's found that the likelihood of complete ED by the age of 70 years was threefold compared 40 years (33). ED also affects the QoL of men's partners, Partners of men with ED experience lower sexual satisfaction, commensurate with the degree of ED in their partners (34).

Berrada et al conducted a population-based study in Africa and evaluated the incidence and correlates of ED in 655 randomly selected men over the age of 25 years living in Casablanca, Morocco. It was revealed that the incidence of risk factors for and comorbidities of ED was similar as those found in Western countries. In general, the prevalence of ED among assessed men was 54%, and its incidence markedly increased with age. Hypertension, heart disease, diabetes, and smoking in this group (35,36).

Shaeer, et al. also assessed the prevalence of ED among men using primary health care clinics in Pakistan, Egypt, and Nigeria. The findings like that of Berrada et al showed that the incidence of ED and other diseases related to the condition in SSA, the Middle East, and South Asia are similar to those in developed nations. Surveys conducted on men seeking primary medical care aged between 35 to 70 years indicates that the age-adjusted prevalence of ED was 57.4% in Nigeria, 63.6% in Egypt, and 80.8% in Pakistan. Diabetes, older age, depression and prostate conditions were associated with higher risk for ED like in other studies (37).

2.5.2 Female Sexual Dysfunction

Female sexual dysfunction mechanism is a multifactorial, age-related, progressive problem. It is an intricate neurovascular phenomenon controlled by psychological, neurovascular, and hormonal factors that may have a huge effect on self-esteem, quality of life, mood, and relations (38).

Female sexual dysfunction constitutes diverse conditions characterized by reported individual distress in one or more of the following areas: desire, arousal, orgasm or pain (4). Although female sexual dysfunction is fairly common, women are unlikely to discuss it with their healthcare providers unless they are asked (39), and most healthcare providers are not

comfortable asking for variety of reasons such as the inadequate knowledge and training to diagnose and manage the condition, insufficient clinical time to address the issue, and underestimation of its prevalence (39).

Approximately 43% of American women reported having experienced sexual problems with twelve percent considering this problem bothersome as it leads to individual distress (40). The prevalence of female sexual dysfunction increases through middle age, from approximately 10% among women aged 18 to 44 years to a peak of 15% among those aged 45–64 years. And the prevalence declines in older age group to about 9% among those aged 65-85 years (40).

In China, the prevalence of female sexual dysfunction was lower than in other studies. A study on the prevalence of sexual dysfunction among the general female population aged 20 to 70 years old in mainland China conducted from February 2014 to January 2016 found a low prevalence rate of 29.7% (41).

2.6 Sexual Dysfunction in the Context of Heart Failure

Heart failure patients may experience sexual dysfunction for various reasons just like the general population. The most common underlying causes include atherosclerosis, neurological conditions, hormonal deficiencies, traumatic injury, side effects of medication, and psychogenic contributions. HF poses unique social, psychological, physiologic, and drug-related consequences contributing to the high incidence of sexual dysfunction.

There exist a close relationship between erectile dysfunction, coronary artery disease and HF as they share risk factors such as hypertension, diabetes mellitus, smoking, and dyslipidemia as well as causal disease mechanisms like atherosclerosis and endothelial dysfunction (42). In addition to this, there are unique sequelae to HF that may also contribute to ED, such as depression, neuro-hormonal change, an inequality of circulating vasodilators, reduced cardiac capacity, and probable negative effects of HF medical therapy. (43)

Conversely, sexual dysfunction in females with heart failure has not received significant awareness, mainly in development of medications for treatment. Steinke in 2010 established that while there exist some therapeutic options for women with sexual dysfunction, this information is not well published. This is further compounded by myths and stereotypes regarding women's sexual function. Public perception as well as many healthcare givers believe that women have less sexual activity interest, mostly if they are postmenopausal (38).

The Heart and Estrogen/Progestin Replacement Study (HERS) study involving 2,763 postmenopausal women with a mean age of 67 years found that 39% of women in HERS were

sexually active and 65% of them reported not less than 1 of 5 sexual problems. Young and married women, fewer years since menopause, higher parity, modest use of alcohol, non-smokers, and absence of depression were independently associated with better sexual function. They concluded that a significant number of women with heart disease still engage in sexual activity into their 70s and more than 65 % of them report discomfort and other forms of sexual function challenges (44).

2.6.1 Prevalence of Sexual Dysfunction in Patients with Heart Failure

The American Heart Association (AHA) estimates that sixty to eighty-seven percent of all heart failure patients suffer from sexual dysfunction including marked reduced sexual interest and activity, One quarter reporting cessation of sexual activity entirely (17).
Schwarz et al sampled a total of 100 patients for a non-randomized study, 74 males and 26 females patients found 84% of males and 87% of females with heart failure reported some degree of sexual dysfunction (45), this data was close to a study by Westlake who reported a noteworthy decrease in sexual function and frequency of sexual relations in 75% of patients with advanced heart failure (46).

In Iran, 100 men with systolic HF were recruited by Sharareh et al for a study to establish the presence of ED and associated factors. The study found that 80% of subjects with erectile dysfunction out of which 36% had severe ED with 26% moderate and 18% mild. ED was associated with medical conditions, drugs for treatment, age, co-morbidities, and psychological disorders. They also found erectile dysfunction had impacted negatively on quality of life of patients with HF (47).

A study on sexual function in both male and female patients with advanced heart failure in NYHA III or IV found roughly three-quarters of the patients had a marked reduced sexual interest and in the frequency of sexual relations caused by illness, with 25% of them having stopped sexual activity. Marked reductions in pleasure or satisfaction from sex were reported by over 50% of the patients with heart failure interviewed. Although few individuals had significant marital problems or arguments with their spouse as a result of their illness(48).

In Africa, Epidemiological literature reveals that little research has been done on sexual dysfunction among heart failure patients resulting in limited epidemiological knowledge. The only study available was carried out by Boombhi from Yaoundé, Cameroon on the prevalence and Risk Factors of Sexual Dysfunction in Patients with Chronic Heart Failure which was found to be 57.7%. Disorders of sexual desire, vaginal lubrication disorders, and men's erectile

disorders were the 3 main disorders identified in this study. Female gender, advancing age above 60 years, the use of beta-blockers, hypertension, and fear of heart attack during sex were commonly associated as independent risk factors (49).

Sexual dysfunction in this study was most frequent in females than males. This is explained by the fact the sample size constituted largely of older participants and post-menopausal women. It is known that menopause is associated with hormonal disorders that alters sexual function (49). There is no available data in Kenya on sexual dysfunction among patients with heart failure but studies of sexual dysfunction in other chronic diseases such as hypertension, diabetic mellitus, and chronic kidney disease have been carried out and showed significant burden and impact on HRQoL of patients with these chronic conditions (50).

2.7 Associated/Risk Factors

2.7.1 Cardiac Capacity and Exercise Tolerance

Sexual activity is closely related to exercise tolerance and conditioning. even though it is hard to standardize exertion during sex amid patients and their partners, it's however, regarded that the 'average' coitus requires almost the same quantity of oxygen consumption as a brisk walk up to two flights of stairs (51).

Exercise capacity in chronic HF is determined by the ability of the patient to increase heart rate and stroke volume past submaximal stage of exercise (52). There are disturbances of preload response, autonomic dysregulation, and excess vascular resistance that are secondary to neurohormonal activation which alters patients' ability to increase exercise capacity among patients with HF (53).

A study by Jaarsma et al in Belgium on Sexual function in advanced heart failure patients found considerable relationship between patient's level of sexual function and the outcome of the six-minute walk test. There is a notable but weaker association between sexual performance and NYHA functional class. According to this study, there is no correlation shown between sexual function and ejection fraction (48).

2.7.2 Psychological Causes

Certainly, psychogenic causes of sexual dysfunction such as anxiety and depression may be confounded in heart failure patients. This is due to the patients' perception of poor prognosis and the greater impact of symptoms due to heart failure on quality of life. In this population, depression is multifactorial and varies with the natural evolution of symptoms of heart failure (54).

Goldstein et al, who studied a triad of depressive symptoms, cardiovascular disease and erectile dysfunction and their correlation have proposed a form of mutually reinforcing triad. He, therefore, proposed a model where a 3-way holistic, mutually reinforcing relationship between depressive symptoms, cardiovascular disease and ED is postulated because they share same risk factors and etiologic association. He further recommends that people presenting with ED symptoms be regularly screened for symptoms of depression and cardiovascular disease and vice versa (55).

Reddy et al did a cross-sectional comparative study on depressed women with sexual dysfunction and established 46 % of them with clinical depression had sexual dysfunction. The difference in sexual dysfunction among cases and controls was found to be statistically significant (56). Furthermore, selective serotonin-reuptake antagonists and non-selective serotonin-reuptake inhibitors used for treatments of depression have been implicated to increase sexual dysfunction while the incident is lower in patients using other anti-depressants such as bupropion, nefazodone (57).

Fear of death during sexual activity and performance anxiety also contribute to ED (58). comorbid anxiety in a patient with chronic heart failure was associated with worse self-care behavior (59).

2.7.3 Vascular Causes

2.7.3.1 Arterial Insufficiency

Many patients with heart failure have underlying atherosclerosis. Atherosclerosis accounts for approximately forty percent of ED in men older than 50 years (60). Atherosclerosis results in reduced arterial inflow into the penile corpora cavernosa by causing penile vessel intimal hyperplasia, focal stenosis, plaque deposition, or often sclerosis, and thus less blood flow through the common iliac, the hypogastric and pudendal arteries (61). Endothelial dysfunction resulting from atherosclerosis, even without definitive arterial stenosis contributes to ED (62). The clitoral and vaginal vascular insufficiency syndromes are associated directly with reduced genital blood flow secondary to atherosclerosis of the pudendal arterial bed. Diminished pelvic blood flow caused by the aortoiliac atherosclerotic disease leads to clitoral smooth muscle fibrosis and vaginal wall dryness. Ultimately this causes vaginal dryness and dyspareunia symptoms (63).

2.7.3.2 Endothelial Dysfunction

It is suggested that endothelial damage results in a reduced available endothelium-derived NO by either decreased production or increased breakdown. mRNA down-regulation of the

endothelial enzymes NO synthase and cyclooxygenase, both of which are essential in producing endothelium-derived vasodilators results in declined production of NO. This insufficiency appears to be specific to the physiologic heart failure state. The production of Oxygen-derived free radicals has also been linked with inhibition of endothelium-dependent vasodilation, increased free radical production causing rapid inactivation of NO (64).
It is postulated that expressions of vaginal endothelial NO synthase and phosphodiesterase 5 may play a vital role in the pathophysiology of FSD(65).

2.7.3.3 Endothelin Elevation

Heart failure is associated with reduction in circulating vasodilators like prostacyclin, as well as an increase in vasoconstrictors such as endothelin. Endothelin-1 potently stimulates gradually, developing long-lasting contractions in the corpus cavernous and penile vessels and is a contributing factor in maintaining the corpus cavernosal smooth muscle tone (66). Endothelin can have a significant impact on penile pathophysiology as modulators of other contractile agents (67). This pathophysiologic state, where an imbalance exists between potent vasoconstrictors and the effects of vasodilators, prohibits the vascular effects needed to attain and maintain sufficient erection (66).

2.7.4 Medications: HF Medication and Other Medication for Related Co-Morbidities

The main groups of drugs used as the cornerstone for HF therapy are known to affect sexual performance or libido.

Renin-Angiotensin-aldosterone system(RAAS)-Yamamoto et al in a study on the effects of replacing dihydropyridine calcium-channel blockers with angiotensin II receptor blockers on the quality of life of hypertensive patients found that patients who are younger than 65 years old had improved sexual function (68). Favorable sexual activity and improvement of sexual function were demonstrated in the valsartan group by a different study comparing sexual side effects of the ARB agent with beta-blocker carvedilol (69).

Patients on valsartan therapy showed improved orgasmic function, intercourse, and general sexual contentment with valsartan for 6 months. in addition, there was an improvement in sexual desire noted (70). Ismail et al in randomized control trials reported improvement in sexual activity with ARBs (valsartan) but erectile functions did not change considerably in ARBs (losartan or telmisartan) treated men as compared to control or placebo (71).

Studies have shown that ACE inhibitors have neutral effects on sexual function (72). A study by Speel et al on long-term improvement of cavernosal perfusion by ACE inhibition in men with advanced atherosclerotic ED shows the number of sexually active men increased, and the

severity of ED decreased in these participants (73). ACE inhibitors as well as ARB can reverse endothelial dysfunction by averting the effect of angiotensin II, extending the half-life of nitric oxide, and decreasing the degradation of bradykinin. The latter substance is a potent nitric oxide stimulator and prostacyclin release and would therefore not expected to cause erectile dysfunction (74).

Beta-adrenergic receptor blockers- A study by Dusing et al on sexual dysfunction among men with hypertension associates beta-blockers with depressed erectile function (72). Initial theories have linked it to diminished perfusion pressure and/or direct impact on smooth muscle. Franzen et al carried out a randomized, double-blinded study on the effects of beta blockers on sexual performance in men with coronary heart disease where 192 subjects were recruited, 97 were put on metoprolol 95 mg, and 95 patients were given a placebo. ED scores were similar in the metoprolol and the placebo group at end of the study (75).

Studies on carvedilol, have also been associated with sexual dysfunction. A prospective study on sexual activity in hypertensive men treated with carvedilol or valsartan showed a decline in sexual activity with the carvedilol-treated group while eventual sexual improvement in the valsartan-treated group. Blood pressure was considerably lowered by both treatments, with a 48% of normalization of blood pressure with valsartan and 45% with carvedilol. In this study, people with comorbidities like diabetes and coronary atherosclerosis were not part of the study. Moreover, it is unknown whether these data represent the beneficial impact of valsartan or the deleterious effects of carvedilol (69).

A recent literature search comparing nebivolol with other beta-blockers in hypertensive and ED patients identified four European studies. It has been reported that erectile function significantly improved with nebivolol in two of the research studies, while the other two studies indicated erectile function does not significantly worsen with nebivolol as compared to other beta-blockers agents. Nebivolol has a distinct mechanism of action that involves the release of nitric oxide that results in penile vasodilation which may be beneficial to male patients with history of hypertension and ED. A lot still remain unanswered before nebivolol is considered the recommended beta-blocker in this patients with ED (76).

Aldosterone antagonists- are known agents affecting sexual performance or libido. Spironolactone, the aldosterone antagonist also with antiandrogen effects, presently used as standard HF therapy, causes erectile dysfunction, gynecomastia, and low libido (77).

Digoxin- although digoxin therapy has no effects on overall heart failure mortality, and it is used in clinical stability and exercise capacity in patients with symptomatic HF.

In a study by Gupta et al in India on the mechanism for modification of human erectile function by digoxin, digoxin at therapeutic concentration is associated with alteration of human erectile function by inhibition of corporeal smooth muscle sodium pump activity that promotes contraction and impedes nitric oxide-induced relaxation (78).

Earlier studies demonstrate that patients on long-term digoxin therapy have higher serum levels of estrogen, decrease serum levels of luteinizing hormone, and decreased plasma levels of testosterone. The decrease in luteinizing hormone and testosterone may be related to increase in estrogen. The precise mechanism is still unknown but it is believed that digoxin can serve as an exogenous substrate for estrogen synthesis (79).

2.7.5 Co-morbidities

Numerous co-morbidities in HF patients might be associated with sexual dysfunction, however, much of the evidence is related with diabetes and anemia (80). ED and diabetes are a well-established combination regarding sexual activity in female and male patients with diabetes mainly due to damaged nerves and small blood vessels (80,81).

Anemia has been reported in most patients with HF and has significant role in determining the sexual activity and quality of life of these patients (81).

A study by Apostolo et al on Erectile Dysfunction in Heart Failure and its association with Exercise Performance, Comorbidities, and Heart Failure Treatment found comorbidities such as diabetes and anemia are frequently associated with ED.(80)

2.7.6 Erectile Dysfunction and Age

A recent review by Jaarsma et al showed that 60 to 87 % of patients with HF report sexual problems and dismally 31% of patients with heart failure younger than 70 years of age have normal sexual function. Although sexual dysfunction prevalence is comparable between healthy older patients and those with HF, male Patients with HF are reporting more Erectile dysfunction. The prevalence of ED in men with cardiac disease is up to 81% compared to 50% in the common population. Some patients perceive their HF symptoms and HF medications contribute to their sexual problems (82).

2.8 Sexual Dysfunction Assessment Tools

2.8.1 The Female Sexual Function Index (FSFI-6)

It is a multidimensional self-report tool used to evaluate female sexual function developed by Rosen et al in the year 2000. It is a 19-item questionnaire with 6 theoretical subscales that assess the key dimension of female sexual function. It is found reliable and psychometrically valid in normal controls and age-matched females (83).

The FSFI-19 is a self-reported instrument that consists of six separate domains of female sexual function, that is desire (1-2), arousal (3-6), lubrication (7-10), orgasm (11-13), satisfaction (14-16), and pain (17-19). This scale has been validated in many languages and is extensively used in research and clinical settings (84). Despite being used regularly, the FSFI-19 may be too long in studies with multiple measures of outcome especially when an assessment of sexual dysfunction is not the main objective of the study. It's for this reason, Isidori et al. developed a shorter version of the scale (i.e., FSFI-6) using receiver operating curves (85).

The FSFI-6 is a brief and easy-to-use measure that contains six of the original nineteen items of the FSFI tool. It is useful where there is limited time frame such as in survey research. Satisfaction and desire are rated on a 5-point Likert scale that ranges from 1 to 5, while the other items are rated on a 6-point Likert scale, ranging from 0 to 5. The total scores range from 2 to 30, with lower scores showing worse sexual functioning. A score of less than 26 is considered sexual dysfunction.

The selection of the 6 items was based on examining the receiver operating characteristic curves of every item of the FSFI-19 for differentiating between women with and without FSD. Several studies have been done on the reliability and validity studies of FSFI. Among Spanish postmenopausal women, it was found a valid and reliable tool for evaluating and discriminating for sexual dysfunction(86) and had internal consistency.

According to a systemic review of 83 studies on the FSFI-19 measurement properties, the evidence of internal consistency was sufficient and of modest quality. The evidence for reliability was sufficient but of low quality. For criterion validity, the evidence was adequate and of high quality. For structural validity, the evidence was inconsistent with low quality. For construct validity, the evidence was inconsistent with moderate quality. The best-performing item for each of the 6 domains of the FSFI-19 was selected to be used in the FSFI-6.

Forbes et al. opined that both tools (FSFI-19 and IIEF) have critical theoretical and measurement challenges to assess sexual problems past the arousal phase, particularly for the sexual desire domains (87). However, Rosen et al. took issue with Forbes et al.'s arguments and pointed out that they conducted a selective literature review on both tools and that they

drew conclusions from findings that are methodologically flawed in a non-representative sample. Nonetheless, the FSFI has been used in many studies worldwide on the women population. Locally it has been translated into the Kiswahili language (50). It has been used in the assessment of sexual dysfunction in other chronic conditions such as CKD and Diabetes (50).

Table 1: Scoring severity of FSD by use of FSFI-6

Severity	FSFI-6 Score
No FSD	26-30
Mild FSD	19-26
Moderate FSD	9-19
Severe FSD	2-9

Adopted from a cross-sectional study done in Egypt in 2021, a new grading system for FSD based on the female sexual function index score (88).

2.8.2 International Index of Erectile Function (IIEF)

IIEF was developed by Rosen et al, in 1997 as a patient-administered, cross-culturally reliable psychometric tool to measure erectile function in men (89). Through literature search from interviews and existing questionnaires of male patients with erectile dysfunction and of their partners, pertinent domains of sexual function across varied cultures were identified.

IIEF is multidimensional, validated extensively psychometric tool used for investigation in the clinical assessment of male erectile dysfunction. The first IIEF tool was administered to erectile dysfunction patients and the findings were reviewed by a panel of international experts. A final 15-item was then linguistically validated in thirty-two languages and used as a primary endpoint in most clinical trials (90). It has specificity, and sensitivity noted at 98% and 88% respectively. (91).

It classifies erectile dysfunction into severity levels ranging from none (22-25) to severe sexual dysfunction (5-7). In evaluating the IIEF, findings showed that the IIEF retains satisfactory properties for identifying the existence and severity of erectile dysfunction(91). The simplified IIEF-5 is also an easy method, which can be used to evaluate erectile dysfunction. But according to Rosen et al., the IIEF focuses on current sexual functioning that is over the last 4 weeks and gives a superficial evaluation of sexual functioning domains apart from erection(90). It gives no information regarding the sexual functioning of participants' partners or relationships and gives an inadequate assessment of other domains namely desire and orgasm.

The tool fails to distinguish between sexual desire disorder types or premature ejaculation and other orgasmic disorders. However, IIEF is a validated tool and has been used in several studies globally including cross-sectional studies and provided consistent results (89). IIEF-5 tool too has been used in several studies in our locality and was translated to Kiswahili language (50).

Table 2: Scoring severity of ED by use of IIEF-5

Severity	IIEF-5 Score
No ED	22-25
Mild ED	12-21
Moderate ED	8-11
Severe ED	5-7

Adopted from Diagnostic evaluation of the erectile function domain of the international index of erectile function by capelleri et al 1999(92).

2.9 Study Justification

The prevalence of HF is increasing both in developing and developed countries and it remains a significant public health concern. HF morbidity and mortality remain high despite advancement in therapy.(10)

Equally, sexual dysfunction is a significant determinant of quality of life among people with heart failure and the prevalence and pattern remain under-diagnosed and underreported. As patients with chronic heart failure are continually increasing, it is important to recognize factors affecting their sexual function in order improve their quality of life.

Sexual health symptoms are often overlooked and not addressed adequately while managing HF patients. This is partly due to cultural and ethnic issues surrounding sex in our African setting and partly due to the absence of appropriate screening tools for addressing sexual dysfunction.

Due to this inconsistency, scanty data is available in our context as limited research has been done on sexual dysfunction among patients with heart failure. This study, therefore, has clinical and epidemiological relevance.

2.11 Research Question

What is the burden of sexual dysfunction among ambulatory Heart Failure patients attending Kenyatta National hospital?

2.12 Study Objectives

2.12.1 Broad Objective

To determine the prevalence of sexual dysfunction and associated factors among ambulatory HF patients attending the adult cardiology clinic at Kenyatta National hospital.

2.12.2 Primary Objectives

a) To determine the prevalence and severity of erectile dysfunction among ambulatory male patients with heart failure attending adult cardiology clinics at Kenyatta National hospital.
b) To determine the prevalence and severity of female sexual dysfunction among female heart failure patients attending the adult cardiology clinic at Kenyatta National hospital

2.12.3 Secondary Objectives

a) To determine some select clinical and sociodemographic factors associated with erectile dysfunction in male patients with heart failure.
b) To determine some select clinical and socio-demographic factors of female sexual dysfunction among females with heart failure attending the cardiology clinic at Kenyatta National hospital.

3.0 CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study Design

This was a single-center cross-sectional descriptive study.

3.2 Study Site

This study was conducted at the KNH specialized Cardiology clinic handling out-patients with heart failure. KNH is a level 6 National Referral Hospital located in Nairobi, Kenya.
Cardiology clinics occur twice weekly on Tuesday and Wednesday from 9.00 AM. These clinics are run by consultant cardiologists from KNH and the University of Nairobi and registrars from the department of medicine rotating in cardiology unit. It caters to all ambulatory adult cardiology cases. Patients seen at cardiology clinic have various cardiac conditions such as Valvular heart diseases, infective endocarditis as well as those with diagnosis of pulmonary embolism and previous coronary artery disease. 1680 patients were seen at cardiology clinic during the study period and 678 patients had documented diagnosis of heart failure.

3.3 Study Population

The study population was ambulatory patients with a diagnosis of heart failure who fulfilled the Framingham criteria and on follow-up at the adult cardiology clinic at KNH.

3.4 Case Definition

Cases were defined as all adult patients with a diagnosis of HF fulfilling the Framingham criteria retrospectively applied and on follow up at the specialized cardiology clinic for at least three months. Documented evidence of either two major criteria or one major and two minor criterions not attributable to another medical condition was required to confirm the diagnosis of heart failure.
The Framingham Diagnostic criteria are as follows.

Major criteria include Acute pulmonary oedema, Cardiomegaly, Hepato-jugular reflex, Pulmonary rales, Third heart sound (S3 Gallop), and Weight loss of 4.5 kg or more in 5 days in response to treatment, neck vein distension, Paroxysmal nocturnal dyspnea, or orthopnea.

Minor Criteria include, Dyspnea on exertion, Ankle edema, Hepatomegaly, Nocturnal cough, Pleural effusion, Tachycardia (defined as HR above 120 beats/min) (93).

3.5 Inclusion Criteria

- ✓ Patients of both genders aged 18 years and over with a documented diagnosis of heart failure attending the Cardiology clinic at the Kenyatta National Hospital who satisfied the Framingham criteria (case definition)
- ✓ HF patients who signed a written informed approval form (ICF).
- ✓ Patients who are either married or were presently in a steady relationship with a partner.

3.6 Exclusion Criteria

- ✓ Patients who were too ill to participate in the study (NHYA class IV).
- ✓ Patients with neuro-cognitive impairments such as dementia, psychosis or depression were unlikely to recall or give an accurate response.

3.7 Sample Size

Calculation in prevalence for cross-sectional studies, fisher et al (1999) formula was used.

$$Sample\ size = \frac{Z_{1-\alpha/2}{}^2\, P\,(1-P)}{d^2}$$

Where:

n–is the sample size required to estimate the proportion of HF patients who meets the criteria.

Z– is the 95% confidence interval (standard value of 1.96)

P–was the estimated proportion of males with erectile dysfunction is 0.84 and the proportion of female patients with sexual dysfunction is 0.87.

There is no African study that determines ED and FSD among patients with heart failure, thus this prevalence is based on a study by schwarz et al. which assessed the Prevalence and clinical relevance of Sexual Dysfunction in women and men with Chronic Heart Failure. (45)

d –margin of error (precision error) = ±5%

$$Samplesize \text{ for women} = \frac{Z_{1-\alpha/2}{}^2\, P\,(1-P)}{d^2} = \frac{1{\cdot}96^2 \text{ x } 0.87 \text{ x } 0.13}{0.0025} = 173$$

$$Samplesize \text{ for male} = \frac{Z_{1-\alpha/2}{}^2\, P\,(1-P)}{d^2} = \frac{1.96^2 \text{x } 0.84 \text{ x } 0.16}{0.0025} = 206$$

The sample size was adjusted for finite population.

$$\text{SS} = \frac{173}{1+172/800} = 142\ females\ patients \qquad \text{SS} = \frac{206}{1+205/800} = 164\ male\ patients$$

A minimum of 142 female and 164 male patients with heart failure patients were sampled to determine erectile dysfunction and female sexual dysfunction in heart failure, within a 5% margin of error.

3.8 Sampling Method

A systematic random sampling technique was used to recruit participants with heart failure presenting at Kenyatta National Hospital. The files of patients with heart failure were identified after obtaining letter of authority from the department of medicine-Kenyatta National hospital. The out-patient number of those files who met the case definition was serialized and entered into excel. These serial numbers were randomized in excel using command "=RAND ()." The randomized numbers in each of the cells were then sorted from smallest to largest. Every serial number that appears in odd category was selected for possible recruitment subject to consenting. In a situation where patient selected for the study declines to participate, the next selected patient was recruited.

3.9 Recruitment of Research Assistant.

The principal investigator recruited two (2) research assistants who helped with the data collection process. The research assistants were qualified nursing officers with a Diploma in nursing and had prior experience in data collection at KNH. Their roles included approaching patients, explaining the purpose of the study, administering the informed written consent, administrating section 1 of the questionnaire that bears patients sociodemographic characteristics and distributing self-administered questionnaire to the patients who were willing to participate in the study. The research assistants were trained before the data collection exercise to enhance their understanding of the study. The principal investigator helped with consenting and data collection as well as monitored the entire data collection process and cross checked the questionnaires to ensure completeness.

3.10 Data Collection Tools/Instruments

3.10.1 International Index of Erectile Function-5 (IIEF-5) For Assessment of Erectile Dysfunction.

The abridged version of the IIEF-5 developed as a 5-item diagnostic tool for ED was utilized. IIEF-5 is a validated tool and has been used in several studies globally as well as locally. Items are rated on a 5-point Likert scale, ranging from 1 to 5. The lowest score is 5 and the highest is 25 signifying the absence of ED. The optimal cut-off score was found to be 22, with men

recording less than or equal to 22 categorized as having ED and those scoring above 22 as not having ED.

The tool was self-administered. A researcher-developed questionnaire was used to gather data on socio-demographic and clinical characteristics (SDC). The researcher developed SDC, and IIEF-5 were administered in one session during the clinic appointment. It took approximately 10 minutes to complete the questionnaires.

3.10.2 Female Sexual Function Index-6 (FSFI-6) For Female Sexual Dysfunction

The FSFI-6 is a short and simple measure that contains six of the original nineteen items of the FSFI tool. It is internationally and locally validated tool for assessment of FSD. Items of desire and satisfaction are rated on a 5-point Likert scale that ranges from 1 to 5. The other items are rated on a 6-point Likert scale that ranges from 0 to 5. Sum scores are ranging from 2 to 30, with lower scores indicating worse sexual functioning.

A score of less than 26 is considered sexual dysfunction. This is a useful scale where there is an inadequate time frame such as in this study.

The tool was self-administered by female patients with HF. The self-administered FSFI-6 together with a study proforma on clinical and socio-demographic characteristics were administered to patients as they attend cardiology clinic on the same day. It took roughly 10 minutes to complete this questionnaire.

3.11 Screening and Recruitment Procedure

Screening of patients' files to identify patients with heart failure was carried out after we obtained letter of authority from KNH -department of medicine. Before each clinic day, the patient files were ordinarily retrieved from KNH central health record and information office and taken to the cardiac clinic records office. This screening was essential as there are many patients with varied heart conditions such as Valvular heart diseases, infective endocarditis as well as pulmonary embolism and previous coronary syndrome who attends the same cardiac clinic. The screening involved retrospectively applying Framingham criteria for patient with a chart diagnosis of heart failure. The out-patient numbers of screened files were documented and serialized. Systematic random sampling technique was used to select participants.

The principal investigator with the help of the research assistant approached patients who have been selected and the purpose of the study, the nature, possible risks, and benefits of the study explain to them. Only those willing to participate in the study were recruited after signing a copy of informed consent.

3.12 Data Collection Process

The data collection process begun once HF patients who met the inclusion criteria and who have been selected for the study consented to participate. The principal investigator with the help of research assistants administered a study proforma containing information such as age, gender, marital status, level of education, alcohol, and smoking history as well as NYHA functional classification. This segment also contained information on the HF duration, heart failure medications, and co-morbidities. The research assistants then handed the participant a copy of the questionnaire and allowed to fill the section 2 of the questionnaire in private and undisturbed. The Section 2 had the self-administered international index of erectile dysfunction (IIEF-5) for male patients or female sexual function index (FSFI-6) for female patients. The IIEF-5 and FSFI-6 versions are validated questionnaires (tools) which were utilized in this study and had been translated from English to Kiswahili and back translated to English with no loss of translation.

3.13 Quality Assurance

The existing hospital protocol and standard operating procedures were applied in this study. The data collection tools were internationally and locally validated. The data collection tool was pre-tested to minimize errors and ensuring that the data obtained was reproduceable. Collected data was counterchecked and cleaned on daily basis. The entire process of the proposal development to statistical analysis and book presentation was done under the guidance of the supervisors and statistician.

3.14 Data Management and Analysis

3.14.1 Data Entry

Data collected via the printed questionnaires was checked for accuracy, completeness, and freedom from error before keeping it in a safe under lock and key and was only accessible to the research assistant and the principal investigator. On completion of the data collection exercise, the raw data was entered into a Microsoft Excel Spreadsheet 2017 and exported to the SPSSS Version 23 for analysis.

3.14.2 Data Analysis

Demographic characteristics

Descriptive analysis was grouped into categorical and continuous variables. Categorical variables were analysed using frequencies (n) and percentages (%). Continuous variables were analysed using mean (SD) and Median (IQR).

The prevalence of erectile dysfunction

Prevalence of erectile dysfunction among heart failure patients was determined as a proportion of men with ED with heart failure in the study and reported as a percentage.

$$\frac{\text{Number of heart patients with erectile dysfunction}}{\text{Total sample size of men with heart failure (n=164)}} * 100$$

The prevalence of female sexual dysfunction

Prevalence of female sexual dysfunction among heart failure patients was determined as a proportion of women with SD with heart failure in the study and reported as a percentage.

$$\frac{\text{Number of heart patients with female sexual dysfunction}}{\text{Total sample size of women with heart failure (n=142)}} * 100$$

The clinical and sociodemographic factors associated with erectile dysfunction in male and female sexual dysfunction among females' patients with heart failure.

Descriptive data were grouped into categorical and continuous variables. Categorical variables were analysed using frequencies (n) and percentages (%). Continuous variables were analysed using mean with standard deviation.

The association between sexual dysfunctions with some selected socio-demographic and clinical characteristics for each gender was analyzed using the Pearson chi-square or Fisher's exact statistics for categorical data, and independent t-tests for continuous data. The odds ratio, as well as the 95% confidence interval, was calculated. Statistical significance for all tests was considered where the $P< 0.05$.

3.15 Ethical Consideration

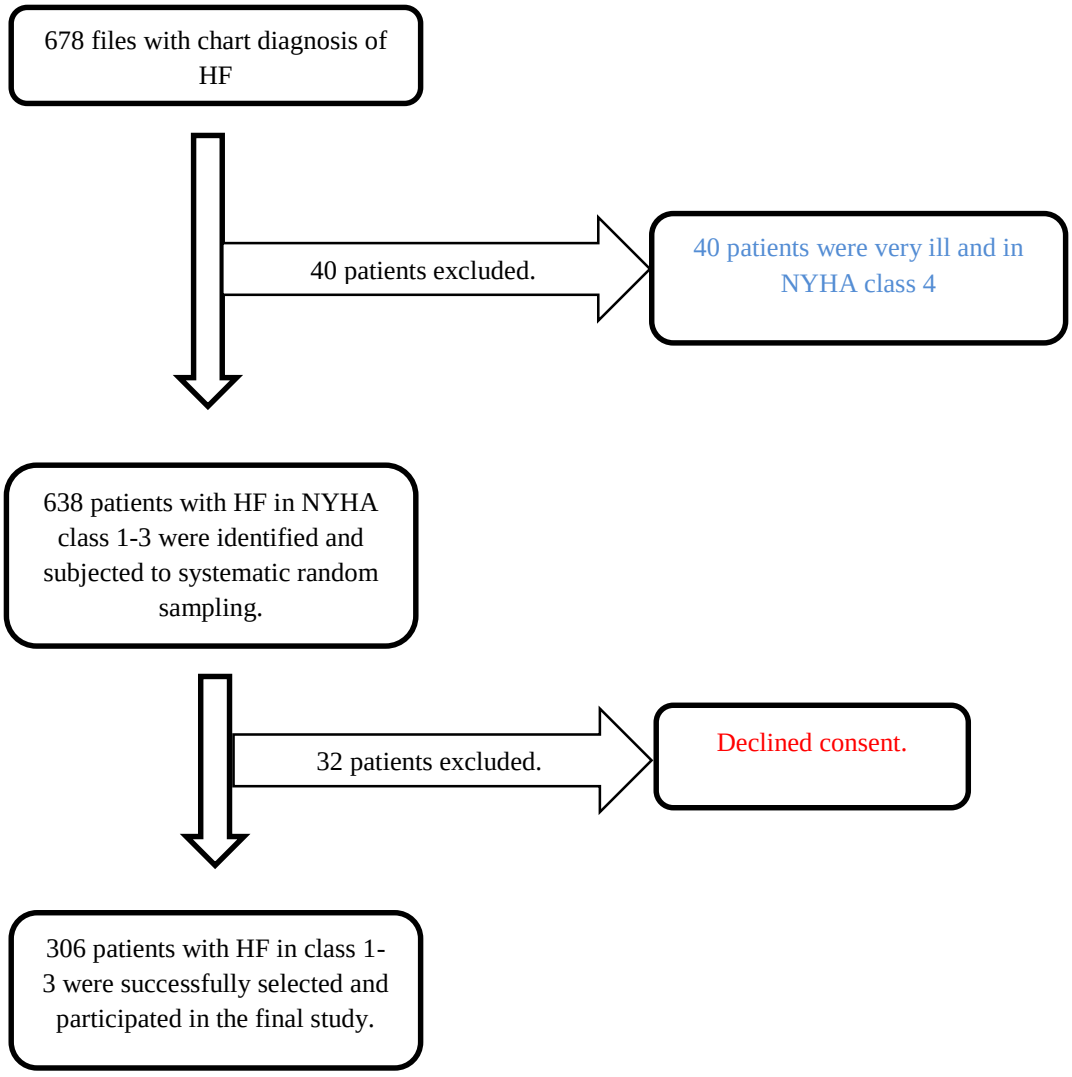
The study was approved by the Department of Clinical Medicine and Therapeutics, Faculty of Health Sciences, University of Nairobi and the KNH/UoN ERC. The study was carried out in conformity with the ethics outlined in the Helsinki declaration on medical research on human subjects.

Access to medical records at the cardiology clinic, was granted by the head of the cardiology unit and the Health Information Systems' Department after ethical approval. A written informed consent was obtained from each participant prior to their recruitment. Participation

was voluntary, and no patient was coerced to participate. Those who participated understood they could withdraw consent at any time during the study. Privacy and confidentiality were always maintained during this study.

4.0 CHAPTER FOUR: RESULTS

678 **HF Patients** were seen at the cardiology clinic during the study period between November 2022 and Jan 2023.



4.1 Characteristics of the study population

A total of **306** heart failure patients were enrolled into the study, 164 (53.6%) were male with mean age of 52 years, and 142 (46.4%) were female with mean age of 53 years. Majority of the participants were married. More than ¾ of our male participant attained primary level of education. As many as 97% of female patients had no history of smoking and alcohol use.

Table 3: Socio-demographic characteristics of the patients by gender

Characteristic		**Male,** *(n=164)*	**Female,** *(n=142)*
Age, *(Mean ± SD)*		52.1 ± 17.2	53.1 ± 15.2
Age, *n (%)*	≤40	50 (30.5)	30 (21.1)
	41- 60	51 (31.1)	64 (45.1)
	>60	63 (38.4)	48 (33.8)
Marital status, *n (%)*	Married	138 (84.1)	95 (66.9)
	Not married	26 (15.9)	47 (33.1)
Employment, *n (%)*	Employed	92 (56.1)	13 (9.2)
	Unemployed	56 (34.1)	125 (88.0)
	Retired	16 (9.8)	4 (2.8)
Education, *n (%)*	Primary	69 (42.1)	76 (53.5)
	Secondary	57 (34.8)	53 (37.3)
	Tertiary	38 (23.2)	13 (9.2)
Smoking, *n (%)*	Never smoked	79 (48.2)	137 (96.5)
	Former smoker	76 (46.3)	5 (3.5)
	Current smoker	9 (5.5)	0 (0.0)
Alcohol, *n (%)*	Yes	60 (36.6)	4 (2.8)
	No	104 (63.4)	138 (97.2)
Sexual episodes, *n (%)* (Number of sexual encounters in the last 4 weeks)	None	29 (17.7)	59 (41.5)
	1 – 2	68 (41.5)	55 (38.7)
	3 – 4	59 (36.0)	27 (19.0)
	>5	8 (4.9)	1 (0.7)

4.2 Medication history

Out of the 306 patients, 203 (66.3%) were on 3 of the 4 recommended drugs (i.e., RAAS blockade, Beta blocker and Mineralocorticoid Antagonist). While only 90 (29.4%) patients were on the 4 **Guideline**-directed medical therapy (GDMT) for **heart failure** (i.e., RAAS blockade, Beta blocker, Mineralocorticoid and SGLT2) (94).

Table 4: Patient medications by gender

Medication	**Male,** *(n=164)*	**Female,** *(n=142)*
Beta blocker, *n (%)*	161 (98.2)	131 (92.3)
RAAS Blockers, *n (%)*	149 (90.9)	117 (82.4)
ACE-I, *n (%)*	85 (51.8)	59 (41.5)
ARB, *n (%)*	60 (36.6)	57 (40.1)
ARNI, *n (%)*	4 (2.4)	1(0.7)
Mineralocorticoid receptor antagonist, *n (%)*	142 (86.6)	107 (75.4)
SGL T2 inhibitor, *n (%)*	88 (53.7)	45 (31.7)
Loop diuretics, *n (%)*	155 (94.5)	124 (87.3)
Digoxin, *n (%)*	69 (42.1)	77 (54.2)
Ivabradine, *n (%)*	6 (3.7)	6 (4.2)
Other drug, *n (%)*	120 (73.2)	53 (37.3)

4.3 Prevalence of ED and FSD in heart failure

The prevalence of ED in heart failure was **71.3%** (95% CI, 64.0% - 77.7%). 45.7% of male patients were having mild, 12.2% with moderate, and 13.4% with severe erectile dysfunction. The results are shown on Table 5.

Table 5: Prevalence of erectile dysfunction (ED)

ED	**Frequency,** *(n=164)*	**Percent**	**95% CI**
Prevalence of ED	**117**	**71.3**	64.0 – 77.7
Severity	**Frequency,** *(n=164)*	**Percent**	
Mild (12 - 21)	75	45.7	
Moderate (8 - 11)	20	12.2	
Severe (5 - 7)	22	13.4	

The prevalence of FSD was **81.0%** (95% CI, 73.8% - 86.6%), with 44.4%, 12% and 24.6% of female having mild, moderate, and severe female sexual dysfunction respectively. The results are shown on Table 6.

Table 6 : Prevalence of female sexual dysfunction (FSD)

FSD	**Frequency,** *(n=142)*	**Percent**	**95% CI**
Prevalence of FSD	**115**	**81.0**	**73.8 – 86.6**
Severity	**Frequency,** *(n=142)*	**Percent**	
Mild (19 - 26)	63	44.4	
Moderate (9 - 19)	17	12.0	
Severe (2 - 8)	35	24.6	

4.4 Socio-demographic correlates of Male ED

This was a descriptive study, and the results for the secondary objectives which assesses the correlation of ED/FSD was explorative inferential analysis. Our study sample size was not powered to assess for correlation, at best these findings are hypothesis generating.

Male heart failure with ED were found to be significantly older at 55.5 compared to those with no ED 43.6 ($p<0.001$). Our study results show the prevalence of ED was significantly higher

in those married, unemployed, and above 60 years of age when compared to younger, unmarried, and employed men with HF.

As level of education increases, the prevalence of ED decreases. Primary educated male participants were 6.7 times more likely to have ED compared to college and university educated men with heart failure (P<0.001).

Table 7: Socio-demographic characteristic by erectile dysfunction

Characteristic		**ED,** *n=117)*	**No ED,** *(n=47)*	**OR (95% CI)**	**p-value**
Age, *(Mean ± SD)*		55.5 ± 16.8	43.6 ± 15.1		**<0.001**
Age, *n (%)*	≤40	26 (22.2)	24 (51.1)	Reference	
	41- 60	36 (30.8)	15 (31.9)	2.2 (1.0 – 5.0)	0.057
	>60	55 (47.0)	8 (17.0)	6.3 (2.5 – 16.0)	**<0.001**
Marital status, *n (%)*	Married	103 (88.0)	35 (74.5)	2.5 (1.1 – 6.0)	**0.035**
	Not married	14 (12.0)	12 (25.5)	Reference	
Employment, *n (%)*	Employed	58 (49.6)	34 (72.3)	Reference	
	Unemployed	46 (39.3)	10 (21.3)	2.7 (1.2 – 6.0)	**0.016**
	Retired	13 (11.1)	3 (6.4)	2.5 (0.7 – 9.6)	0.168
Education, *n (%)*	Primary	60 (51.3)	9 (19.1)	6.7 (2.6 – 17.2)	**<0.001**
	Secondary	38 (32.5)	19 (40.4)	2.0 (0.9 – 4.6)	0.106
	Tertiary	19 (16.2)	19 (40.4)	Reference	
Smoking, *n (%)*	Never smoked	51 (43.6)	28 (59.6)	Reference	
	Former smoker	57 (48.7)	19 (404.)	1.6 (0.8–3.3)	
	Current smoker	9 (7.7)	0 (0.0)	-	
Alcohol, *n (%)*	Yes	43 (36.8)	17 (36.2)	1.0 (0.5 – 2.1)	0.944
	No	74 (63.2)	30 (63.8)	Reference	

4.5 Clinical correlates for male ED

Those with diabetes were six times likely to have ED compared to those without. Patients with hypertension were twice likely to have ED compared to those without hypertension and this was statistically significant (p<0.05). There was a significant increase in ED among those with longer duration of HF and advanced NYHA class when compared to short duration of HF and lower NYHA class.

Table 8: Male patient's clinical characteristics by erectile dysfunction

Characteristic		ED, *(n=117)*	No ED, *(n=47)*	OR (95% CI)	p-value
Diabetes mellitus, *n (%)*	Yes	41 (35.0)	4 (8.5)	5.8 (2.0 – 17.3)	**0.002**
	No	76 (65.0)	43 (91.5)	Reference	
Hypertension, *n (%)*	Yes	76 (65.0)	23 (48.9)	1.9 (1.3 – 3.8)	**0.006**
	No	41 (35.0)	24 (51.1)	Reference	
History of stroke, *n (%)*	Yes	6 (5.1)	1 (2.1)	2.5 (0.3 – 21.2)	0.405
	No	111 (94.9)	46 (97.9)	Reference	
Chronic kidney disease, *n (%)*	Yes	13 (11.1)	5 (10.6)	1.1 (0.4 – 3.1)	0.930
	No	104 (88.9)	42 (89.4)	Reference	
Duration of heart failure, *n (%)*	Less than 1 year	19 (16.2)	17 (36.2)	Reference	
	1 – 5 years	65 (55.6)	27 (57.4)	2.2 (1.0 – 4.8)	0.058
	Over 5 years	33 (28.2)	3 (6.4)	9.8 (2.5 – 38.0)	**0.001**
NYHA class, *n (%)*	Class 1	14 (12.0)	23 (48.9)	Reference	
	Class 2	45 (38.5)	16 (34.0)	4.6 (1.9 – 11.1)	**0.001**
	Class 3	58 (49.5)	8 (17.1)	11.9 (4.4 – 32.2)	**<0.001**

4.6 Socio-demographic and Clinical correlates of Female FSD

Although this was a descriptive study and our sample size was not powered for correlation analysis, an explorative analysis was done to elucidate for trends between some select clinical and socio-demographic characteristics and FSD.

SD was more prevalent among the older female participants according to our study. The unemployed female participants were twice likely to have FSD compared to those with employment, but there were no statistical differences between the two groups.

Table 9 : Socio-demographic characteristic by female sexual dysfunction

Characteristic		FSD, *(n=115)*	No FSD, *(n=27)*	OR (95% CI)	p-value
Age, *(Mean ± SD)*		53.1 ± 14.8	53.3 ± 16.7		0.958
Age, *n (%)*	≤40	25 (21.7)	5 (18.5)	Reference	
	41- 60	52 (45.3)	12 (44.5)	3.9 (1.3 – 2.7)	**0.007**
	>60	38 (33.0)	10 (37.0)	1.8 (1.2 – 6.5)	**0.001**
Marital status, *n (%)*	Married	77 (67.0)	18 (66.7)	1.0 (0.4 – 2.5)	0.977
	Not married	38 (33.0)	9 (33.3)	Reference	
Employment, *n (%)*	Employed	9 (7.8)	4 (14.8)	Reference	
	Unemployed	102 (88.7)	23 (85.2)	2.0 (0.6 – 7.0)	0.292
	Retired	4 (3.5)	0 (0.0)	-	
Education, *n (%)*	Primary	63 (54.8)	13 (48.2)	0.9 (0.2 – 4.5)	0.878
	Secondary	41 (35.7)	12 (44.4)	0.6 (0.1 – 3.2)	0.569
	Tertiary	11 (9.5)	2 (7.4)	Reference	
Smoking, *n (%)*	Never smoked	110 (95.7)	27 (100.0)	-	0.270
	Smoking history	5 (4.3)	0 (0.0)		
Alcohol, *n (%)*	Yes	4 (3.5)	0 (0.0)	-	0.326
	No	111 (96.5)	27 (100.0)		

4.7 Clinical correlates for Female FSD

Female HF patients in advanced NYHA class were observed to have increased odd of sexual dysfunction. It was noted that those in NHYA 3 was 6.7 times more likely to have FSD compared to those in NHYA class 1 (P<0.001).

From our study analysis, presence of comorbidities such as diabetes, hypertension was associated with increased odds of female sexual dysfunction and this was found to be statistically significant.

Table 10 : Female patient's disease condition by female sexual dysfunction

Characteristic		FSD, *(n=115)*	No FSD, *(n=27)*	OR (95% CI)	p-value
Diabetes mellitus, *n (%)*	Yes	28 (24.3)	5 (18.5)	2.4 (1.5 – 4.1)	**0.002**
	No	87 (75.7)	22 (81.5)	Reference	
Hypertension, *n (%)*	Yes	86 (74.8)	19 (70.4)	2.2 (1.3 – 6.2)	**0.039**
	No	29 (25.2)	8 (29.6)	Reference	
History of stroke, *n (%)*	Yes	9 (7.8)	1 (3.7)	2.2 (0.3 – 18.2)	0.462
	No	106 (92.2)	26 (96.3)	Reference	
Chronic kidney disease, *n (%)*	Yes	13 (11.3)	2 (7.4)	1.6 (0.3 – 7.5)	0.556
	No	102 (88.7)	25 (92.6)	Reference	
Duration of heart failure, *n (%)*	Less than 1 year	21 (18.3)	5 (18.5)	Reference	
	1 – 5 years	50 (43.5)	16 (59.3)	0.7 (0.2 – 2.3)	0.607
	Over 5 years	44 (38.2)	6 (22.2)	1.7 (0.5 – 6.4)	0.399
NYHA class, *n (%)*	Class 1	14 (12.2)	12 (44.4)	Reference	
	Class 2	54 (47.0)	9 (33.3)	5.2 (1.8 – 14.6)	**0.002**
	Class 3	47 (40.8)	6 (22.2)	6.7 (2.1 – 21.2)	**0.001**

5.0 CHAPTER FIVE: DISCUSSION

HF is more prevalent among older individuals according to data in other part of the world. A systematic review by Groenewegen et al, the average age for HF patients in Europe is 64 years, 66 years in America and 60 years among Asians population, our study participants represents a much younger population with average age of 53 years (95)

These finding is consistent with studies in Africa, and it can be attributed to increased unhealthy lifestyle, poor management of risk factors such as hypertension, ischemic heart diseases, rheumatic heart disease as well as delayed health seeking practices and untimely medical interventions. (20)

In our context, data concerning sexual dysfunction in heart failure population are scarce, leading us to conduct this study with the aim of determine prevalence and risk factors of sexual dysfunction in patient with heart failure**. Our study shows Seventy-one percent of men with heart failure in NYHA classes I–III fulfilled criteria for ED out of which 13% had severe erectile dysfunction while majority (46%) had mild Erectile dysfunction**.

This finding is consistent with the results from other studies. In study conducted in Milan, Italy by Apostolo et al on Erectile Dysfunction on 100 Heart Failure patients aged below 70 years found ED prevalence of 69%. (80) A similar cross-sectional descriptive survey by Medina et al, on 45 HF patients in NYHA class 2 &3, between the age of 44-84 years predominately married male in the Midwest-USA, found erectile problems in 74% of male participants. (96)

This is close to data from earlier study by Westlake C et al at UCLA-California on Sexuality of Patients with Advanced HF and their spouses who reported a significant decrease in sexual function and frequency of sexual relations in 75% of patients with advanced heart failure. (46) Study performed by Schwarz et al. on the prevalence and clinical relevance of sexual dysfunction in women and men with chronic heart failure showed slightly higher prevalence of erectile dysfunction of 84%. This study had slightly older population and ischemic heart disease as predominant cause of HF, which from other studies have been implicated as an independent risk factor for ED. (45)

In a study by Sharareh et al on sexual dysfunction in males with heart failure and associated factors, they found that 36% had severe 26% moderate and 18% with mild ED. (47) contrastingly, our findings were 13% with severe ED, 12% moderate while majority (46%) were having mild ED. contrary to our study, sherareh sample was composed of older male with

different ethnicity predominantly Persian decent. Increasing age is associated with increased severity of ED. Sexual activity closely related to exercise tolerance and conditioning which declines with advancing age, as well as evolution of atherosclerosis that develops above the age 50 years. (48) Our study is comparable to a study by apostolo et al in 2009 that found more patients had severe ED (25%) compared moderate ED with 12%. (80)

In our current study, statistically significant association was found between increasing age and erectile dysfunction. This is in line with the findings of Apostolo et al. and Steinke et al. which showed relationship between age and erectile dysfunction in men with systolic heart failure. It is postulated that altered penal vasculature, reduced penile circulation, reduced androgen, reduced smooth myocytes, reduced nitric oxide production that are involved in severe erectile dysfunction in patients with HF. (80,97)

Patients with severe HF, in NYHA class 2 or 3 have the greater prevalence of ED this were similar to Apostolo et at. (86) Diabetes and hypertension were independently associated with sexual dysfunction; this is similar to a study by Boombhi et al who found association between ED and DM, hypertension as comorbidity in HF patients. (49) This finding can be explained by the direct effect of oxidative stress and atherosclerosis in vessels implicated in erection that worsens with hyperglycemia. Furthermore, diabetes has been postulated to reduce male hormones associated with ED among patients with HF.

In our study, erectile dysfunction was found to be significantly related to education and employment in which the highest rate of erectile dysfunction was found among primary educated participants and those with no employment and retired subjects. This is consistent with the results of shererah et al. and Holden et al. who revealed that demographic and social variables are related to erectile dysfunction. (47,98). it is believed that those who received formal education and those with source of income have better compliance to HF medications and overall have better understanding of their condition.

81% of women with heart failure in NYHA class I-III fulfilled criteria for female sexual dysfunction. This is like a study by Schwarz et al who investigated the prevalence and clinical relevance of sexual dysfunction in women and men with chronic heart failure and found a prevalence of FSD of 87%. (45)

It is postulated that atherosclerosis and endothelial dysfunction results in increased expressions of vaginal endothelial NO synthase and phosphodiesterase 5 may play a vital role in the pathophysiology of FSD.

Sexual dysfunction is mostly frequent in female 82% compared to male ED 73% in our study. These findings are similar to study by Boombhi et al, who found that female participants were independent risk factors for sexual dysfunction. (49). This can be explained by the fact that our female sample was mainly constituted by older participants and post-menopausal women, knowing that menopause is associated with hormonal disorders that frequently alter sexual function. (49)

Majority fall on the spectrum of mild SD but significant number (1/4) having severe SD. Findings consistent with Westlake et al who found that 25% of their female study participants had severe sexual dysfunction. (46)

Our study found association between female sexual dysfunction diabetes, hypertension as well as worsening heart failure symptoms. Those in NHYA class 2 and 3 were found to have worsening sexual dysfunction. This can be explained by the fact worsening dyspnea is associated with exercise intolerance and sexual exertions. (48)

Conclusions

This study demonstrated that majority of heart failure patients have sexual dysfunction with majority of those lying in the mild SD spectra. Poor control of HF symptoms as demonstrated by advancing NYHA class and presence of comorbities such as diabetes, hypertension as reported in our study may be impacting negatively on sexual dysfunction.

Recommendations

HF patients should routinely be screened for sexual dysfunction to detect its presence, address the treatment, and improve their quality of life.

The result of this study lay a foundation for further studies that set out to determine the burden of sexual dysfunction in a larger population and mitigation measures directed towards sexual problems.

Strength

The study population is a homogenous patient with heart failure done in both male and female categories and this was the main strength of this study. In addition, no such study has been conducted in East Africa. The other single study in Africa was carried-out in Cameroon. This forms the basis for future studies to identify treatment target and goals, not only locally but also in Africa to improve long term outcome in heart failure patients with sexual dysfunction.

Limitations

This is a single center study, and these findings are specific to a single facility making it difficult for generalizability. However, this study was conducted at Kenyatta National Hospital which receives patients from other parts of the country and region making the findings from the study somewhat generalizable across Kenya.

The study did not account for effects of heart failure medications on sexual dysfunctions that are known from other studies to cause sexual problems. Importantly, being an observational study, conclusions about causality were not drawn regarding sexual dysfunction.

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APPENDICES

Appendix I: Informed Consent Form

Study Number…… Sex……..……

Age ……..……

Introduction

Hello. I am **Mohamed Yarow Farah,** a post-graduate student in the Department of Clinical Medicine and Therapeutics, University of Nairobi. This information form seeks informed consent for your participation in the study that seeks to assess "**The Prevalence of Sexual Dysfunction among Ambulant Heart Failure Patients Attending Kenyatta National Hospital".** Sexual dysfunction is a very important determinant of health-related quality of life in patients with Heart Failure. The findings of this study will be an evidence-based epidemiological and clinical research reference point that could be utilized in informing decisions in patient care and management.

Purpose of the Study

- To assess the prevalence of sexual dysfunction and associated factors among ambulant heart failure patients attending Kenyatta National Hospital.

Procedure

If you agree to participate in this study, you will receive an identification number. Depending on your gender, you will be given two questionnaires to fill yourself. The questions in the questionnaires are about socio-demographic and clinical data and the second is on self-reporting of individual domains of sexual dysfunction.

Risks/ Discomforts

There are no anticipated risks in participating in this study. However, if there are any problems that may arise due to your participation, you will be assisted accordingly.

Benefits

It is hoped that the outcome of the study will lead to awareness of the prevalence of sexual dysfunction in regard to heart failure, and hence enable/lead to a greater understanding of how to manage the conditions. If you are found to have a sexual dysfunction you will be managed accordingly.

Alternatives to participation/withdrawal from the study

If you decide not to take part in this study no one will force you to, so you will be free to make your own decision. You are free to withdraw from the study, and this shall not affect your care in any way, and you will not be discriminated against in any way. You can also choose to take part in any other studies in the future.

Confidentiality

Any information you provide during the study will be kept strictly confidential. Your name will not appear on any study document and instead, a unique number shall be assigned to your questionnaire that will match both questionnaires.

Voluntariness

Your participation in this study, which will be in the form of a self-reported interview. You are free to choose whether to participate in this study. You are also free to withdraw from the study at any time you wish to do so.

In case of any questions or concerns about this study, please feel free to contact any of the following persons:

Principal Investigator:

Mohamed Yarow Farah,
Department of Clinical Medicine and Therapeutics
University of Nairobi
Tel:0722151482
Email: yarowzcky@gmail.com

Supervisors:

Dr. Eugene Kalman Genga
Department of Clinical Medicine and Therapeutics
University of Nairobi
Tel: 0723596189
Email: eugenekalman@gmail.com

Prof. Elijah S. N. Ogola
Department of Clinical Medicine and Therapeutics
University of Nairobi
Tel:0722737944
Email: Elijah.ogola@uonbi.ac.ke

Or

The Secretary
KNH/ERC (Kenyatta National Hospital/Ethics & Review Committee)
TEL: 020-2726300/0722829500/0733606400/EXT 44102. P.O. Box 20723, Nairobi

Declaration

I have read and understood the study information. I have been given the opportunity to ask questions about the study. I understand that my taking part is voluntary; I can withdraw from the study at any time, and I will not be asked questions about why I no longer want to take part. I understand my personal details will be kept private. I hereby consent to participate in the said study as has been explained and as I have understood.

Participants' name: .....

Participants' signature: .....

Date: .....

Name of the Investigator: Mohamed Yarrow Farah,

Signature of the Investigator: .....

Date: .....

Appendix II: Informed Consent Form (Kiswahili Version)

Fomu ya Ridhaa

Nambari ya masomo/utafiti ……

Jina …… Umri ... ……

Utangulizi

Mimi ni **Dkt Mohamed Yarow Farah**, kutoka Chuo Kikuu cha Nairobi. Kwa sasa na somea uzamili katika Tiba ya Ndani. Kama sehemu ya masomo yangu yauzamifu,nahitajika kufanya mradi wautafiti.Ninafanya uchunguzi kuhusu hali ya ugonjwa wa shida ya kudindisha/matatizo ya kushiriki katika kitendo cha ngono kwa wagonjwa walio na ugonjwa wa moyo katika Hospitali ya Kitaifa ya Kenyatta.

Wakati huo huo, shida ya kudindisha/matatizo ya kushiriki katika kitendo cha ngono ni mpangilio muhimu sana wa maisha yanayohusiana na kutathmini afya kwa wagonjwa walio na ugonjwa wa moyo. Matokeo ya utafiti huu yatakuwa kumbukumbu ya msingi wa uchunguzi wa ugonjwa na wa utafiti wa kliniki ambayo inaweza kutumika katika kuarifu maamuzi katika utunzaji na usimamizi wa mgonjwa.

Kusudi la utafiti

- Untathmini wa hali ya ugonjwa wa shida ya kudindisha/matatizo ya kushiriki katika kitendo cha ngono kwa wagonjwa wa moyo.

Utaratibu

Ikiwa unakubali kushiriki katika utafiti huu, utapokea nambari ya kujitambulisha. Kulingana na jinsia yako, utapewa hojaji mbili za kujaza wewe mwenyewe. Maswali yaliyo kwenye dodoso ni juu ya data ya jamii na data ya kliniki na ya pili ni juu ya taarifa ya kibinafsi ya kikoa cha shida ya ngono.

Hatari / Ubaya

Hakuna hatari zinazotarajiwa kushiriki katika utafiti huu. Walakini, ikiwa kuna shida yoyote ambayo inaweza kutokea kwa sababu ya ushiriki wako, utasaidiwa ipasavyo.

Faida

Inatarajiwa kuwa matokeo ya utafiti yatasababisha mwamko wa utathmini kwa matatizo ya kushiriki katika kitendo cha ngono kwa wagonjwa walio na ugonjwa wa moto na kwa hivyo kuwezesha - au kusababisha uelewa mkubwa juu ya jinsi ya kudhibiti ugonjwa/tatizi hili.

Ukigundulika kuwa na tatizo ya kushiriki katika kitendo cha ngono utasimamiwa ipasavyo.

Njia mbadala za kushiriki / kujiondoa kutoka kwa masomo

Ukiamua kutoshiriki katika utafiti huu hakuna atakayekulazimisha, kwa hivyo utakuwa huru kufanya uamuzi wako mwenyewe. Uko huru kujiondoa kwenye masomo, na hii haitaathiri utunzaji wako kwa njia yoyote, na hautabaguliwa kwa njia yoyote ile. Unaweza pia kuchagua kushiriki katika masomo mengine yoyote katika siku zijazo.

Usiri

Habari zozote unazotoa wakati wa masomo zitahifadhiwa kwa siri. Jina lako halitaonekana kwenye hati yoyote ya kusoma na badala yake, nambari ya kipekee itapewa kwa dodoso lako litakalofanana na dodoso zote mbili.

Kujitolea

Ushiriki wako katika utafiti huu, ambao utakuwa katika hali ya mahojiano yaliyoripotiwa. Uko huru kuchagua au kushiriki katika utafiti huu. Pia uko huru kujiondoa kutoka kwa masomo

Ukiwa na maswali au maoni yeyote Kuhusu utafiti huu unaweza kuwasliana na wafuatao:

Mtafiti Mkuu:

Dkt. Mohamed Yarow Farah,
Department of Clinical Medicine and Therapeutics
University of Nairobi
Simu: 0722151482
Barua pepe: yarowzcky@gmail.com

Wasimamizi:

Dkt. Eugene Kalman Genga
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Prof. Elijah S. N. Ogola
Department of Clinical Medicine and Therapeutics
University of Nairobi
Simu: 0722737944
Barua Pepe:Elijah.ogola@uonbi.ac.ke

Au

Katibu / Mwenyekiti

KNH / UoN ERC Hospitali ya Kitaifa ya Kenyatta –Kamati ya Maadili ya Utafiti ya Chuo Kikuu cha Nairobi kwa Namba ya simu 2726300 Ext. 44102 barua pepe uonknh_erc@uonbi.ac.ke.

Azimio

Nimesoma na kuelewa habari ya kuhusu utafiti huu. Nimepewa nafasi ya kuuliza maswali juu ya utafiti huo. Ninaelewa kuwa kushiriki kwangu ni kwa hiari; Naweza kujiondoa kutoka kwa masomo wakati wowote na sitaulizwa maswali juu ya kwanini sitaki tena kushiriki. Ninaelewa maelezo yangu ya kibinafsi yatawekwa siri. Kwa hivyo ninakubali kushiriki katika utafiti uliyosemwa kama ilivyoelezea na kama nimeelewa.

Jina la mshiriki wa utafiti: ……

Saini ya mshiriki wa utafiti: **……**

Tarehe: .....

Jina la Mpelelezi: Dkt. Mohamed Yarow Farah

Appendix III: English Version of the Socio-demographic and Clinical Characteristics Questionnaire

Patient Identifier (KNH-Clinic File No): Date of interview:

Question Number	Question	Coding categories	Response
1.	How old are you?	Number in years	[ ]
2.	Gender?	M = Male F=Female	[ ]
3.	Highest level of education completed?	1=None 2=primary 3=secondary 4=tertiary	[ ]
4.	Are you married?	1=yes 2=no	
5.	Do you smoke cigarette? (Classified as smokers (current or quit < 5 years), former smokers (quit ≥ 5 years) or had never smoked)	1=Current smoker 2=Former smoker 3=Never smoked	[ ]
6.	Are you currently employed?	1=Employed 2=Unemployed 3=Retired	[ ]
7.	Do you take alcohol?	1=Yes 0=No	[ ]
8.	Are you sexually active?	1=Yes 0=No	[ ]
9.	If yes, how many episodes in the last four weeks?	1= None 2= 1-–2 episodes 3= 3-–4 episodes 4= >5 episodes	[ ]
	Co-morbid conditions		
10.	Diabetes mellitus	1=Yes 0=No	[ ]
	Hypertension	11.	Disease condition
	History of stroke	1=Yes 0=No	[ ]
	Chronic kidney disease/ESRD	1=Yes	[ ]

		0=No	
	NYHA Class	1=class 1, 2=class 2, 3=class 3	
	Duration of heart failure	1=less than 1 year 2=1-5 years 3=over 5 years	[ ]

12.	What are the patients current Medications?	From patients' file/records counter confirmed by patients	
	Beta-blocker	1=Yes 0=No	[ ]
	ACE inhibitor	1=Yes 0=No	[ ]
	Angiotensin receptor blocker	1=Yes 0=No	[ ]
	Mineralocorticoid receptor antagonist	1=Yes 0=No	[ ]
	SGLT2 inhibitors	1=Yes 0=No	[ ]
	Loop diuretics	1=Yes 0=No	[ ]
	Digoxin	1=Yes 0=No	[ ]
	Ivabradine	1=Yes 0=No	[ ]
	ARNI	1=Yes 0=No	[ ]
	Other drugs	1=Yes 0=No	[ ]

Appendix IV: Kiswahili Version of the Socio-demographic and Clinical Characteristics Questionnaire

Taarifa Binafsi Na Historia Ya Kiafya

Nambari ya swali	Swali	Aina ya kodi	Jibu
1.	Umri?	Miaka	[ ]
2.	Jinsia?	M = Kiume F=Kike	[ ]
3.	Umefikisha wapi masomo?	1=Hujasoma 2=Shule ya msingi 3=Shule ya upili 4= chuo cha katu na Mhitimu chuo kikuu na zaidi	[ ]
4.	Unaishi na mpenzi?	1=Ndiyo 0=Hapana	[ ]
5.	Ulishawahi kuvuta sigara?	1=Anavuta sigara 2=Aliiacha kuvuta sigara 3=Hujawahi vuta sigara	[ ]
6.	Unafanya kazi kwa sasa?	1=Umeajiriwa 2=Hujaajiriwa 3=Kupokea pensheni	[ ]
7.	Unatumia kileo/pombe?	1=Ndiyo 0=Hapana	[ ]
8.	Amilifu kufanya ngono?	1=Ndiyo 0=Hapana	[ ]
9.	Ikiwa ni ndiyo, vipindi vingapi kwa wiki nne zilizopita?	1= Hakuna 2= vipindi 1-–2 3= vipindi 3-–4 4= Zaidi ya 5	[ ]
	Magonjwa mengine yanayotokea		
10.	Ugonjwa la kisukari	1=Ndiyo 0=Hapana	[ ]
	Shinikizo la damu/blood pressure	1=Ndiyo 0=Hapana	[ ]
	Historia ya tukio mshipal/stroke	1=Ndiyo 0=Hapana	[ ]
	Kutofanya kwa figo	1=Ndiyo 0=Hapana	[ ]

11	Hali ya ugongjwa kwa sasa		
	Kwa muda ngapi unayo ugonjwa wa heart failure	1= chini ya mwaka moja 2= kati ya mwaka moja na miaka mitano 3= Zaidi ya miaka mitano	
	LVEF	1=chini ya 40% 2=kati 40-50% 3=Zaidi ya asilimia hamsini	
12.	Dawa gani unatumia kwa sasa?		
	Beta blocker	1=Ndiyo 0=Hapana	[ ]
	ACE inhibitor	1=Ndiyo 0=Hapana	[ ]
	Angiotensin receptor blocker	1=Ndiyo 0=Hapana	[ ]
	Mineralocorticoid receptor antagonist	1=Ndiyo 0=Hapana	[ ]
	SGLT-2 inhibitors	1=Ndiyo 0=Hapana	[ ]
	Digoxin	1=Ndiyo 0=Hapana	[ ]
	Loop diuretics	1=Ndiyo 0=Hapana	[ ]
	Ivabradine	1=Ndiyo 0=Hapana	[ ]
	Dawa zingine/other drugs	1=Ndiyo 0=Hapana	[ ]

Appendix V: English Version of the International Index of Erectile Dysfunction (IIEF-5)

Patient Identifier: _____	Date of interview:

Purpose: To assess erectile dysfunction using the abridged international index of erectile dysfunction index (IIEF-5).

Please choose the appropriate box for each question about your sexual abilities over the past 4 weeks.

1. How do you rate your confidence that you can get and keep your erection?
   - ☐ Very low
   - ☐ Low
   - ☐ Moderate
   - ☐ High
   - ☐ Very high
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?
   - ☐ Never or almost never
   - ☐ A few time
   - ☐ Sometimes
   - ☐ Most times
   - ☐ Almost always or always
3. During sexual intercourse how often were you able to maintain your erection after you had penetrated (entered) your partner?
   - ☐ Never or almost never
   - ☐ A few time
   - ☐ Sometimes
   - ☐ Most times
   - ☐ Almost always or always

4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

- ☐ Never or almost never
- ☐ A few time
- ☐ Sometimes
- ☐ Most times
- ☐ Almost always or always

5. When you attempted sexual intercourse, how often was it satisfactory for you?

- ☐ Never or almost never
- ☐ A few time
- ☐ Sometimes
- ☐ Most times
- ☐ Almost always or always

Appendix VI: Kiswahili Version of International Index of Erectile Dysfunction (IIEF-5)

Namba ya Hospitali:_____ Tarehe ya Usajili:_____

Madhumuni: Kutathmini hali ya ugonjwa wa shida ya kudindisha (matatizo ya kushiriki katika kitendo cha ngono) katika wagonjwa wa kiume tukitumia dodoso/maswali ya IIEF-5

Tafadhali chagua jibu inayoelezea kabisa hali ya uhusiano wako na uwezo wako katika tendo la ndoa/ngono katika kipindi cha wiki nne zilizopita

1. Je, imani yako katika uwezo wako wa kuanzisha kusimamisha (kudindisha) na kubaki umesimamisha uume wima ni wa kiasi gani?

   ☐ Chini zaidi

   ☐ Chini

   ☐ Wastani

   ☐ Juu

   ☐ Juu zaidi

2. Je wakati ulipata Kudindisha/ kusimamisha uume wima, ni kwa mara ngapi ulifaulu kujamii/kumwingia mwenzio?

   ☐ Sijaweza kamwe

   ☐ Mara chache

   ☐ Mara kwa mara

   ☐ Mara nyingi

   ☐ Wakati wote

3. Wakati wa tendo la ndoa ni mara ngapi uliweza kukaa kama umedindisha/kubaki umesimamisha uume wima baada ya kumwingia mwenzio?

   ☐ Sijaweza kamwe

   ☐ Mara chache

   ☐ Mara kwa mara

   ☐

Mara nyingi

☐ Wakati wote

4. Wakati wa tendo la ndoa, ni mara ngapi umeweza kudumisha hali ya uume kuwa wima kutoka kumwingia mwenzio hadi mwisho wa kitendo cha ndoa?

☐ Sijaweza kamwe
☐ Mara chache
☐ Mara kwa mara
☐ Mara nyingi
☐ Wakati wote

5. Wakati ulipojaribu kushiriki katika tendo la ndoa, ni kwa mara ngapi tendo hilo lilikuwa la kuridhisha kwako?

☐ Sijaweza kamwe
☐ Mara chache
☐ Mara kwa mara
☐ Mara nyingi
☐ Wakati wote

Appendix VII: English Version of the Female Sexual Function Index (FSFI)

Patient Identifier: _____	Date of interview:

Purpose: To assess female sexual dysfunction using the abridged female sexual function index (FSFI-6)

Please choose the appropriate box for each question about your sexual abilities over the past 4 weeks.

1. Over the past 4 weeks, how would you rate your **level** (degree) of sexual desire or interest?

   ☐ Very high

   ☐ High

   ☐ Moderate Low

   ☐ Very low or none at all

2. Over the past 4 weeks, how would you rate your **level** of sexual arousal ("turn on") during sexual activity or intercourse?

   ☐ No sexual activity

   ☐ Very high

   ☐ High

   ☐ Moderate Low

   ☐ Very low or none at all

3. Over the past 4 weeks, how **often** did you become lubricated ("wet") during sexual activity or intercourse?

   ☐ No sexual activity

   ☐ Almost always or always

   ☐ Most times (more than half the time)

- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

4. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **often** did you reach orgasm (climax)?
   - ☐ No sexual activity
   - ☐ Almost always or always
   - ☐ Most times (more than half the time)
   - ☐ Sometimes (about half the time)
   - ☐ A few times (less than half the time)
   - ☐ Almost never or never
5. Over the past 4 weeks, how **satisfied** have you been with your overall sexual life?
   - ☐ Very Satisfied
   - ☐ Moderately Satisfied
   - ☐ About Equally Satisfied and Dissatisfied
   - ☐ Moderately Dissatisfied
   - ☐ Very Dissatisfied
6. Over the past 4 weeks, how **often** did you experience discomfort or pain during vaginal penetration?
   - ☐ Did not attempt intercourse.
   - ☐ Almost always or always
   - ☐ Most times (more than half the time)
   - ☐ Sometimes (about half the time)

☐ A few times (less than half the time)

☐ Almost never or never

Appendix VIII: Kiswahili Version of the Female Sexual Function Index (FSFI)

Namba ya hospitali: _____	Tarehe ya usaili: _____

Madhumuni: Kutathmini hali ya ugonjwa wa shida ya au matatizo ya kushiriki katika kitendo cha ngono katika wagonjwa wenye ugonjwa sugu wa figo tukitumia dodoso/maswali ya FSFI-6
Tafadhali chagua safu/jibu inayoelezea kabisa hali ya uhusiano wako na uwezo wako katika tendo la ndoa/ngono katika kipindi cha wiki nne zilizopita

1. Katika kipindi cha wiki nne iliyopita, unatathminije **kiwango** chako cha hamu ya kufanya mapenzi?

   ☐ Kiko juu sana

   ☐ Kiko juu

   ☐ Wastani

   ☐ Kiko chini

   ☐ Kiko chini sana au hakuna kabisa

2. Katika kipindi cha wiki nne iliyopita, unatathminije **kiwango** chako cha kuchangamkia kufanya mapenzi ("kuamka") ulipokuwa unafanya mapenzi?

   ☐ Hakuna kufanya mapenzi

   ☐ Kiko juu sana

   ☐ Kiko juu

   ☐ Wastani

   ☐ Kiko chini

   ☐ Kiko chini sana au hakuna kabisa

3. Katika kipindi cha wiki nne iliyopita, **mara ngapi** ulikuwa laini ("unyevunyevu") ulipokuwa unafanya mapenzi?

- ☐ Hakuna kufanya mapenzi
- ☐ Karibu kila mara/mara zote
- ☐ Mara nyingi (zaidi ya nusu ya safari nilizojaribu kufanya)
- ☐ Kama nusu ya safari nilizojaribu kufanya
- ☐ Mara chache chini ya nusu ya safari nilizojaribu kufanya
- ☐ Kama haijawahi kutokea/Haijawahi kutokea kabisa

4. Katika kipindi cha wiki nne iliyopita, ulipopata kupata hamasa ya kimapenzi au kufanya mapenzi, **ni mara ngapi** ulipata hisia za kufika kileleni (kilele)?

- ☐ Hakuna kufanya mapenzi
- ☐ Karibu kila mara/mara zote
- ☐ Mara nyingi (zaidi ya nusu ya safari nilizojaribu kufanya)
- ☐ Kama nusu ya safari nilizojaribu kufanya
- ☐ Mara chache chini ya nusu ya safari nilizojaribu kufanya
- ☐ Kama haijawahi kutokea/Haijawahi kutokea kabisa

5. Katika kipindi cha wiki nne iliyopita, unaionaje hali yako kwa ujumla kuhusiana na suala la kufanya mapenzi?

- ☐ Nimeridhika sana
- ☐ Nimeridhika kwa wastani
- ☐ Niko nusu nusu
- ☐ Sijaridhika kwa kiasi fulani
- ☐ Sijaridhika nayo kabisa

6. Katika kipindi cha wiki nne iliyopita, ni **mara ngapi** ulipata usumbufu au maumivu wakati wa kupenyeza uke?

- ☐ Sikujaribu kufanya mapenzi
- ☐ Karibu kila mara/mara zote
- ☐ Mara nyingi (zaidi ya nusu ya safari nilizojaribu kufanya)
- ☐ Kama nusu ya safari nilizojaribu kufanya
- ☐ Mara chache (chini ya nusu ya safari nilizojaribu kufanya)
- ☐ Kama haijawahi kutokea/Haijawahi kutokea kabisa

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Tel: 7263000
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/431

28th October, 2022

Dr. Mohammed Yarrow Farah
Reg No. H58/37592/2020
Dept of Clinical Medicine & Therapeutics
Faculty of Health Sciences
University of Nairobi

28 OCT 2022

Dear Dr. Farah,

RESEARCH PROPOSAL: THE PREVALENCE OF SEXUAL DYSFUNCTION AND ASSOCIATED FACTORS AMONG AMBULANT HEART FAILURE PATIENTS ATTENDING KENYATTA NATIONAL HOSPITAL (P439/05/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P439/05/2022**. The approval period is 28th October 2022 – 27th October 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- UoN ERC
The Chair, Dept. of Clinical Medicine & Therapeutics, UoN
Supervisors: Prof. Elijah S.N.Ogola, Dept. of Clinical Medicine & Therapeutics, UoN
Dr. Eugene Kaiman Genga, Dept of Clinical Medicine & Therapeutics, UoN

LEAD SUPERVISOR AND CHAIRMAN OF DEPARTMENT

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

1. **Prof. Elijah S. N. Ogola**
   Professor of Medicine
   Consultant Physician and Cardiologist
   Department of Clinical Medicine and Therapeutics
   University of Nairobi

   Signature..... Date..09/11/2023

2. **Prof E.O Amayo**
   Chairman
   Consultant Physician and Neurologist
   Department of clinical medicine and therapeutics
   University of Nairobi

   UNIVERSITY OF NAIROBI
   COLLEGE OF HEALTH SCIENCES

   Signature..... Date..14/11/2023

04/11/2023

THE PREVALENCE OF SEXUAL DYSFUNCTION AND ASSOCIATED FACTORS AMONG AMBULANT HEART FAILURE PATIENTS ATTENDING KENYATTA NATIONAL HOSPITAL

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