THE PREVALENCE AND ASSOCIATED FACTORS OF SEXUAL DYSFUNCTION AMONG PROSTATE CANCER PATIENTS ON GOSERELIN ANDROGEN DEPRIVATION THERAPY IN KENYATTA NATIONAL HOSPITAL.

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DECLARATION

I declare that this research dissertation was undertaken in partial fulfillment of the Masters of Medicine in Urology from the University of Nairobi and will be my original work and has not been undertaken and presented for a degree in any other university.

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OPERATIONAL DEFINITIONS

For this research, the following shall be adopted as the operational definitions for the following terms:

Androgen Deprivation Therapy: It is a mode of treatment widely used in the community setting to treat men with clinically localized prostate cancer, biochemical recurrence after radical prostatectomy, locally advanced disease, lymph node metastases, and asymptomatic metastatic disease. The main modality of Androgen deprivation therapy focused on in this study is Goserelin.

Severe Co-morbid illnesses: Is the presence of two (2) or more synchronous diseases co-occurring along with the primary disease and the severity of the illnesses shall be defined by the disease classification assigned by the World Health Organization (WHO).

DISCLOSURES

I acknowledge that I do not have any conflict of interest in conducting this study on Goserelin and have no other disclosures to declare.

ACRONYMS AND ABBREVIATIONS

ADT: Androgen Deprivation Therapy

AR: Androgen Receptor

EAU: European Association of Urology

ECOG: Eastern Cooperative Oncology Group

FSH: Follicle Stimulating Hormone

GHRH: Gonadotropin hormone-releasing hormone

IIEF: International Index of Erectile Function

KNH: Kenyatta National Hospital

LH: Luteinizing Hormone

LHRH: Luteinizing hormone Releasing Hormone

M0: No metastasis

M+: Metastasis

OS: Overall Survival

PCa: Prostate Cancer

PFS: Progression-Free Survival

QoL: Quality of Life

T: Testosterone

WHO: World Health Organization

ABSTRACT

Background: The main modality of prostate cancer treatment has been Androgen deprivation therapy (ADT) which has been demonstrated in randomized studies to enhance overall survival when utilized for radiation for intermediate and high risk localized disease as well as for locally advanced and node-positive disease and also for the node-positive disease after surgery. Though ADT may enhance survival, it can cause serious morbidity and a decrease in life quality, the most significant of which is sexual dysfunction. There is no local study that has been done on this important subject and the studies elsewhere indicate that the prevalence of sexual dysfunction is high among this population.

Objective: To determine the prevalence and factors that are associated with sexual dysfunction amongst prostate cancer patients on Goserelin Androgen deprivation therapy in Kenyatta National Hospital.

Methods: This was a cross-sectional study done at Kenyatta National Hospital (KNH) Urology and Oncology outpatient clinics among patients who on follow-up for cancer of the prostate. Ninety-nine (99) were recruited through convenient sampling after giving consent. The principal researcher and two research assistants using a questionnaire collected the data. Each patient recruited into the study was given a special serialized number for purposes of ordering the data collection documents. Data on the demographics of patients, nutritional status, social habits, sexual function status using international index of erectile function (IIEF) score, disease stage, Goserelin dosage, duration of treatment, co-morbid and ECOG status was collected. Data analysis was done using statistical package for social sciences (SPSS) version 25. Bivariable analysis was done using pearson and Fischer's exact test while binary logistic regression was used to conduct multivariable analysis. The level of significance was investigated at 0.05.

Results: The average age of the participants was 70.4 (SD±8) years, the average body mass index was 29.6 (SD±3) kg/m². The mean baseline and current Prostate-Specific Antigen (PSA) was 673.6 (SD±59) ng/ml and 51.4 (SD±16) ng/ml respectively. The findings revealed that 90% (89) of the respondents had sexual dysfunction as shown in Figure 4.1 with a 95% CI (82.2, 95.1). Bi-variable analysis showed that, Alcohol and cigarette smoking, cOR =10.3, 95%CI: 2.0,53.04, p =0.005, tumor staging T4, cOR =16, 95%CI: 2.8, 92.4, p =0.002. very high NCCN risk classification, cOR = 9, 95%CI:1.9, 43.1, p =0.006 and symptomatic but completely ambulatory ECOG status cOR = 7.3, 95% CI:2.84,10.9, p=0.002 were found to be associated with sexual dysfunction. The independent risk factors associated with sexual dysfunction were alcohol and cigarette smoking, aOR = 5, 95% CI: 1.9, 14.6, p = 0.010 and tumor staging T4, aOR =11.1, 95% CI:4.6,32.1, p<0.009.

Conclusion and recommendation: The findings have showed that majority of prostate cancer patients have sexual dysfunction with tumor staging, cigarette smoking and alcohol use key predictors. Thus, there is need educate prostate cancer patients on Goserelin ADT about getting extra psychosexual support and physical sexual therapy, as well as availing to patients' options such as penile rehabilitation during hormone therapy.

CHAPTER ONE: INTRODUCTION

1.1.Background

Prostate adenocarcinoma has been identified as the commonest type of malignancy affecting men in the United States following skin cancer and about 11.6percent of males being detected with the disease at some point during their lifetime (1). In Africa, a theatrical annual upsurge in the cases of prostate cancer incidences was noted following a twenty (20)-year review in Harare, Zimbabwe six point four (6.4)%, and in Uganda five point four (5.4) % (3,4). In a descriptive case series of patients presenting with prostate cancer in Kenyatta National hospital done by Magoha et al eighty-seven point five percent (87.5%) of patients presented with progressive disease phases, majorly III and IV of prostate cancer (3). This subset of patients is the majority of patients in which ADT is indicated. According to the EAU, treatment with LHRH agonists are the gold standard in metastatic disease of prostate cancer (4). ADT is provided to patients to offer symptomatic control of prostate cancer in patients who cannot be treated definitively with surgery or radiation (5). Gonadotrophin-releasing hormone (GnRH) analogues with or without anti-androgen drugs have become an important and effective treatment modality for patients diagnosed with locally progressive and metastatic PCa. (6) (7). At diagnosis, the median patients' survival with metastatic disease is roughly 5 – 6 years and severe adverse effects are experienced with further cancer progression, most notably sexual dysfunction (8).

In up to 90 % of cases, Androgen deprivation therapy will cause a significant decline of prostate-specific antigen (PSA) (7). While it leads to a state of severe hypogonadism, ADT has been associated with significant sexual dysfunction and a notable reduction in life quality (6). The gonadal function also decreases with age. Male aging entails changes in

hormone levels that come with variable and insidious psychological and physical repercussions (9). The EAU Guidelines propose that ADT not be withheld except in patients who have a strong desire to avoid side effects linked to treatment (8). The morbid adverse effect profile of these medications may affect the treatment outcomes of the disease process (10). Therefore, it is important for considering the possible impact of ADT in treatment decisions on sexual dysfunction. In the elderly, this is especially important because trivial complications may be debilitating, permanently life-changing, or fatal (11). Additionally, androgen deficiency in the aging male (ADAM), also recognized as late-onset hypogonadism (LOH), is becoming an increasingly important issue because the prevalence of ADAM is thought to be high (9). An observational cohort study was done by Massachusetts's Male Aging research undertaken on healthy men with an age of 40 to 70 years established that the prevalence of ADAM was twenty-five point three (25.3) percent to thirty-nine point three (39.3) percent. However, when the strict application of LOH was applied, the prevalence dropped from 6% to 12% (12). Therefore, though it is difficult to distinguish ADAM from natural aging, what is clear is that sexual dysfunction is associated with both cases (13).

While this is so, the most important life quality component for PCa patients on ADT of which the majority are aging males is the sexual dysfunction that arises from their treatment (14). Libido losses range from fifty-eight (58) percent to ninety-one point four (91.4) percent, erectile disorders from seventy-three point three (73.3) percent to ninety-five (95) percent, and penile lengths are reduced by > one (1) cm by ninety-three (93) percent (15). The impact of sexual dysfunction among ADT sufferers was described by an ADT survival working group to include changes in relationships, cognitive and emotional conditions

including such mental illness (16). Because of this, men enduring ADT for prostate cancer were found to have a clinically significantly reduced quality of life particularly in their sexual and physical aspects (17).

The impact on QoL of a loss of libido, ED, or reduced penile length should not be underestimated since the potential consequences on alteration of masculinity, the patient's perceived self-body image, consequences on the patient's intimacy and relationships with partners, have a direct impact on treatment outcomes (18). The treatment outcomes of ADT on prostate cancer include; development of Castration-Resistant Prostate Cancer (CRPC), Progression-free survival (PFS), or Overall Survival (OS). The consequences of ADT in PCa patients are important as they do not only affect the sexuality, intimacy, and couple's relationship but also have a substantial impact on treatment outcomes of prostate cancer. There is, therefore, a need to establish the prevalence as well as associated factors of sexual dysfunction among PCa patients on ADT as there has been no local study to assess this important subject.

CHAPTER TWO: LITERATURE REVIEW

2.1.Mechanism of action of Androgens

Since prostate cancer is largely a hormone-driven tumor, it is important to understand the pathway for androgen signaling, its roles in cell development, and the vulnerable points for manipulation in pharmacological therapy (19). The androgen signaling pathway was first investigated from the level of the centralized hormonal control of Testosterone. The hypothalamus initiates Testosterone secretion through the pulsatile discharge of LHRH. Consequently, it binds to and stimulates the LHRH receptors located in the anterior pituitary gland, which ultimately leads to the discharge of follicle-stimulating (FSH) and luteinizing (LH) hormones. LH will then bind to and stimulate receptors on the cells of Leydig in the testes to induce the production of Testosterone. LHRH agonists (also known as gonadotropin-releasing hormone (GnRH) agonists and antagonists diminish the circulating levels of testosterone by acting to suppress this hypothalamic-pituitary-gonadal axis (19).

2.2.Historical Perspective of Androgen Deprivation Therapy

Though largely unmentioned, it was the Swiss scientist Paul Neihans who first published his thirteen (13) years of experience on the treatment and prevention of cancer of the prostate with ADT in 1940 (20). However, it was Charles Huggins and his colleague Clarence Hodges who first reported the striking clinical effects of lowering the levels of serum testosterone in men with advanced prostate cancer in 1941(21). ADT was executed through surgical castration or repression of LHRH production at the hypothalamus with diethylstilbestrol (DES). They observed that castration both surgically and pharmacologically lead to a dramatic alleviation of painful osseous metastases, decreased

post-void residual urine volume, and improved quality of life. Hormonal therapy then became widely recognized and accepted within a short period as the standard of treatment for advanced prostate cancer. In 1966, Huggins and Hodges were awarded the Nobel prize for Physiology or Medicine for this pioneering work for discovering in 1941 that hormones could be used to control the spread of some cancers (22).

2.3.Utility of ADT in PCa

Gonadotropin-releasing hormone (GnRH) agonists are administered currently to approximately one-third of the projected 2 million United States survivors of PCa. The backbone of metastatic PCa management is the long-lasting administration of a GnRH agonist which is an integral part of the treatment of several men with non-metastatic PCa (23)(24). These groups of drugs have been found to improve the OS of patients with locally advanced cancer of the prostate (25)(26). The utility or toxicity of GnRH inhibitors is yet to be properly defined in conditions such as primary treatment for early-stage prostate cancer and increasing PSA levels as the only evidence of disease recurrence (also referred to as “PSA-only” prostate cancer) (27). The significance of comprehending and averting adverse events due to GnRH agonists use has since increased with their increasing usage with resultant hypogonadism (28). Hypogonadism is the intentional consequence of treating with a GnRH agonist. Testosterone serum concentrations are decreased by GnRH agonists by over ninety-five (95%) percent and by estrogen by approximately eighty (80%) percent (29)(30). The differentiating factor between age-related andropause and GnRH agonist treatment is the onset speed and gonadal steroid deficiency severity. GnRH agonists, therefore, come with a heterogeneity of adverse effects that are related to gonadal steroid deficiency. Amongst the diverse effects are vasomotor flushing, libido loss,

reduction in the bone mineral density, an increase in fat mass, and diminished muscle mass (27). The indications of ADT have been summarized in table one (1) below that were embraced and improved from Pagliaruol et al, Cancer Council of Australia, and the EUA.

Table 2.1: The Indicators of ADT.

INDICATIONS OF ADT			
Mx	Categories	ADT	Duration
Neoadjuvant/adjuvant ADT with curative intent therapy			
M0:	Localized S0, Low Risk		Not applicable
	Intermediate Risk	"Neoadjuvant with RT"	4 to 6 months
	High Risk	"Neoadjuvant with RT"	2 to 3 years
Palliative / not suitable for curative intent therapy			

M0	Locally Advanced		Indefinitely
		"Neoadjuvant with palliative RT"	Indefinitely
	PSA Recurrence		"Inconclusive"
		"Primary deferred"	Indefinitely
M1	N positive after surgery	Adjuvant	Inconclusive
	S1	Primary immediate	Indefinitely
	S0	Primary deferred	Inconclusive
		Primary immediate if PSA level >50ng/l, doubling time <12 months, or symptomatic	Indefinitely
	CRPC		Indefinitely

Key: ATT: "Androgen-targeted-therapy", M; "metastasis", N; "Lymph-node status", RT; "Radiotherapy", S0, "Asymptomatic".(31)(8)

2.4.Sexual Dysfunction and Androgen Deprivation Therapy

Notwithstanding the survival benefits, ADT is linked with significant side effects (32). A long record exists of castration-induced adverse effects of Goserelin ADT, therefore prominence is placed on those effects directly linked to increased morbidity and mortality (33). Reduced quality of life through sexual dysfunction is a major life-threatening consequence of ADT (6). Androgen blockade using Goserelin to the cancerous cells of the prostate institutes a cascade of complex endocrinological events on the body's homeostasis that are consequently compromised (15). The reduction in testosterone leads to both loss of libido and erectile function due to venous leakage, decreased arterial flow, and altered production of nitric oxide leading to sexual function (34)(35).

2.5.Risk factors for Sexual Dysfunction

ADT influences sexual function not only by the extent of disease or type of therapy (intermittent or continuous) but mostly by age of the patient and sexual function before the onset of treatment (35). Sexual function status before therapy is normal in some patients while significantly reduced in others due to several other factors. These include ADAM, the presence of co-morbidity like diabetes, hypertension, cardiovascular disease, or use of chronic medications that may have a significant impact on sexual function. In addition, other factors that lead to a reduction in the sexual function in this subset of patients on treatment with ADT include psychosocial reasons such as substantial deterioration in cognition (majorly attention and memory) in the elderly who are commonly afflicted by prostate cancer, mood disorders and depression (36).

2.6.Erectile Dysfunction (ED)

ED was defined by the National Institutes of Health Consensus Conference as the "consistent inability of to achieve or maintain a penile erection or both sufficient for adequate sexual relationship" (37) As per the Massachusetts Male Aging Study (MMAS) ED prevalence in the non-institutionalized cohort between the age 40 to 70 years was 52% (38). ED in patients on ADT may present as a result of physical or emotional factors, or a combination of both (39). The endothelium of the penile vasculature is both an active and dynamic tissue that is responsible for most regulatory functions like vascular tone regulation, local homeostasis, proliferative processes, perfusion conservation, coagulation, and inflammatory responses (40). The normal aging process and its associated risk factors lead to accumulative endothelial destruction that eventually causes endothelial dysfunction. Over eighty (80) % have an organic etiology the commonest of which are vascular alterations. This suggests a direct correlation between the existence of vascular risk factors (hypertension, atherosclerosis, hyperlipidemia, and Diabetes) which have a direct bearing on severe sexual dysfunction (41).

2.7.Other components of Sexual Dysfunction associated with Goserelin ADT

ADT causes climacturia, alterations in anatomy of penis and testes (mainly a reduction in penile length and testicular atrophy), dry ejaculation, and altered ejaculation experience due to weakening of the ejaculatory reflex which comprises both emission and expulsion (35). Other added effects of Goserelin ADT on sexual function include loss in libido, changes in the physical perception of body image, and fatigue and emotional changes the latter of which occurs in up to 30 and 40 % of patients (42) (43).

2.8.Treatment Outcomes of Goserelin ADT

2.8.1. Progression-Free Survival (PFS)

PFS is described as the duration of time in which a patient lives with the disease during and after prostate cancer and does not get worse. In prostate cancer disease, the measurable disease progression outcomes include factors such as Gleason grading, prostate cancer staging, rise in PSA levels, and bone metastasis (44). Metastatic prostate cancer bears a dismal five-year overall survival (OS) rate of twenty-nine point three (29.3) percent in stark contrast to the approximate hundred (100) percent five-year survival for low volume organ-confined disease (45). PFS is an important predictor outcome of OS in CRPC. The use of ADT may affect the OS of patients. Patients who had a PSA of less than zero point four (<0.4) ng/ml following an uninterrupted use of Goserelin and Bicalutamide for seven (7) months followed by continuous use of ADT had an overall survival of 75 months (46).

2.8.2. Biochemical Recurrence

One of the key essential prognostic markers of clinical progression of prostate cancer is PSA (47). Despite ADT, the disease will progress to CRPC (48). The use of Goserelin along with a chemotherapeutic agent reduces the progression of PSA. In a comparative study between a three-weekly addition of Docetaxel to ADT on one arm and ADT alone on the other arm that was conducted by Gravis et al., a substantial PSA level reduction in 6 months was noted (50). In a different review by Kim et al., the independent risk factors that influence the first postoperative serum PSA were pre and post ADT levels of PSA and Gleason score. Hence, the risk stratification after surgery may be an important lead in patients who are to receive adjuvant therapies (51). Patients with prostate cancer who have localized disease and in whom ADT is administered and their PSA levels were over zero point two (0.2) ng/ mL were found to be at high risks of dying from PCa (52). Prostate

cancer mortality is associated with PSA failure as was indicated by Stewart et al. In addition, a level of PSA greater than zero point two (0.2) ng/mL following an eight (8) month period of ADT after surgery or radiation is linked with an increase in mortalities (14). The Goserelin use with Flutamide plus EBRT with EBRT alone was compared by Roach et al. with the former group being noted to have a reduced biochemical recurrence and distant metastasis risks (53).

2.9.THE PROBLEM, JUSTIFICATION, AND OBJECTIVES

2.9.1. Statement of the Problem

The main modality of localized and metastatic prostate cancer treatment is Androgen deprivation therapy (ADT) which has been demonstrated in randomly selected studies to enhance overall survival when utilized for radiation for intermediate and risky localized diseases as well as for locally advanced and node-positive diseases and node-positive disease after surgery. Though ADT may enhance survival, it can cause serious morbidity and a decrease in life quality, the most significant of which is sexual dysfunction (49). It is worthwhile in men who have advanced symptomatic prostate cancer or who have radiotherapy as Neoadjuvant therapy. However, the many challenges in the management of patients with age-related comorbidity and changes in physiology deserve special attention. Late-onset hypogonadism also explains the age-related reduction phenomenon of free testosterone underneath regular levels (thirty (30) percent and fifty (50) percent of patients aged seventy (70) and eighty (80) years, respectively (15). The presence of Androgen deficiency of the aging male, compounded by the morbidity of prostate cancer and the presence of comorbidities in this special subset of elderly patients has an impact on their sexual function. This is exacerbated by the addition of ADT, which adds to the

burden of the patient’s already declining sexual function by further worsening their sexual status through the chemical castration caused by the lowered testosterone level by ADT.

In addition, the clonal assortment of less androgen reliant cells of prostate cancer could lead to reduced effectiveness of treatment in hypogonadal men. The recent guidelines from the European Association of Urology (EAU) incorporated a consensus of the Prostate Cancers Working Group of the International Society of Geriatric Oncology (SIOG). It proposes a comprehensive study of adult men well before treatment is initiated using fragility test methods, including the questionnaire 'Geriatric 8.' In the setup of KNH, such prescreening methods are seldom employed before initiation of lifelong burdensome treatments such as Goserelin ADT.

2.9.2. Justification

The prescription of ADT is often done at a period when prostate cancer patients are informed of the overwhelming nature of their condition. Moreover, the hormonal vicissitude triggered by Goserelin may exacerbate the patient's depressive symptoms already in a state of catastrophe (50). The prostate cancer patients who attend care at the Kenyatta National hospital are not only older and in need of specialized geriatric care but are a special subset of patients who are already challenged with the burden of their oncologic illness and the possibility of ongoing co-morbidities. In addition to this, there is a lack of proper screening assessments of the patients in whom ADT in as much as will be efficacious, are likely to suffer debilitating adverse effects from it that will ultimately affect their quality of life and have lifelong disastrous systemic effects. Furthermore, there is a multiplicity of factors that influence their sexual function at a time when they are vulnerable and distressed. The sexual dysfunction that results from the addition of ADT,

which is the cornerstone of their management, further worsens their predicament in terms of their sexuality and intimacy with their partners who are their key support system during this difficult period. The prompt management of sexual dysfunction in these patients may ultimately help delay the onset of Castration-Resistant Prostate cancer (CRPC) whose burden of disease and cost is indeed debilitating. There is a paucity of data on the actual burden of sexual dysfunction caused by ADT in the metastatic prostate subset of cancer patients in the African continent and the East African region in general, and therefore this study seeks to add to the body of knowledge available on this important topic. Through the information gathered in this study, advocacy for a specialized uro-oncology team will be made for this vulnerable group of patients and this will ultimately enhance their standard of care and provide these patients with the support they need by setting up policies aimed at standardizing the care of patients under Goserelin ADT in KNH.

2.9.3. Research question

i. What is the prevalence of sexual dysfunction among metastatic prostate cancer patients on Goserelin ADT on follow-up at Kenyatta National Hospital?

ii. What are the associated factors that influence sexual dysfunction among prostate cancer patients on ADT in Kenyatta National Hospital?

2.9.4. Objectives of the study

Broad objective:

To determine the prevalence and factors associated with sexual dysfunction amongst prostate cancer patients on Goserelin Androgen deprivation therapy in Kenyatta National Hospital.

Specific Objectives:

1. To determine the prevalence of sexual dysfunction amongst prostate cancer patients receiving Goserelin therapy in Kenyatta National Hospital.

2. To describe the factors that influence sexual dysfunction among prostate cancer patients on Goserelin ADT in Kenyatta National Hospital.

Conceptual Framework

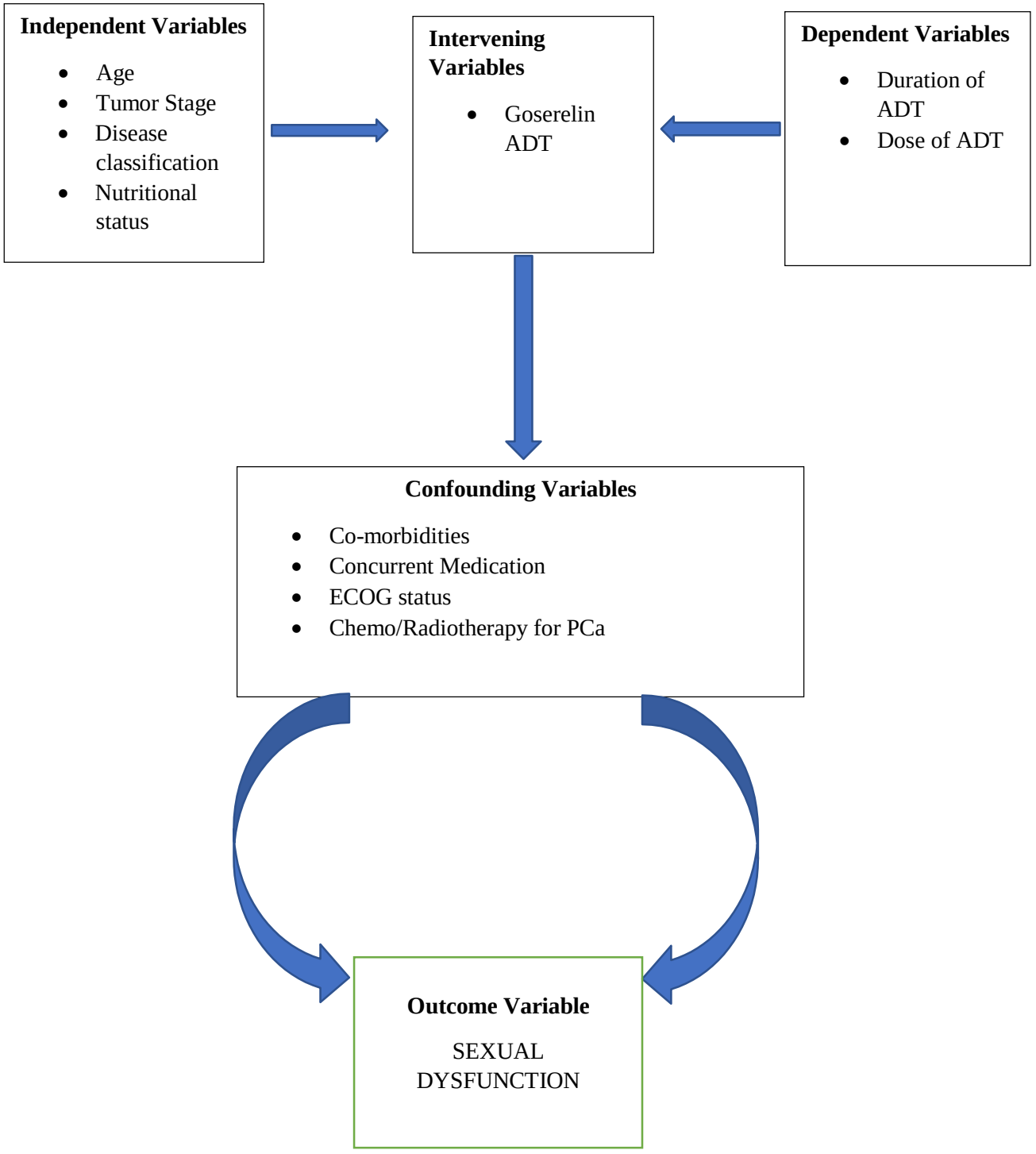

Figure 2.0 Conceptual framework outline

CHAPTER THREE: RESEARCH METHODOLOGY

3.1.Study design

This was a cross-sectional study design

3.2.Study Setting

The study was done at Kenyatta National Hospital (KNH) Urology and Oncology outpatient clinics. KNH is a tertiary referral hospital in Nairobi County, Kenya. The hospital has a bed capacity of 1,800 with about 40 patients with prostate cancer being attended to weekly in the Urology and Oncology clinics that run from Monday to Wednesday and daily every week respectively.

3.3.Study Population

The population of the study consisted of patients who are on follow-up for cancer of the prostate at KNH Urology and Oncology clinics on ADT.

3.4.Selection Criteria

Inclusion Criteria

1. Patients with locally advanced and metastatic prostate cancer attending the KNH Urology and Oncology clinics on ADT.

Exclusion Criteria

1. Patients with severe comorbid illnesses, which involve other organ systems as severe illness, could affect the outcome of treatment with ADT.

3.5.Sampling Method

Convenience sampling method was employed to attain the desired sample size. All patients who fulfill the criteria and consent to the study were included in the study.

3.6.Sample size determination

The sample size for this study was computed using Fischer's formula by Fisher et al (1991).

$$n = \frac{Z2x\ (1 - P)}{d2}$$

Where,

$\boldsymbol{n}$ is the required sample size based on a finite population of patients with localized and Metastatic Prostate Cancer

$\boldsymbol{Z}$ is the standard normal distribution value consistent with desired confidence; it is taken to be 1.96 for a 95% confidence interval

$\boldsymbol{P}$ is the proportion of patients receiving ADT, put at 38% in a meta-analysis study done by Liede et al (51).

$\boldsymbol{d}$ is the desired precision level at 0.05

$$\boldsymbol{n} = \frac{1.962x\ 0.38(1 - 0.38)}{0.052}$$

$\boldsymbol{n}$ = 362 patients

“For finite population” N-= “Total number of patients that were on ADT during the four years"

no/ 1+no/N

=362 1+362/120.

=90 patients

Consideration for attrition of data at 10% gives a sample size of 219

Thus, a sample size of 99 were recruited.

3.7.Study Flow

The flow diagram below indicates how the study will be conducted.

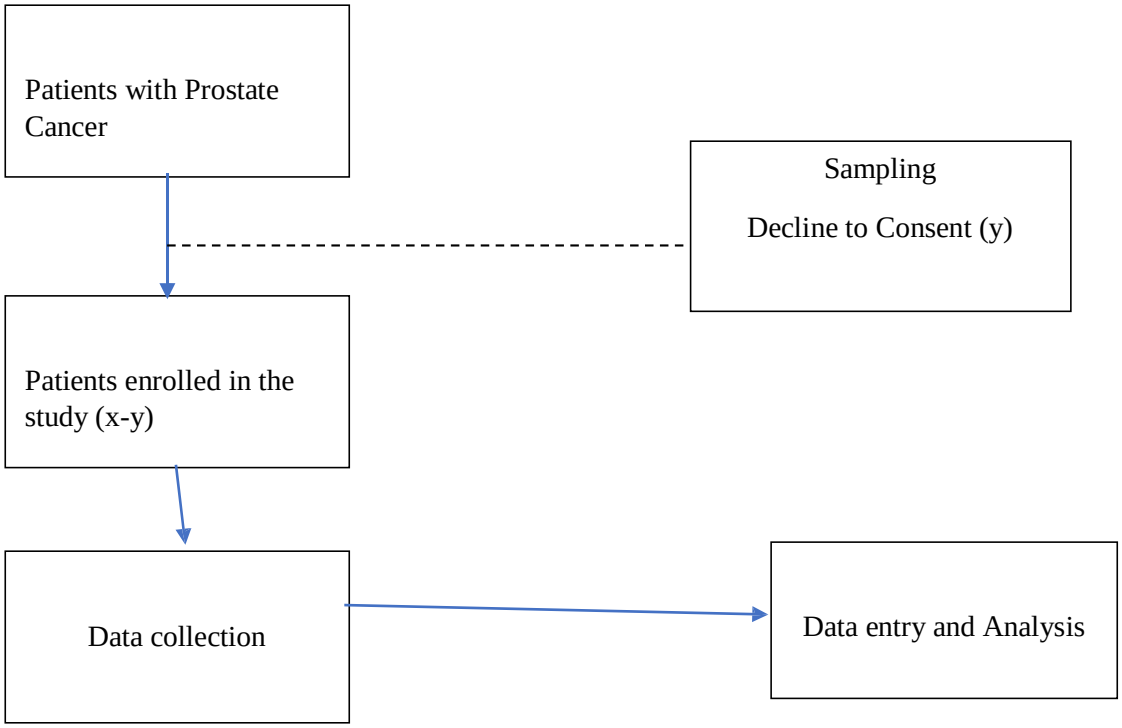

Figure 3.1 Study flow

3.8.Measures to mitigate against COVID 19

The researcher and research assistants were protected against Covid-19 by observing the guidelines set by the Government of Kenya for mitigating the spread of the disease. They

were required to adhere to infection prevention measures such as maintaining proper hand hygiene by handwashing with soap and water and sanitization. They wore 3 ply face masks covering the mouth and nose, observe cough etiquette, and used appropriate personal protective equipment. They were also required to observe physical distancing of at least 1.5 meters. Only research assistants who are symptom-free were allowed to participate in data collection. The respondents were remotely screened for Covid-19 symptoms, and in case anyone is suspected to be having Covid-19, they were not directly involved in the study. They were instead be transferred to the Ministry of health for extra diagnosis and conceivable separation. (52)

3.9.Quality Assurance procedures

Strict adherence to the research protocol was carried out to ensure that the quality of collected data meets the required standards.

3.10. Ethical Considerations

The researcher obtained department of surgery (UON) and KNH Ethics and Research committee approvals. Pre-consent counseling of all eligible participants was carried out, after which individual informed consent was obtained. The consented participants were then enrolled in the study. Those who declined participation proceeded with their treatment and were not be denied service because of refusal to consent.

Patient's information was treated with maximum discretion and was only used for the intended purpose of this study. There was no invasive procedures involved in the study and the participant did not incur any extra cost. The participants were given unique identifiers

to aid in maintaining the confidentiality and the data sheets were shredded upon completion of the study.

3.11. Study Enrollment

In this study, patients who were on follow-up for metastatic cancer of the prostate in the Urology and Oncology clinics at KNH were targeted population. The principal researcher and the research assistants explained the objectives of the study. Patients who accepted to consent were taken to a room for consenting and were given a form which they read and signed (Appendix I). An interviewer-guided questionnaire (Appendix III) was administered at this point with clinical information obtained from the patient's records.

3.12. Training and data quality procedures

The questionnaire was presented to the department for approval and later on pretested before administration to the participants. The research assistants who were two registered nurses and were trained on data collection and handling.

3.13. Data collection and handling

The principal researcher and two research assistants using a questionnaire collected data. The research assistants were two qualified nurses registered by the Nursing Council of Kenya. They were taken through the data collection tool to familiarize themselves with it. Each patient recruited into the study was given a special serialized number for purposes of ordering the data collection documents. The data collected was then entered into a Microsoft Excel spreadsheet which was password protected, with the password known to the principal researcher and assistants only.

3.14. Study variables

The independent variables to be investigated in the study were: Age (years), BMI (kg/m2), Disease classification (TNM stage and disease grade)

Dependent variables were Dose of ADT, Duration of ADT.

Table 3.1: Study variables

Independent Variables	**Dependent Variables**
Age	Duration of ADT
Tumor Stage	Dose of ADT
Disease Classification	
Nutritional Status (BMI= kg/m2)	

3.15. Data Management and Analysis

Raw data was entered into an excel sheet for cleaning of data and later analysis utilizing statistical package for social sciences (SPSS) for windows version 23. Statistical analysis such as mean, median, frequency, and correlation were used to describe the data. The prevalence of the side effects of ADT was analyzed in terms of proportions. Proportions given to each of the independent variables: Age, tumor stage, disease classification (PSA, Gleason grade), Nutritional status (BMI = kg/m2). Chi-square was used to analyze the observed side effects of ADT against the expected side effects profile as previously elucidated in the literature review. A multivariate analysis was done to determine the

association between the side effects and the ADT. The results were presented using tables, pie charts, and graphs.

3.16. Study Bias and Limitations

1. There was a limitation of sample selection bias, as KNH is a national and regional referral hospital, which largely receives patients referred from facilities all over the country.
2. The indications for ADT and determination of the sexual dysfunction were taken as those prescribed by the attending Oncologist or Urologist.

CHAPTER FOUR: RESULTS

4.1.Descriptive characteristics

4.1.1. Characteristics of prostate cancer patients on Goserelin Androgen deprivation therapy in Kenyatta National Hospital

The findings revealed that the average age of the participants was 70.4 (SD±8) years most of whom had a body mass index of 29.6 (SD±3) kg/m². The mean baseline and current Prostate-Specific Antigen (PSA) was 673.6 (SD±59) ng/ml and 51.4 (SD±16) ng/ml respectively. The commonest co-morbidity among the participants was hypertension at 40.4% (n =40) as shown in Table 1.

Table 4.1: Characteristics of prostate cancer patients on Goserelin Androgen deprivation therapy

Patient characteristics	Frequency	Percent
Age (Mean ±SD) years	70.4±8	
BMI(Mean ±SD) kg/m²	29.6±3	
18.5 - 24.9	5	5.1
25 - 29.9	49	49.5
30 and above	45	45.5
Baseline PSA (Mean ±SD) ng/ml	673.6±59	
Current PSA(Mean ±SD) ng/ml	51.4±16	
Social habits		
Alcohol	27	27.3
Alcohol and Cigarette smoking	21	21.2
None	51	51.5
Alcohol quantity per week (n =48)		
1 -2 bottles	8	16.7
3 - 4 bottles	13	27.0
5 - 6 bottles	12	25
7 or more	15	31.3
Cigarette smoking packs (n =21)		
1 – 2	1	4.8
3 – 4	7	33.3
5 – 6	5	23.8
≥ 7	8	38.1
Hypertension		
Yes	40	40.4
No	59	59.6
Diabetes Mellitus		

Yes	16	16.2
No	83	83.8
Rheumatoid Arthritis		
Yes	3	3.0
No	96	97.0
Cardiovascular disease		
Yes	12	12.1
No	87	87.9
Renal failure		
Yes	4	4.0
No	95	96.0
Chronic respiratory failure		
Yes	2	2.0
No	97	98.0

4.1.2. TNM classification of prostate cancer patients on Goserelin Androgen deprivation therapy

The results as showed in Table 2 established that 63.6% (n =63) of the participants presented at T4 while 27.3% (n =27) presented at T3. As for nodal and metastatic staging, 61.6% (n =61) had Nx, while 70.7% (n =70) had Mx and 26.3% (n =26) had M1. The NCCN disease stratification revealed that 76.8% (n =76) of the respondents had very high risk disease as shown in Table 2.

Table 4.2: TNM Classification

Profile	**Frequency**	**Percent**
Tumor staging		
T2	9	9.1
T3	27	27.3
T4	63	63.6
Lymph node		
Nx	61	61.6
N0	4	4.0
N1	34	34.3
Metastasis		
Mx	70	70.7
M0	3	3.0

M1	26	26.3
Metastasis status		
Metastasis status not assessed	69	69.7
Pelvis Metastasis	17	18.2
Visceral Metastasis	6	6.1
Bone Metastasis	6	6.1
NCCN disease stratification		
High	11	11.1
Intermediate	12	12.1
Very high	76	76.8

4.1.3. Treatment characteristics of prostate cancer patients on Goserelin Androgen deprivation therapy

The average duration of use of ADT by the participants was 14.8 (SD±8) months with 55.6% (n =55) having an ECOG 2 status while 36.4% (n =36) were in ECOG 3 category status and 45.4% (n =45) were on chronic medication. There were 97% (n =96) of participants on monotherapy and continuous ADT as shown in Table 4.3.

Table 4.3: Treatment characteristics of prostate cancer patients on Goserelin Androgen deprivation therapy in Kenyatta National Hospital

Treatment factors	**Frequency**	**Percent**
Duration of ADT (Mean ±SD) months	14.8±8	
ECOG status		
Asymptomatic	8	8.1
Symptomatic but completely ambulatory	36	36.4
Symptomatic <50% during the day	55	55.6
Chronic medication		
Yes	45	45.5
No	54	54.5
Type of chronic medication (n =45)		
Anti-hypertensive medication	38	84.4
Oral hypoglycemic medication	6	13.3
Anti-heart failure medications	3	6.7
ADT combination		
Monotherapy (Goserelin only)	96	97.0
Combined Androgen Blockade (with Bicalutamide)	3	3.0
Type of ADT		
Continuous ADT	96	97.0

Intermittent ADT	3	3.0
History of chemotherapy (Docetaxel)		
Yes	6	6.1
No	93	93.9
History of radiotherapy (External beam radiotherapy)		
Yes	3	3.0
No	96	97.0

4.2.Sexual dysfunction characteristics of prostate cancer patients on Goserelin Androgen deprivation therapy

The findings showed that 96% (n =95) reported having erectile dysfunction, 91.9% (n =91) had excessive fatigue most of the day with 79.8% (n =79) having loss of libido. However, 93.9% and 88.9% of the participants did not experience climacturia and change in size of penis respectively with the least experienced symptoms being ejaculatory disturbance at 7% (n =70) and change in self-perception of body image at 66.7% (n =66) as shown in Table 4.4

Table 4.4: Sexual dysfunction characteristics of prostate cancer patients on Goserelin Androgen deprivation therapy

Sexual dysfunction parameters	**Yes n (%)**	**No n (%)**
Loss of libido	79(79.8)	20(20.2)
Change in size of Penis (Length and Girth)	11(11.1)	88(88.9)
Erectile dysfunction	95(96)	4(4)
Changes in Self-perception of body image	33(33.3)	66(66.7)
Ejaculatory disturbance (Dry/Altered ejaculation)	29(29.3)	70(70.7)
Excessive fatigue most of the day	91(91.9)	8(8.1)
Emotional disturbance	50(50.5)	49(49.5)
Climacturia (orgasm-associated incontinence)	6(6.1)	93(93.9)

4.2.1. Prevalence of sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

The prevalence of sexual dysfunction was assessed based on the using international index of erectile function (IIEF). The findings revealed that 90% (89) of the respondents had sexual dysfunction as shown in Figure 4.1 with a 95% CI (82.2, 95.1).

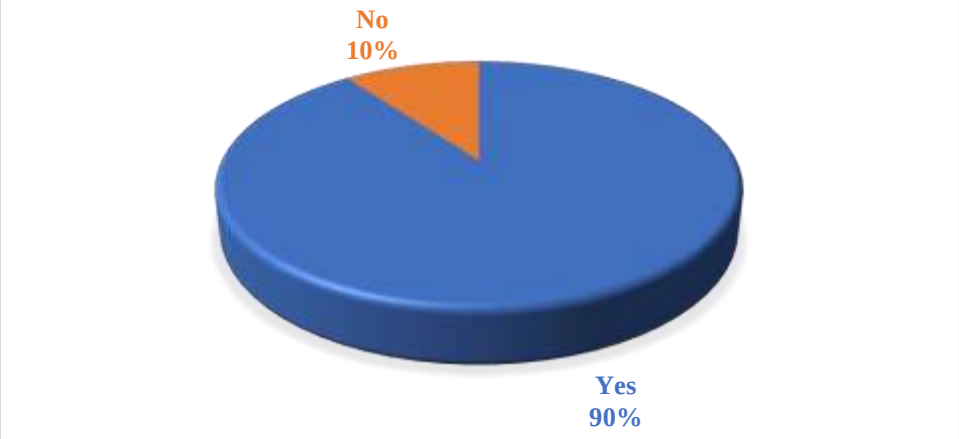

Figure 4.1: Prevalence of sexual dysfunction

4.2.2. Sexual dysfunction components among prostate cancer patients on Goserelin Androgen deprivation therapy

The findings revealed that among the respondents with sexual dysfunction 34.8% (n =31) had severe sexual dysfunction, 33.7% (n =30) had mild - moderate sexual dysfunction, 19.1% (n =17) had moderate sexual dysfunction with 12.4% (n =11) having mild sexual dysfunction a shown in Figure 4.2

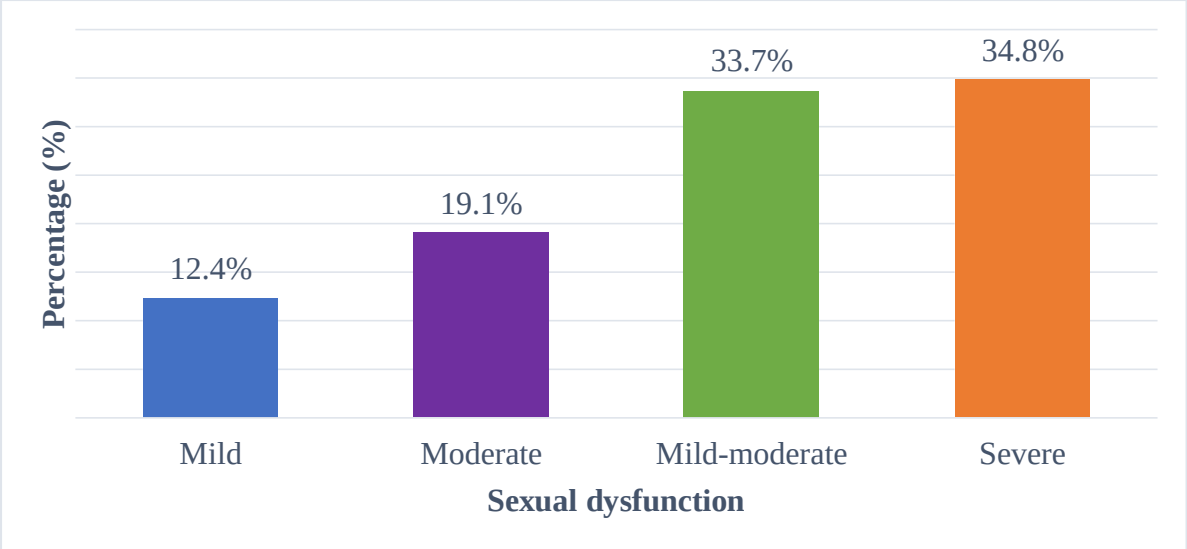

Figure 4.2: Sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

4.3.Association between patient characteristics and sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

The findings of the Independent sample t-test and Fischer's exact test showed that participants with sexual dysfunction had significantly higher baseline PSA, (715) (SD±12ng/ml) compared to those without sexual dysfunction, (302) (SD±83) ng/ml, p = 0.011. There was also significant association between social habits and sexual dysfunction ($p<0.001$) as shown in Table 4.5

Table 4.5: Association between patient characteristics and sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

	Sexual dysfunction		
Patient factors	**Present n(%)**	**Absent n (%)**	**P-value**
Age	70.1±8	71.4±8	0.646*
Baseline PSA	715±12	302.5±83	0.011*
Current PSA	55±12	17±2	0.058*
BMI			
18.5 - 24.9	4(4.5)	1(10)	
25 - 29.9	45(50.6)	4(40)	0.673**
30 and above	40(44.9)	5(50)	
Social habits			
Alcohol	19(21.3)	8(80)	
Smoking and Cigarette smoking	21(23.6)	0	<0.001**
None	49(55.1)	2(20)	
Hypertension			
Yes	37(41.6)	3(30)	0.364**
No	52(58.4)	7(70)	
Diabetes Mellitus			
Yes	15(16.9)	1(10)	0.494**
No	74(83.1)	9(90)	
Cardiovascular disease			
Yes	11(12.4)	1(10)	0.652**
No	78(87.6)	9(90)	
Renal failure			
Yes	4(4.5)	0	0.649**
No	85(95.5)	10(100)	
Chronic respiratory failure			
Yes	2(2.2)	0	0.807**
No	87(97.8)	10(100)	
Rheumatoid Arthritis			
Yes	3(3.4)	0	0.724**
No	86(96.6)	10(100)	

**Independent sample t-test, ** Fischer's exact test*

*4.4.*Association between disease characteristics and sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

Fischer's exact test was conducted to investigate the association between disease characteristics and sexual dysfunction. The results showed that there was significant association between sexual dysfunction and tumor stage (p =0.001), lymph node status (p

= 0.003), metastasis (p =0.001) as well as NCCN risk classification (p =0.007) as presented in Table 4.6.

Table 4.6: Association between disease characteristics and sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

	Sexual dysfunction		
Disease characteristics	**Present n (%)**	**Absent n (%)**	**p-value**
Tumor staging			
T2	5(5.6)	4(40)	
T3	24(27)	3(30)	0.001
T4	60(67.4)	3(30)	
Lymph node			
Nx	53(53)	8(80)	
N0	2(2.2)	2(20)	0.003
N1	34(38.2)	0	
Metastasis			
Mx	62(69.7)	8(80)	
M0	1(1.1)	2(20)	0.001
M1	26(29.2)	0	
NCCN risk classification			
High	9(10.1)	2(20)	
Intermediate	8(9)	4(40)	0.007
Very high	72(80.9)	4(40)	

4.5.Association between treatment characteristics and sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

The ECOG status (p<0.001) and type of ADT (p =0.001) were significantly associated with sexual dysfunction as shown in Table 4.7

Table 4.7: Association between treatment characteristics and sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

Treatment factors	Sexual dysfunction		p-value
	Present n (%)	Absent n (%)	
Duration of ADT (Mean ±SD) months	14.87±9	14.1±8	0.646*
ECOG status			
Asymptomatic	4(4.5)	4(40)	
Symptomatic but completely ambulatory	33(37.1)	3(30)	<0.001**
Symptomatic <50% during the day	52(58.4)	3(30)	
Chronic medication use			
Yes	40(44.9)	5(50)	0.509**
No	49(55.1)	5(50)	
ADT Combination			
Monotherapy (Goserelin only)	87(97.8)	8(88.9)	0.253**
Combined Androgen Blockade (with Bicalutamide)	2(2.2)	1(11.1)	
Type of ADT			
Continuous ADT	89(100)	7(70)	0.001**
Intermittent ADT	0	3(30)	
History of chemotherapy			
Yes	6(6.7)	0	0.519**
No	83(93.3)	10(100)	
History of radiotherapy			
Yes	3(3.4)	0	0.724**
No	86(96.6)	10(100)	

**Independent sample t-test, ** Fischer's exact test*

4.6.Independent factors associated with sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

Binary logistic regression was conducted to investigate factors associated with sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy as shown in Table 4.8. Bi-variable analysis showed that, Alcohol and cigarette smoking, Tumor staging T4, very high NCCN risk classification and symptomatic but completely ambulatory ECOG status were found to be associated with sexual dysfunction. Prostate cancer patients who took alcohol and smoked cigarette were 10 times more likely to have

sexual dysfunction compared to those without social habits, cOR =10.3, 95%CI: 2.0,53.04, p =0.005. Respondents who had T4 tumor staging were 16 times more likely to have sexual dysfunction compared to those with T2 tumor staging, cOR =16, 95%CI: 2.8, 92.4, p =0.002. The findings also established that respondents who had very high NCCN risk classification were 9 times more likely to have sexual dysfunction compared to those with intermediate risk, cOR = 9, 95%CI:1.9, 43.1, p =0.006. The results showed that respondents who were symptomatic but completely ambulatory were 7 times more likely to have sexual dysfunction compared to patients who were asymptomatic, cOR = 7.3, 95% CI:2.84,10.9, p=0.002.

A multivariable analysis was conducted to control for confounders. The results revealed that alcohol and cigarette smokers and tumor staging T4 were independently associated with sexual dysfunction. Respondents who alcohol consumers as well as cigarette smokers were 5 times more likely to have sexual dysfunction compared to those without social habits, aOR = 5, 95% CI: 1.9, 14.6, p = 0.010. Prostate cancer patients with tumor staging T4 were 11 times more likely to have sexual dysfunction compared to those with T2, aOR =11.1, 95% CI:4.6,32.1, p<0.009.

Table 4.8: Independent factors associated with sexual dysfunction among prostate cancer patients on Goserelin Androgen deprivation therapy

	Bivariate analysis		**Multivariable analysis**	
Factors	**cOR (95%CI)**	**p-value**	**aOR(95%CI)**	**P-value**
Baseline PSA	0.999(0.998,1.0)	0.330		
Social habits				
None	Ref		Ref	
Alcohol and Cigarette smoking	10.3(2.0,53.04)	**0.005**	5(1.9,14.6)	**0.010**
Alcohol use	0.000	0.998	0.000	0.998
Tumor staging				
T2	Ref		Ref	
T3	2.5(0.47,13.3)	0.282	2.2(0.15,31.54)	0.571
T4	16.0(2.8, 92.4)	**0.002**	11.12(4.62,32.12)	**0.009**
Metastasis				
Mx	Ref			
M0		0.998		
M1		0.998		
NCCN risk				
Intermediate	Ref		Ref	
High	4(0.64,25.02)	0.138	1.29(0.08,22.27)	0.860
Very high	9(1.9,43.1)	**0.006**	0.55(0.02,18.03)	0.735
ECOG status				
Asymptomatic	Ref		Ref	
Symptomatic but completely ambulatory	7.3(2.84,10.9)	**0.002**	4.18(0.19,10.61)	0.368
Symptomatic <50% during the day	1.6(0.3,8.3)	0.591	0.5(0.05,5.211)	0.558

CHAPTER FIVE: DISCUSSION

The present study investigated the prevalence and factors associated with sexual dysfunction among prostate cancer patients on Goserelin Androgen Deprivation therapy at Kenyatta national referral hospital in Kenya. The average age of the respondents was 70.4 (SD±8) years. Prostate cancer is highly prevalent in older adults, as observed in this present study. Similar findings have also been observed in past researchers. A report published by Cancer.Net established that around 60% of cases are diagnosed in men age 65 or older. The average age at the time of diagnosis is 66 years. The disease is rarely identified in those younger than 40 (53). These findings were also comparable with a prospective study in Canada by Crook, which found that the average age at presentation of patients with prostate cancer was 70 years (58). The average BMI among the patients in our study was 29.6 (SD±3) kg/m², which shows that majority of the patients were either overweight (49.5%) or obese (45.5%). Higher BMI has been associated with increased disease risk among prostate cancer patients. There is also a positive association between higher BMI and ADT use since weight gain is one of the major side effects of ADT experienced among prostate cancer patients (54).

Bandini et al., in their study assessing obesity and prostate cancer, it was affirmed that obesity is associated with an increased incidence of aggressive PCa, an increased risk of biochemical failure after radical prostatectomy and external-beam radiotherapy, a higher frequency of complications after androgen-deprivation therapy, and an increased PCa-specific mortality, despite possibly a lower overall PCa incidence (55). It has been affirmed that the association between body mass index (BMI) and prostate cancer risk may be complicated because obesity is linked to a variety of hormonal variables, and the influence

of BMI may alter depending on whether the malignancies are hereditary or sporadic. However, Giovannuci et al. found that the risk of prostate cancer in men with higher BMI ($\geq$30 kg/m^2) was lower than that in men with a lower BMI (23–24.9 kg/m^2) but only if they were younger (<60 years old) (56). Thus, the exact effect of body mass index among prostate cancer patients remains controversial.

The prevalence of sexual dysfunction in the present study was 90% based on the international index of erectile function scoring system. The common components of sexual function that were affected among the patients in the study included erectile dysfunction (96%), excessive fatigue most of the day, and loss of libido (79.8%). Past research has shown that ADT use is associated with the worst sexual experiences among patients with prostate cancer. These findings from the present study are comparable to a study by Schover, which found that men who are undergoing androgen deprivation therapy (ADT) have the highest rates of sexual dysfunction. According to Schover, men's desire for sex is reduced even after 3 to 4 months of ADT, and irreparable damage to the erectile tissue in the penis may occur. He postulated that the sexual function caused by ADT is so severe such that even when ADT is stopped, about half of men's erections do not recover (57). However, their study also revealed that intermittent ADT allows some recovery of sexual function since serum testosterone requires around 9 -12 months off ADT to recover. Nevertheless, despite the sexual dysfunction challenges associated with prostate cancer patients on ADT, a small percentage of men still achieve reliable erections.

In our present study, around 4% of patients on Goserelin did not have erectile dysfunction. This could explain, to a greater extent, the presence of patients without sexual dysfunction. A study conducted by Fode and Sonksen found a higher prevalence of sexual dysfunction,

94%, among prostate cancer patients undergoing ADT (58). Our present findings also align with their study on the proportion of prostate cancer patients who maintain a certain degree of libido. In our study, 20% of the patients maintained their libido while on Goserelin ADT which was comparable to Fode and Sonksen, who also found a similar percentage; 20% of patients maintained their libido and sexual function, although, in the present study, 10% maintained their sexual function. The sexual function among prostate cancer patients on ADT is mainly necessitated by partner considerations, maintenance of intimacy, and maintaining a sense of masculinity may all be reasons for attempting to uphold a sex life.

Alcohol use, cigarette smoking and tumor staging were independent factors associated with sexual dysfunction among prostate cancer patients on Goserelin ADT. Patients with advanced cancer (T4) were 11 times more likely to have sexual dysfunction compared to patients with T2 prostate cancer. These findings align with those from Kinnaird et al., which revealed that in advanced prostate cancer, sexual dysfunction is a key concern. Since ADT is the backbone of prostate cancer management and is frequently used as a long-term treatment for the disease, a long-term reduction in sexual function and desire is unavoidable. Because of their lowered sex drive, many men do not see the benefits of recovery and, as a result, do not seek or refuse therapy leading to poor adherence to this life prolonging drug. (59).

The odds of sexual dysfunction among prostate cancer patients on ADT who both used alcohol and were cigarette smokers and were five times higher compared to those who did neither consumed alcohol nor smoked cigarettes. These findings are consistent with a study conducted by Kinnaird et al., who identified that smoking cessation plays a fundamental role in reducing the risk of sexual dysfunction (59). Further, Polsky et al. found that patients

with erectile dysfunction were two times more likely to be former smokers compared to those with no history of smoking. Alcohol use was also associated with reduced libido and a higher level of erectile dysfunction (60).

The findings from our present study, however, contrast those from Donovan et al. in the United States, which revealed that age was a significant factor in predicting sexual dysfunction among older adults with prostate cancer on ADT. In our present study, age was not found to be significantly associated with sexual dysfunction. In their study, ADT patients reported worsening sexual function and greater bother with time. In males on ADT when compared to men not on ADT, age younger than 83 years indicated considerably poorer sexual function, and age younger than 78 years predicted higher sexual discomfort at 12 months (61).

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

Conclusion

The average age of prostate cancer patients on Goserelin ADT was 70 years, and the mean BMI was 29 kg/m². The findings from our present study have shown a high level of sexual dysfunction, 90% among prostate cancer patients on Goserelin ADT. Alcohol and cigarette smoking and tumor staging (T4) were independent factors associated with sexual dysfunction.

Recommendations

- To educate prostate cancer patients on Goserelin ADT about getting extra psychosexual support and physical sexual therapy, as well as availing to patients' options such as penile rehabilitation during hormone therapy.
- To provide patients with information on reaching orgasm and coping with problems such as dry orgasm, pain with orgasm, and urinary incontinence during sex also should be provided.
- To encourage supervised and/or home exercise programs that significantly improve ADT-related fatigue, metabolic/cardiovascular side effects, and cognitive dysfunction.
- To encourage alcohol use and smoking cessation among all prostate cancer patients, similar to the general population.

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APPENDICES

Appendix 1: Informed Consent Form

Appendix 2: Study Questionnaire

1a Consent Form (English Version)

This informed consent form is for prostate cancer patients who will be attending the KNH Urology and Oncology clinics on ADT.

The informed consent contains 3 parts:

1. Information sheet

2. Certificate of consent

3. Statement by the researcher

PART 1: INFORMATION SHEET

TITLE: THE PREVALENCE AND FACTORS ASSOCIATED WITH SEXUAL DYSFUNCTION AMONG PROSTATE CANCER PATIENTS ON GOSERELIN ANDROGEN DEPRIVATION THERAPY AT KENYATTA NATIONAL HOSPITAL

INVESTIGATORS STATEMENT

I am Dr. Allan Yienya Odundo, a medical doctor undertaking postgraduate studies at the University of Nairobi, Department of Surgery, Urology Unit. I am conducting a study on 'The prevalence and factors associated with sexual dysfunction amongst prostate cancer patients of Goserelin ADT in Kenyatta National Hospital'. "I am going to give you

information about this study and invite you to participate in the study". "Before you decide, you are free to ask for clarifications". "This consent form may contain words that you do not understand". "Please ask me to stop as we go through the information and I will take time to explain". "If you have questions later please feel free to ask".

Purpose of the research

The purpose of the study will be to determine the prevalence and factors associated with sexual dysfunction amongst prostate cancer patients of Goserelin ADT in Kenyatta National Hospital. This will be done using a standardized questionnaire to establish if age, tumor classification such as TNM stage of the disease, PSA or Gleason grading; nutritional status has an impact on the adverse effects of prostate cancer. The information gathered will assist the medical personnel in anticipating, managing, and mitigating the adverse effects of ADT on sexual function in prostate cancer patients. It will also help in developing a standardized approach to the management and follow-up of these patients.

Type of Intervention

Should you choose to participate in the study, you will be handed a questionnaire to fill which should take not more than 10 minutes of your time.

Risks involved in the study

No risks or adverse events have been identified in participating in the study, no personal identifying information will be collected and data will remain anonymous and cannot be traced back to you.

Benefits of participating in the study

Your participation is likely to help us build the body of knowledge on the actual burden of adverse effects of ADT in metastatic prostate cancer patients in KNH and their management.

Questions and choices

You are free to address any questions to the principal investigator via the contact information provided at the end of this document. Your participation is voluntary and you may choose to decline to participate in the study.

PART 2: CERTIFICATE OF CONSENT

I have fully read this consent form or had the contents read to me. My questions, if any, have been answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is completely voluntary and I may choose to withdraw at any time without repercussions. I freely choose to take part in this study.

Signed……. Date…….

PARTICIPANT'S STATEMENT

PART 3: RESEARCHER'S STATEMENT

I, the undersigned have fully explained the relevant details of this research study to the participant and believe the participant has understood and has freely and willingly given his/her consent.

Researchers Name: ……

Signature…… Date: ……

For more information, contact:

The Principal Investigator,

DR. ALLAN YIENYA ODUNDO

Phone: +254 721 679 142

Email: ayienya@yahoo.com

Department of Surgery, University of Nairobi

CONSENT FORM (SWAHILI VERSION)

FOMU YA MAKUBALIANO KUSHIRIKI KATIKA UTAFITI

Fomu hii ya ridhaa iliyo na habari ni ya wagonjwa wanaotolewa kutoka wodi za upasuaji katika Hospitali ya Kitaifa ya Kenyatta.

Idhini iliyo na habari ina sehemu tatu (3):

1. Karatasi ya habari

2. Cheti cha idhini

3. Taarifa ya mtafiti

SEHEMU 1: SHEMA YA HABARI

MADA: KUENEA KWA, NA MAMBO YANAYOSHIRIKIANA NA HITILAFU YA NGONO KWA WAGONJWA WANAO TIBIWA SARATANI YA KIBOFU KWA DAWA YA GOSERELIN KATIKA HOSPITALI YA TAIFA YA KENYATTA

Mimi ni Dkt. Allan Yienya Odundo, daktari anayesoma masomo ya shahada ya kwanza katika Chuo Kikuu cha Nairobi, Idara ya Upasuaji, Kitengo cha Urolojia.

Ninafanya utafiti juu ya 'Kuenea kwa, na Mambo yanayoshirikiana na hitilafu ya ngono kwa wagonjwa wanaotibiwa saratani ya kibofu kwa dawa ya Goserelin katika hospitali ya kitaifa ya Kenyatta. Nitakupa habari kuhusu utafiti huu na kukualika kushiriki katika utafiti huu. Kabla ya kuamua, uko huru kuuliza ufafanuzi. Fomu hii ya idhini inaweza kuwa na maneno ambayo huelewi. Tafadhali niulize niache wakati tunapitia habari hiyo na nitachukua muda kuelezea. Ikiwa una maswali baadaye, tafadhali jisikie huru kuuliza.

Madhumuni ya utafiti

Kusudi la utafiti itakuwa 'Kuenea kwa, na Mambo yanayoshirikiana na hitilafu ya ngono kwa wagonjwa wanaotibiwa saratani ya kibofu kwa dawa ya Goserelin katika hospitali ya kitaifa ya Kenyatta. Hii itafanywa kwa kutumia dodoso iliyokadiriwa ili kubainisha ikiwa umri, uainishaji wa uvimbe kama vile hatua ya TNM ya ugonjwa, PSA au upangaji wa

Gleason; hali ya lishe ina athari kwa athari mbaya ya saratani ya kibofu. Habari iliyokusanywa itasaidia wafanyikazi wa matibabu kutarajia, kusimamia na kupunguza athari mbaya za kwa wagonjwa kama hao. Ingesaidia pia kukuza njia sanifu kwa usimamizi na ufuatiliaji wa wagonjwa hawa.

Aina ya Uingiliaji

Ikiwa utachagua kushiriki kwenye utafiti, utapewa dodoso la kujaza ambalo halipaswi kukuchukua zaidi ya dakika 10 za wakati wako.

Hakuna hatari au matukio mabaya yaliyotambuliwa katika kushiriki katika utafiti, hakuna habari ya kitambulisho cha kibinafsi itakayokusanywa na data itabaki haijulikani na haiwezi kufuatiliwa kwako.

Kushiriki kwako kunaweza kutusaidia kujenga mwili wa maarifa juu ya mzigo halisi wa athari mbaya kwa wagonjwa wa saratani ya kibofu ya kibofu katika KNH na usimamizi wao.

Maswali na uchaguzi

Uko huru kushughulikia maswali yoyote kwa mchunguzi mkuu kupitia habari ya mawasiliano iliyotolewa mwishoni mwa hati hii.

Ushiriki wako ni wa hiari kabisa na unaweza kuchagua kukataa kushiriki katika utafiti au kwa

Saini…… Tarehe:……

Kwa habari zaidi, wasiliana na: DR.

ALLAN YIENYA ODUNDO

Nambari ya Simu: +254 721 679 142

APPENDIX I: STUDY QUESTIONNAIRE

STUDY TITLE: PREVALENCE AND FACTORS ASSOCIATED WITH SEXUAL DYSFUNCTION AMONG PROSTATE CANCER PATIENTS ON GOSERELIN ANDROGEN DEPRIVATION THERAPY IN KENYATTA NATIONAL HOSPITAL.

Date …….

Time ……

Section I (to be administered to all the study participants by the research assistant; kindly tick the boxes as appropriate)

Serial Number:

Year of Birth: …. /…. /…. BMI (Kg/m2): ……. (Weight….

Height….) PSA: Baseline…… Current ……

TNM Stage..... Metastatic Status: ……. (Specify region of metastasis)

Disease classification (according to the NCCN staging) …….

Duration of time on ADT..... ECOG Status ……

Social Habits: Alcohol intake (Quantity)……. Smoking (Quantity)……

Comorbidities:

1. Hypertension: Yes…. No ….
2. Diabetes Mellitus: Yes…. No ….
3. Rheumatoid Arthritis: Yes… No ….
4. Cardiovascular Disease: Yes…. No ….
5. Chronic Renal Failure: Yes ……. No ……
6. Chronic Respiratory Failure: Yes …… No …….

Are you on any chronic medications that you have been using to treat any long-term medical or surgical illness?

Yes: ..... No: …….

If Yes, Kindly elaborate:

……

What dosage of Goserelin are you on: 10.8mg ……. 3.6mgs ……

Type of ADT: Monotherapy (Goserelin only) …… Combined Androgen Blockade (with Bicalutamide) ……

Are you on:

Intermittent ADT……. Continuous ADT …….

Do you have any history of Chemotherapy? Yes…. No……. If yes, Which one:…….

Do you have any history of Radiotherapy? Yes…… No……. If yes, Which one…….

On a scale of 1 – 5 where:

i. Strongly Agree

ii. Agree

iii. Undecided

iv. Disagree

v. Strongly disagree

Have you experienced any of the following sexual dysfunction?

1. Loss of Libido Yes…. No…….
   Score….

2. Change in size of Penis (Length and Girth): Yes…. No…….
   Score….

3. Erectile dysfunction Yes…. No…….
   Score….

4. Changes in Self-perception of body image Yes…. No…….
   Score….

5. Ejaculatory disturbance (Dry/Altered ejaculation) Yes…. No…….
   Score….

6. Excessive fatigue most of the day Yes…. No…….
   Score….

7. Emotional disturbance Yes…. No…….
   Score….

8. Climacturia (orgasm-associated incontinence) Yes…. No…….
   Score….

THE INTERNATIONATIONAL INDEX OF SEXUAL FUNCTION SCORE.

Background

The 15-question International Index of Erectile Function (IIEF) Questionnaire is a validated, multi-dimensional, self-administered investigation that has been found useful in the clinical assessment of erectile dysfunction and treatment outcomes in clinical trials. A score of 0-5 is awarded to each of the 15 questions that examine the 4 main domains of male sexual function: erectile function, orgasmic function, sexual desire and intercourse satisfaction.

The questions that you are about to be asked shall seek to inquire about the effects that your erection problems have had on your sex life since you started your treatment with Goserelin. We urge you to be as honest and clear as possible. In answering the questions, the following definitions shall apply:

- Sexual Activity: Includes intercourse, caressing, foreplay & masturbation
- Sexual intercourse: is defined as sexual penetration of your partner
- Sexual stimulation: includes situation such as foreplay, erotic pictures etc.
- Ejaculation: is the ejection of semen from the penis (or the feeling of this)
- Orgasm: is the fulfillment or climax following sexual stimulation or intercourse

☐ Q1	**How often were you able to get an erection during sexual activity?**	0 No sexual activity 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
☐ Q2	**When you had erections with sexual stimulation, how often were your erections hard enough for penetration?**	0 No sexual activity 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
☐ Q3	**When you attempted intercourse, how often were you able to penetrate (enter) your partner?**	0 Did not attempt intercourse 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
☐ Q4	**During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?**	0 Did not attempt intercourse 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
☐ Q5	**During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?**	0 Did not attempt intercourse 1 Extremely difficult 2 Very difficult 3 Difficult 4 Slightly difficult 5 Not difficult

☐ Q6	**How many times have you attempted sexual intercourse?**	0 No attempts 1 One to two attempts 2 Three to four attempts 3 Five to six attempts 4 Seven to ten attempts 5 Eleven or more attempts
☐ Q7	**When you attempted sexual intercourse, how often was it satisfactory for you?**	0 Did not attempt intercourse 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
☐ Q8	**How much have you enjoyed sexual intercourse?**	0 No intercourse 1 No enjoyment at all 2 Not very enjoyable 3 Fairly enjoyable 4 Highly enjoyable 5 Very highly enjoyable
☐ Q9	**When you had sexual stimulation or intercourse, how often did you ejaculate?**	0 No sexual stimulation or intercourse 1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
☐ Q10	**When you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax?**	1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
☐ Q11	**How often have you felt sexual desire?**	1 Almost never or never 2 A few times (less than half the time) 3 Sometimes (about half the time) 4 Most times (more than half the time) 5 Almost always or always
☐ Q12	**How would you rate your level of sexual desire?**	1 Very low or none at all 2 Low 3 Moderate 4 High 5 Very high
☐ Q13	**How satisfied have you been with your overall sex life?**	1 Very dissatisfied 2 Moderately dissatisfied 3 Equally satisfied & dissatisfied 4 Moderately satisfied 5 Very satisfied
☐ Q14	**How satisfied have you been with your sexual relationship with your partner?**	1 Very dissatisfied 2 Moderately dissatisfied 3 Equally satisfied & dissatisfied 4 Moderately satisfied 5 Very satisfied
☐ Q15	**How do you rate your confidence that you could get and keep an erection?**	1 Very low 2 Low 3 Moderate 4 High 5 Very high

Interpretation:
26-30 No ED, 22-25 Mild ED, 17-21 Mild to Moderate ED, 11-16 Moderate ED and 6-10 Severe ED.