SEXUAL DYSFUNCTION IN PATIENTS UNDERGOING NON-SURGICAL MANAGEMENT OF BENIGN PROSTATIC ENLARGEMENT AT KENYATTA NATIONAL HOSPITAL

University of Nairobi

THIS DISSERTATION IS PRESENTED AS PART OF FULFILMENT FOR THE AWARD OF THE DEGREE OF MASTERS OF MEDICINE IN UROLOGY AT THE UNIVERSITY OF NAIROBI

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H58/75036/2014

DECLARATION

I declare that this study is my original work and has not been presented for the award of any degree at any other institution or university.

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LIST OF ACRONYMS AND ABBREVIATIONS

5ARI-5 alpha reductase inhibitors

BPE-benign prostatic enlargement

BPH-benign prostatic hyperplasia

CCSM-corpus carvenosum smooth muscle

DHT-dihydro testosterone

ED-erectile dysfunction

IIEF-international index of erectile function

IPSS-international prostate symptoms score

KNH-Kenyatta National hospital

LUTS-lower urinary tract symptoms

PBOO-partial bladder outlet obstruction

PSA-prostate specific antigen

RhoA-ROCK- Rho-associated protein kinase

SD-sexual dysfunction

SM-smooth muscle

SPSS-statistical package for social sciences

UON-The University of Nairobi

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ABSTRACT

Background: Sexual dysfunction is a major complaint of patients with benign prostatic enlargement undergoing treatment at Kenyatta National Hospital (KNH). This could result from the primary pathology, various pharmacological agents used for treatment of the same, age, severity of lower urinary tract symptoms or various unknown factors.

Study Objective: To determine the prevalence and associated factors of sexual dysfunction (SD) amongst patients undergoing treatment for benign prostatic enlargement (BPE) at the Kenyatta national hospital (KNH).

Methodology: The study was a cross sectional study where 80 patients undergoing treatment for benign prostatic enlargement at the urology clinics were recruited. All patients enrolled in the study had their bio-data, history, clinical examination, and prostate specific antigen test and ultrasound findings recorded. A standard assessment of erectile dysfunction was done using the international index of erectile function score (IIEF) tool. Detailed history of the medication that was being used was taken and analyzed. Severity of lower urinary tract symptoms (LUTS) was assessed using the international prostatic symptom score (IPSS). Data collection was done using a pretested structured questionnaire and analyzed using IBM SPSS and presented in the form of bar graphs and tables. A P value of 0.05 and confidence interval of 95 % was used to determine significance of collected data.

Study results: The study was conducted between May 2019–August 2019 Patients were recruited by consecutive random sampling until the sample size of 80 was achieved. The mean age of patients was 68 yrs. The prevalence of erectile dysfunction (ED) was 81%. 47.7% had severe ED, and 6.2% had moderate ED, 24.5% had mild to moderate ED while 21.5% had mild ED. 61% of patients had moderate lower urinary tract symptoms, while, 35 % had severe lower urinary tract symptoms. Only 4% had mild symptoms. 90% of the patients enrolled were on medication for BPH while the remaining 10% were not or had not been started on medication for BPH. 3% of the study population had diabetes mellitus, 38% had hypertension, while 13% had both diabetes mellitus and hypertension.

Conclusion: This study demonstrated that Sexual dysfunction in BPE is associated with age, lower urinary tract symptoms, diabetes mellitus, hypertension and medication used in BPH while Prostate size and PSA levels were not associated with sexual dysfunction in BPH.

1.0 INTRODUCTION

A correlation between lower urinary tract symptoms (LUTS) and sexual dysfunction (SD) has been demonstrated in men with Benign Prostatic Enlargement (BPE) through various studies. Both conditions are highly prevalent in men with BPE with the associations between them being independent of age and comorbidities such as diabetes and hypertension (1).

As the prevalence of histological stromal and glandular hyperplasia increases, so does the incidence of LUTS. The rate of sexual dysfunction similarly increases with advancing age (2).

Moreover, in the Multinational Survey of the Ageing Male (MSAM-7), LUTS prevailed at 90%, while the prevalence of SD was 49%, demonstrating that rate of SD was significantly influenced by age and also correlated with LUTS. (3)

Sexual dysfunction in BPE can also be impacted upon by various medications used for treatment of BPE. The various subset groups of drugs each have their unique set of sexual adverse effects which should be established in our local population to create a good understanding of the side effect profile. Both BPE/ LUTS and sexual dysfunction impact negatively on the quality of life and are considered a serious socio-economic problem (4). The prevalence of sexual dysfunction is high in these patients and is also strongly related to the severity of the symptoms. It should be considered when treating ageing men with LUTS.

This aspect of BPE has tended to be ignored despite impacting negatively on patients' lives and so it is important to establish the magnitude of this problem, its causes and associated factors so as to give awareness to clinicians to have this as an important consideration in the management of patients with BPE. Assessment of sexual disorders prior to any treatment and after treatment can help to clarify whether the relationship between benign prostatic diseases and sexual dysfunction. This could either be causal or consequential or as result of the two (3). This study will set out to establish and assess sexual function in patients undergoing medical treatment for BPE.

2.0 LITERATURE REVIEW

Benign prostatic hyperplasia is characterized by uncontrolled proliferation of both the stromal and glandular epithelial elements in the prostatic transition zone. It typically occurs in men above the 4th decade and its prevalence increases with increase in age (5). Prostatic tissue consists of two components; an epithelial part composed of ducts and acini and a stromal part consisting of connective tissue and smooth muscle. In BPH, cellular proliferation results in increasing volume and smooth muscle tone of the prostate (5).

BPH usually progresses in two phases with the first phase resulting in an increase in nodules in the transitional zone and the second phase resulting in an increase in the size of the transitional nodules. This leads to the development of the characteristic LUTS in BPH (5). The increase in the prevalence of hyperplasia is accompanied by increased incidence of LUTS and ED. (6) SD consists of various clinical forms which are: disorders of sexual desire, erectile dysfunction, ejaculatory disorders and disorders of orgasm.

2.1 PATHOPHYSIOLOGY OF SEXUAL DYSFUNCTION IN BENIGN PROSTATIC ENLARGEMENT

2.1.1 LOWER URINARY TRACT SYMPTOMS IN BENIGN PROSTATIC ENLARGEMENT AND SEXUAL DYSFUNCTION

Various factors imply a pathophysiological interaction between ED and LUTS/BPH. LUTS result in a higher prevalence of ED independent of age. Multiple studies have established that LUTS in BPH as an important risk factor for ED. This has been postulated to occur due to various factors listed below.

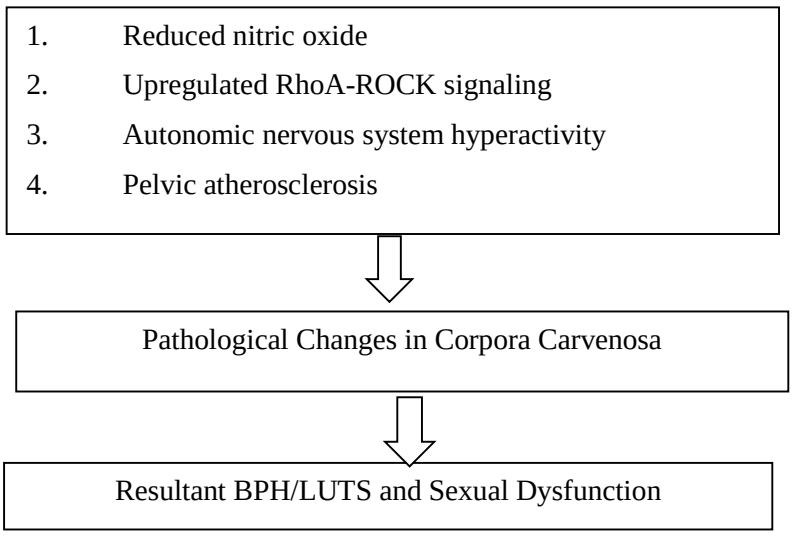


Figure 1: Common Pathogenic Mechanisms in the development of benign prostatic enlargement

Corpus cavernous smooth muscle (CCSM) from rabbits with bladder dysfunction secondary to partial bladder outlet obstruction (PBOO) demonstrated increased force in response to laboratory stimulation; it also had impaired relaxation to electrical stimulation, in comparison to sham-operated animals (7). An increase in CCSM tone mediated by Rho kinase has also been demonstrated. Increased smooth muscle basal phosphorylation which is necessary for contraction resulting from increased Rho kinase expression/activity, makes it more difficult for the CCSM to relax and thus impairing erections (8). Up regulation of the RhoA–ROCK signaling may diminish relaxation of smooth muscle, leading to ED and LUTS. Penile RhoA–ROCK signaling is increased in comorbidities associated with ED like diabetes mellitus. ROCK inhibition limits bladder hyperactivity and improves erectile function (1). Partial obstruction of the urethra to elucidate PBOO, can alter erectile function in rats leading to lower erectile feedback as compared with control animals (7).

Increased adrenergic stimulus can affect both urinary tract and erectile function through an increase in smooth muscle tone. In rats, unilateral sympathectomy led to an ipsilateral increase in prostate hypertrophy (9). Furthermore, the prostate gland has significant nitrergic innervation that is usually diminished in BPH. This pathway is important in maintaining erections via nitric oxide and impairment leads to ED (7).

Arteriosclerosis is prevalent in elderly men. It causes pelvic arterial insufficiency resulting in hypoxia. Resultant increase the expression of TGF-β (transforming growth factor beta) from fibroblasts and interference in prostanoids production, leads to fibrosis of smooth muscles of the penis, bladder and prostate leading to LUTS/BPH and ED (6).

The prostate gland is a major site of androgen action. A reduction in the volume of the gland may be suggestive of hypogonadism. This however has not been correlated with measurement of prostate size via digital rectal exam (DRE) in subjects with sexual dysfunction (10).

2.2 COMORBIDITIES IMPACTING ON SEXUAL DYSFUNCTION IN BPE

The Massachusetts Male Aging Study demonstrated age as the most common variable in patients with impotence. Other associated factors were diabetes, hypertension, medications, cardiac diseases and anger and depression (11).

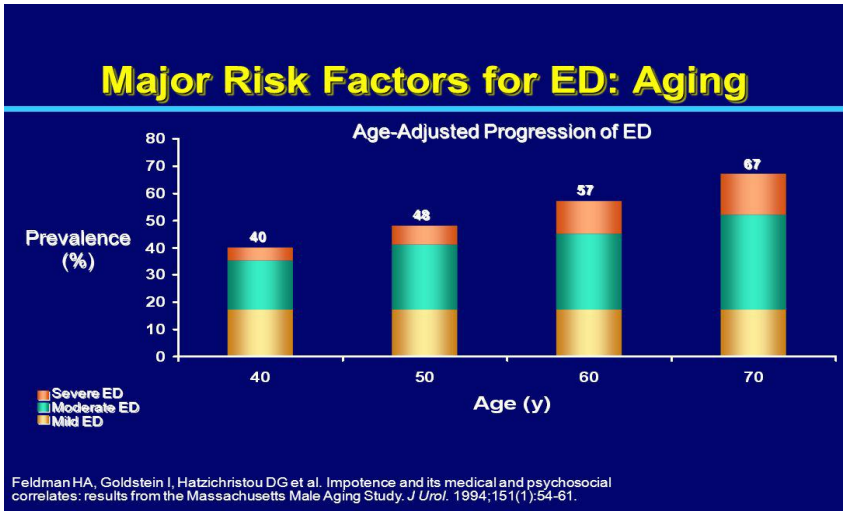


Figure 2: Risk factors for erectile dysfunction (Adapted from Massachusetts Male Aging Study)

2.3 MEDICATION USED FOR BPE AND SEXUAL DYSFUNCTION

Various guidelines for medical management of BPH adopt the use of α-blockers (AB) and 5-α reductase inhibitors (5ARI), as single agents or in combination which have been associated with adverse effects such as sexual dysfunction. Different components of sexual dysfunction result from different drugs within the same group or different groups of drugs thus a need for adequate assessment and strict adherence to guidelines while issuing medication (12).

Despite the improvement of urinary symptoms with this medication, the occurrence of sexual dysfunction (SD) leads to the inability to sustain a satisfactory sexual relationship and poor adherence to the medication. (12) The sexual side effects of these individual drugs and drug groups are variant and (13) clinical assessment of men with LUTS secondary to BPE should include the evaluation of sexual function to establish an initial baseline. (12)

Every treatment for LUTS/BPE may have adverse effects on sexual function therefore warranting that men being treated for LUTS related to BPE should be alerted of all possible sexual side effects of each medication. Doctors should also monitor the evolution of sexual function during these treatments (1).

2.3.1 ALPHA BLOCKERS

The α1 receptors are postsynaptic adrenergic receptors present in both vascular and nonvascular smooth muscles. The various subtypes of α1 receptors which include α1A, α1B, and α1D. The α1A receptors are mainly located in the genitourinary tract. They regulate smooth muscle tone in the prostate and bladder neck. The α1B receptors are located in blood

vessel smooth muscle and regulate vascular tone. The α1D receptors are also located in the genitourinary system and mediate contraction of the bladder neck and prostatic muscle (17).

Alfuzosin and tamsulosin are the α1 antagonists most frequently used in KNH for BPE. They have minimal hemodynamic adverse effects. They also offer good symptomatic improvement in subjects with BPH either as single agents or in combination. Tamsulosin and silodosin selectively antagonize the α1a adrenoceptor subtype which is widely distributed in organs (epididymis, vas deferens, seminal vesicle, prostate gland, prostatic urethra and bladder neck). This receptor modulates the emission phase of ejaculation, and thus explaining for the high occurrence of ejaculatory dysfunction (18).

Tamsulosin also has a high affinity for D2-like dopamine and 5HT1A serotonin receptors, which plays a role in central control of ejaculation, and thus is also suspected to have a central effect on ejaculation. (19) Silodosin has a high incidence of ejaculatory disorders. The mechanism of this is intricately related to development of retrograde ejaculation impaired contraction of the seminal vesicles, and dysrhythmic contraction of the muscles of the pelvic floor (20). Alfuzosin is uroselective but not receptor subtypes selective, and does not significantly affect vascular alpha-adrenergic receptors.

2.3.2 5 ALPHA REDUCTASE INHIBITORS

DHT is the active form of the hormone testosterone that is obtained from testosterone through the enzyme 5-α-reductase of which two types of the isoenzyme are known; 5α-Reductase type 1 and 5α-Reductase type 2. (14). It is important in male sexuality and prostate gland function (15) and as it maintains prostate function, a reduction in its levels through inhibition of 5-alpha-reductase, through the administration of 5ARIs, is one of the approaches useful in the management of BPE. (16)

Two 5ARI inhibitors are currently available in the Kenyan market: finasteride and dutasteride. Finasteride selectively antagonizes type 2 5ARI and reduces serum DHT by approximately 70% while dutasteride antagonizes both Type 1 and Type 2 5ARI isoenzymes (16) thus reducing serum DHT by approximately 90%. The two 5ARIs are indicated for the management of patients with LUTS resulting from BPH (a) with an increased risk of progression, (b) to reduce the size of the prostate gland and lastly (c) to minimize the incidence of the risks associated with disease progression (10). These risks consist of acute urinary retention (AUR), hematuria and the progression to need for surgical treatment for prostatic adenoma (11).

Various studies performed on patients with BPH under 5 ARIs have reported a reduction in prostatic volume, an improvement in IPSS scores, an improved urinary flow, reduction in acute retention of urine and reduction in progression to surgical treatment (17). Sexual adverse effects associated with 5ARIs include erectile dysfunction, ejaculatory disorders and loss of libido.

2.3.3 PHOSPHODIESTERASE 5 INHIBITORS

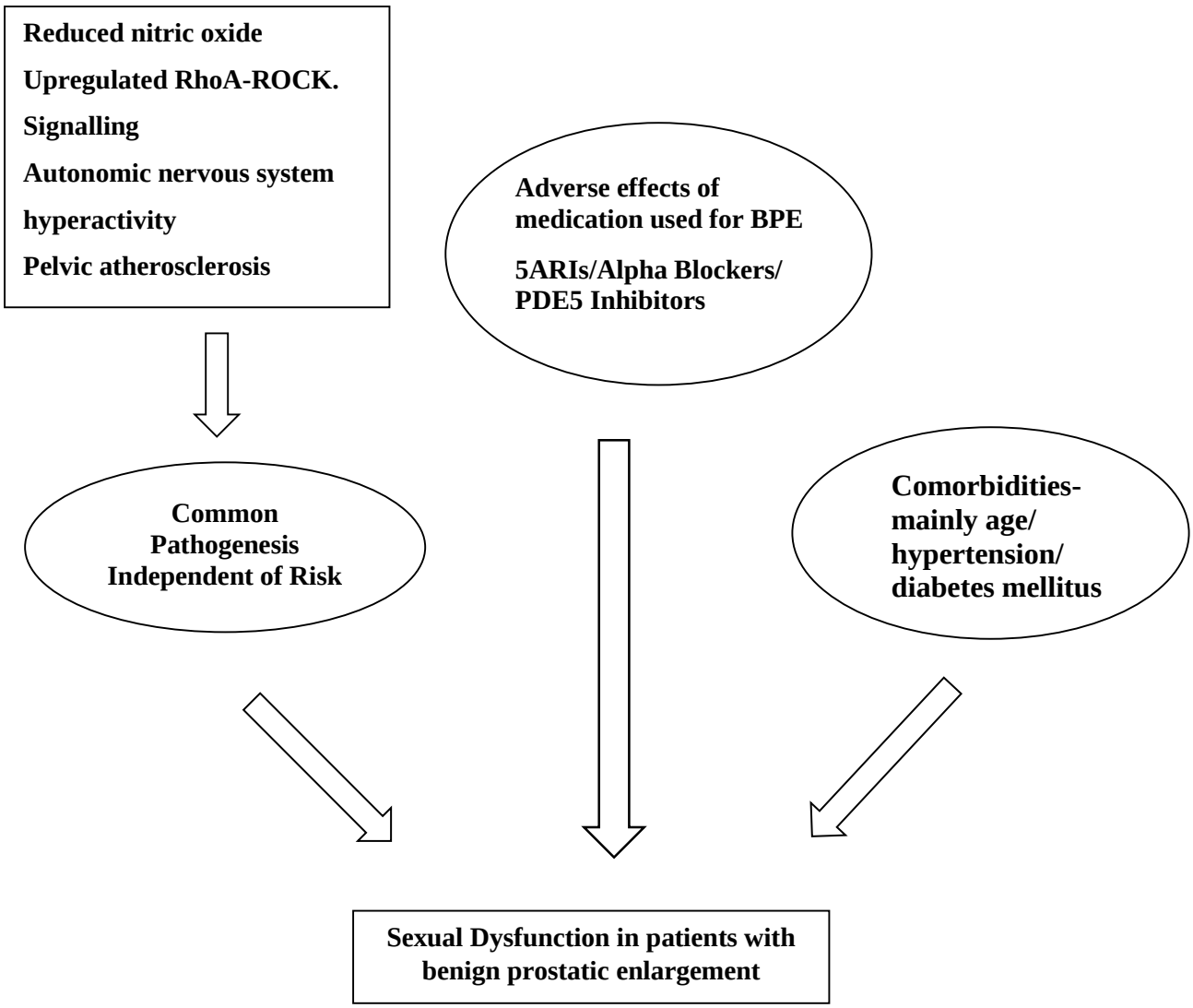
Tadalafil is a PDE5 (phosphodiesterase type 5) inhibitor currently approved for the treatment of lower urinary tract symptoms resulting from benign prostatic enlargement. (21) Its efficacy and safety profile is documented and it is a viable alternative to currently established treatment for LUTS. In addition to being an established treatment for ED and is the only drug currently available that can simultaneously treat the two conditions. (22)

PDE5 isoenzymes inhibition relaxes smooth muscle in the prostate and bladder neck, increases perfusion to the prostate and bladder, and decreases bladder afferent nerve activity (21). Once daily administration of tadalafil 5 mg and finasteride 5mg has been shown to be effective for early symptom improvement terms of LUTS and sexual function in men with prostatic enlargement secondary to BPH (21). Daily co-administration of α-blockers with tadalafil 5 mg in men with lower urinary tract symptoms secondary to benign prostatic hyperplasia has been shown to be safe in terms of haemodynamic side effects apart from doxazosin (23). Significant improvements in both LUTS and ED have been noted in combination therapy using alpha blockers and daily dosage of tadalafil 5 mg for BPE patients (24).

The International Index of Erectile Function is a self-reporting questionnaire used in the assessment of the whole spectrum of sexual dysfunction. It is also important for diagnosis, assessment of severity of erectile dysfunction and the evaluation of male sexual function. (25) A shorter abridged version with five questions (IIEF-5) exists for assessment of erectile dysfunction (26). This study will utilize the IIEF questionnaire to capture the whole spectrum of sexual dysfunction.

3.0 CONCEPTUAL FRAMEWORK FOR THE STUDY

Various pathophysiological pathways of sexual dysfunction in benign prostatic enlargement



4. 0 STUDY JUSTIFICATION

There is a paucity of local data on sexual dysfunction in BPE. No local study has been done on the above, and it will be essential to establish the prevalence and associated factors sexual dysfunction in at KNH. The data obtained from this study will be used as a baseline to formulate clinical guidelines and to optimize management of BPE patients as sexual dysfunction is a major complaint of this subset of patients that have tended to be ignored.

From previous international studies, sexual dysfunction and LUTS in men are quite prevalent especially with an increase in age. ED and LUTS/BPH both diminish the psychological and relational fitness of patients, resulting in a reduction in their overall quality of life (10). Most patients suffering from LUTS/BPH consider sexual relations as important in their lives (27). This study will include validated tools to assess and diagnose sexual dysfunction induced by medications used in the management of BPE. It will also establish the incidence and the significance of this finding (13).

Men with sexual dysfunction also have comorbid conditions such as cardiovascular disease diabetes, hypertension, dyslipidemia, smoking and obesity. The study will capture some of these (diabetes and hypertension) and assess their influence on ED. Given the high prevalence of comorbidities in men with ED vis- a-vis the medication used for BPE. This will help to choose an appropriate treatment that maintains its efficacy and tolerability in the presence of the comorbidities (28) as ED may contribute to poor adherence to medication use because poor quality sexual function may be an unwanted adverse effect of medication used for these comorbidities or medication used for the treatment of BPH/LUTS (4).

5.0 STUDY OBJECTIVES

5.1 MAIN OBJECTIVE

To determine prevalence and factors associated with sexual dysfunction in patients undergoing treatment for benign prostatic enlargement at Kenyatta national hospital.

5.2 SPECIFIC OBJECTIVES

1. To determine prevalence of erectile dysfunction in patients undergoing treatment for benign prostatic enlargement at KNH.

2. To determine the risk factors associated with sexual dysfunction in BPE.

3. To correlate the various risk factors and sexual dysfunction in BPE.

6.0 METHODOLOGY

6.1 STUDY DESIGN

The study was a cross-sectional study limited to a single interaction with the patient.

6.2 STUDY SETTING

The study was conducted at the Kenyatta National Hospital urology clinics. KNH is a teaching hospital for the University of Nairobi, Faculty of Medicine and visiting students from other institutions. Three clinics are run per week by three different firms on Monday afternoon, Tuesday morning and Wednesday afternoon at clinic 24.

6.3 STUDY POPULATION

The study included male patients undergoing treatment (conservative and medical) for BPE at the KNH general outpatient urology clinics, diagnosis having been made by clinical, and laboratory and imaging studies. With KNH being a referral hospital, majority of these patients would normally had done the baseline investigations at the point of encounter with the clinicians at the urology clinics. Any further tests or whenever deemed necessary, a repeat of the baseline tests was done. Routinely, patients who presented to the clinic with either abnormal DREs or elevated PSA levels underwent further tests to exclude prostate cancer which will included a MRI and prostate biopsies. The costs for the investigations were taken care of by the patients as part of their routine management but not for purposes of being included in the study.

6.4 SAMPLE SIZE DETERMINATION

Kenyatta National Hospital records and expert opinion indicated an annual turnover of 100 patients with BPE. This study therefore utilized this indicative patient turnover as its population. The sample size was calculated using Krejcie formula as follows:

$$s = \frac{Z^2(1-\infty/2) \times NP(1-P)}{d^2 (N-1) + Z^2(1-\infty/2) P(1-P)}$$

Where;

s = sample size to be determined

Z^2 (1-∞/2) =is the standard error of the mean corresponding to a 95% confidence interval and the corresponding value from a t-table is 1.96.

N = Estimated population size (100) (average turnover of BPE patients according to data at KNH records department for the past 5 years)

P =is the expected prevalence of the event to occur. Value of P was 0.2 (20% by Obazee et al, closest study to our setting) (29).

d = is the target margin of error which will be 5 % (0.05) to increase precision.

Therefore, the sample size becomes:

$$s = \frac{1.96^{2\,x}\ 100 \times 0.2\ (1 - 0.2)}{0.05^2 \times 99 + 1.96^2 \times 0.2 \times 0.8}$$

Hence s = **80**.

6.5 SAMPLING METHOD

Consecutive sampling was done for all patients who met the inclusion criteria, in the urology clinics at KNH until the sample size of 80 was reached.

6.6 INCLUSION CRITERIA

Patients undergoing medical treatment for BPE, with the diagnosis of BPE made by the researcher and research assistant by virtue of symptomatology, DRE, PSA and initial imaging which was an ultrasound, either a KUB (kidney, ureter and bladder) or a Trans rectal ultrasound were included in the study.

6.7 EXCLUSION CRITERIA

1. Patients who refused to consent to the study.

2. Patients who had a prior surgical intervention for either BPE or urethral stricture disease.

3. Patients who did not have all the investigations necessary for conducting the study.

6.8 RECRUITMENT AND CONSENTING PROCEDURE

Before commencement of the study and upon approval of the protocol by the KNH-UON ERC and the KNH research committee, a sensitization meeting with the staff at the urology clinic was done and posters placed to notify patients and staff about the study. All patients attending the urology clinic during the time of the study were offered a health talk about BPE and about the study after completion of their appointment visit. Those willing to be enrolled to the study and meeting the minimum criteria as per the patient records were requested to sit in an isolated area within the urology clinic for administration of the questionnaire.

The research assistants were medical students or medical doctors, who were thoroughly briefed on BPE, sexual dysfunction, the study, data collection questionnaire and tools (IIEF AND IPSS score forms). They were familiarized on the consenting procedure and confidentiality.

The details and significance of the study were given in written and verbal form to the patient by the principal investigator or research assistant. Only those who consented by signing on the consent form (or using a thumb print for the non-schooled ones) were included in this study and subjected to the study questionnaire.

6.9 ETHICAL CONSIDERATIONS

1. Ethical approval was sought from the department of surgery (UON) and KNH Ethics and Research Committee before commencing the study.

2. Counselling was done prior to consent to give the patient background information on the study.

3. Patients who accepted to consent for the study had their data handled with confidentiality and were allowed to drop out of the study on their own volition if need be.

4. Raw data was destroyed pending completion of the study

5. Those that declined to participate in the study were not denied treatment

6. The study participants did not incur any extra financial costs. Patients were not be asked to do routine workups like PSA and KUB ultrasounds to be included in the study, but were only be incorporated into the study having done these as part of their routine clinical visits.

7. The principal investigator did not attain any monetary benefits from this study

8. The results will be published to allow other medical practitioners to benefit from the study.

6.10 DATA COLLECTION PROCEDURE

Patients who had completed the workups for establishment of a diagnosis of BPE and met the inclusion criteria as above in the clinics were recruited into the study by either the researcher or the research assistant at the KNH urology outpatient clinics after their routine clinic visit. After consenting, a questionnaire, the international index of erectile function form (26) and aggregation table, international prostate symptom score form was then issued to the study

participant to fill. This was then completed by the researcher or research assistant to capture of vital information relevant to this study.

Questionnaire pretesting was done via a participating pretest, where the respondents went through the questionnaire in an interview setting and determine whether it's usable or understandable.

6.11 DATA MANAGEMENT ANALYSIS

The data from the questionnaires was entered into MS Excel data sheets that were protected from access by unauthorized persons. Continuous data such as age and duration of symptoms have been expressed as mean, median and mode, while categorical data such as types of complications have been expressed as numbers and percentages of the population.

At the end of data entry, data was cleaned, verified and imported to and analyzed using SPSS VERSION 22 (Statistical Package for Social Sciences). Measures such as mean, median and standard deviation have been used to describe the data. For categorical data, Fischer's exact test will be used for analysis. The findings of this study will be presented using tables, pie charts and graphs.

6.12 STUDY LIMITATION

1. The above outcomes can be affected by other comorbidities that will not be looked at in the study like heart disease and obesity. The study only assessed hypertension and diabetes mellitus.

2. The cost of doing various tests like PSA and imaging (which are essential in the diagnosis of BPH) was a barrier to some patients.

7.0 RESULTS

During the study period (May 2019 –August 2019), 80 patients on non-surgical management of BPH at the KNH urology clinics who met the inclusion and exclusion criteria and consented to be included in the study were enrolled and evaluated.

DEMOGRAPHIC CHARACTERISTICS

Majority of the patients were residents of Nairobi county and Kiambu county. The other counties of residence were evenly distributed. The age distribution was from 50 to 93 years, with a mean age of 68 years. 61% (49) of patients were within the 50-70 years' age group. 31% (39) of the patients where 70 years and above. (Table 1)

Table 1: Participant's characteristics

Characteristics		
	N	%
Total (N, %)	80	100
Residence		
Bomet	1	1
Kajiado	5	6
Kericho	1	1
Kiambu	14	18
Kirinyaga	3	4
Kisii	2	3
Kisumu	2	3
Kitui	4	5
Machakos	4	5
Meru	3	4
Muranga	4	5
Nairobi	30	38
Nakuru	2	3
Nyandarua	2	3
Nyeri	1	1
Age (Mean | SD)	68.26	8.356
Age (Range| Min Max)	50	93
Age Category		
50-70	49	61
71 and above	31	39

The prevalence of ED was 81% (65), with 19% (15) of patients having no ED. Of the patients with ED, 47.7% (31) had severe ED, and 6.2% (4) had moderate ED, 24.5 % (16) had mild to moderate ED and 21.5 %(14) had mild ED.(table 2)

Prostate sizes in the study population ranged from 19 to 472 grams, with a mean of 78.71. TPSA ranged from 0.04ng/ml to 44 ng/ml with a mean of 5.239ng/ml. (table 3 and table 4)

Table 2: prevalence and features of ED

Prevalence of ED	N	%
ED	65	81
No ED	15	19
Severity of ED		
Severe	31	47.7
Moderate	4	6.2
Mild moderate	16	24.5
Mild	14	21.5

Table 3: prostate size

Prostate size		
Mean and standard deviation	78.71	81.47
Range (Min| Max)	19.26	472

Table 4: TPSA levels

PSA Level		
Mean and standard deviation	5.239	7.989
Range (Min| Max)	0.004	44.0

AGE AND ERECTILE DYSFUNCTION

With univariate logistic regression, age was significantly associated with erectile dysfunction (p-0.006, Odds Ratio (95% CI) 1.135972 (1.037621 -1.243646)).

MEDICATION AND SEXUAL DYSFUNCTION

72 patients (90%) of the patients enrolled were on medication for BPH. 8 (10%) of patients were not or had not been started on medication for BPH. (Table 5)

Table 5: Medication for BPH

Whether on medication for BPH	N	%
Yes	72	90
No	8	10

In total, (45) 56% of patients were on 5ARI AB combination therapy, (24) 30% on alpha blockers while (3) 4% were on 5 ARI monotherapy. Majority of the patients at the KNH urology clinics, 35% (28), on medication were on finasteride tamsulosin combination therapy 26% (21) of patients were on tamsulosin monotherapy while 17% (14) were on dutasteride tamsulosin combination therapy. Of the remaining patients 8% (6) were on finasteride monotherapy while 4% (3) were on alfuzosin. The mean duration of medication was 15.9 months. (Table 6/Table 7)

Table 6: Medication name

Name of medication	N	%
Alfuzosin	3	4
Dutasteride/tamsulosin	14	17
Finasteride	6	8
Finasteride/tamsulosin	28	35
Tamsulosin	21	26
None	8	10

Table 7: Medication type

Type of medication	N	%
5-ARI	3	4
Alpha Blocker	24	30
5ARI AB Combination	45	56
None	8	10
Length of time on BPH medication (months)		
Mean |standard deviation	15.90	31.108

Medication for BPH was significantly associated with erectile dysfunction (p-0.0036). Sub-analysis and regression of the individual medication was not possible due to the sample size.

Table 8: Mean SD characteristics by type of medication

Type of medication		Orgasmic function	Erectile function	Sexual desire	Intercourse Satisfaction	Overall satisfaction
None	Mean	5.63	11.38	5.63	5.50	6.00
	n	8	8	8	8	8
	SD	3.815	9.456	1.598	4.957	2.828
Alfuzosin	Mean	7.00	20.67	7.33	10.33	8.67
	N	3	3	3	3	3
	SD	1.732	4.041	1.528	2.082	0.577
Dutasteride/ tamsulosin	Mean	4.29	9.93	5.21	4.36	5.43
	n	14	14	14	14	14
	SD	2.234	6.754	1.626	3.754	1.284
finasteride	Mean	5.33	14.83	4.67	6.17	7.17
	n	6	6	6	6	6
	SD	2.422	10.304	1.506	6.047	0.983
Finosin/ tamsulosin	Mean	3.54	10.43	5.32	4.00	6.00
	n	28	28	28	28	28
	SD	2.835	10.546	2.127	5.157	2.194
tamsulosin	Mean	5.62	14.90	6.19	6.48	6.81
	n	21	21	21	21	21
	SD	2.819	7.974	1.662	4.457	1.887
Total	Mean	4.69	12.33	5.59	5.26	6.30
	n	80	80	80	80	80
	SD	2.893	9.162	1.853	4.815	2.028

The means of the various medications and combinations in regards to the elements of sexual dysfunction were obtained and compared to the population not on medication and the international controls as described by Rosen et al(2).

Patients on alfuzosin were observed to have higher means in terms of orgasmic function (7.00) than the population not on medication (5.63) and Rosen's control group (5.3). They also had better means in terms of erectile function (20.67 vs 11.38 vs 10.7), sexual desire (7.33 vs 5.63 vs 6.3) intercourse satisfaction (10.33 vs 5.50 vs 5.5) and overall satisfaction (8.67 vs 6.00 vs 4.4).

The group on dutasteride tamsulosin combination therapy had lower means in regards to orgasmic function (4.29 vs 5.63 vs 5.3), erectile function (9.93 vs 11.38 vs 10.7), sexual desire (5.21 vs 5.63 vs 6.3) intercourse satisfaction (4.36 vs 5.50 vs 5.5) and overall satisfaction (5.43 vs 6.00 vs 4.4) as compared to patient's not on medication and Rosen's controls.

Patients on finasteride were observed to have lower means in terms of orgasmic function (5.33 vs 5.63 vs 5.3), and sexual desire (4.67 vs 5.63 vs 6.3), but higher means in erectile function

(14.83 vs 11.38 vs 10.7), intercourse satisfaction (6.17 vs 5.50 vs 5.5) and overall satisfaction (7.17 vs 6.00 vs 4.4) as compared to patients not on medication and Rosen's controls.

Patients on finasteride/tamsulosin combination therapy were observed to have lower means in terms of orgasmic function (3.54 vs 5.63 vs 5.3), erectile function (10.43 vs 11.38 vs 10.7), sexual desire (5.32 vs 5.63 vs 6.3) intercourse satisfaction (10.33 vs 5.50 vs 5.5) and overall satisfaction (8.67 vs 6.00 vs 4.4) as compared to patients not on medication and Rosen's controls.

Tamsulosin was associated with a lower mean in terms of orgasmic function (5.62 vs 5.63 vs 5.3), but higher means in terms of erectile function (14.90 vs 11.38 vs 10.7), intercourse satisfaction (6.48 vs 5.50 vs 5.5) and overall satisfaction (6.81 vs 6.00 vs 4.4 as compared to patients not on medication and Rosen's controls.

COMORBIDITIES (HYPERTENSION AND DIABETES MELLITUS) AND ERECTILE DYSFUNCTION

Of the patients seen at the urology clinic, 48% had neither of the comorbidities being looked at in the study (diabetes mellitus and hypertension).3% of the study population had diabetes mellitus, 38% had hypertension, while 13% had both diabetes mellitus and hypertension.

Table 9: Diabetes mellitus or hypertension treatment

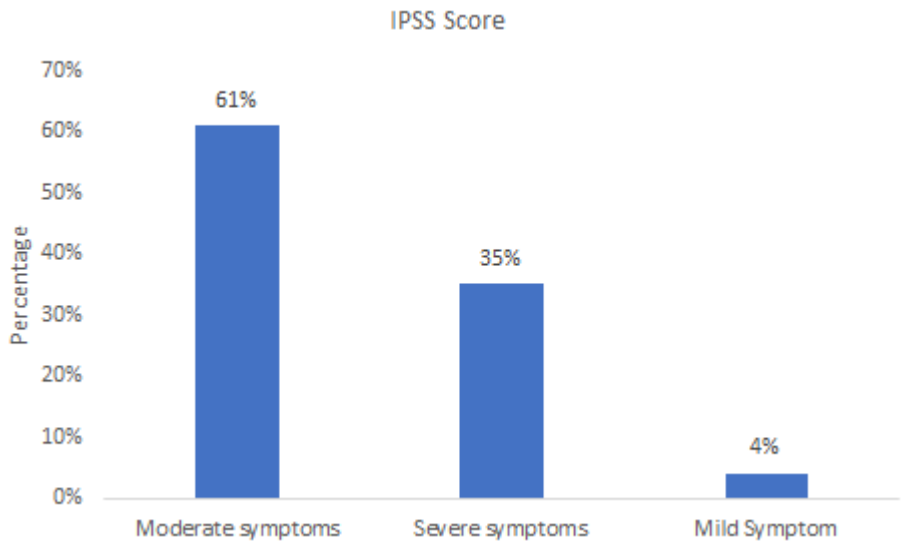
Treatment for diabetes mellitus or hypertension	N	%
None	38	48
Diabetes	2	3
Hypertension	30	38
Both DM & HTN	10	13

Presence of diabetes mellitus and hypertension was significantly associated with erectile dysfunction (p-0.029, Odds Ratio (95% CI) 1.925292 (1.069987 -3.464296)

IPSS SCORE AND ERECTILE DYSFUNCTION

61% (49) of patients had moderate lower urinary tract symptoms, while, 35% (28) had severe lower urinary tract symptoms. Only 4% (3) had mild symptoms. (Graph 1)

Graph 1: IPSS score



Presence of moderate and severe lower urinary tract symptoms was associated with erectile dysfunction (p-0.0049, Odds Ratio (95% CI) 1.037167 (0.9476546 -1.135134)

8.0 DISCUSSION

Sexual dysfunction is a major complaint of patients undergoing management of benign prostatic hyperplasia being associated with various factors such as increase in age, lower urinary tract symptoms, medication used for BPE apart from being linked independently to similar pathophysiological mechanisms as BPE.

This study aimed to establish the prevalence of erectile dysfunction in patients undergoing non-surgical management of BPE at KNH urology clinics, to establish the risk factors associated with sexual dysfunction and to correlate various risk factors and sexual dysfunction in BPE. The factors looked at in this study were age, diabetes mellitus, hypertension, lower urinary tract symptoms, prostate specific antigen, prostate size and medication used for the routine management of BPE.

The study incorporated 80 patients who were being managed at the urology clinics at Kenyatta national hospital being a single institution prospective cross-sectional study. Majority of the patients were residents of Nairobi county (38%) and Kiambu county (18%) with the rest having even distribution amongst thirteen other counties in the country as shown in table 1. This shows that majority of patients seen at KNH urology clinics are mainly drawn from Nairobi

and its neighboring counties and that majority of patients in far flung counties do not access services at KNH with probably happening due to various challenges such as ignorance, distances involved to travel to Nairobi and associated financial implications of the same of which a big part of the country's population cannot afford.

The age of the patients ranged from 50 to 93 years, with a mean age of 68 years. Majority of the patients (61%) were in the 50-70 years old age bracket which in comparison to other international studies namely the Massachusetts ageing male study (40-70 years) and the multinational survey of the ageing male (50-80 years) did not show a big variation in the age group of the subjects showing that similar age groups are affected by both lower urinary tract symptoms and sexual dysfunction.This further enhanced homogeneity of the compared populations, thus allowing for observation of trends for both similarity and disparity.

The prevalence of ED was 81%, with 15% of patients having no ED with this was found to be significantly higher than previous international studies such as the Massachusetts male ageing study (52%) and the multinational survey of the ageing male (49%).It further demonstrates that the prevalence of ED has been downplayed or under reported and should be an important matter of interest in this population and in patients on management for LUTS and BPE. Of the patients with ED, 47.7% had severe ED, and 6.2% had moderate ED, 24.5 % had mild to moderate ED and 21.5 % had mild ED. This is significantly higher than other studies like Obazee et al (20%) in Nigeria (1) and other international studies like the Massachusetts Male Aging Study (52%)(3) and can be probably explained by the older mean age group and by the fact that majority of the population on this study was on active treatment for symptomatic BPH.

72 patients (90%) were on medication for BPH while 8 (10%) of patients were not or had not been started on medication for BPH. Medication for BPH was found to be positively associated with erectile dysfunction. In total, 56% of patients were on 5ARI AB combination therapy, 30% on alpha blockers while 4% were on 5 ARI monotherapy. Majority of the patients at the KNH urology clinics on medication were on finasteride tamsulosin combination therapy (35%). 26% of patients were on tamsulosin monotherapy while 17% were on dutasteride tamsulosin combination therapy. Of the remaining patients 8% were on finasteride monotherapy while 4% were on alfuzosin. The mean duration of medication was 15.9 months. Sub analysis and regression of the individual medication was not possible due to the sample size. Future studies with bigger sample sizes could be done to address these shortcomings.

Of the patients seen at the urology clinic, 48% had neither of the comorbidities being looked at in the study (diabetes mellitus and hypertension). 3% of the study population had diabetes mellitus, 38% had hypertension, while 13% had both diabetes mellitus and hypertension.

Presence of diabetes mellitus, hypertension or both was associated with erectile dysfunction. This is consistent with various international studies(11)(4).

The other factor looked at was lower urinary tract symptoms. 61% of patients had moderate lower urinary tract symptoms, while, 35% had severe lower urinary tract symptoms. Only 4% had mild symptoms. Moderate and severe symptoms were associated with erectile dysfunction. This is consistent and has been demonstrated in previous studies such as The Massachusetts Male Aging Study (11) and the multinational survey of the aging male (MSAM-7)(3).

In this study Prostate size and PSA levels were not associated with sexual dysfunction in BPH in contrast to other studies(10) thus showing a difference in the local population.

9.0 STUDY LIMITATION

1. The IPSS and IIEF proved to be difficult to understand to a significant number of patients who needed close assistance and interpretation. In view of these, versions of these questionnaires in local languages may be of great help.

2. The sample size of this study did not allow for regression and sub analysis for the various medication or groups of medication. A larger series should be done to enable correlation of these medication and various aspects of sexual dysfunction.

3. Sexual health is a taboo subject in our setting and it was a challenge for some patients to have this discussion despite having consented for the study.

10.0 CONCLUSION

This study demonstrated that:

1. Sexual dysfunction in BPE is associated with age, lower urinary tract symptoms, diabetes mellitus, hypertension and medication used in BPH.
2. Prostate size and PSA levels were not associated with sexual dysfunction in BPH.

11.0 RECOMMENDATIONS

1. Need for complete assessment and documentation while managing patients with BPH especially by internationally approved and standardized questionnaires such as the IPSS and IIEF questionnaires.
2. Paying special attention to the various aspects of sexual dysfunction while balancing this with the patient's symptomatology, to achieve minimal sexual adverse effects and a good quality of life.
3. Given the high prevalence of sexual dysfunction and more particularly erectile dysfunction, it is important to incorporate PDE 5 inhibitors (tadalafil) as part of treatment of LUTS and erectile dysfunction.

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13.0 STUDY TIME FRAME

ACTIVITY	DEC 2018	JAN 2018	FEB 2018	MAR 2019	APR 2019	MAY 2019	JUNE 2019	JULY 2019	AUG 2019	SEP 2019
Proposal development										
Ethical approval										
Data collection										
Data analysis										
Dissertation submission										

14.0 ANNEXES

ANNEX 1: STUDY BUDGET

ITEM	**COST (KShs)**
Research fees	2,000
Stationery	10,000
Statistician	40,000
Research Assistant	30,000
Printing & Binding	20,000
Contingencies	20,000
TOTAL	122,000

ANNEX 2: DATA COLLECTION SHEET

Demographic data:

1. Study number.....

2. Age (years).....

3. What is your Occupation? .....

4. Where do you reside? .....

5. Are you on medication for BPH?

☐YES ☐NO

6. If so, state the medication you are on……..

(To be filled by researcher)

☐5-ARI ☐ALPHA BLOCKER ☐ 5ARI AB COMBINATION ☐PDE-5 INHIBITOR NONE ☐

☐Others……...

7. For How long have you taken the above medication……. (months)

8. Are you on treatment for either diabetes mellitus or hypertension?

NONE ☐ DIABETES ☐ HYPERTENSION ☐

9. Have you had any previous urinary tract surgery?

YES ☐ ☐

To be filled by researcher

From patient's medical record, should be within one year from test to data collection date.

10. Prostate size on ultrasound……..……

11. PSA level…….....

ANNEX 3: FOMU YA KUKUSANYA DATA

Data ya demografia:

1. Nambari ya utafiti.....

2. Uko na miaka mingapi?.....

3. Unafanya kazi gani?.....

4. Makao yako ni wapi? .....

5. Unapokea matibabu ya tenzi kibofu?

☐NDIO ☐HAPANA

6. Kama unapokea matibabu, ni madawa zipi unazotumia/ni dawa ipi unayoitumia
……..……..

Kujazwa na mtafiti

☐5-ARI ☐ALPHA BLOCKER ☐ 5ARI AB COMBINATION ☐PDE-5 INHIBITOR
HAKUNA ☐

☐madawa mengine …….……..

7. Umelichukua dawa hii/Umezichukua madawa hizi kwa mda gani…….

8. Unapokea matibabu kwa ugonjwa wa sukari ama shinikizo la damu?

LA ☐ HTN ☐ DM ☐

9. Umefanyiwa upasuaji wowote kwenye uume wako ?

NDIO ☐ LA ☐

Kujazwa na mtafiti

10. Ukubwa wa tenzi kibofu kwenye picha ya ultrasound……..

11. Kiwango cha PSA ……

ANNEX 4: INTERNATIONAL INDEX OF ERECTILE FUNCTION FORM

INTERNATIONAL INDEX OF ERECTILE FUNCTION

Patient Questionnaire

HOSPITAL NUMBER (IF KNOWN) ☐☐☐☐☐☐

NAME .....

DATE OF BIRTH ☐☐ ☐☐ ☐☐☐☐ AGE ☐☐

ADDRESS .....

.....

.....

TELEPHONE .....

These questions ask about the effects that your erection problems have had on your sex life over the last four weeks. Please try to answer the questions as honestly and as clearly as you are able. Your answers will help your doctor to choose the most effective treatment suited to your condition. In answering the questions, the following definitions 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 fulfilment or climax following sexual stimulation or intercourse

---

OVER THE PAST 4 WEEKS
CHECK ONE BOX ONLY

☐ 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

Area	Questions	Score Range	Maximum Score	Your Score
Erectile Function	1-5 & 15	0-5	30	
Orgasmic Function	9-10	0-5	10	
Sexual Desire	11-12	1-5	10	
Intercourse Satisfaction	6-8	0-5	15	
Overall Satisfaction	13-14	1-5	10	

ANNEX 5: INTERNATIONAL PROSTATE SYMPTOM SCORE

IPSS QUESTIONNAIRE

Having to urinate more frequently, as well as more urgently, can definitely interrupt the flow of your day. You should know that frequent urination is often a symptom of benign prostatic hyperplasia (BPH), a noncancerous enlargement of the prostate gland. BPH is a common condition among men over the age of 50. Waking up several times a night to urinate and having a weaker, slower, or delayed urine stream are other common symptoms.

Patient Name _____ **Date** _____

Circle the number that best applies to you.

	Not at all	Less than 1 time in 5	Less than 1/2 the time	About 1/2 the time	More than 1/2 the time	Almost always
1. Incomplete Emptying Over the last month how, often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5
2. Frequency During the last month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
3. Intermittency During the last month, how often have you stopped and started again several times when you urinate?	0	1	2	3	4	5
4. Urgency During the last month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
5. Weak Stream During the last month, how often have you had a weak urinary stream?	0	1	2	3	4	5
6. Straining During the last month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
7. Nocturia During the last month, how many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning?	0	1	2	3	4	5

Add the score for each number above, and write the total in the space to the right **TOTAL_____**

SYMPTOM SCORE: **1-7 = MILD** **8-19 = MODERATE** **20-35 = SEVERE**

0=Delighted 1=Pleased 2=Mostly Satisfied 3=Mixed 4=Mostly Not Satisfied 5=Unhappy

8. Quality of life How would you feel if you had to live with your urinary condition the way it is now, no better, no worse, for the rest of your life?	0	1	2	3	4	5

ANNEX 6: INFORMED CONSENT FORM

This Informed Consent form is for patients in the wards and those attending Urology Outpatient Clinic at KNH. It will be administered to the eligible patients. We are requesting these patients to participate in this research project whose title is "**SEXUAL DYSFUNCTION IN PATIENTS UNDERGOING NON-SURGICAL MANAGEMENT OF BENIGN PROSTATIC ENLARGEMENT AT KENYATTA NATIONAL HOSPITAL**''.

Principal Investigator: Dr. Fredrick Omitto

Institution: Department of Surgery, School of Medicine, University of Nairobi.

This Informed Consent Form has three parts:

Information Sheet (informs you in a brief overview about the research with you).

Certificate of Consent (for you to sign if you agree to take part).

Statement by the researcher/person taking consent.

A copy of the informed consent form will be provided.

PART I: Information Sheet

Introduction

My name is Dr. Fredrick Omitto, a postgraduate student in urology at the University of Nairobi. I am carrying out research to determine sexual dysfunction in patients undergoing treatment for benign prostatic enlargement at Kenyatta national hospital.

Purpose of the research

I will provide information and invite you to be a participant in this research. There may be some words that you don't comprehend. Please ask me to explain as we go through the information and I will explain. After receiving the information concerning the study, you are encouraged to seek clarification in case of any doubt. This study will establish the prevalence and associated factors of sexual dysfunction including lower urinary tract symptoms amongst patients undergoing treatment for benign prostatic enlargement at KNH. It will also seek to classify the different pharmacological agents used for the treatment of benign prostatic enlargement and their effect on sexual dysfunction. The study will also aim to justify whether the treatment of sexual dysfunction should be essential to consider in the management of benign prostatic enlargement.

Type of Research Intervention

This research will involve use of questionnaires to assess and quantify your symptoms and medical records with your doctor's permission [or their representative] to obtain the signs of your illness, imaging and laboratory investigation results.

Voluntary participation/right to refuse or withdraw

It is your decision to participate or not. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you decide against participating, you will be offered the treatment that is routinely provided in this hospital for your condition. You have a choice to refuse or withdraw your participation in this study at any point.

Confidentiality

The information obtained in this study will be treated with confidentiality and only be available to the principal investigator and the study team. Your name will not be used. Any personal information will have a number on it instead of your name. We will not be sharing the identity of those participating in this research.

Sharing the results

The knowledge obtained from this study will be shared with the policymakers in the Ministry of Health and doctors through publications and conferences. Confidential information will not be shared.

Benefits

The benefits of joining the study include:

Contribution to the advancement of patient management.

Improvement the medical treatment of BPE recognizing and adequately managing sexual adverse effects.

Risks

There will be no risk involved by enlisting for this study

Cost and compensation

There will be no extra cost incurred for participating in this study nor is there compensation offered.

This research proposal has been reviewed and approved by the UON/KNH Ethics Committee, which is a Committee whose task is to make sure that research participants are protected from harm.

Who to contact

If you wish to ask any questions later, you may contact:

PRINCIPAL RESEARCHER:

DR. FREDRICK OMITTO

DEPARTMENT OF SURGERY, SCHOOL OF MEDICINE, UNIVERSITY OF NAIROBI

P.O. BOX 19676 KNH, NAIROBI 00202.

MOBILE NO. 0722959816

University of Nairobi /Kenyatta national hospital Supervisors:

PROF. PETER MUNGAI NGUGI

MB.CHB. M.MED. (SURG.), CERT. UROL (RCS), FCS (ECSA)

ASSOCIATE PROFESSOR & CONSULTANT SURGEON AND UROLOGIST

DEPARTMENT OF SURGERY

UNIVERSITY OF NAIROBI

DR. JAMES ADUNGO IKOL

MBCHB (NRB), MMED SURG (NRB), FELLOW UROLOGY (ASEA)

CONSULTANT UROLOGIST,

KENYATTA NATIONAL HOSPITAL

If you have any ethical concerns, you may contact:

Secretary, UON/KNH-ERC,

P.O. Box 20723- 00202,

KNH, Nairobi.

Tel: 020-726300-9 EXT 44355

Email: uonknh_erc@uonbi.ac.ke

PART II: Certificate of Consent

I have read the above information/the above information has been read out to me. I have had the opportunity to ask questions and the questions that I have asked have been answered to my satisfaction. I voluntarily agree and consent to participate in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

If Non -literate:

I have witnessed the reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I can confirm that the individual has given consent voluntarily.

Print Name of witness_____

Signature of witness _____

Date _____

Thumb print of participant

PART III: Statement by the researcher

I have read out the information sheet to the participant, and made sure that the participant understands that the following will be done:

A decision to refuse to participate or withdrawal from the study will not in any way compromise the care of treatment.

All information given will be handled with confidentiality.

The results of this study might be published to facilitate research and improved clinical guidelines. I can confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the approval has been given voluntarily.

A copy of the Informed Consent Form has been provided to the participant.

Name of researcher/person taking consent _____

Signature of researcher/person taking consent _____

Date_____

ANNEX 7: FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI WA "SEXUAL DYSFUNCTION IN PATIENTS UNDERGOING NON SURGICAL MANAGEMENT OF BENIGN PROSTATIC ENLARGEMENT AT KENYATTA NATIONAL HOSPITAL"

Fomu hii ya makubaliano ni ya wale wanaume ambao wanahudumiwa kwenye kliniki za Urolojia na waliyolazwa katika hospitali ya KNH na wamealikwa kujiunga na utafiti "SEXUAL DYSFUNCTION IN PATIENTS UNDERGOING NON SURGICAL MANAGEMENT OF BENIGN PROSTATIC ENLARGEMENT AT KENYATTA NATIONAL HOSPITAL"

Mtafiti mkuu: Dkt.Fredrick Omitto

Kituo: Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi.

Fomu hii ya makubaliano ina sehemu tatu:

Habari itakayo kusaidia kukata kauli

Fomu ya makubaliano (utakapo weka sahihi)

Ujumbe kutoka kwa mtafiti

Utapewa nakala ya fomu hii.

SEHEMU YA KWANZA: Ukurasa wa habari

Kitambulizi

Jina langu ni Dkt. Fredrick Omitto. Mimi ni daktari ninaesomea urolojia katika Chuo Kikuu cha Nairobi,idara ya upasuaji. Ninafanya utafiti kwa anwani ya**, "SEXUAL DYSFUNCTION IN PATIENTS UNDERGOING NON SURGICAL MANAGEMENT OF BENIGN PROSTATIC ENLARGEMENT AT KENYATTA NATIONAL HOSPITAL".**

Lengo kuu la utafiti.

Uvimbe wa tenzi-kibovu na mkuwadi ni mojawapo ya magonjwa kuu yanayowaathiri wanaume walio na umri wa zaidi ya miaka 40 nchini Kenya. Magonjwa hayo hutokea pamoja kwa kawaida. Kunapo pia madawa tofauti yanayotumiwa kudhibiti uvimbe wa tenzi-kibovu,na yaana maadhara ambayo huchangia kuwepo kwa mkuwadi. Utafiti huu unadhamiri kuchunguza matukio ya mkuwadi kwa wagonjwa wanaopokea matibabu ya uvimbe wa tenzi kibofu. Ina chunguza pia madhara yanayotokana na madawa tofauti za kudhibiti uvimbe wa tenzi-kibovu kwa minajili ya uchunguzi wa kisayansi, hivyo basi kudhibitisha umuhimu wa kuzingatia haswa hili tatizo la mkuwadi kwa wagonjwa wanapokea matibabu kwa uvimbe wa tenzi kibovu.

Napania kukupa ujumbe kamili kuhusu utafiti huu na hivyo basi kukualika kujiunga katika utafiti. Yapo maneno ya taminolojia ambayo kwako yatakuwa ngumu kuelewa. Utakapokumbana na maneno hayo, tafadhali niarifu niweze kukufafanulia zaidi. Unawajibika kuuliza kwa kina ili uweze kuelewa vipasavyo.

Aina ya utafiti

Utafiti huu utahusika na kuchunguza na kunakili hali yako ya afya na matibabu ambayo umewahi pokea hapo awali tukishapokea uidhinisho kutoka kwako. Tutaangazia mwelekeo wa ugonjwa wako, madhara husika na vipimo vya mahabara vinavyoambatana nayo. Madhara hayo haswa mkuwadi, yatarekodiwa namajibu kutafsiriwa kisayansi.

Haki ya kukataa utafiti

Kushiriki kwako kwa utafiti huu ni kwa hiari yako. Una uhuru wa kukataa kushiriki, na kukataa kwako hakutatumiwa kukunyima tiba. Uko na haki ya kujitoa katika utafiti wakati wowote unapoamua.

Tandhima ya siri

Ujumbe kuhusu majibu yako yatahifadhiwa . Ujumbe kuhusu ushiriki wako katika utafiti huu utawezekana kupatikana na wewe na wanaoandaa utafiti na wala si yeyote mwingine. Jina lako halitatumika bali ujumbe wowote kukuhusu itapewa nambari badili ya jina yako.

Faida za kushiriki.

Utachangia katika kuendeleza umakinifu wa afya ya kisayansi.

Kuimarisha tiba ya uvimbe wa tenzi kibofu kutumia madawa kwa kuzingatia kutibu na kuzuia mukwadi.

Adhari za kushiriki.

Hakutakuwa na madhara yoyote kwa kushiriki katika utafiti huu.

Anwani za Wahusika

Ikiwa uko na maswali ungependa kuuliza baadaye, unaweza kuwasiliana na:

Mtafiti Mkuu:

DKT.FREDRICK OMITTO,

KITENGO CHA UPASUAJI, SHULE YA AFYA, CHUO KIKUU CHA NAIROBI,

SLP 19676 KNH, NAIROBI 00202.

NAMBARI LA SIMU: 0722959816

Wahadhiri wahusika:

PROF. PETER MUNGAI NGUGI

MB.CHB. M.MED. (SURG.), CERT. UROL (RCS), FCS (ECSA)

PROFESA WA UPASUAJI NA UROLOJIA

IDARA YA UPASUAJI, SHULE YA UTABIBU, CHUO KIKUU CHA NAIROBI

SLP 19676 KNH, NAIROBI 00202.

DR. JAMES ADUNGO IKOL

MBCHB (NRB), MMED SURG (NRB), FELLOW UROLOGY (ASEA)

DAKTARI WA UPASUAJI NA UROLOJIA,

HOSPITALI KUU YA KENYATTA

SLP 19676 KNH, NAIROBI 00202.

Wahusika wa maslahi yako katika Utafiti:

Karani,

KNH/UON-ERC

SLP 20723 KNH, Nairobi 00202

Simu: +254-020-2726300-9 Ext 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

SEHEMU YA PILI: Fomu ya makubaliano

Nimeelezewa utafiti huu kwa kina. NakubaIi kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la Mshiriki_____

Sahihi ya mshiriki _____

Tarehe_____

Kwa wasioweza kusoma na kuandika:

Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nathibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi_____

Sahihi la shahidi_____

Tarehe _____

Alama ya kidole cha mshiriki

SEHEMU YA TATU: Ujumbe kutoka kwa mtafiti

Nimemsomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuatayo:

Kutoshiriki au kujitoa kwenye utafiti huu hautadhuru kupata kwake kwa matibabu.

Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.

Matokeo ya utafiti huu yanaweza chapishwa ili kuwezesha kuzuia na kutibu matatizo yanayosababishwa na prostate biopsy.

Ninathibitisha kuwa mshiriki alipewa nafasi ya kuuliza maswali na yote yakajibiwa vilivyo. Ninahakikisha kuwa mshiriki alitoa ruhusa bila ya kulazimishwa.

Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti _____

Sahihi ya Mtafiti _____

Tarehe_____