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DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS

PREVALENCE OF SEXUAL DYSFUNCTION IN CHRONIC KIDNEY DISEASE PATIENTS ATTENDING RENAL CLINIC AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

This is to declare that this thesis is my original work, carried out with guidance from my supervisors, and references made to work done by others have been indicated.

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I would like to thank first Allah, second my supervisors and my parents.

LIST OF ABBREVIATIONS

CKD	Chronic kidney disease
KNH	Kenyatta National Hospital
UoN	University of Nairobi
ERC	Ethical Research Committee
HRQoL	Health-related-quality of life
IIEF	International Index of Erectile Function
IIEF-5	Five-item International Index of Erectile Function
FSFI	Female Sexual Function Index
FSFI-6	Six-item Female Sexual Function Index
K/DOQI	Kidney Disease Outcomes Quality Initiative
BMI	Body Mass Index
GFR	Glomerular Filtration Rate
FSD	Female Sexual Dysfunction
ED	Erectile Dysfunction
ESRD/ESCKD	End-Stage Renal Disease/End-Stage Chronic Kidney Disease
CRRT	Continuous Renal Replacement Therapy
ICF	Informed Consent Form
SDCcov	Sociodemographic and clinical covariates
SD	Sexual dysfunction

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ABSTRACT

Background: Sexual dysfunction (SD) is frequent but still underdiagnosed in chronic kidney disease (CKD) patients in Kenya. Moreover, the inconsistent usage of validated assessment (diagnostic) tools makes it problematic to define accurately the prevalence of SD.

Objective: To assess the prevalence and correlates of SD in CKD patients.

Design and Setting: A single centre cross-sectional study conducted between September 2019 and December 2019 at the Kenyatta National Hospital (KNH) Renal Clinic, Nairobi–Kenya.

Methods: SD was assessed in 306 patients using abridged International Index of Erectile Function (IIEF-5), and Female Sexual Function Index (FSFI-6), a shortened form of the FSFI-19 that all assess sexual function over the past month. Lower scores represented SD. Correlates of SD was identified in an aged and employment status adjusted Poisson model with a robust variance estimator.

Results: Of all the 306 patients, SD was reported in 81.4%. The prevalence of erectile dysfunction (ED) and female sexual dysfunction (FSD) was 88.9% (136/153) and 73.9% (113/153), respectively. The correlates of increased risk of ED were as follows: males with history of a cardiovascular event [adjusted risk ratio (adj. RR) = 1.12, confidence interval (CI): 1.01, 1.25, p <0.01], use of beta-blocker (adj. RR = 1.15, CI: 1.05, 1.26, p<0.001), angiotensin receptor blocker (adj. RR = 1.12, CI: 1.0, 1.26, p<0.01), and lipid-lowering therapy (adj. RR = 1.13, CI: 1.01, 1.27, p<0.01). For the females, former smokers had 33% increased risk of FSD (adj. RR = 1.33, CI: 1.11, 1.6, p<0.01) than never smokers. Female patients with endocrine dysfunction comorbidity had 14% increased risk of SD (adj. RR = 1.14, CI: 1.04, 1.26, p<0.01), those taking angiotensin receptor blocker had 52% increased risk (adj. RR = 1.52, CI: 1.25, 1.86, p<0.001) while those taking antipsychotics had 49% increased risk of SD (adj. RR = 1.49, CI: 1.25, 1.78, p<0.001).

Conclusions: SD in both males and females was highly prevalent in CKD patients. Given the correlates of increased risk of SD, the results showed that there is an unmet need for interventions to manage it. Patients being treated or managed for CKD should, therefore, be routinely screened for SD using validated psychometric instruments.

CHAPTER ONE

1. INTRODUCTION

1.1 Background of study

Chronic kidney disease (CKD) is a global public health problem. One of the problems is SD, a prevalent feature of CKD. According to Kidney Disease Quality Outcome Initiative (K/DOQI), CKD is kidney damage measured by glomerular filtration rate (GFR) level of <60 mL/min/1.73m^2 lasting for more than 3 months [1]. Irreversible kidney damage leads to an inability to do its crucial functions in homeostasis, excretion, and synthesis.

Compared to the members of the general population, people with CKD have greater morbidity and mortality, it affects 10% of the global population [2]. In Africa, studies at the community-level report CKD prevalence ranging from 2% to as high as 41% [3]. CKD is associated with kidney failure, can potentiate the risk for cardiovascular disease and untimely death.

Apart from the impaired renal function, CKD patients commonly encounter numerous other losses including losing place within the family and at the workplace, financial losses, losing well-being, and sexual function [4–8]. Loss of sexual function or SD is a very frequent and important condition accompanying CKD [9,10].

Owing to the advances and innovations in therapy, CKD patients' life expectancy has been prolonged. These achievements have resulted in the recognition of problems of sexual functioning that were previously overlooked but have had a negative influence on the health-related quality of life (HRQoL) of CKD patients [11].

SD is exemplified by physical, social, and psychological changes resulting in the inability to satisfactorily engage in sexual activities [12]. The problems suffered by people with CKD

include difficulties reaching orgasm in both males and females, erectile dysfunction (ED) and reduced libido in males. In females, the problems are delayed sexual development, dysmenorrhoea, dyspareunia, impaired vaginal lubrication, and sexual arousal difficulties [13].

Generally, SD under-recognized and under-reported. Importantly, the prevalence and correlates of SD have remained poorly described in Africa in general and Kenya in particular. Additionally, there is a marked dearth of evidence-based research on SD among CKD patients and no comparative data on sociodemographic and clinical characteristics of CKD patients disaggregated by sexual function. This necessitates a study on patients with CKD to assess the prevalence and correlates of SD in patients with chronic kidney disease and to shed more light.

The prevalence of SD was assessed by the abridged versions validated International Index of Erectile Function (IIEF) [14,15] and Female Sexual Function Index (FSFI-6) [16] scores. Sociodemographic and clinical data were obtained. The prevalence of several SD index domains in both men and women are essential to recognize to put priorities for clinical and epidemiologic research.

CHAPTER TWO

2. REVIEW OF LITERATURE

2.1 Pathophysiology and Classification of CKD

Lack of consensus on a standardized way of defining and describing CKD previously confused both healthcare providers and patients [17–19], and also led to controversies in literature [20] that were later resolved. CKD is defined by a decline in GFR (estimates the kidneys' filtering ability), increased excretion of urinary albumin (albuminuria), or both [21] because of multiple aetiologies. The definition was initially provided in 2002 K/DOQI guidelines classifying CKD progression stages without considering pathology and was later revised.

CKD has been historically called chronic renal failure (CRF) and includes all grading of reduced renal function. In the year 2004, the Kidney Disease: Improving Global Outcomes (KDIGO) defined CKD as damage of the kidney for at least three months characterized by functional or structural abnormalities, with/without reduced GFR, can of result in reduced GFR, manifesting as other pathologic abnormalities or markers of kidney damage, such as imaging test, urine or blood composition abnormalities [22]. CKD can range from normal (>90mL/min/1.73m^2), mild (60–89 mL/min/1.73m^2), moderate (30–59mL/min/1.73m^2), severe (15–29mL/min/1.73m^2), kidney failure (<15mL/min/1.73m^2) which are stages 1 to 5 respectively.

For better reflection of prognosis, KDIGO included staging by albuminuria level to have stage 3 subdivided into A (45-59mL/min/1.73m^2) and B (30-44mL/min/1.73m^2) [20,23–25]. Stage 6 is End-stage renal disease (ESRD). ESRD calls for renal replacement therapy like hemodialysis [26].

With the deterioration of kidney function, pathophysiologic complications develop. To begin, the blood flowing to the kidneys is around 20% of the amount pumped by the heart in a minute. The

blood flow rate in the kidneys of about 400 ml/100g/min is higher than the heart, liver, and brain [27]. This makes the kidney to be exposed to a substantial amount of circulating substances or agents that may be harmful.

Next, the glomerular filtration also depends on relatively great intra- and transglomerular pressure, making the capillaries of the glomerulus susceptible to haemodynamic injury, compared to other capillary beds. The main cause of CKD is glomerular hypertension that leads to glomerular hyperfiltration [28].

The glomerular filtration membrane contains molecules that are negatively charged serving as an electrostatic barrier holding back anionic macromolecules. A disruption of this enables plasma protein to move into the glomerular filtrate.

The sequential arrangement of the microvasculature of the nephron and the tubuli's downstream position about glomeruli enables the spread of glomerular injury to the compartment of tubulointerstitium, and in this way exposes the epithelial cells of the tubule to the abnormal ultrafiltrate. It's the tubulointerstitium that is involved in progression to CKD [29]. Because peritubular vasculature lies beneath glomerular blood flow to the mediators of inflammation might pass over into the circulation to the peritubular capillaries leading to the interstitial inflammatory reaction.

Additionally, any reduction in glomerular perfusion or preglomerular results in a reduction in blood circulation to the peritubular capillaries, which, relying on the hypoxia, involves tubulointerstitial injury and remodeling of the tissue.

Since glomerulus is a functional unit, damage to one of its constituents such as visceral, mesangial, endothelial, and parietal epithelial cells – podocytes as well as the extracellular matrix will affect the other via a variety of mechanisms, soluble mediators, cell-cell links.

Progression to CKD consists of glomerulosclerosis (depositing of excess extracellular matrix within the glomerular) and tubulointerstitial fibrosis (collagen depositing in the interstitial region between tubules), which lead to the damage of the kidney structure, peritubular capillary injury (microvascular capillary dysfunction/rarefaction, hypoxia and tubular atrophy [29–33] ultimately resulting in irreversible scarring.

2.2 Aetiology, Clinical Presentation, Treatment and Management of CKD

CKD causes vary worldwide. CKD, and eventually ESRD, is frequently caused by several major diseases which include type 2 diabetes mellitus, high blood pressure, primary (unaccompanied by disease) glomerulonephritis, type 1 diabetes mellitus, chronic tubulointerstitial nephritis, hereditary or cystic diseases, neoplasm or plasma cell dyscrasias, secondary glomerulonephritis or vasculitis, sickle cell nephropathy [34,35] including HIV infection, especially Anti-Retroviral Therapy-naïve HIV-positive patients [36]. A retrospective study by Yao et al. [37] showed that the CKD aetiologies were hypertension, 59.9%; chronic glomerulonephritis, 25%; HIV infection, 9.1%; and diabetes, 4.8%.

Kidney disease could present in several ways, firstly, as the screening of asymptomatic people, secondly, as people having clinical signs and symptoms that have arisen from kidney dysfunction, and thirdly, with signs and symptoms of an underlying kidney (systemic) disease that already developed into kidney dysfunction [38].

All in all, kidney diseases are largely asymptomatic. The clinical signs are nonspecific or unclear, and therefore detection depends on a mixture of clinical suspicion and simple investigations, such as estimation of GFR and urinalysis. However, in some tubulointerstitial diseases, symptoms are linked with the kidneys or lower urinary tract. An array of abnormalities in urine like sediments and blood tests or imaging tests (studies)/ultrasound findings constitute the specific CKD clinical presentations [39].

Given the asymptomatic nature of kidney diseases, late presentation at referral facilities is predominant. Data et al. [40] established in Nigeria that due to this, abnormal renal ultrasound results, high serum creatinine and urea, and urine abnormalities were very common, and the most frequent symptoms were malaise, decreased urinary flow and oedema are common symptoms amongst patients. Somewhat similar to Data et al.'s study, a Ghanaian study by Amoako et al. [41] reported that, at presentation, the common CKD complications are anaemia (86.7%), pulmonary oedema (31%), high blood pressure (55%), and infection.

CKD treatment comprises a definite therapy, on the diagnostic basis that includes managing comorbidity, slowing down the deterioration of renal function, preventing and treating cardiovascular disease and problems of reduced renal function, preparing for renal failure and replacement therapy of the kidney [39] and dialysis or transplantation to replace the function of the kidney, if uremic syndrome sets in. Details of CKD clinical management are well described in the paper by Methven and MacGregor [42].

2.3 Epidemiology of CKD

2.3.1 Incidence and Prevalence of CKD

The CKD classification provided critical insight into the burden, incidence, and prevalence of kidney diseases [43,44]. In a 2015 systematic review, Mills et al. [44] recounted that of 109.9 million people with CKD in high-come countries, 43.9% were men and 56.1% women. Correspondingly, in lower-middle-income countries, of 387.5 million affected, 45.8% and 54.2% were men and women respectively. The global prevalence of CKD is high and is consistently between 11–13% with stage 3 most prevalent at 7·6% [45]. Although CKD is a global issue, it disproportionately impacts developing countries. In Southeast Asia, the prevalence of 10.6% has been reported in Nepal and 23.3% (Pakistan).

In Africa, a systematic review in 2018 reported CKD prevalence ranges from 2%–41% and was in keeping with the ranges obtained by Stanifer et al. [46]. The 2018 review found that CKD is largely ascribed to high-risk disease groups such as high blood pressure and diabetes. In HIV patients, prevalence ranges from 1%–46%, 11%–90% in diabetic patients and 13%-51% in hypertensive patients [3]. Previously, Stanifer et al. [46] found the CKD overall prevalence estimate in 2014 was 13·9%. Just like in the global studies, stage 3A of CKD appears to be the most common (62.01%) as reported in Cameroon [47] as in New Zealand [48].

In Kenya, there are very few studies on CKD. Mwenda et al. [49] reported a CKD prevalence of 38.6% among KNH inpatients. An earlier study in HIV high-risk group in western Kenya found 11.5% prevalence of renal insufficiency [50]. Owing to the scarcity of studies, it appears that Stanifer et al.'s [46] pooled CKD prevalence of 0·040 (0·021–0·073) for Kenya doesn't give a clear picture of the burden of CKD in Kenya and such estimates also appeared dogged by poor

heterogeneity. From the CKD literature, it's clear that CKD is underdiagnosed in Kenya and is a serious problem that deserves comprehensive investigation.

2.3.2 Comorbidities, Risk Factors, and Mortality

Okwuonu et al. [51] reported that the risk factors for CKD were high blood pressure (hypertension), 36.9%; old age, 36.3%; diabetes mellitus, 7.9%; while the history of kidney disease in the family was 6.4% –all of which were predicted kidney disease. Obesity is also independently correlated with CKD. Among hypertensive patients in Cameroon, findings by Hamadou et al. [47] showed that anemia, 44.5%; obesity, 39.75%; diabetes, 32%; using traditional medicines, 15.75%; besides hyperuricemia, 10.75% were the major comorbidities of CKD. Among ESRD patients, diabetes and hypertension coexistence is the very common [52]. Additionally, social deprivation has also been identified to increase CKD risk [48].

Among several correlates, the body mass index (BMI) abnormality, waist circumference, and waist-to-height ratio are associated with the CKD cumulative risk of CKD [53]. Non-traditional risk factors like working in agriculture and exposure to agrochemicals [54] also play a part.

Over the past decade, global deaths due to CKD has increased by close to 32% [55]. Among the most common causes of death, kidney disease was ranked the 12th, and it explains over 1 million global deaths. Therefore mortality risk is higher in CKD [56] and the disease is also linked with increased healthcare utilization (specialized healthcare) [57–59]. Studies have reported that concerning people without CKD, the hazard ratios of mortality range from 1.2–1.5 for people with stages 3–5 [59,60] and have a likelihood of hospitalization of 1.6–2.2 times [57].

Among pre-dialysis and transplant patients, together with the traditional risk factors, like hypertension, anaemia proteinuria, diabetes, dyslipidaemia, and bone mineral disorder, patient

and donor ages, relapse of glomerular disease, preexisting cardiovascular problems, time patient is on dialysis and side-effects of medications, which could eventually result in severe endothelial derangement, also lead to graft loss and death [61].

Among older patients, the study findings by Saeed et al. [62] indicated that the prognostic factors heralding high one-year death are rising age, congestive heart failure, lack of arteriovenous fistulae, and an absence of predialysis nephrology care. About 60% of mortalities are attributed to non-cardiovascular causes such as cancer.

2.4 Sexual Dysfunction in the context of Chronic Kidney Disease

2.4.1 Male sexual (Erectile) dysfunction

ED is the persistent inability to attain and maintain a penile erection to sufficiently perform a sexual function satisfactorily [63]. ED is frequent in CKD, and mostly in ESRD. While ED seems to be most common with deteriorating GFR, from stage 3, the rate is high [10].

Mechanisms for the development of ED in CKD is multifactorial. For normal sexual function, an intricate balance of psychological, physiological, hormonal, emotional, neurological, and vascular (arterial) systems or factors [64], and pharmacologic factors [65] is required. Men with CKD may show abnormalities in a single of or these factors/systems altogether [66].

Generally, the ED estimate in males with CKD is 70% with a 95% confidence interval of 62%-77%. Studies have reported that ED prevalence rates could reach 70 to 80% in males with CKD similar to rates in End-Stage CKD [67]. Several factors are involved in ED development these CKD patients, that includes the drugs used, zinc deficiency, elevated parathyroid hormone serum levels, increased prolactin serum levels, reduced testosterone serum levels, as well as psychological factors [68].

In a study done by Costa et al. [69], ED was present in 71.0% and severe in 36.7%. The risk factors were age >50 years, BMI <25, diabetes mellitus, benign prostatic hyperplasia, CKD stages 4/5, smoking, cardiac conduction disturbances, alcohol consumption, albumin, and creatinine clearance 15–29mL/min/1.73m^2. Somewhat similar findings were obtained by Nishida et al. [70] of which the absence of hyperuricemia affected ED.

It might be interesting to know how prevalence compares especially regarding diabetic kidney disease. Among Type 2 Diabetic Patients, a multinational cross-sectional study found a prevalence of 83% of ED and 47% severe form of ED. The strongest correlate was symptoms of depression. Age, unemployed/ being pensioned, and inter-dialytic weight gain. However, married men had a lower ED risk. A high prevalence of 94% was found in unmarried and unemployed or retired men with depression. Other studies have also reported clinical depression was most strongly associated with SD [71].

Using IIEF, a study found that ED was mild, 21.5%; mild to moderate, 14.1%; moderate, 6.3%; and severe, 11.9% but highly prevalent in men older than 40 [72]. Among men with conservatively treated CKD, another study found out that SDs were common but not strongly correlated to testosterone levels, prolactin levels, and survey responses in patients with CKD [73].

In Brazil, erectile function was found in 66.3% of patients, with a mean IIFE-5 score of 19.45 (mild erectile function). The frequency of patients with erectile function was higher among 51-60 years-old and diabetes mellitus men (81.6%).

2.4.2 Female Sexual dysfunction

Mechanisms of female sexual dysfunction (FSD) in CKD is also multifactorial. SD in women is primarily because of hormonal factors and expresses mostly as amenorrhea, menstrual (disturbances) irregularities, absence of vaginal lubrication, as well as failure to conceive [65] but other systems or factors also contribute. It's associated with physiological, anatomical, medical, biological, and psychological factors that may have a huge effect on self-esteem, HRQoL, mood, and relations. The intricacy of FSD is amplified by CKD [74].

Endocrine abnormalities are prevalent in CKD and lead to SD, hyperparathyroidism, anemia, and alterations in mineral metabolism [75]. Clinical complications encompass a reduction in libido and infertility in both genders. Organic factors tend to be conspicuous and are associated with uremia and comorbid diseases. Psychological factors and depressive symptoms may exacerbate the primary problem. Visible modifications in the hypothalamic-pituitary axis are manifested early in CKD and are likely to deteriorate on dialysis initiation.

Like in males, FSD is also a common issue in ESRD. Among peritoneal dialysis and hemodialysis patients, the prevalence of FSD was 94.1% and 100% respectively [76]. The study reported depression rates of 75.3 and 43.8 respectively.

A meta-analysis reported that prevalence values of SD range from 30% to 80% in women with CKD [68], however, the prevalence may be over 80% depending on the stage, for instance, hemodialytic patients. A multinational study reported no sexual activity or low sexual functioning in hemodialytic women [77]. This aforementioned multinational study reported that the FSFI orgasm domain was 75.1%; arousal, 64.0%; lubrication, 63.3%; pain, 60.7%; satisfaction, 60.1%; sexual desire 58.0%. And depression was associated with worse pain and

lubrication scores whilst those who previously had cardiovascular episode had higher scores for pain.

SD also occurs in comorbid patients. In type 2 diabetic patients, Rutte et al. [71] reported that 70% of women had some form of SD and clinical depression was strongly associated with SD. In another study, FSD has been diagnosed in 67.9% of the women [78]. Enzlin et al. [79] reported 35% FSD among type 1 diabetics. There was a loss of libido loss, 57%; orgasmic problems, 51%; lubrication, 47%; arousal, 38%; and pain, 21%. In Slovenia, a study found 31% prevalence and equally a strong correlation between the claims of desire and arousal, arousal and lubrication, lubrication and pain, orgasm and lubrication, satisfaction, and orgasm, and pain and arousal [80].

2.4.3 International Index of Erectile Function (IIEF) and Female Sexual Function Index (FSFI)

2.4.3.1 International Index of Erectile Function (IIEF)

IIEF is a self-administered brief psychometric tool developed by Rosen et al. [81]. It was developed by conducting a literature search from interviews and questionnaires on ED among male patients to identify relevant sexual function domains across varied cultures. The first IIEF tool was administered to ED patients and the findings reviewed by a panel of international experts. A final 15-item was then linguistically validated and examined for specificity, sensitivity, reliability, and construct validity.

IIEF is an extensively used, multidimensional psychometric tool for the evaluation of male sexual function [15]. It categorizes ED into one of five groups: absent, 26–30 score; mild, 22–25 score; mild to moderate, 17–21 score; moderate, 11–16 score; and severe, 1–10 score. In evaluating the IIEF, findings showed that the IIEF retains satisfactory properties for identifying

the existence and severity of ED [14]. The simplified IIEF-5 is also an easy method, which can be used to evaluate ED in studies with an increased sampled [72].

IIEF has been criticized for not being a conclusive diagnostic instrument to differentiate the pathophysiological sources of ED [63]. According to Rosen et al. [15], the tool focuses only on current sexual functioning and gives a superficial evaluation of sexual functioning domains apart from erection. It gives no information about the partner sexual functioning or relationship and gives a limited evaluation of the sexual desire and orgasm domains. The IIEF doesn't distinguish between sexual desire disorder types or premature ejaculation and other orgasmic disorders.

However, IIEF is a validated tool and has been used in numerous studies globally. It has found use in a multinational cross-sectional study and provided consistent results [82].

2.4.3.2 Female Sexual Function Index (FSFI)

FSFI is a brief self-report measurement tool of female sexual function developed by Rosen et al. [16]. It is a 19-item multidimensional self-report inventory for assessing the main dimensions of female sexual function [16] with tremendous consistency. It consists of six domains: desire (2 items), arousal (4 items), lubrication (4 items), orgasm (3 items), satisfaction (3 items), and pain (3 items). Each question gets a score that ranges from 0 – 5, and the end is the sum of scores for each domain, multiplied by a correction factor that homogenizes the influence of each domain. A total score of no more than 26 shows SD.

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 SD [83]. It was also found to be reliable and psychometrically valid in normal controls and age-matched females [16] and had internal consistency [84].

Within a women population, Meston [85] found that the range of divergent validity and internal consistency of the tool was acceptable. The tool has also been found sensitive to therapeutically-induced change in sexual functioning in women [86]. Being a "gold standard", a six-item female sexual function index (FSFI-6) has been developed and equally found to be a consistent and reliable tool for FSD screening in Brazilian women [87].

Typically, as with self-reports, FSFI too has limitations. The fact that FSFI wants women to self-report on their levels of sexual arousal even though they are most of the time not accurate at assessing their level of arousal is a limitation [88].

It has also been found that FSFI gives biased results for sexually inactive women in the past four weeks [89]. Of the 19 questions, 15 have a response choice of "No sexual activity" or "Did not attempt intercourse" given a score of zero [90]. This choice presents problems since it reduces the FSFI scores, therefore, portraying more severe SD. Women were maybe sexually inactive in the past month for reasons such as absent partners among others. The fact that the FSFI utilizes vague terminologies on response options, especially on the scale referring to the four weeks has been criticized. Additionally, the distinctions of the sexual domains (for instance, desire and arousal) and retaining desire and arousal as separate entities of sexual function.

Forbes et al. [91] pointed out that both tools have critical measurement and theoretical problems for evaluating sexual problems beyond sexual arousal, and particularly sexual desire domains. However, Rosen et al. [92] took issue with the Forbes et al.'s arguments and opined that they conducted a selective review of literature 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 including a multinational cross-sectional study [77] in the women population.

2.5 Conceptual Framework

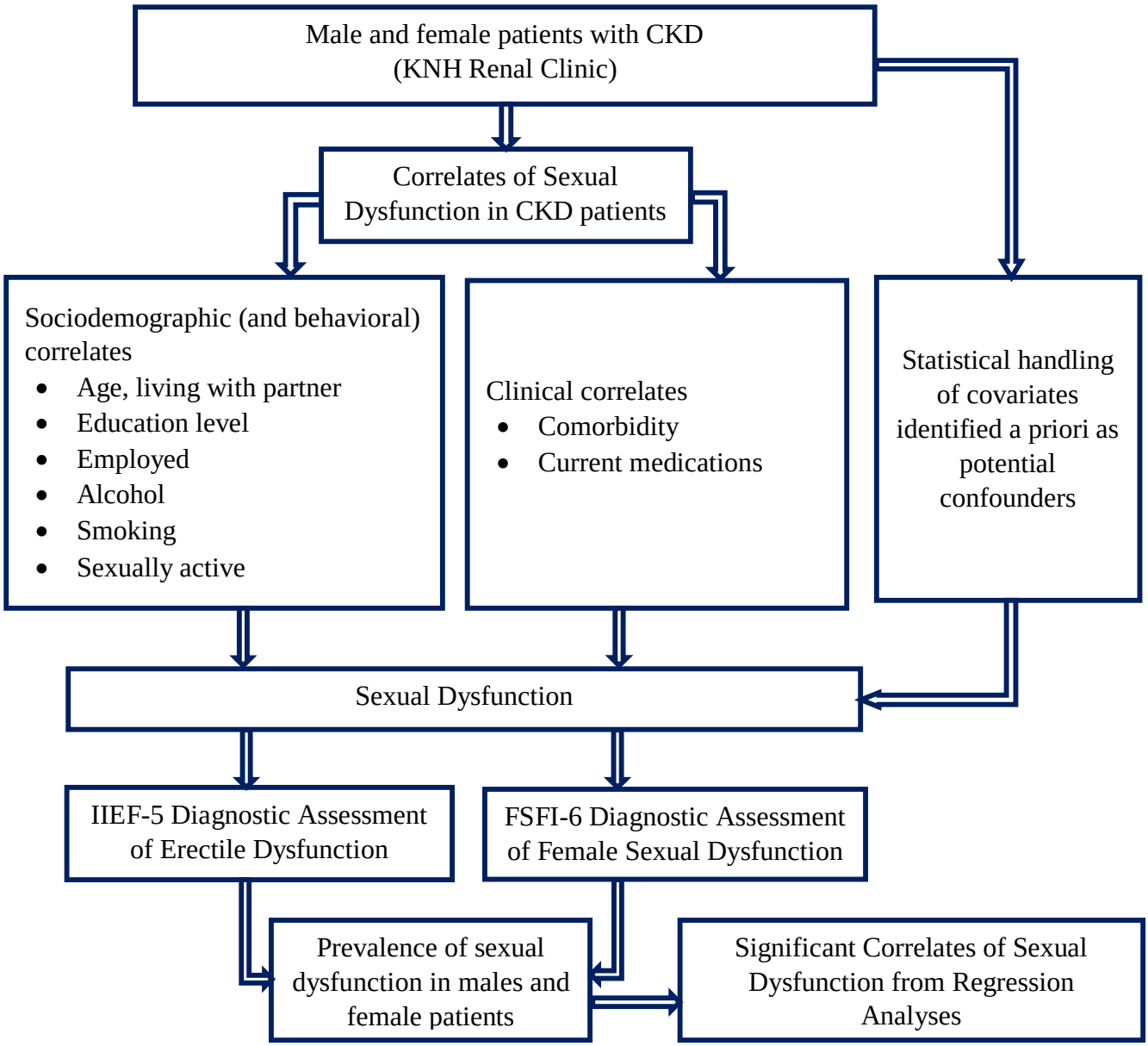

Figure 1. Conceptual Framework

2.6 Study Justification

Among chronic diseases, kidney disease is the most neglected [93]. Equally, SD is a very important determinant of HRQoL in CKD patients but also underdiagnosed and underreported. Frequently, specialists avoid studying sexual health symptoms because of fears of inadequate time or absence of appropriate tools for addressing SD. The inconsistent usage of validated assessment (diagnostic) tools makes it problematic to define accurately the prevalence of, and sociodemographic and clinical correlates of SD. However, the utility of validated psychometric questionnaires such as IIEF and FSFI could be used as references [94] and provide consistent means of describing SD in patients with dysfunctional kidney.

Epidemiological literature reveals that little research has been done on SD in CKD patients in Africa resulting in limited epidemiological knowledge. Some of the few available studies in Africa are uncertain and unsystematically done. Moreover, the existence of confounders such as comorbidity introduces bias in several studies, minimal or no attention to SD among females with CKD literature presents challenges and opportunities to be addressed by this study.

Two recent studies, the systematic reviews by Abd ElHafeez et. al. [3] and meta-analysis by Kaze et. al. [95] in Africa, clearly demonstrates a lack of research on patients with CKD. Even when available, the few studies show variability in methodological approach, for instance, the suboptimal or the low quality and discrepancies identified by Abd ElHafeez et. al. [3] including the aforesaid inconsistencies. The variability of results between various populations is attributable to multiple factors such as cultural and ethnic differences [96]. Just 22% of patients with problems of sexual function seek medical assistance [76].

This study has clinical and epidemiological relevance. Exploring the prevalence of SD and characteristics of index sexual functioning domains improves the knowledge and understanding

of the specific sexual experiences of CKD patients to inform a patient-centered research agenda to transform patient care. Assessment of sociodemographic and clinical characteristics associated with CKD and SD provides more insight into the underlying physiology of HRQoL in CKD patients and has prognostic significance in querying the pathway by which such correlates affect different domains of sexual function.

In brief, this study is of practical and scholarly relevance. It provides an evidence-based epidemiological and clinical research reference point that could be utilized in informing decisions in patient care and management.

2.7 Research Question

What is the prevalence of sexual dysfunction among male and female chronic kidney disease patients?

2.8 Objectives

2.8.1 Broad objective

To assess the prevalence of sexual dysfunction in patients with chronic kidney disease using the abridged versions of the international index for erectile function (IIEF-5) and female sexual function index (FSFI-6).

2.8.2 Primary objectives

i) To assess the prevalence of erectile dysfunction in chronic kidney disease patients using the abridged international index for erectile function (IIEF-5).

ii) To assess the prevalence of female sexual dysfunction in chronic kidney disease patients using the abridged female sexual function index (FSFI-6).

2.8.3 Secondary objectives

i) To determine the correlates of erectile dysfunction in chronic kidney disease patients.

ii) To determine the correlates of female sexual dysfunction in chronic kidney disease patients.

CHAPTER THREE

3. RESEARCH METHODOLOGY

3.1 Study Design

This was a single centre cross-sectional study.

3.2 Study Site

This study was conducted at the urology/andrology/outpatient clinics handling renal conditions (all hereafter, Renal Clinic) of the Kenyatta National Hospital (KNH). The KNH is located in the Nairobi City County, 3.5 km west of the Nairobi Central Business District and sits on 45.7 acres. KNH was established in 1901 and 1952 it was called George VI hospital. It is the leading Kenya national government-funded referral and teaching hospital. Within the hospital are the College of Health Sciences of the University of Nairobi (UoN) and the Kenya Medical Training College.

KNH averagely receives greater than 2,000 in-patients and 1,500 outpatients daily [97] and caters to a variety of patients. Patients (3.6%) are referred from as far as, but not limited to, East African countries. It has all the medical specialists and/or consultants for specialized care, a characteristic of a fully-fledged referral hospital. Of the specialized departments, is the Department of Clinical Medicine and Therapeutics of UoN, and the KNH Renal Clinic established in 1984 [97].

The Renal Clinic (Unit) of KNH has various specialties such as Haemodialysis, Outpatient services, Pre- and post-Transplant clinic, and Renal Biopsy specialty. The influx of kidney patients to the Unit has risen considerably. The hospital has specialized equipment such the acute multi-therapeutic Continuous Renal Replacement Therapy (CRRT) machines used in the treatment of sepsis, multiple organ failure, trauma, and lupus. The CRRT is used in the critically ill in the intensive care unit having acute kidney injury.

KNH/UoN also has East African Kidney Institute. The institute contributes to sustained efforts to address kidney diseases and renal failure by addressing treatment, research, building capacity, and knowledge management.

3.3 Study Population

Male or female CKD patients attending the Renal Clinic of the KNH.

3.3.1 Inclusion criteria

- Patients of both genders, not less than 18 years, attending the Renal Clinic for outpatient services.
- Male and female CKD patients that were willing to sign a written informed consent form (ICF) to participate in the research study.

3.3.2 Exclusion Criteria

- Male or female patients less than 18 years of age and not more than 65 years of age
- Not willing to sign ICF to participate in the study.
- Patients with an indeterminate pathophysiologic cause or neurocognitive disorders.
- Patients who were participating in another medical study.
- Patients with known major psychiatric disorders.
- Patients with uncontrolled congestive heart failure.

3.4 Sample Size Calculation

In prevalence/cross-sectional studies, the formula below would be used for computing the adequate sample size of a single population proportion [98,99].

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

Where $Z_{1-\alpha/2}$ = 1.96, the standard normal variate at 5% type 1 error ($p<0.05$). P is the expected proportion in population-based on past studies and d is the precision/absolute error. However, from the primary objective of assessing the prevalence of SD in CKD patients, both male and female patients were sampled and different tools used. Given the use of gender-specific tools (IIEF-5 and FSFI-6), one sample size calculation technique for proportions won't be directly used but instead, a hypothesis approach in Cohen's [100] formula. The null hypothesis is that there is no difference in SD prevalence estimates of males and females, while the alternative hypothesis; one unknown gender has a higher prevalence. Implying a two-sided alternative test.

There are no Kenyan studies specific to SD in CKD patients. Based on well-established data from literature review elsewhere, the prevalence of ED is about 70% [69,101] and FSD is about 84% [77,102], the minimum sample size needed for a 5% significance level in the results and 80% test power is computed at 278 (139 per gender group) and a difference as little as 5%. The sample size was adjusted for 10% non-response to 306 (153 per group).

The sample size is computed using the formula of Cohen [100] and implemented by Champely et al. [103] in R (version 3.6.2) [104]. For taking an equal sample in both genders:

```
> pwr.2p.test(h = ES.h(p1 = 0.70, p2 = 0.84), sig.level = 0.05, power = .80) # library(pwr)
```

Where p1, the prevalence of ED in CKD (in men); p2, prevalence of SD in women, and ES.h, calculates the effect size, h. For unequal sample sizes:

```
> pwr.2p2n.test(h=0.3362458, n1=138.8427, n2=, sig.level=.05,power=.80) #yields the same result as with equal sample size.
```

3.5 Sampling Procedure

The study participants were identified from the Renal Clinic. The sampling method was largely be determined by the multiplicity of factors including those cited in Chapter Two, that is, the pathophysiology, aetiology and clinical presentation (not all patients at the outpatient clinic had CKD but comorbidity was expected), practicality–affluence or flow of patients at the Renal Clinic and the sample size. The expectation is that the KNH Renal Clinic is affluent since sampling design is dependent on the patient burden at the facility.

Although random sampling is essentially the ideal for eliminating bias, systematic-random sampling was used to allow for more statistical power. The total number of patients in the Renal Clinic was recorded for the entire duration of the study then divided by the sample size (n=306) to obtain a constant (k). The sequence of participants was computed from R (version 3.5.1) [104] until the 306^{th} as follows:

```
> seq(sample(1:k,1), 306, k)
```

The methodology of sampling ought to be flexible, conditional on the study environment. Male and female patients were approached while they are attending the Renal Clinic. The study objectives were explained to them, and the signed ICFs were got from those willing to participate. Every participant was evaluated in conformity with standard KNH protocols such as general medical checkup and urologic/andrologic exams.

3.6 Variables and Measures

3.6.1 Independent variables – Sociodemographic and clinical correlates

Sociodemographic (and some behavioural) correlates

- Age

- Living with a partner
- Education level
- Employment status.
- Alcohol abuse.
- History of cigarette smoking.
- Being sexually active

Clinical correlates

- Comorbid conditions
- Current medications

3.6.2 Dependent (Outcome) variable

The prevalence of SD in CKD patients disaggregated by gender. Prevalence of index domains of both IIEF-5 and FSFI-6.

3.7 Data Collection Instruments

Data was collected using validated versions of the questionnaires (Tools) in the English and Kiswahili language; that is, the IIEF-5 (males) and FSFI-6 (females) and both genders completed an additional study developed questionnaire, the Sociodemographic and Clinical covariates (SDCcov) to collect sociodemographic and clinical correlates (Appendix II). SDCcov was also be translated be to Kiswahili.

Together with a trained Research Assistant (survey administrators) conversant with CKD, the Principal Investigator (PI) administered the SDCcov for the baseline data. The questionnaire was used to collect data that included sociodemographics, CKD duration, hemodialysis duration, information on comorbidity, medications used, and clinical laboratory data. The IIEF-5 and FSFI-

6 diagnostic tools were attached appropriately to the SDCcov with baseline information, depending on gender.

The printed SDCcov, IIEF-5, and FSFI-6 were self-administered in one session and concurrently with a renal appointment. The two psychometric/diagnostic tools were carried out confidentially at an individual level and were assembled with de-identified SDCcov. The SDCcov with the attached psychometric tools bore codes that were allocated to every participant. It was expected that just a few patients would need assistance from the Principal Investigator or survey administrators in clarifying some of the questions. The tools took averagely 15 minutes to complete.

3.8 Recruitment and Data Collection

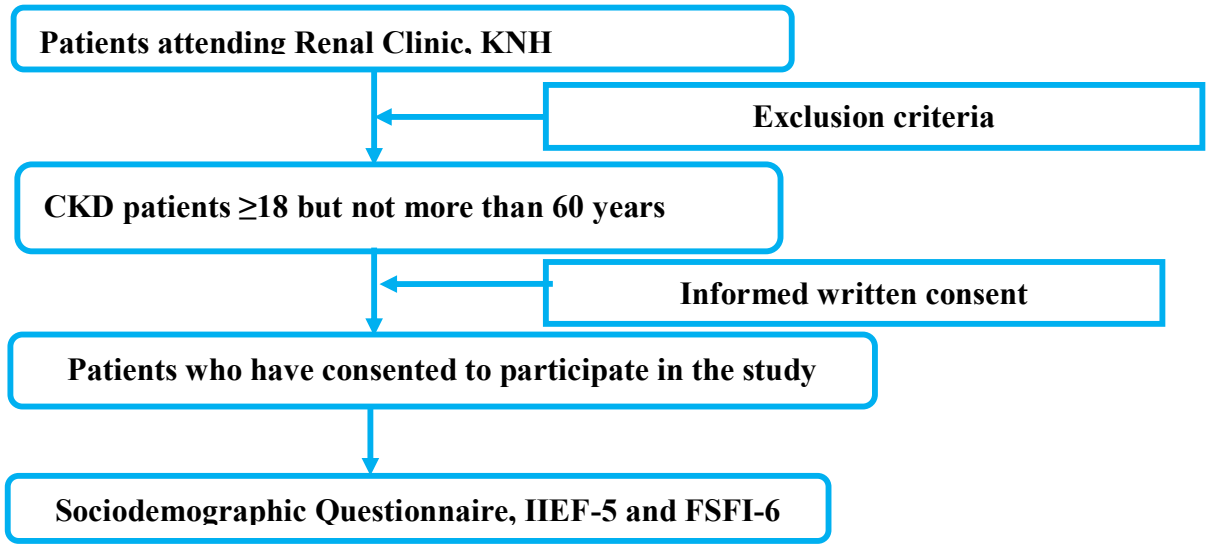

Figure 2: Recruitment and Data Collection

3.9 Quality Assurance

The well-trained survey administrators assisted in the survey administration of psychometric tools. The data was counterchecked by the Principal Investigator and the survey administrator to remove errors. Cross-culturally validated and back-translated psychometric tools were used. This was to

avoid problems previously encountered by Esho [105] in which survey language was culturally insensitive and limited research. In situations where a survey administrator assisted the participant in completing the Tools, the principal Investigator was very observant of how the survey was conducted, monitoring the process and the behaviour of the survey administrator to guarantee complete professionalism. This carefulness was to avoid inconsistencies and evade quality influenced stratified data analysis. However, it's expected that such cases won't occur.

3.10 Data Management

Patient-related identifiers were removed and by de-identification (codes/serial numbers). The paper-and-pen copies were kept safely to evade data loss before entry. The data was then be entered into password secured Excel. The data were double entered and inconsistencies resolved by counterchecking against the paper-and-pen copies. The data was thoroughly cleaned and analyzed immediately.

3.11 Ethical Considerations

The study was presented for consideration and approval by the Ethical Research Committee (ERC) of the KNH and University of Nairobi (KNH-UoN ERC). After favourable opinion from KNH-UoN ERC, the study was done in conformity with the Helsinki Declaration and Good Clinical Practice. The study design and procedure were described in detail and all participants signed a written ICF either in English or Swahili as they deem fit. For patients unable to read and self-complete the tools, the ICF was read, and the fingerprint of the index finger taken instead of a signature.

The Research Assistant was a mature male and female, particularly those trained and experienced in human immunodeficiency virus testing and counseling (given the comparable level of sensitivity and confidentiality in sexual health). The research assistants were trained as

test administrators and sat with individual participants and ask the questions in the Sociodemographic and Clinical covariates tools and document their responses. The Research Assistants were trained in a standard way, certainly not to involve in discussion with the study participants, in order not to sway their responses. Research Assistants only repeated the questions, to enable the participant to consider their responses. In this way, both the quality and medical research ethical standards were upheld. The use of test administrators has been successfully implemented in a study requiring self-reported responses in Uganda [106] in cases of illiteracy.

The data was handled with the utmost confidentiality. Due to the cultural sensitivity of the research questions and to maintain the right of privacy of the participants, appropriate consultations were made with the participants whether to share the results with their primary physician for standard care – a standard practice in medical research. Further, protection of the participant's private data and intimacy were safeguarded by applying the Rosen and Beck [107] guidelines. The access to the data entered into the Excel database was controlled by creating a password to maintain privacy. During post-analysis, the hard copies of the tools were destroyed/burnt. The anonymous electronic data was archived in a secure server, this was explained to the participants and their permission sought during ICF. After the work is published, the electronic data was also destroyed after five years.

3.12 Data Analysis

The overall prevalence of SD was examined using Isidori et al.'s [108] and Rhoden et al.'s [72] cutoffs respectively. Using IIEF-5 classification, a binary variable was generated, in which scores from 8–21 were considered mild to moderate and 5–7 considered as severe ED. Using the FSFI-6 cutoff, the FSD was further categorized by severity into mild to moderate1(FSFI-6 scores

of 10–19), severe (FSFI-6 scores of 2–9). The distribution of levels of function in all domains of the FSFI-6 and IIEF-5 were also be examined.

Sociodemographic, lifestyle, and clinical characteristics were summarized as mean and (standard deviation or SD) for continuous variables and as frequencies and percentages for categorical variables. Mann–Whitney U-tests and Pearson chi-square (χ^2)-tests were used for assessing the difference in the proportion of the characteristics of no SD and any (mild to moderate and severe) form of SD in CKD patients. Using analysis of variance for trend on ranks and Mantel–Haenszel χ^2-test on continuous and categorical variables respectively, the sociodemographic, lifestyle, and clinical characteristics were further compared for trend (none, mild-moderate and severe). Multivariable regression analysis was used to examine independent associations between correlates of interest in both male and female CKD patients' SD over the past 4 weeks. The Log-binomial model was used as the first method of multivariable analysis, but convergence was not reached, then a Poisson regression model with a robust variance estimator, implemented in R software [104] was used.

The correlates of risk associated with SD were assessed by estimating the risk ratios (RR) and were interpreted as recommended by Martinez et al. [109] and their 95% confidence intervals (CIs) provided. The significance of all the statistical tests was at $p<0.05$ and 95% CIs appropriately. The RRs and 95% CIs estimated by log-Poisson regression models were valid, however, they have a slightly reduced efficiency than log-binomial models estimates [109]. All regression models were adjusted for age and employment status at the time of the 2020 data collection. Adjusted RRs showed the risk that CKD patients of a given category have SD compared to a reference category (referent) while adjusting for age and current employment

status. Statistical interactions were tested between gender and each of the covariates of exposures interest at p-value < 0.05.

CHAPTER FOUR

4. RESULTS

4.1 Sociodemographic and clinical profiles/characteristics of participants by the severity of sexual dysfunction

Among the 306 study participants, the mean age (years) was 47.5 [standard deviation (SD), 13.5], while the overall median age was 49.5 (IQR 37-60) years. The minimum age of the patients was 18 years, whereas the maximum age was 66 years. The male respondents mean age was 50.8 (SD, 12.7) years, while the median age was 55.0 (IQR 41-62). Of all the participants, 249 (81.4%) reported experiencing SD. One hundred and forty-five (47.4%) reported mild to moderate SD and 104 (34.0%) severe SD. The distribution of participants' demographic and clinical characteristics is as shown in Table 1. Nearly 52% (158/306 participants) reported being sexually active, as well as virtually all participants [52/57 (91.2%)] without SD. Study participants without SD frequently reported 1–2 episodes of sex/week [34/57 respondents (59.6%)], similar to those with mild to moderate SD [76/145 (52.4%)] and participants with severe SD reported almost no sexual episodes per week [100/104 (96.2%)].

Unlike male participants, female participants were either never or former smokers with approximately all reporting being never smokers [149/153 (97.4%)]. Among male participants, 54.9% (84/153) were never smokers and only 6.5% (10/153) reported being current smokers. Of the participants with any SD, 60.6% (151/249) reported having hypertension. The percentage of participants with any form of SD was 75.0, 71.9, 90.4% for participants between 18 and 35 years, between 36 and 45, and >55 years, respectively. The results are summarized in Table 1 below.

Table 1. Distribution of participant sociodemographic and clinical profiles among CKD patients visitting the renal clinic at KNH, Nairobi – Kenya, according to the severity of SD (n = 306)

Characteristics	**All patients (n = 306)**	**No SD (n=57)**	**Mild–moderate SD (n=145)**	**Severe SD (n=104)**	***p*-value (any vs no SD)**[1]	***p*-value (trend in severity)**
Age (years), mean ± SD	47.5±13.5	42.2±12.1	49.4±12.9	47.7± 14.3	<0.001	<0.001
Education, n (%)					<0.001	<0.001
No education/ incomplete primary	35 (11.4)	1 (1.8)	16 (11.0)	18 (17.3)		
Primary	99 (32.4)	12 (21.1)	41 (28.3)	46 (44.2)		
Secondary or middle-level college	146 (47.7)	33 (57.9)	80 (55.2)	33 (31.7)		
Graduate and above	26 (8.5)	11 (19.3)	8 (5.5)	7 (6.7)		
Living without a partner, n (%)	98 (32.0)	6 (10.5)	28 (19.3)	64 (61.5)	<0.001	<0.001
Smoking, *n* (%)					0.03	0.13
Current smoker	10 (3.3)	1 (1.8)	8 (5.5)	1 (1.0)		
Former smoker	63 (20.6)	5 (8.8)	50 (34.5)	8 (7.7)		
Never smoked	233 (76.1)	51 (89.5)	87 (60.0)	95 (91.3)		
Employed in any occupation, n (%)					0.01	<0.001
Employed	129 (42.2)	34 (59.6)	61 (42.1)	34 (32.7)		
Unemployed	159 (52.0)	21 (36.8)	71 (49.0)	67 (64.4)		
Receiving pension	18 (5.9)	2 (3.5)	13 (9.0)	3 (2.9)		
Alcohol abuse, *n* (%)	53 (17.3)	16 (28.1)	32 (22.1)	5 (4.8)	0.03	<0.001
Sexually active, *n* (%)	158 (51.6)	52 (91.2)	98 (67.6)	8 (7.7)	<0.001	<0.001

[1] *p* value for the Chi-square ($\chi 2$)-tests. SD, Sexual dysfunction; vs = versus.

Table 2 below shows the frequency distribution of sexual episodes per week, co-morbidity and medications used by the chronic kidney disease patients. Among the participants with severe SD, 27/104 (26.0%) reported having been prescribed diuretic, 25/104 (24.0%) ACE inhibitor, and erythropoietin apiece, 15/104 (14.4) anti-depressant medications. Frequency of sexual activity (*p*-value <0.001) was all associated with any SD. Furthermore, severe SD was associated with taking antipsychotic medication (*p*-value = 0.016). In contrast, those with diabetes mellitus, hypertension, cardiovascular event history, endocrine dysfunction comorbid conditions, phosphodiesterase inhibitors and those taking beta-blockers, ace inhibitor, angiotensin receptor blocker, diuretic, erythropoietin, nitrate, lipid-lowering therapy, anti-depressant, and antipsychotic medications had no difference in risk of any form of SD for no SD versus no SD and across the severity of SD.

Table 2. Frequency distribution of sexual episodes per week, co-morbidity and medications used by the CKD patients visiting the renal clinic at KNH, Nairobi – Kenya, according to the severity of SD (n = 306)

Characteristics	**All patients (n = 306)**	**No SD (n=57)**	**Mild–moderate SD (n=145)**	**Severe SD (n=104)**	***p*-value (any vs no SD)**[2]	***p*-value (trend in SD severity)**
Sexual activity, number of episodes per week					<0.0001	<0.0001
None	152 (49.7)	3 (5.3)	49 (33.8)	100 (96.2)		
1-–2 episodes	114 (37.3)	34 (59.6)	76 (52.4)	4 (3.8)		
3-–4 episodes	34 (11.1)	15 (26.3)	19 (13.1)	0 (0.0)		
5-–6 episodes	4 (1.3)	3 (5.3)	1 (0.7%)	0 (0.0)		
7-–10 episodes	2 (0.7)	2 (3.5)	0 (0.0)	0 (0.0)		
Co-morbid conditions, *n* (%)						
Diabetes mellitus	83 (27.1)	12 (21.1)	44 (30.3)	27 (26.0)	0.33	0.68
Hypertension	183 (59.8)	32 (56.1)	90 (62.1)	61 (58.7)	0.63	0.88

[2] *p* value for the Chi-square ($\chi 2$)-tests.

	Cardiovascular event history	19 (6.2)	1 (1.8)	10 (6.9)	8 (7.7)	0.22	0.17
	Endocrine dysfunction	2 (0.7)	0 (0.0)	2 (1.4)	0 (0.0)	1.00	0.76
Medication, *n* (%)							
	Phosphodiesterase inhibitors	2 (0.7)	0 (0.0)	2 (1.4)	0 (0.0)	1.00	0.76
	Beta-blocker	36 (11.8)	2 (3.5)	21 (14.5)	13 (12.5)	0.06	0.17
	ACE inhibitor	76 (24.8)	17 (29.8)	34 (23.4)	25 (24.0)	0.43	0.49
	Angiotensin receptor blocker	15 (4.9)	0 (0.0)	9 (6.2)	6 (5.8)	0.12	0.17
	Diuretic	76 (24.8)	14 (24.6)	35 (24.1)	27 (26.0)	1.00	0.80
	Erythropoietin	77 (25.2)	17 (29.8)	35 (24.1)	25 (24.0)	0.47	0.48
	Nitrate	9 (2.9)	2 (3.5)	6 (4.1)	1 (1.0)	1.000	0.26
	Lipid-lowering therapy	29 (9.5)	4 (7.0)	14 (9.7)	11 (10.6)	0.65	0.48
	Anti-depressant	64 (20.9)	14 (24.6)	35 (24.1)	15 (14.4)	0.57	0.08
	Antipsychotic	4 (1.3)	0 (0.0)	0 (0.0)	4 (3.8)	0.75	0.016

4.2 Prevalence of ED in CKD patients using the IIEF-5

Using the IIEF-5 tool, the prevalence of ED was 88.9% with 13.1% of the males having a severe form (Table 3). The prevalence of ED was 66.0% and 88.0% among sexually active male participants and those living with partners, respectively. Responses to the IIEF-5 tool are also summarized in Table 3. The IIEF-5 mean total score was lower than and consistent with the mean scores (≤ 21) of ED patients as described by Rosen et al. [14]. The domain-specific scores are at about a mean score ranging from 2.8 to 3.3 suggesting moderate or thereabout on the 5-point Likert scale used comparable with 136 abnormal scores in Table 3 above. Among sexually active male participants, the total score of 17.9 (SD, 4.3) was a little closer to Rosen et al.'s cutoff value for males.

Table 3. Distribution of prevalence of ED and sexual problems, overall and stratified by severity, sexual activity, and partner status

Prevalence of ED[3]		**All males (n = 153)**	**Sexually active (n =101)**	**Living with partner (n = 125)**
	Overall	136 (88.9)	85 (66.0)	110 (88.0)
	Mild	53 (34.6)	50 (49.5)	44 (35.2)
	Mild–Moderate	41 (26.8)	29 (28.7)	35 (28.0)
	Moderate	22 (14.4)	3 (3.0)	16 (12.8)
	Severe	20 (13.1)	3 (3.0)	15 (12.0)
IIEF-5 domain-specific scores[4]				
	IIEF-5 total score	15.2 (6.8)	17.9 (4.3)	15.4 (5.7)
	Erectile function confidence domain	2.8 (1.3)	3.3 (1.1)	2.8 (1.3)
	Erectile hardness for penetration domain	3.0 (1.6)	3.7 (1.1)	3.1 (1.4)
	Erectile maintenance after penetration domain	3.0 (1.5)	3.8 (1.1)	3.1 (1.4)
	Erectile maintenance difficulty to intercourse completion domain	3.3 (1.5)	3.4 (1.4)	3.2 (1.5)
	Intercourse satisfaction domain	3.0 (1.5)	3.8 (1.2)	3.2 (1.5)

4.3 Prevalence of FSD in CKD patients using the FSFI-6

The prevalence of FSD was 73.9% (113/153), 26.6% (21/79), and 56.6% (47/83) among all female participants, that reporting being sexually active and living with a partner, respectively. The data is presented in Table 4. The proportion of female participants who had scores within the two lowermost classes for each FSFI-6 item—apart from the sexual pain domain which had to be reverse-scored, was 57.5% for problems of sexual desire and 15.7%, apiece, for problems with sexual arousal and not being satisfied with the sexual life. Additionally, for the sexual arousal domain, 74 participants (48.4%) reported lack of sexual activity then 14.9% (98) stated having very low or absence of sexual arousal. In the domain of lubrication, 17 participants (11.1%) reported a few times or almost never or never and 88 participants (57.5%) reported they had no sexual activity.

[3] An IIEF-5 score of ≤21 is the cut-off erectile dysfunction (ED). ED categorized into 4 classes: "severe ED" [5–7], "moderate ED" [8–11], "mild–moderate ED" [12–16] and "mild ED" [17–21].
[4] Values are mean (SD).

In the domain of orgasm, 61.9% of the participants (94) reported they had not experienced sexual activity and 14 participants (9.2%) stated they had problems with reaching orgasm. In the pain domain, 85 participants (55.6%) indicated they hadn't experienced any sexual activity whereas 9 (5.9%) stated they had very high levels of pain during sexual intercourse. Seventy-nine female participants (48.4%) reported being sexually active. The prevalence among the sexually active and those living partners are as presented in Table 4.

Table 4. Distribution of prevalence of overall FSD and sexual problems stratified by sexual activity and partner status and FSFI-6 domain-specific scores

FSFI-6[5] Domain	**All females (n = 153)**	**Sexually active[6] (n = 79)**	**Living with a partner (n = 83)**	**Female FSFI-6 Scores[7]**	
	n (%)	**n (%)**	**n (%)**	**No. of Patients**	**Mean score**
Overall[8]	113 (73.9)	21 (26.6)	47 (56.6)	153	12.4 (8.3)
Problems with sexual desire	88 (57.5)	16 (20.3)	33 (39.8)	153	2.2 (1.1)
Problems with sexual arousal	24 (15.7)	24 (30.4)	10 (12.0)	79	2.9 (1.8)
Problems with lubrication	17 (11.1)	17 (21.5)	12 (14.5)	65	3.5 (1.9)
Problems with orgasm	14 (9.2)	14 (17.7)	11 (13.3)	59	3.7 (2.0)
Lack of satisfaction with sexual life	24 (15.7)	24 (30.4)	11 (13.3)	153	3.9 (1.3)
Pain during penetration[9] (dyspareunia)	9 (5.9)	9 (11.4)	9 (10.8)	68	4.0 (2.2)

4.4 Correlates of sexual dysfunction in males and females

Table 5 summarizes the sociodemographic and clinical characteristics that were correlates of risk associated with SD in multivariate regression model adjusting for the patient's age (years) and status of employment. Independent predictors correlated with SD (IIEF-5 scores ≤ 21 and FSFI-6

[5] Female Sexual Function Index (FSFI-6), evaluates female sexual function in the past-month.
[6] Sexual activity was considered when a response of "no sexual activity" to at least one of the FSFI-6 items in the past-month.
[7] FSFI-6 maximum possible total score is 30, and maximum possible domain scores are 5.
[8] FSFI-6 score of ≤ 19 taken as the cut-off of FSD. Specific sexual problems was considered as the proportion of females scoring in the two lowest classes for each item—with the exception of the domain of pain in which case the reverse was true.
[9] Scores were reversed to measure FSD

score ≤ 19) in the last 4 weeks are presented and are adjusted for the patient's age and employment standing in the "All patients" column in Table 5. Correlates of increased risk of SD were being male, being a former smoker, having a cardiovascular event, kidney transplant, endocrine dysfunction, treatments such as phosphodiesterase inhibitors, beta-blockers, angiotensin receptor blocker, lipid-lowering therapy, antipsychotic medications. Being sexually active and living with a partner were correlates of reduced risk of SD. However, effect modification by gender was evident that needed to be considered for the implications of the correlates to hold. That is, there was a real effect whose magnitude was different in either of the genders. Gender status modified the associations of sexually active, partner status, being former smoker, alcohol abuse, and use of angiotensin receptor blocker medication (in Table 5, the *p*-values for the interaction of gender with other variables in the model). Comparison of the age and employment status adjusted multivariate regression models for experiencing SD stratified by gender status, the risk ratio (RR) estimates associated being sexually active and living with a partner were larger for male participants than female participants.

4.4.1 Correlates of erectile dysfunction in CKD patients

Table 5 summarize the sociodemographic and clinical profiles that were associated either with any group of ED or with severe ED in multivariate regression model. In an age and employment status adjusted model, among male participants, being sexually active was an important correlate with a 14% reduced risk of experiencing ED (RR = 0.86, CI: 0.76, 0.97, *p* value<0.01). Taking ACE inhibitor medication was also associated with 16% lower risk of ED (RR = 0.84, CI: 0.68, 1.04, *p* value<0.05). However, history of a cardiovascular event (RR = 1.12, CI: 1.01, 1.25, p <0.01), use of beta-blocker (RR = 1.15, CI: 1.05, 1.26, p<0.001), angiotensin receptor blocker (RR = 1.12, CI: 1.0, 1.26, p<0.01), nitrate (RR = 1.11, CI: 1.02, 1.22, p<0.01) and lipid-

lowering therapy (RR = 1.13, CI: 1.01, 1.27, p<0.01) medications were correlates of increased risk of experiencing ED at 12%, 15%, 12%, 11% and 13%, respectively.

4.4.2 Correlates of female sexual dysfunction in CKD patients

In an age and employment status adjusted multivariate model, among female participants, being sexually active linked with a 60% reduced risk of experiencing SD (RR = 0.40, CI: 0.28, 0.57, *p*-value<0.001). Living with a partner was also associated with 37% decrease in female SD (RR = 0.63, CI: 0.53, 0.75, p<0.001). Interestingly, those taking alcohol had a 59% reduction in symptoms of SD (RR = 0.41, CI: 0.17, 1.0, p<0.05). Conversely, former smokers had a 33% increased risk of SD (RR = 1.33, CI: 1.11, 1.6, p<0.01) compared to never smokers. Those who had a kidney transplant had a 47% increased risk of experiencing any form of SD (RR = 1.47, CI: 1.22, 1.75, p<0.01) while having endocrine dysfunction (RR = 1.14, CI: 1.04, 1.26, p<0.01) was a correlate with a 14% increased risk of SD. Female participants taking angiotensin receptor blocker (RR = 1.52, CI: 1.25, 1.86, p<0.001) and antipsychotic (RR = 1.49, CI: 1.25, 1.78, p<0.001) had 52% and 49% increased risk of SD (Table 5).

Table 5. Multivariable adjusted risk ratios estimating differences in risk of experiencing any symptoms of SD in all CKD patients visiting renal clinic, Kenyatta National Hospital, Nairobi – Kenya, and stratified by gender

	Adjusted Risk Ratios (95% CI[10])[11]			
Characteristics	**All patients (n = 306)**	**Males (n = 153)**	**Females (n = 153)**	***p*-values[12]**
Gender				
Female	Referent	–	–	–
Male	1.18 (1.04, 1.35)**	–	–	–
Sexually active				
No	Referent	Referent	Referent	–
Yes	0.71 (0.62, 0.81)***	0.86 (0.76, 0.97)**	0.4 (0.28, 0.57)***	<0.001
Partner status				
Unpartnered	Referent	Referent	Referent	–

[10] Confidence intervals; SD, sexual dysfunction.
[11] All regression models were adjusted for employment status and patient's age specific to the time (year 2020) when the SD data was collected.
* *p*-value < 0.05; ** *p*-value < 0.01; *** *p*-value < 0.001
[12] The *p*-values for the gender and exposures/correlates (with every variable) interactions in all patients (n = 306).

Table 5. Multivariable adjusted risk ratios estimating differences in risk of experiencing any symptoms of SD in all CKD patients visiting renal clinic, Kenyatta National Hospital, Nairobi – Kenya, and stratified by gender

		Adjusted Risk Ratios (95% CI[10])[11]			
Characteristics		**All patients (n = 306)**	**Males (n = 153)**	**Females (n = 153)**	***p*-values**[12]
	Partnered	0.79 (0.72, 0.88)***	0.93 (0.81, 1.07)	0.63 (0.53, 0.75)***	< 0.001
Smoking history					
	Never smoker	Referent	Referent	Referent	–
	Former smoker	1.12 (1, 1.25)*	1.03 (0.89, 1.2)	1.33 (1.11, 1.6)**	<0.001
	Current smoker	1.18 (0.95, 1.48)	1.04 (0.83, 1.3)	–	–
Co-morbid conditions					
	Diabetes mellitus vs. none	0.99 (0.86, 1.14)	0.98 (0.82, 1.17)	1.02 (0.81, 1.3)	0.253
	Hypertension vs. none	0.95 (0.85, 1.07)	0.95 (0.85, 1.06)	0.96 (0.75, 1.23)	0.378
	History of a cardiovascular event vs. none	1.13 (1, 1.29)*	1.12 (1.01, 1.25)**	1.23 (0.98, 1.53)	0.232
	Endocrine dysfunction vs. none	1.12 (0.99, 1.26)*	1.15 (0.87, 1.51)	1.14 (1.04, 1.26)**	0.273
Medication					
	Phosphodiesterase inhibitors vs. none	1.1 (0.97, 1.24)*	1.15 (0.87, 1.51)	1.09 (0.98, 1.22)	0.405
	Beta-blocker vs. none	1.19 (1.07, 1.34)***	1.15 (1.05, 1.26)***	1.23 (1, 1.52)*	0.498
	ACE inhibitor vs. none	0.89 (0.76, 1.04)	0.84 (0.68, 1.04)*	0.96 (0.76, 1.21)	0.161
	Angiotensin receptor blocker vs. none	1.22 (1.12, 1.33)***	1.12 (1, 1.26)**	1.52 (1.25, 1.86)***	<0.001
	Diuretic vs. none	0.96 (0.83, 1.11)	0.98 (0.84, 1.16)	0.96 (0.75, 1.23)	0.753
	Erythropoietin vs. none	0.92 (0.81, 1.05)	0.92 (0.79, 1.07)	0.96 (0.78, 1.19)	0.616
	Nitrate vs. none	0.96 (0.68, 1.35)	1.11 (1.02, 1.22)**	0.54 (0.12, 2.46)	0.323
	Lipid-lowering therapy vs. none	1.05 (0.9, 1.23)	1.13 (1.01, 1.27)**	1.03 (0.79, 1.35	0.778
	Anti-depressant vs. none	0.87 (0.76, 0.99)	0.87 (0.73, 1.03)	0.86 (0.69, 1.06)	0.610
	Antipsychotic vs. none	1.32 (1.2, 1.44)***	–	1.49 (1.25, 1.78)***	

CHAPTER FIVE

5. DISCUSSION AND CONCLUSIONS

5.1 Discussion

The objective of this current study was to assess the prevalence and correlates of SD in patients with CKD among patients at KNH using validated instruments. A high prevalence of past-month SD comparable with estimates from prior studies was found [77,82,110]. Slightly greater than half of all the patients reported they being sexually active and/or recently sexually active, and the mean scores revealed that most male and female participants were moderately satisfied with sexual intercourse and with their overall sexual lives, respectively.

The ED was prevalent in 88.9% of the males. The ED prevalence is so high but somewhat expected since the participants were CKD patients. It was also found that in males who lived with partners, there was still a higher prevalence of ED (88.0%), however, ED was relatively lower in sexually active males (66.0%). The IIEF-5 scores that this current study reports are also quite in line with mean scores of ED described by Rosen et al. [14]. The high prevalence of ED in this study may also be elucidated in terms of co-morbid conditions like hypertension, diabetes mellitus, cardiovascular event history and endocrine dysfunction that were reported in the male patients. Age was also a great factor that contributed to ED.

Prevalence of FSD was high but not as high as in males. The percentage of the female CKD patients with SD was about 74%. More females reporting living with partner experienced SD symptoms (56.6%) than those who reported being sexually active (26.6%). The sociodemographic data disclosed that FSD was linked with advancing age (years), more especially above 50 years, just like in the male population. The result is in concurrence with the high prevalence among older people reported by Hasan et al. [111] in a systematic review in

south Asian region (a developing region). Most of the female had sexual desire problems (57.5%) and the FSD appeared to be associated with co-morbidity. Saglimbene et al. [77] reported 58.0% prevalence of sexual desires among women in a multinational study similar to this current study. Just as with age, the oldest females had a statistically significant higher sexual desire problems than younger ones and the results compares well with those obtained by Jiann et al. [112] on risks on domain scores. The high prevalence of sexual problems in the females can also be explained given the higher proportions of women who were sexually inactive (51.6%).

Past research studies have supported the health benefits of sexual activity [113–116]. This study found that being sexually active and living with a partner were correlates of reduced risk of SD. More male and female participants reported sexual activity, however, SD appeared lower in male than female participants as aforementioned – though underlying SD clinical symptoms may have a contribution too. Another significant outcome that resonates with the findings of an SD working group [82] and Saglimbene et al. [77] was that a unit year increase in age was associated with an elevated risk of experiencing ED and FSD, so that older age is a correlate of SD.

Male participants with ED were highly probable (significantly) to be sexually inactive than sexually active ones. While ED in the males with CKD was mostly found to be mild to moderate, very few report getting specific pharmacological management. The explanations behind these low rates of intervention are uncertain and require further research, though they are expected to consist of patient embarrassment, clinicians being largely unaware, and the importance of ED on the general health of the patient or a lack of enough evidence to support intervention [117].

History of a cardiovascular event was the strongly correlated with ED, signifying that treatment of a coexisting cardiovascular event might be a suitable approach for ED management in this situation. However, the use of nitrate-containing medication (for instance, those used in the

treatment of angina) was positively correlated with ED, and this could be due to a dangerously low blood pressure/severe hypotension [118]. Previous studies have reported a non-linear correlation[13] between ED and diastolic blood pressure, confirming the relationship between hypertension/ hypotension and ED [119,120].

Remarkably, no statistically significant differences considering the use of anti-depressant medications between male participants having ED and those without existed. This could be due to anti-depressants not uncommonly leading to SD, although improvement of depression may help in reducing ED [82].

A high prevalence of sexual problems was found in female participants who reported being sexually active in the past-month. These results highlight the fact that SD in CKD patients is often very high and may need additional research to recognize the clinical significance of these outcomes from the viewpoint of a patient. Important correlates of increased risk of FSD included being a former smoker, kidney transplant, endocrine dysfunction, taking angiotensin receptor blocker, and antipsychotic treatments. Prior studies have shown that SD has a relationship with depression as well as anxiety in patients with CKD [121]. However, sexual activity and living with a partner lowered the FSD risk. More research on diverse populations might, perhaps, be needed to ascertain if alcohol abuse indeed is associated with lower FSD.

The cross-sectional characteristic of this study excludes interpretations of causality. Again, all potential correlates of SD, for instance, sexual functioning of the study participants' partners as well as other meaningful psychological or physical measures were not taken. Even so, as the only study on SD in patients with CKD ever done in Kenya, this study develops an

[13] It usually means that the relationship is first decreasing and then increasing, or vice versa.

understanding of the numerous correlates of high occurrence/prevalence of SD among males and females with CKD.

5.2 Limitations

The results from this study should be interpreted with respect to the limitations presented in this study. The results should be interpreted with caution since a correlation does not imply causation. Recall (of events or exposures) due to misreporting was unavoidable given that the outcome measures in the IIEF-5 and FSFI-6 were self-reported may lead to incompleteness and inaccuracies. Admission bias could have led to data exclusion on wait-listing and introduce the potential for bias. Measurement bias or misclassifying participants would imply that the participants are categorized as CKD when not, this results in over- or underestimation of associations between outcome and correlates. Residual confounding may occur due to other comorbid conditions, but models were adjusted to take care of these. Confounding may affect associations. Importantly, being an observational study, conclusions about causality were not drawn regarding SD.

5.3 Strength of the study

The study population was a homogenous patient CKD group for both male and female categories and this was the main strength of this study. The calculated sample size gave an acceptable quantity of type II error in the results presented and the results are generalizable to a similar patient group.

5.4 Conclusions

The overall prevalence SD was very high among CKD patients studied. In terms of the primary objectives, SD, as was assessed using the IIEF-5 and FSFI-6, was found highly prevalent in patients of both genders with CKD and was found often moderate to severe. The prevalence in male patients was 88.9% and 73.9% in female patients. In both genders, the correlates of increased risk of SD in CKD patients was the use of beta-blockers and angiotensin receptor

blocker. The correlates of ED were having a history of a cardiovascular event, use of nitrate (severe hypotension), and lipid-lowering therapy. For females, being former smoker, endocrine dysfunction, and antipsychotic medications were associated with FSD. Despite the high prevalence and its hitherto established correlates/associations with compromised life quality in the CKD population, patients with SD have an unmet need for effective interventions.

5.5 Recommendations

This study may be appropriate for further assessment in more diverse male and female patients with CKD. A longitudinal patient-centered follow-up study for outcomes might increase the ability to evaluate a change in SD as age increases with an increase in prevalent comorbid conditions. Such results would enlighten the advancement of practical interventions for patients with CKD in the future. Screening and managing SD need to be obligatory to attain improvement of quality of life. Again. patients being treated or managed for CKD needs to be routinely screened for SD using validated Tools.

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APPENDICES

APPENDIX I: INFORMED CONSENT FORM

Study number…… Sex……

Name…… Age...……

Introduction

Hello. I am Dr. Abdullahi Hadi Omar, 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 and correlates of sexual dysfunction in patients with chronic kidney disease at the Renal Clinic at the Kenyatta National Hospital.

Among chronic diseases, kidney disease is the most neglected. At the same time, sexual dysfunction is a very important determinant of health-related quality of life in patients with chronic kidney disease that has is underdiagnosed and underreported. 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

1. To assess the prevalence of erectile dysfunction in chronic kidney disease patients using the abridged international index for erectile function (IIEF-5).
2. To assess the prevalence of female sexual dysfunction in chronic kidney disease patients using the abridged female sexual function index (FSFI-6).

List of investigators

Name	Role	Institution/Affiliation
Dr. Abdullahi Hadi Omar	Principal Investigator	University of Nairobi
Prof Mcligeyo S. O	Co-investigator	University of Nairobi

Dr. Kwasa Thomas	Co-investigator	University of Nairobi

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 sociodemographic 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 regards to this chronic kidney disease, 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 or not to participate in this study. You are also free to withdraw from the study at any time you wish to do so.

Who to contact

You are encouraged to ask any questions to clarify any issues at any time during your participation in the study. If you need more information on the study, here are the contacts of persons coordinating the study.

Name	**Mobile phone number**	**email address**
Dr. Abdullahi Hadi Omar	0728382332	abdallahaadi@gmail.com

For more information about your rights, research problems or questions about your rights as a research participant, you may contact the KNH/UoN ERC through the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

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: Dr. Abdullahi Hadi Omar

Signature of the Investigator: .....

Date: .....

APPENDIX II: INFORMED CONSENT FORM (KISWAHILI VERSION)

FOMU YA RIDHAA

Nambari ya masomo/utafiti

……

……

Jina …… Umri ... ……

Utangulizi

Habari. Mimi ni Dkt Abdullahi Hadi Omar, mwanafunzi wahitimu wa kuhitimu katika Idara ya Tiba ya Tiba ya Tiba na Tiba, Chuo Kikuu cha Nairobi. Fomu hii ya ridhaa inatafuta idhini ya kuhusika kwako katika utafiti huu ambao unakagua hali ya ugonjwa wa shida ya kudindisha/matatizo ya kushiriki katika kitendo cha ngono kwa wagonjwa walio na ugonjwa sugu wa figo katika Kliniki ya Figo katika Hospitali ya Kitaifa ya Kenyatta.

Kati ya magonjwa sugu, ugonjwa wa figo ndio unaopuuzwa zaidi. 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 sugu wa figo ambao umepatikana bila kutambuliwa na haujafadhiliwa. 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

1. Untathmini/unakagua hali ya ugonjwa wa shida ya kudindisha/matatizo ya kushiriki katika kitendo cha ngono kwa wagonjwa walio na ugonjwa sugu wa figo kwa kutumia fahirisi ya kimataifa ya wanaume (IIEF-5).
2. Untathmini/unakagua hali ya ugonjwa wa shida ya/ matatizo ya kushiriki katika kitendo cha ngono kwa wagonjwa walio na ugonjwa sugu wa figo kwa kutumia fahirisi ya kimataifa ya wanawake (FSFI-6).

Orodha ya wachunguzi

Jina	Jukumu	Taasisi
Dr. Abdullahi Hadi Omar	Mtafiti mkuu	Chuo Kikuu cha Nairobi
Prof Mcligeyo S. O	Mtafiti	Chuo Kikuu cha Nairobi
Dr. Kwasa Thomas	Mtafiti	Chuo Kikuu cha Nairobi

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 sugu wa figo 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 wakati wowote unavyotaka kufanya hivyo.

Nani wa kuwasiliana

Unahimizwa kuuliza maswali yoyote kufafanua masuala yoyote wakati wowote wakati wa kushiriki kwako kwenye utafiti. Ikiwa unahitaji habari zaidi juu ya utafiti, hapa kuna anwani za watu kuratibu masomo.

Nambari anwani ya barua pepe ya Simu ya Mkononi

Dk Abdullahi Hadi Omar 0728382332 abdallahaadi@gmail.com

Kwa habari zaidi juu ya haki zako, shida za utafiti au maswali juu ya haki zako kama mshiriki wa utafiti, unaweza kuwasiliana na KNH / UoN ERC kupitia Katibu / Mwenyekiti, 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 sutafiti. 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: Dr Abdullahi Hadi Omar

APPENDIX III: ENGLISH VERSION OF THE SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS QUESTIONNAIRE

SOCIODEMOGRAPHIC CHARACTERISTICS

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

Question Number	Question	Coding categories	Response
1.	How old are you?	Number of completed years	[ ]
2.	Gender?	M = Male F=Female	[ ]
3.	Highest level of education?	1=No education 2=Incomplete Primary 3=Primary 4=Secondary and middle level college 5=Graduate and above	[ ]
4.	Do you live with a partner?	1=Yes 0=No	[ ]
5.	What's your cigarette smoking history?	1=Current smoker 2=Former smoker 3=Never smoked	[ ]
6.	Are you currently employed in any occupation?	1=Employed 2=Unemployed 3=Receiving pension	[ ]
7.	Do you take alcohol?	1=Yes 0=No	[ ]
8.	Are you sexually active?	1=Yes 0=No	[ ]
9.	If yes, how episodes per week?	1= None 2= 1-–2 episodes 3= 3-–4 episodes 4= 5-–6 episodes 5= 7-–10 episodes 6= >11 episodes	[ ]
	Co-morbid conditions		
10.	Diabetes mellitus	1=Yes 0=No	[ ]
	Hypertension	1=Yes 0=No	[ ]
	History of a cardiovascular event	1=Yes 0=No	[ ]
	Kidney transplant	1=Yes 0=No	[ ]

	Endocrine dysfunction	1=Yes 0=No	[ ]
	Neurological function/History of stroke	1=Yes 0=No	
11.	On what current Medication?		
	Phosphodiesterase inhibitors	1=Yes 0=No	[ ]
	Beta blocker	1=Yes 0=No	[ ]
	ACE inhibitor	1=Yes 0=No	[ ]
	Angiotensin receptor blocker	1=Yes 0=No	[ ]
	Diuretic	1=Yes 0=No	[ ]
	Erythropoietin	1=Yes 0=No	[ ]
	Nitrate	1=Yes 0=No	[ ]
	Lipid-lowering therapy	1=Yes 0=No	[ ]
	Anti-depressant	1=Yes 0=No	[ ]
	Antipsychotic	1=Yes 0=No	[ ]
	Anxiolytic	1=Yes 0=No	[ ]

APPENDIX IV: KISWAHILI VERSION OF THE SOCIODEMOGRAPHIC 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.	Highest level of education?	1=Hujasoma 2=Hujamaliza shule ya msingi 3=Shule ya msingi 4=Shule ya upili na chuo kikuu cha katu 5=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?	1= Hakuna 2= vipindi 1-–2 3= vipindi 3-–4 4= vipindi 5-–6 5= vipindi 7-–10 6= vipindi >11	[ ]
	Magonjwa mengine yanayotokea		
10.	Ugonjwa la kisukari	1=Ndiyo 0=Hapana	[ ]
	Shinikizo la damu katika familia	1=Ndiyo 0=Hapana	[ ]
	Historia ya tukio la moyo na mshipal	1=Ndiyo 0=Hapana	[ ]
	Kutofanya kazi sawa endokrini	1=Ndiyo 0=Hapana	[ ]

	kazi ya neva/Historia ya kiharusi	1=Ndiyo 0=Hapana	
11.	Dawa gani unatumia kwa sasa?		
	Phosphodiesterase inhibitors	1=Ndiyo 0=Hapana	[ ]
	Beta blocker	1=Ndiyo 0=Hapana	[ ]
	ACE inhibitor	1=Ndiyo 0=Hapana	[ ]
	Angiotensin receptor blocker	1=Ndiyo 0=Hapana	[ ]
	Diuretic	1=Ndiyo 0=Hapana	[ ]
	Erythropoietin	1=Ndiyo 0=Hapana	[ ]
	Nitrate	1=Ndiyo 0=Hapana	[ ]
	Lipid-lowering therapy	1=Ndiyo 0=Hapana	[ ]
	Anti-depressant	1=Ndiyo 0=Hapana	[ ]
	Antipsychotic	1=Ndiyo 0=Hapana	[ ]
	Anxiolytic	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 female sexual function 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 THE INTERNATIONAL INDEX OF ERECTILE DYSFUNCTION (IIEF-5)

Namba ya hospitali: _____	Tarehe ya usaili: _____

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 <u>during</u> 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

APPENDIX IX: BUDGET

Research stage	Description	Units	Unit cost (Ksh)	Total cost(Ksh)
Proposal development	Proposal drafts	10	800	8,000
	Proposal copies	5	800	4,000
	ERC fee	-	-	2,000
Data collection	Stationery and printing cost			15,000
	Research assistant training and remuneration	1	20,000	20,000
Data analysis	Statistician	1	30,000	30,000
Thesis write up	Printing drafts	5	800	4,000
	Printing thesis	3	3,000	9,000
Contingency fund		-	-	15,000
TOTAL				107,000

APPENDIX X: TIMELINE-SCHEDULE OF ACTIVITIES

	July-Sep 2019	Oct 2019	Dec 2019	Jan 2020	Feb 2020	Mar 2020	Apr 2020	May 2020
Proposal Development								
Protocol presentation								
Ethical approval								
Data collection								
Data analysis								
Results presentation								