ERECTILE DYSFUNCTION RATES AND ASSOCIATED FACTORS DUE TO PRIAPISM IN ADULT PATIENTS AT THE KENYATTA NATIONAL HOSPITAL

Research Submitted in Partial Fulfillment of the Award of the Degree of Master of Medicine in Urology, University of Nairobi

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DECLARATION

This research was undertaken in partial fulfillment of the Master of Medicine in Urology and is my original work and has not been presented for a degree in any other University.

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LIST OF ABBREVIATIONS AND ACRONYMS

C.C	Corpus cavernosum
C.D.U	Color Doppler ultrasound
E.A.U	European Association of Urologists
E.D	Erectile Dysfunction
G.N.R.H	Gonadotrophin releasing hormone
H.F.P	High flow priapism
I.I.E.F	International Index of Erectile Function
K.N.H	Kenyatta National Hospital
M.M.A.S	Massachusetts Male Aging Study
M.R.I	Magnetic Resonance Imaging
Q.O.L	Quality of Life
S.C.D	Sickle cell disease
S.P.S.S	Statistical Package for Social Scientists Software

OPERATIONAL DEFINITIONS

Erectile dysfunction: Persistent inability to attain and maintain an erection sufficient to permit sexual function.

Priapism: Priapism is a pathological condition of prolonged penile tumescence for four or more hours that persists beyond or is unrelated to sexual stimulation

Stuttering: Intermittent or recurring priapism

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ABSTRACT

Introduction: Priapism is prolonged penile tumescence for four or more hours that goes on past or is unassociated with sexual stimulation. It's a urological emergency whose poor management can result in severe penile fibrosis, penile deformity, length loss and erectile dysfunction with substantial impact on quality of life. Therefore, understanding the rate and factors contributing to erectile dysfunction in patients managed for priapism can help formulate interventions aimed at reducing these rates. In Kenya and our region there is paucity of data regarding the erectile function outcomes following management for priapism.

Objectives: To establish the pattern of priapism occurrence and the associated complications of erectile dysfunction (ED) in adult male patients at The Kenyatta National Hospital (KNH) between 2010 and 2020.

Methodology: Using a cross-sectional study**,** 79 adult male patients managed for priapism between 2010 and 2020 at KNH urology clinic, urology ward and other medical wards were sampled and interviewed using IIEF-5 questionnaire to elaborate on the rate of Erectile dysfunction (ED) and associated factors.

Data analysis: Descriptive statistics including mean, medians and proportions were run to describe the characteristics of the study participants and the rates of occurrence of ED after priapism. For hypothesis testing, Chi square was used to determine the association between categorical variables with Students T test for continuous variables. P-values <0.05 were regarded statistically significant.

Results: Mean age was 30.4 years (SD 7.65, range 17 to 47) with majority (74.4%) having studied up to secondary. Seventy-seven (98.7%) of participants had ischemic priapism

while only one had non-ischemic type. Median duration of symptoms prior to presentation was 72 hours with a mean of 112 hours (range 12 - 720). Priapism was mostly idiopathic in 21 (26.9%). Other causes significant included Chronic myeloid leukemia in 20 (25.6%), Sickle Cell Disease, 14 (18%), use of antipsychotics in 11 (14.1%) and Post-coital in 6 (7.7%). T-shunt (Lue) was mostly used for treatment in 51 (65.4%), followed by Winter, 13 (16.7%), Ebbehoj, 5 (6.4%), Aspiration, 5 (6.4%), Burnett, 2 (2.6%) and Conservative 2 (2.6%). The prevalence of ED after priapism was 100% as compared to 74.4% before priapism. However, ED occurred in varying categories after onset of priapism with majority 46 (59%) developing severe ED. Factors associated with occurrence of ED was duration of presentation p value 0.001 with longer duration associated with severity of ED and treatment method used with T-shunt, Winter, and Burnett being significant risk factors.

Conclusion: This study found the prevalence of ED after priapism to be high in this population. Contributory factors were late presentation and treatment method used. There is need for public health awareness on the condition to inform patients on need for early presentation following a suspicion of the condition as well as use of methods of treatment least likely to contribute to ED. There is also a need to procure penile prosthesis and make them accessible to patients suffering ED following priapism.

Key words: Priapism, Erectile Dysfunction

CHAPTER ONE

1.0 INTRODUCTION

Erectile dysfunction (ED) is the persistent inability to attain and maintain an erection sufficient for satisfactory sexual function and it has a considerable effect on quality of life (1, 2).

Priapism is a pathological condition of prolonged penile tumescence for four or more hours that persists beyond or is not associated with sexual stimulation (3). Priapism is a urological emergency. This has been emphasized locally by Magoha in Priapism: A historical and update review (4).

The normal sequelae of untreated ischaemic priapism is severe penile fibrosis resulting in penile deformity, loss of penile length and ED.

Priapism is categorized into ischaemic (low flow or veno-occlusive), arterial (high flow/non-ischemic) and stuttering (recurrent or intermittent). Each type of priapism has distinct pathophysiology as well as management options.

The commonest form of priapism is ischaemic priapism. Accounts for over 95% of all episodes of priapism (3)

Initial treatment of ischaemic priapism is therapeutic aspiration with or without irrigation of the corpora cavernosum or intracavernosal injection of sympathomimetic. Surgical shunts is utilized after failure of the initial non-surgical management (6)

The initial management of non-ischaemic priapism is conservative with ice packs and perineal compression. Selective arterial embolization is recommended when conservative therapy fails (7).

The goal of stuttering priapism is to prevent future episodes and ischaemic priapism (8).

Erectile dysfunction following priapism is influenced by the duration of symptoms, causative factors, intervention modality used and number of interventions employed. Multiple studies have shown that the longer the duration of priapism, the worse the outcome. Ugwumba F.O et al found that the interval between onset of symptoms to presentation to a health facility ranged from 6 hours to 28 days with only 20% presenting within 12 hours (mean of 96 hours) (9). ED occurred in 46.6% of these patients with 33.3% having severe ED unresponsive to PDE5 inhibitors. Dilip Kumar et al used the IIEF-5 questionnaire to evaluate ED in patients managed for priapism (10). Out of 19 sexually active men in this study, only five preserved normal erectile function. The poor result was attributed to prolonged duration of priapism (10).

Ali Tabibi et al, 2010 found that the ED rates for Winter, Al-Ghorab and Grayhack was 50%, 66.7% and 75% respectively. The outcomes were worse with subsequent procedures (11).

In Kenya and our region, we have inadequate data regarding the incidence of ED and erectile function outcomes following management for priapism.

EAU guidelines states that cases whose priapism lasts more than 36 hours may be considered for an acute penile prosthesis implantation as this helps to maintain penile length (5). In our set up, penile prosthesis is majorly unavailable and out of reach for most of our patients. Determining the ED rates and factors associated with ED in these patients will help in making informed decisions when counselling patients who present with priapism on the need for penile prosthesis. The largest series of acute malleable penile prostheses for ischaemic priapism shows a 96% rate of satisfaction of patients as it permits patients to maintain their penile rigidity and length (12).

CHAPTER TWO

2.0 : LITERATURE REVIEW

2.1 Erectile Dysfunction

ED is the persistent inability to attain and maintain an erection that is adequate enough for satisfactory sexual function (1). ED can interfere with the psychosocial and physical wellbeing and can have a substantial impact on the quality of life (QoL) of the individual as well as related partners (2). Epidemiological statistics have shown a high occurrence of ED globally. The Massachusetts Male Aging Study (MMAS) showed an overall 52% prevalence in men that were non-institutionalised aged 40-70 years in the area of Boston (1). In the Cologne Study of men aged 30-80 years, the prevalence was 19.2% (13).

2.2 International Index of Erectile Function - 5

IIEF-5 is a brief, validated, multidimensional, self-administered tool to assess erectile function. It addresses the main sexual function domains in men (erectile function, orgasmic function, sexual desire, intercourse fulfilment and overall satisfaction) and is psychometrically sound. The probable IIEF-5 score varies between 5 to 25, and ED is divided into 5 categories depending on the scores: with (5-7) as severe, moderate ranges from (8-11), (12-16) is mild to moderate ED, mild (17-21), and at range (22-25) means no ED.

ED can be categorized as psychogenic, mixed psychogenic and organic. The latter is the dominant. Organic causes can be neurogenic, hormonal, vascular or drug induced. Among the veno-occlusive dysfunction causes of ED is priapism which has a devastating consequence on the sexual function of men if not treated promptly. Natural sequelae of untreated ischaemic priapism or priapism refractory to interventions is severe penile fibrosis which results in penile deformity, length loss and erectile dysfunction.

2.3 Priapism

The word priapism originated from the Greek god Priapus, god of potency, lust and guardian of gardening (14). Priapus is memorized in statues for his enormous phallus. Priapism is a complete or incomplete erection that lasts for over 4 hours beyond stimulation of sex and orgasm or is not associated to sexual stimulation (3). Only the corpora cavernosa is involved in priapism without involvement of the corpus spongiosum and glans (6). Interventions past 48 to 72 hours of onset may help relieve erection and pain but have little benefit in preserving potency. Ischemic priapism is an emergency. If left untreated, resolution may take days and ED invariably occurs. Magoha in Priapism: A historical and update review (4) opined that priapism must be taken to be a urological emergency and early clinical intervention should be commenced immediately to prevent the erectile impotence risk and significant medico-legal repercussions.

The objective of management of all patients with priapism is to achieve detumesence and retain erectile function. Unfortunately, part of the treatment aimed at correcting priapism have the potential complication of erectile dysfunction.

Burnett AL et al created and evaluated a psychometric instrument that measured the impact of experiencing priapism from the patient perspective, they found that priapism adversely affects the life-style, sexual function and physical wellbeing (16). Due to its rarity and unpredictability, priapism management literature is neither large nor voluminous, comprising mainly small case series and case reports rather than controlled trials.

There are three subtypes of priapism: Ischemic (low-flow, anoxic, veno-occlusive), nonischemic (high-flow, arterial) and stuttering (recurrent, intermittent). In a population based retrospective cohort study comprising 145,071 men, Eland I.A et al found that the

incidence rate of developing priapism was 1.5 per 100,000 persons per year (45). Roghmann F, et al in a study of emergency department visits between 2006 and 2009 in the United States found an incidence of 0.73 per 100,000 men per year. This corresponded to 32, 462 visits for priapism (15).

2.4 Ischaemic Priapism

Ischaemic Priapism (IP) is the commonest form of priapism. Accounts for approximately 95% of all episodes of priapism (3). Normally painful, with a firm erection characterized clinically by lack of or low intra cavernous blood flow. In IP, there are time dependent modifications in the corporal metabolic environment, progressively leading to hypoxia, hypercapnia, and acidosis (3).

Ischaemic priapism consists of an imbalance of vasorelaxatory and vasoconstrictive mechanisms predisposing the penis to hypoxia and acidosis. In vitro studies have demonstrated that when corporal smooth muscle strips and cultured corporal smooth muscle cells are exposed to hypoxic conditions, alpha adrenergic stimulation fails to induce corporal smooth muscle contraction (8). Extended periods of severe anoxia significantly impair corporal smooth muscle contractility and cause significant apoptosis of smooth muscle cells and, ultimately, fibrosis of the corporal cavernosum.

Although priapism is a rare disorder, patient populations with Sickle cell disease (SCD) are affected with greater frequency relative to the general population (17). The lifetime probability for the development of priapism in men living with SCD is 42% with ED rates following these episodes exceeding 30% (17-19). SCD is the commonest cause of priapism in children accounting for 63% of cases and it is the primary etiology of low flow priapism in 23% of adult cases (20). Dilip K et al (2016) in a prospective institutional study on

outcome and erectile function following treatment of priapism found that idiopathic causes were the highest at 26% followed by PDE5 inhibitors use at 15% (10). Chronic myeloid Leukemia (CML) in Dilip K et al contributed 5%. Three different studies in Nigeria found SCD, use of local aphrodisiac *(bura-ntashi)* and use of antipsychotic medications as the commonest causes of low flow priapism (17-19).

The duration of priapism is strongly associated with the incidence of subsequent erectile dysfunction. 90% of patients experiencing ischemic priapism for 24 hours develop ED. Histologically examined corporal specimens shows interstitial edema by 12 hours, advancing to sinusoidal endothelium damage, basement membrane exposure, and thrombocyte adherence at 24 hours. After 48 hours thrombus can be found in the sinusoidal spaces, and smooth muscle necrosis with fibroblast-like cell transformation is evident (50) In developing countries, delay in presentation is the norm either because of ignorance or inadequate health care. These patients are sometime seen by unqualified healthcare workers who tend to manage them conservatively and only refer them to specialized centers when it's too late with attendant high incidence of ED. These factors probably work in synergy to worsen the outcome. In contrast, in developed countries, presentation is early and intervention prompt (22-24).

Ugwumba F.O et al in a retrospective study found that the onset to presentation interval ranged from 6 hours to 28 days with only 20% presenting within 12 hours (mean of 96 hours). ED occurred in 46.6% of these patients with 33.3% having severe ED unresponsive to PDE5 inhibitors (9). In Muhammed A et al study on predictive factors and outcome of management of ischemic priapism in Zaria, Nigeria, the shortest period of presentation to health facility after the onset of symptoms was found to be 18 hours with 10 days being

the longest with a mean of 105.5 hours (4 days) (21). 52.2% of these patients presented after 48 hrs. ED rate in this study was 78.7% with severe ED in those who presented past 48 hours.

Duration of priapism varied from 20 to 480 hours (mean 96.7 hours) in Dilip K, et al (10). In a prospective study, Dilip K, et al used the IIEF-5 questionnaire and found that only 5 of the 19 patients preserved normal erectile function after 13.6 months follow up. ElBahnasawy M.S et al while assessing for the risk factors of ED in low – flow priapism in Mansoura, Egypt found a median duration of priapism of 48 hours (6-240 hours) (25). ED rate was 57%. 43% reported conserved erectile function and such was in patients having short priapism (less than 48 hours). The remaining patients had a consequent persistent priapism attacks and were all effectively managed as they presented just after their commencement.

Table 1: Relationship between duration of priapism and ED Rates

Study	**N**	**Duration of study**	**mean duration**	**ED Rate**
Nigeria (Ugwumba F)	15	10 years	96 hours	46.6%
Nigeria (Mohamed A*)*	35	12 years	105.5 hours	78.8%
India (Dilip K*)*	19	2 years	96 hours	73%
Egypt (El-Bahnasawy*)*	50	18 years	48 hours	57%
Iran (Ali Tabibi)	16	10 years	51.2 hours	50%

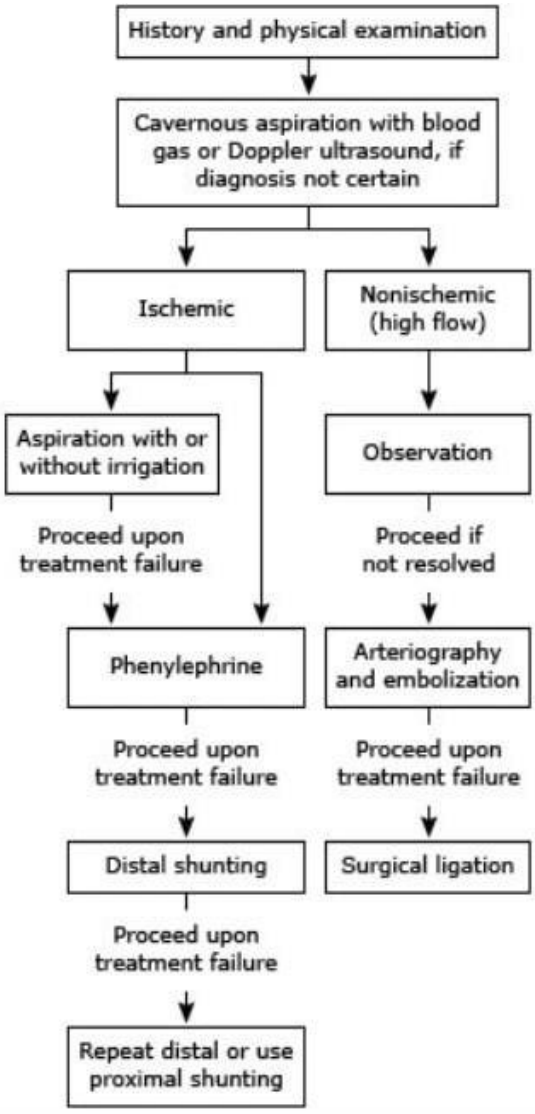
In IP the patient typically presents with a painful and rigid erection. In rare cases, ischemic priapism can present with penile gangrene, resulting in necrosis of the entire penis (26).

Duration of erection, medications, episodes that occur before, leisure drugs utilization, history of hematological disease, penile or perineal trauma and presence and severity of pain should be obtained in the history. There is need to examine the genitalia, abdomen and perineum for rigidity of the penis and trauma symptoms or malignancy. Cavernosal blood gas analysis can distinguish ischemic from non-ischemic priapism. In Low-flow priapism corporal blood gas analysis will indicate hypoxemia, hypercabia and acidemia. Color doppler ultrasonography (CDU) will show minimal or absent blood flow in the cavernosal arteries in ischemic priapism, whereas normal to high blood flow is observed in non-ischemic priapism. CDU can also detect cavernous arterial fistula, pseudo aneurysm and other anatomic abnormalities.

Ischemic priapism requires rapid detumescence to avoid long term sequelae. According to American Urological Association (AUA) (3), IP management need to go on in a stepwise fashion to attain resolution as early as possible. Initial intervention utilizes aspiration with or without irrigation or intracavernosal injection of sympathomimetic e.g. phenylephrine.

Use of surgical shunts need to be regarded following intracavernous injection of sympathomimetic. Distal shunts (cavernoglanular) need to be prioritized in the events of shunting. If distal shunting procedures fail, proximal shunting procedures may be warranted. The rate of success for distal shunts is 66-77% while for proximal shunt is 50% (6).

Figure 1: American Urological Association Algorithm (AUA) for management of priapism (2009)



Original figure modified for this publication. Reproduced from: Montague, DK, Jarow, J, Broderick, GA, et al. American Urological Association Guideline on the Management of

Table 2: Surgical Techniques for Different Types of Shunts

Distal Shunts	
Winter	'Tru-cut' biopsy needle insertion directly via the glans to the corpora cavernosum (CC)
Ebbehoj	Inserting of no. 11 scalpel through directly the glans into the CC severally
T-shunt (Lue)	No. 10 scalpel is input via the glans to one of the CC, rotated 90^{o} away from the urethra and extracted followed by intracavernosal tunnelling with a 20-Fr dilator.
Al-Ghorab	A 2-cm incision is created across just distal to the coronal sulcus. A corporalglandular shunt is created by excision of tunica albuginea layer of both CC
Burnett (corporal snake)	inserting a 7/8 retrogade Hegar dilator into the end of each CC via the original Al-Ghorab glanular excision followed by compressing the penis manually
Proximal Shunts	
Quackels	Forming cavernospongiosus shunt unilaterally by anastomosing proximal CC to corpus Spongiosum
Sacher	Bilateral corporalspongiosal shunt
Grayhack	Caverno-saphenous shunt
Barry	Caverno-dorsal vein shunt

Different Types of Shunts

Figure 2: Distal Shunts for surgical management of priapism

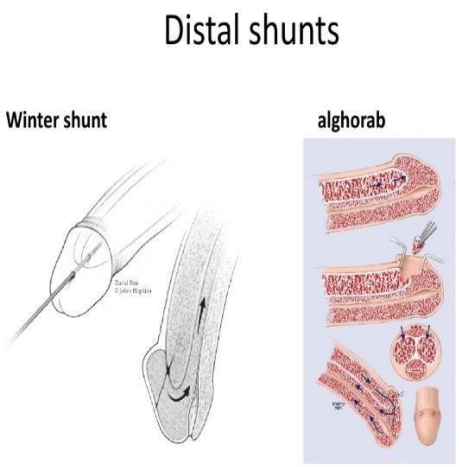


Figure 3: T shunt with and without tunneling

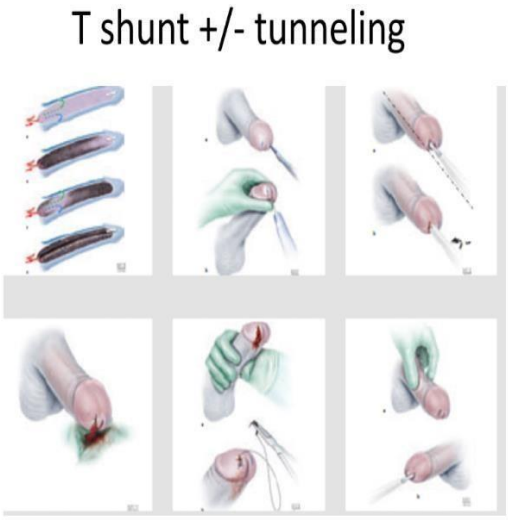


Figure 4: Quackels procedure, Sacher's technique

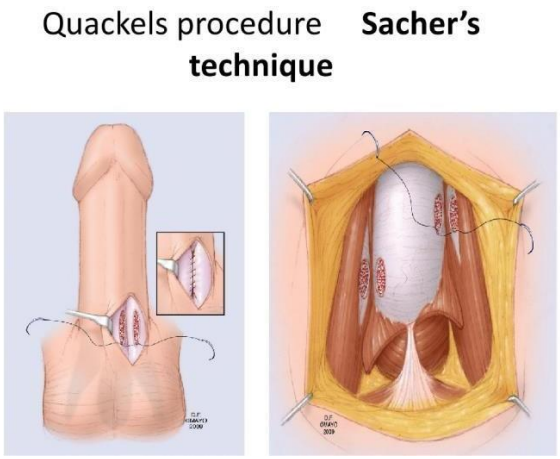
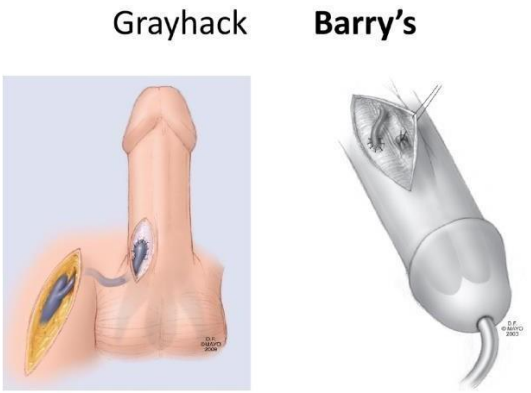


Figure 5: Proximal shunts, Grayhack and Barry's procedures



Photos adopted from Campbell-Walsh-Wein Urology, 12th edition Randy G, et al, 2003 while assessing efficacy of shunt surgery for refractory low flow priapism found that 50% of their patients required reoperation for failed detumescence following a cavernosa-to-spongiosum shunt. In this study the Winter shunt had a 92.3% failure rate, whereas

reoperation was uncommonly required following an Al-Ghorab or Quackels shunt. 90% of the patients had ED on follow up (27).

Ali Tabibi et al, *2010* found that the ED rates for Winter, Al-Ghorab and Grayhack was 50%, 66.7% and 75% respectively. The outcomes were worse with subsequent procedures (11). Dilip K reported ED rates of 81.9% and 80% for distal and proximal shunts respectively (10). The success rate in this study was 66%, 74% and 60% for Winter, AlGhorab and Bunnet respectively. Ugwumba et al reported ED rates of 46.7% after AlGhorab shunt (9).

2.5 Stuttering Priapism

Stuttering/intermittent priapism is characterised by a pattern of recurrence. Patients typically awaken with an erection that persists up to 4 hours and becomes progressively painful secondary to ischemia. Patients with SCD may experience stuttering priapism from childhood. Adeyoju et al. (2002*)* reported that out of 46 SCD patients who had priapism, 33 (72%) had stuttering priapism (28). The onset of stuttering priapism is usually during sleep with persistence upon waking.

Aetiology of stuttering priapism is similar to ischaemic priapism. The frequency and duration of these episodes is variable and can progress into a major ischaemic episode. Men who have suffered from an acute ischaemic priapic event are at risk of developing stuttering priapism (8). The primary goal of management of patients with stuttering priapism is the prevention of future episodes. The management of each acute episode is similar to that for ischaemic priapism.

Alpha adrenergic agonists daily dosing has shown effective prevention of stuttering priapism. Pseudoephedrine can be used as first line treatment (29,30). Hormonal

manipulations of circulating testosterone using GnRH agonist and anti-androgens appears to be the most efficacious and safe and are recommended as primary treatments in adult men. Other treatment modalities include use of digoxin (31-33), terbutaline, gabapentin (34), baclofen (35), hydroxyurea (31, 32, 36) and intracavernosal injection of sympathomimetic agents (31,32).

2.6 Non-Ischaemic Priapism

High flow priapism (HFP) is a persistent erection caused by unregulated cavernous arterial inflow. commonly caused by blunt perineal or penile trauma (37). Iatrogenic needle injury has also been reported to cause HFP. Dubocq FM, et al and Inamoto T, et al described vascular erosions complicating metastatic infiltration of the corpora (38, 39). It has also been reported following internal urethrotomy (40) and Nesbit procedure (41). Seftel et al, described a HFP complicating an ischaemic priapism (42). This is thought to be due to mechanical disruption of arteriolar or sinusoidal anatomy and dysregulation of vasorelaxing/vasoconstricting factors resulting from ischaemic damage (43,44)

Sustained partial erections may develop 24 hours after perineal or blunt penile blunt trauma due to disruption of clot during nocturnal erection. In HFP corpora are tumescent but neither rigid nor painful. There is no hypercabia, hypoxia or acidosis on corporal blood gas analysis in HFP.

Colour Doppler Ultrasound of the penis can differentiate ischaemic from nonischaemic priapism. Data analysis shows spontaneous resolution to be the outcome of untreated nonischemic priapism in up to 62% of the reported cases with an associated complaint of erectile difficulties in 33% of patients (44).

The initial management of HFP is conservative with ice packs and perineal compression. Selective arterial embolization is recommended in patients who request treatment. Pyor J, et al, 2004 reported success rates of up to 89% with arterial embolization (7). Selective ligation should only be considered when there are contraindications for selective embolization. Surgical management carries the risk of ED due to accidental ligation of the cavernous artery instead of the fistula.

2.7 Prosthesis Implantation

Intractable, therapy resistant ischaemic priapism or episodes lasting more than 48-72 hours usually result in complete erectile dysfunction along with possibly major penile deformity. Immediate penile prosthesis surgery is advised (46-49). Relative indications for implanting a penile prosthesis in a man with acute ischaemic priapism includes: ischaemia for more than 36 hours (48), failure of aspiration and sympathomimetic intracavernous injections, failure of distal and proximal shunting and MRI or corporal biopsy evidence of smooth muscle necrosis (8, 46)

Immediate insertion of a penile prosthesis is recommended. Dense fibrosis of the corpora cavernosa develops during extended priapism complicating later insertion of prosthesis (12). Placement of a malleable prosthesis sustains penile length (12,50), permits early reinstatement of sexual activity (50,51) and avoids surgical difficulty and complication risks with delayed surgery (52).

In Kenya, penile prosthesis are not readily available and are way out of reach for many Kenyans. This study will elucidate the burden of priapism and subsequent ED rates in the country. This will form the basis for development of protocols for advocating for availability of prosthesis at affordable cost.

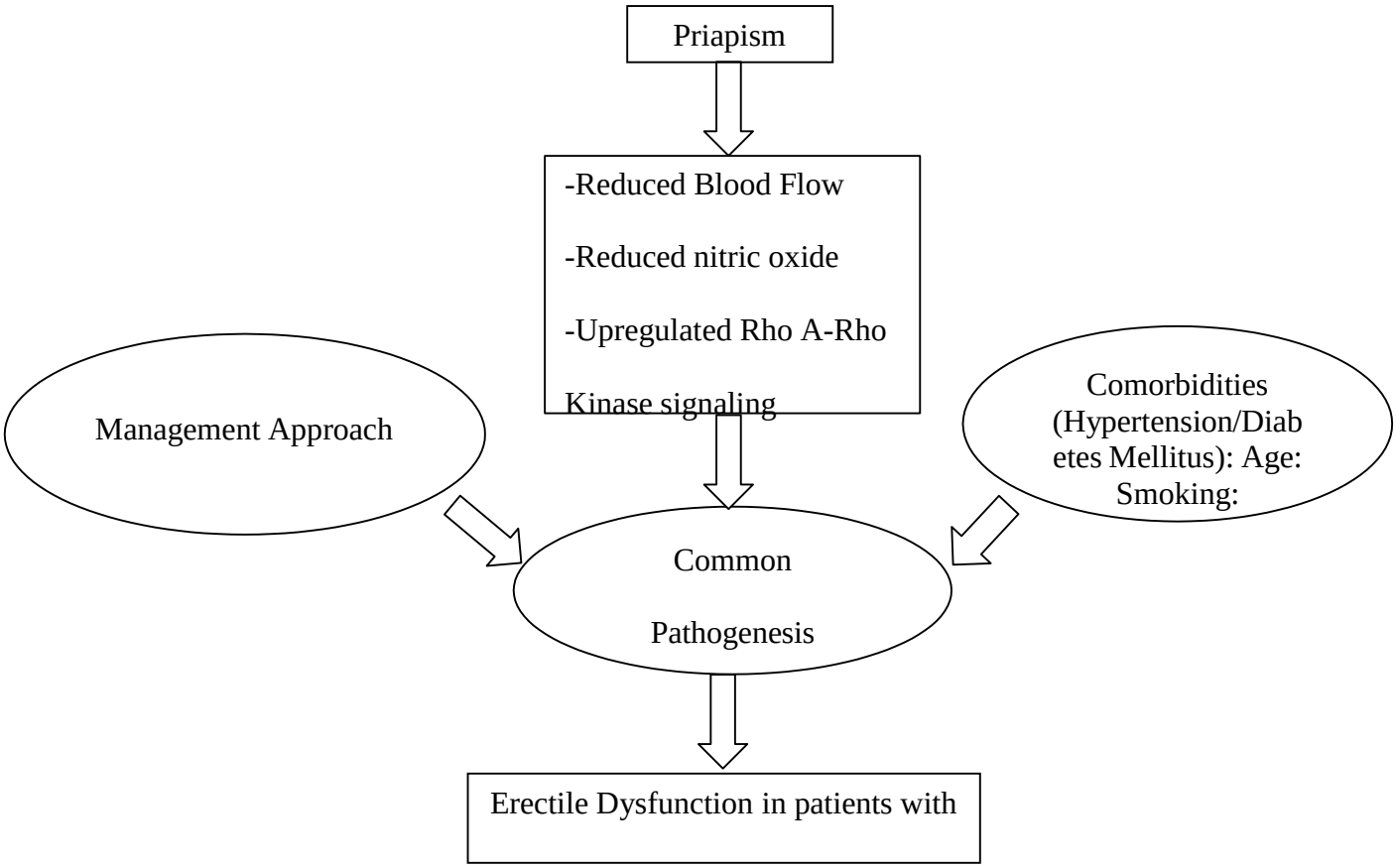
2.8 CONCEPTUAL FRAMEWORK

2.8.1 Narrative

The International Index of Erectile Function is a self-reporting questionnaire used in the assessment of the whole spectrum of sexual dysfunction. Patients who present with priapism have a higher likelihood of developing erectile dysfunction. The development of erectile dysfunction may be determined by multiple factors among them the cause, time before definitive management, management approach and other patient related factors such as age and preexisting medical conditions. In this study we utilized the IIEF-5 questionnaire to capture the spectrum of erectile dysfunction among men who present with priapism.

2.8.2 Figurative Presentation

Figure 6: The Conceptual framework indicating associations of Erectile Dysfunction after priapism



2.9 STUDY JUSTIFICATION

There is paucity of data for erectile dysfunction among men presenting with priapism in Kenya and the East Africa region. Equally, factors associated with and thought to contribute to ED in our set up have not been documented. Understanding the rate and factors contributing to erectile dysfunction in patients presenting with priapism will therefore help formulate policies and intervention measures aimed at reducing these rates.

Moreover, this study will help in establishing the need for procuring and making penile prostheses accessible to such patients as well as in public education on priapism.

2.10 STUDY QUESTIONS

1. What is the prevalence of erectile dysfunction after priapism?

2. How does the duration of symptoms influence the severity of ED after priapism?

3. Does management method influence the occurrence of ED after priapism?

2.11 STUDY OBJECTIVES

2.11.1 Broad Objective

To establish the pattern of priapism occurrence and the associated complications of erectile dysfunction in adult male patients managed at The Kenyatta National Hospital between 2010 to 2020.

2.11.2 Specific Objectives

1. To establish the prevalence of erectile dysfunction due to priapism using the IIEF-5 severity score.

2. To establish the association between the duration of symptoms and development of erectile dysfunction

3. To establish the association between the management method employed and development of erectile dysfunction

CHAPTER THREE

3.0 METHODOLOGY

3.1: Study Design

This was a cross-sectional study. A cohort of patients who were managed for priapism at the KNH between 2010 and 2020 were evaluated for the development of erectile dysfunction using the IIEF-5 score. A description of the factors associated with the development of erectile dysfunction was determined from the patients file.

3.2: Study Setting

The study was conducted at the KNH records department, urology clinic, and the urology ward, ward 5B. The KNH is a teaching hospital for the University of Nairobi, College of Health Sciences and visiting students from other institutions. It has a bed capacity of 1800 and a staff of about 5000. It serves as a national referral hospital for Kenya and the wider Eastern Africa region. The hospital offers round the clock, highly specialized services to hundreds of thousands of patients yearly. The hospital offers comprehensive specialty services including urological services. The urology unit is domiciled in ward 5B and run specialty outpatient clinics.

3.3: Study Population

The study included all adult male patients who underwent management for priapism at the KNH between 2010 to 2020.

3.4: Sample Size Determination and Formula

The sample size was determined using The Cochrane formula for desired sample size and adjusted for population size:

$n = (Z^2 \text{ x } P(1 / P))/e^2$

Where:

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P is expected true proportion

e is desired precision (half desired CI width).

For small populations n can be adjusted so that n(adjusted) = (Nxn)/(N+n).

Adjustment for finite population size is described by Thrusfield M, 2005. Veterinary Epidemiology, 2nd Edition, Blackwell Science, Oxford, UK (p 183).

The expected true proportion, P, is 0.5

(this is dependent on the known prevalence of ED after priapism in the literature review of which ranges from 20 – 60%. Therefore, using a 50% as the known prevalence of ED.

And with an estimation of urology department having managed about 100 cases in the last 10 years with Priapism. So the finite population is 100)

Thus in this study, considering above, the ideal sample size is 80 participants.

3.5: Sampling Procedure

Research assistants retrieved all the files for patients with a diagnosis of priapism from the KNH records department for the period of the study. The files were then serially labelled before data extraction. A sample survey of all the 80 files was done. All the files were included in the study. The clinical and in-patient clinical notes of the patients were reviewed in detail and contact details taken for contacting the patients. Any file that did not respond to the questions in the data abstraction tool was replaced by a randomly selected file from the same pool.

3.6 : Recruitment and Consenting Procedures

Once identified, the patient files were separated from the rest of the records for data abstraction and identification of the phone numbers. A test run for the identified phone numbers was done and only patients with successful encounter were enrolled in the study. Patients still on follow up in any of the hospital clinics were recruited for interviewing during the clinic. The rest of the patients were contacted and facilitated to get to KNH urology clinic for consenting and administration of the questionnaire

3.6.1 : Inclusion Criteria

1. All adult patients who were managed for priapism at the KNH between 2010 and 2020
2. Age above 18 years

3.6.2 : Exclusion Criteria

1. Lack of contact details in the patient's file

3.7 : Data Variables

Table 3: Data Variables

Variable	Variable Classification	Source Document
Erectile dysfunction	Dependent	Questionnaire
Time between symptoms and development of erectile dysfunction	Intermediate	Questionnaire
Management approach for priapism	Independent	Patient's file

3.8 : Data Collection Procedures

This study was cross-sectional in nature. Following permission to collect data from the KNH research committee and the health information department, the principal investigator and the two research assistants retrieved patients' files chosen as per the sampling procedure and the data extracted and captured using a specially designed data capture tool. Using the specially designed questionnaire and the IIEF tool, the patients who consented, were interviewed and further information obtained and recorded in a password protected excel software for analysis.

3.9 : Study Materials

A detailed data entry capture tool was filled in for each of the patient who was managed for priapism during the study period. Data on socio demographics, medical history, surgical history, and management of priapism was abstracted from the patients' files. Data on the probable development of erectile dysfunction was collected from the questionnaires.

3.10 : Training Procedures

Research assistants with medical background (urology residents) were used during the data collection process. They underwent a rigorous training on data collection practices such as confidentiality and the techniques for extracting retrospective data accurately both from the patients' files and using the phone.

3.11 : Quality Assurance Procedures

Measures to make sure the data collected is of high integrity and is acceptable scientifically were put in place. Data capture tools were checked for accuracy by the data manager and data cleaned daily before uploading on the SPSS software for analysis. Additionally, the questionnaire was piloted using dummy patients to assess the length of time taken to

conduct the study and the quality of data that is likely to be extracted using phone interviews.

3.12 : ETHICAL CONSIDERATION

3.12.1 Ethical Clearance

Before recruitment of participants and collection of data, this study was availed to the Ethics Review Committee of UoN and KNH for approval. Any recommendations raised was considered and implemented. Covid19 guidelines were implemented including proper wearing of masks, hand washing and social distancing at all times.

3.12.2 Confidentiality

Throughout the cycle of this project, confidentiality of patients was maintained. Private information like names were not taken on our data collection tools. Furthermore, the statistician and the principal investigator are the only people that were permitted access to the collected data. The data capture tools filled with data were stored in cabinets under lock. Databases were exceptionally accessed by individuals authorized and equally were password protected.

3.13 : DATA MANAGEMENT

Data was uploaded in a spreadsheet for cleaning before analysis using the SPSS Software (SPSS version 21).

Descriptive statistics such as mean, mode, median and proportions were used to describe the characteristics of the study participants.

For hypothesis testing, categorical variables were tested using the Chi-square and Fisher's Exact test with, whereas continuous variables were tested using Students t-test if data was parametric and Mann Whitney U-test if data was non-parametric. P values of <0.05 were regarded statistically significant.

3.14 : STUDY RESULTS DISSEMINATION PLAN

Two major avenues to disseminate this knowledge to clinicians and the research community were to be explored. First, the novel findings generated from this study was to be sent for publication in peer reviewed journals. Second, findings were to be presented in meetings hosted by the department of Urology at the UoN, conferences hosted locally by the Ministry of Health (MOH) of Kenya and by regional and international bodies.

3.15 : STUDY LIMITATIONS AND HOW TO MINIMIZE THEM

Data was collected in retrospect from the files of patients. This might have been a major source of bias for this study. Information loss is common whenever data is collected retrospectively. Moreover, there were difficulties in reaching the patients who had changed their contacts or gave the wrong contacts. Since the information as captured by the KNH included next of kin, all the avenues were exhausted by reaching out to them too in case the primary patients could not be reached.

CHAPTER FOUR

4.0 RESULTS

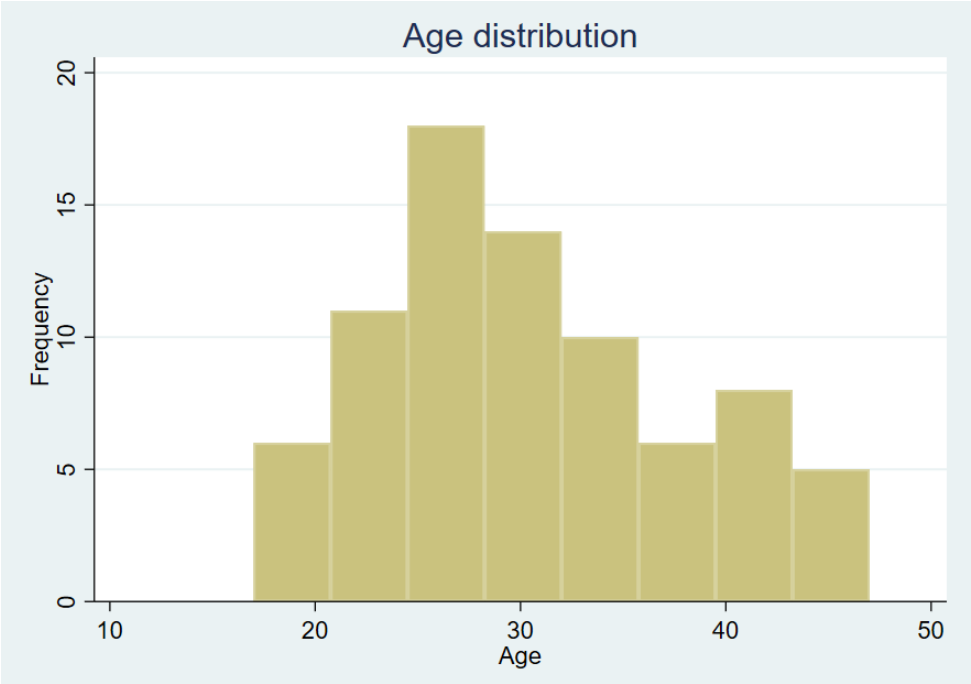
Eighty participants were interviewed, however, 2 were excluded for incomplete data and failure to contact them. Statistical analysis was done for 78 participants.

4.1 Clinical characteristics

4.1.1 Age

Mean age of the study participants was 30.4 yrs (SD 7.65, range 17 to 47) (Figure 7)

Figure 7: Histogram showing age distribution



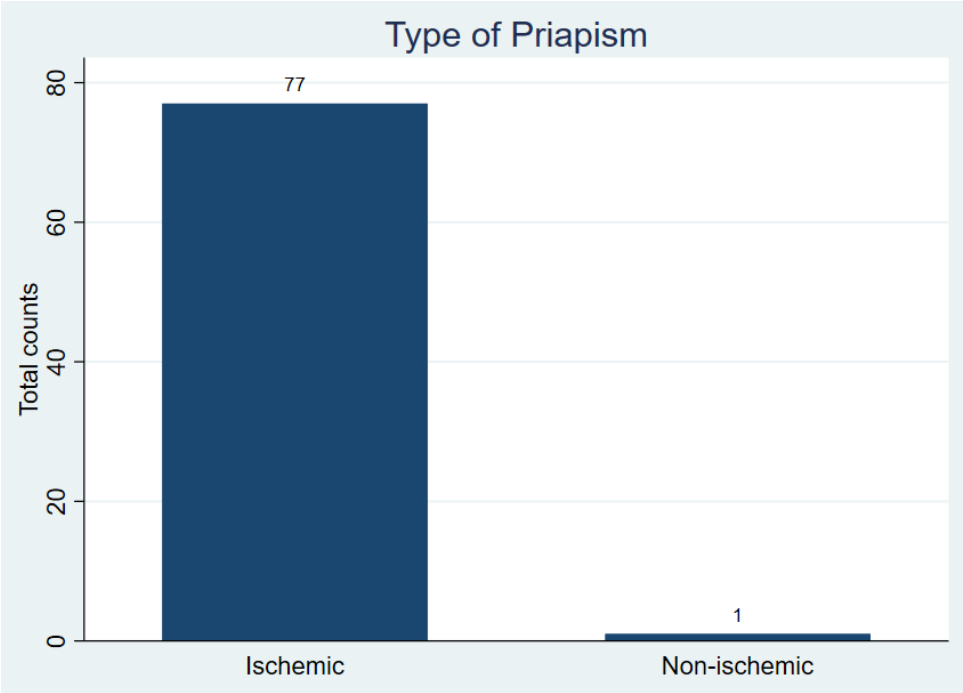
4.1.2 Level of education

According to the level of education, only 39 out of 78 participants had responses which included, 7 (18.0%) at primary level, 29 (74.4%) at secondary level and 3 (7.7%) at tertiary level.

4.1.3 Type of Priapism

Ischemic type of priapism was the most prevalent with 77 (98.7%) participants compared to 1 (1.3%) who had non-ischemic type (Figure 8).

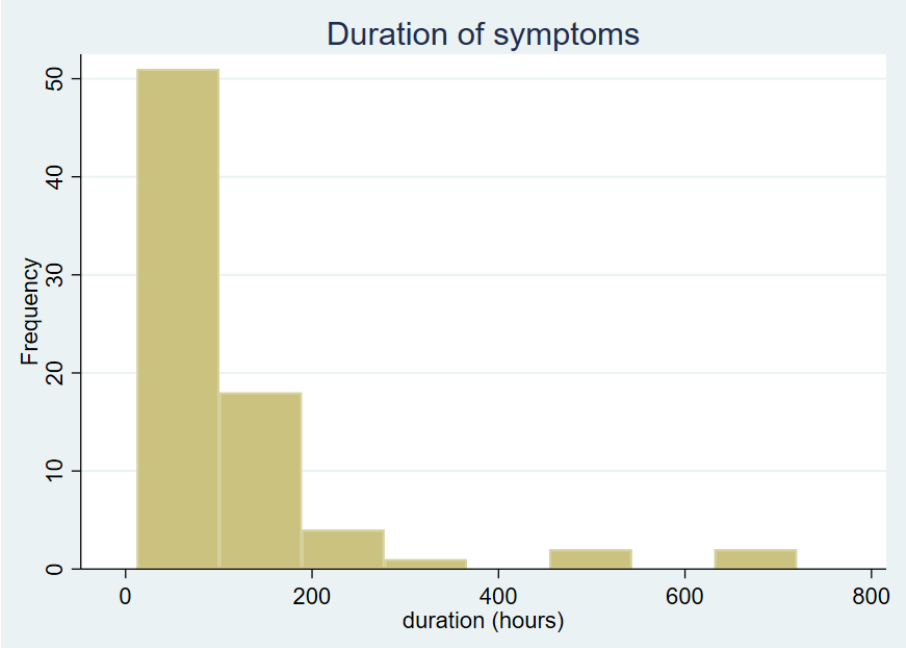
Figure 8: Bar graph showing frequency of types of priapism



4.1.4 Duration of symptoms

In terms of duration of symptoms prior to presentation, Median was 72hours, mean 112.8hours (range 12 to 720) (Figure 9).

Figure 9: Histogram showing duration of symptoms prior to presentation



4.1.5 Cause of priapism

Participants reported various causes of priapism as shown in table below.

Table 4: Table showing causes of priapism

Cause	Frequency	Percent
Idiopathic	21	26.9
Chronic Myeloid Leukemia	20	25.6
Sickle Cell Disease	14	18.0
Anti-psychotic medications	11	14.1
Post-coital	6	7.7
Chronic Kidney disease	1	1.3
During Sex	1	1.3
Excessive binge drinking	1	1.3
Phophodiesterase 5 inhibitors	1	1.3

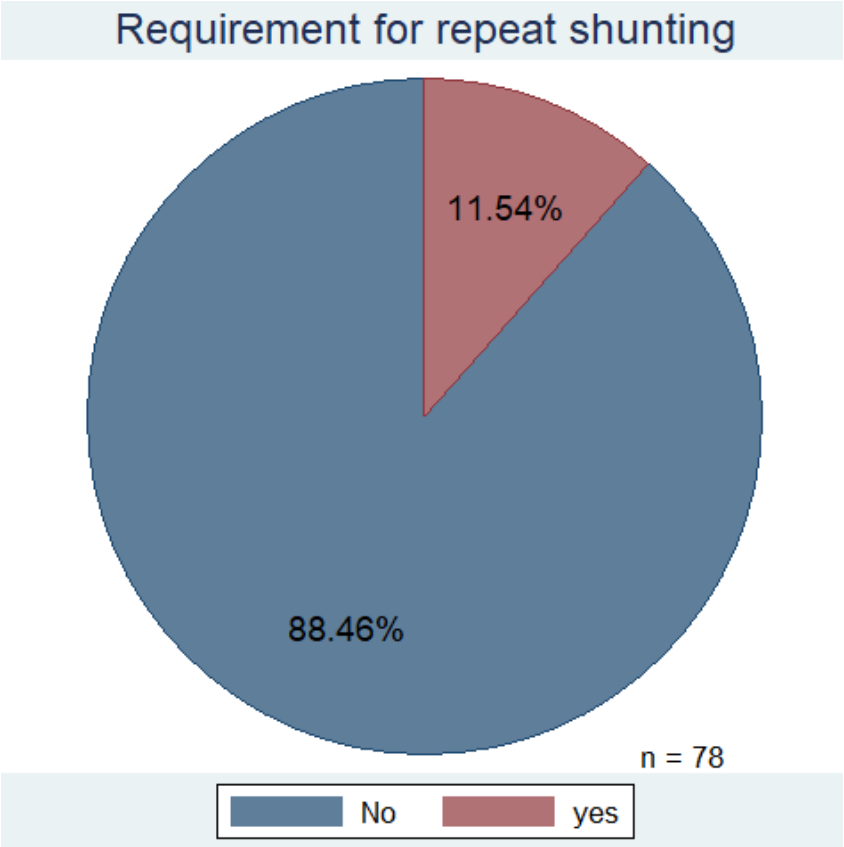
Trauma	1	1.3
Unknown drug injection	1	1.3
Total	78	100

Note: CKD chronic kidney disease; CML chronic myeloid leukemia, SCD Sickle Cell disease

4.1.6 Repeat shunting

Of the 78 participants, 9 (11.54%) required repeat shunting with 69 (88.5%) participants not requiring repeat shunting.

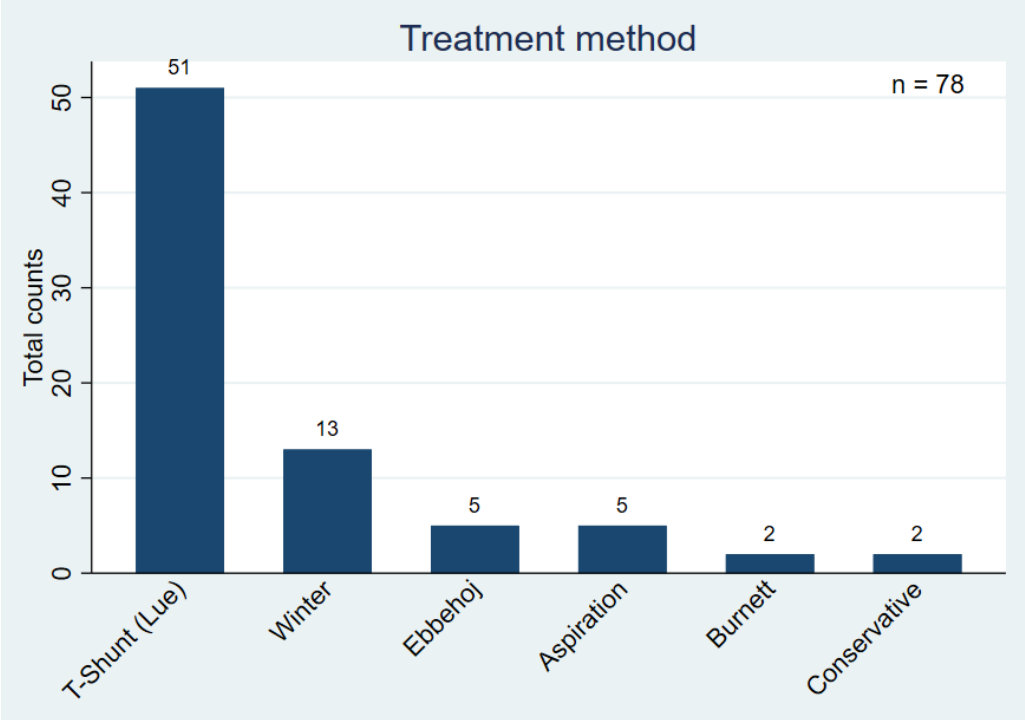
Figure 10: Pie chart showing requirement for repeat shunting



4.1.7 Treatment method

Majority of participants, underwent T shunt(Lue), 51 (65.4%), Winter, 13 (16.7%), Ebbehoj, 5 (6.4%), Aspiration, 5 (6.4%), Burnett, 2 (2.6%) and Conservative 2 (2.6%)

Figure 11: Bar graph showing treatment method used



4.2 Prevalence of ED after priapism

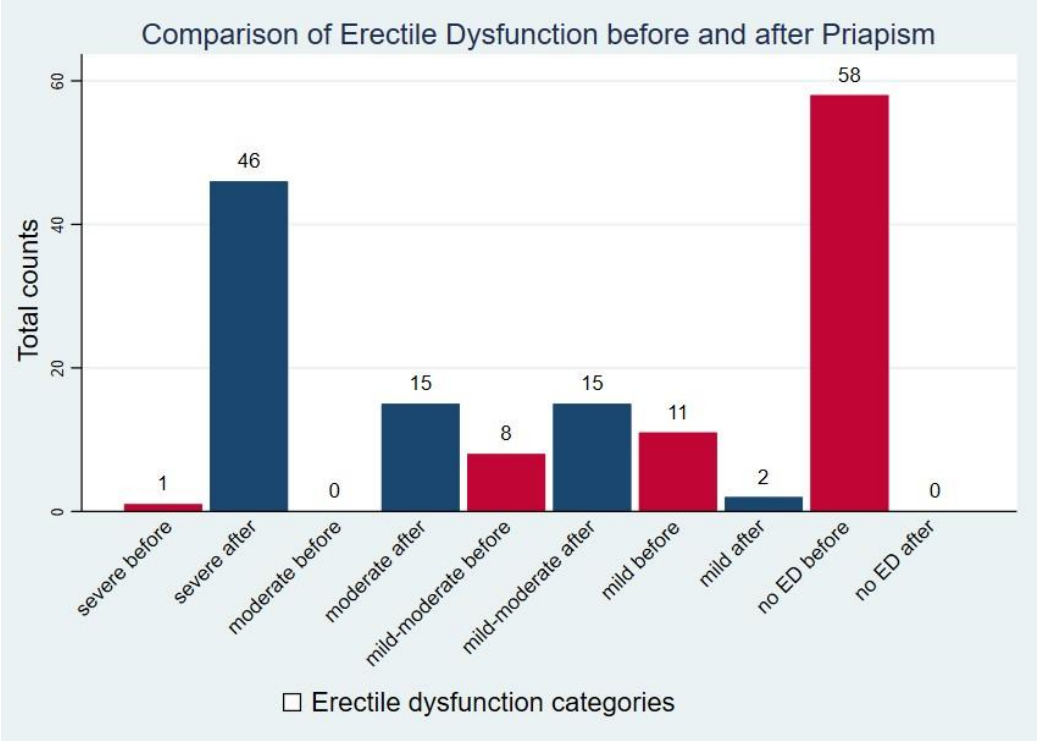
The prevalence of ED after occurrence of priapism was 100% as compared to 74.4% before priapism. However, ED occurred in varying categories after onset of priapism (Table 5 & Figure 12)

Table 5: Categories of Erectile dysfunction before and after priapism

Categories of ED	ED Before priapism		ED After Priapism	
	Frequency	Percent	Frequency	Percent
No ED	58	74.4%	0	0

Mild	11	14.1%	2	2.6%
Mild-moderate	8	10.3%	15	19.2
Moderate	0	0	15	19.2
Severe	1	1.3%	46	59.0%
Total	78	100%	78	100%

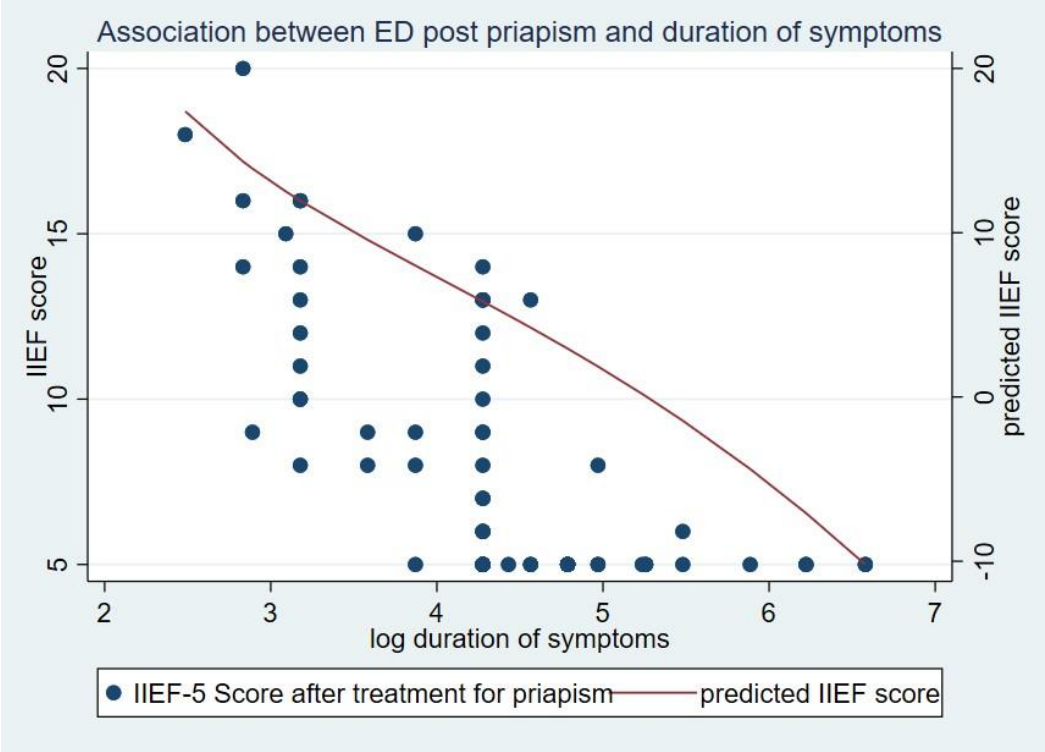
Figure 12: Bar graph showing comparison of ED before and After priapism



4.3 Duration of symptoms vs occurrence of ED

Duration of symptoms was inversely associated with the occurrence of ED, p value 0.001, spearman rho coefficient -0.7341. As duration of symptoms increases, the IIEF reduces. Patients who took longer to present to hospital, had worse ED scores (Figure 13).

Figure 13: Association between ED post priapism and duration of symptoms



4.4 Method of treatment as a risk factor

Objective 3: Association between management method used and development of Erectile dysfunction

From the table below, Aspiration method was not associated with occurrence of severe ED. Hence other methods were compared with aspiration to assess the risk of severe ED, aspiration was compared to other methods.

Table 6: Table showing association between treatment method and occurrence of Severe ED

Treatment method	**Severe ED**		**Total**
	No	**Yes**	

Burnett	0	2	2
Ebbehoj	3	2	5
T-shunt (Lue)	20	31	51
Aspiration	5	0	5
Conservative	1	1	2
Winter	3	10	13
Total	**32**	**46**	**78**

4.4.1 Comparison of aspiration vs assorted methods of treatment.

In the following table, risk of Ed in aspiration was compared to that of T shunt with a p value of 0.014**.**

Table 7: Comparison of severe ED in aspiration and other treatment methods

Treatment method	**Severe ED**		**Total**	**P value**
	No	**Yes**		
Aspiration	5	0	5	Reference
T shunt (Lue)	20	31	51	0.014
Winter	3	10	13	0.003
Burnett	0	2	2	0.048
Ebbehoj	3	2	5	0.44
Conservative	1	1	2	0.286

Thus, from the above tables, it is evident that various surgical procedures such as T shunt, Winter, Burnett were associated with ED. Aspiration was not associated with Erectile dysfunction.

4.4.2 Comparison of repeat shunting vs severe ED

Repeat shunting was significantly associated with occurrence of severe ED, p value 0.074

Table 8: Comparison of repeat shunting and occurrence of severe ED

Repeat shunting	**Severe ED**		**Total**
	No	**Yes**	
No	31	38	69
Yes	1	8	9
Total	32	46	56
Fishers exact p value 0.074			

CHAPTER FIVE

5.0 DISCUSSION

Priapism is a potentially painful medical condition with complete or incomplete erection that lasts for over 4 hours beyond stimulation of sex and orgasm or is not associated to sexual stimulation (3). There is paucity of data for erectile dysfunction among men presenting with priapism in Kenya and the East Africa region. Equally factors associated with and thought to contribute to ED in our set up have not been documented. This study aimed at providing data on the rate and factors contributing to erectile dysfunction in patients presenting with priapism, therefore help formulate policies and intervention measures aimed at reducing these rates.

Our study population included 78 adult male patients who underwent management for priapism. This was a change from our initial sample size of 80 patients interviewed with 2 being excluded for incomplete data. Evaluation for the development of erectile dysfunction and associated complications was established among the patients during the interview. The mean age of the study participants was 30.4 years ranging from 17 to 47 with an SD of 7.65.

Montague DK. *Et al,* scholarly on guideline on the management of priapism indicated the commonest form of priapism was ischaemic priapism which accounted for over 95% of all episodes of priapism. Similarly, to our study, Ischemic type of priapism was the most prevalent with 77 (98.7%) participants compared to 1 (1.3%) who had non-ischemic type. This is a concern as the normal sequelae of untreated ischaemic priapism has shown to be severe penile fibrosis resulting in penile deformity, loss of penile length and erectile dysfunction (4).

Priapism has been described as an important urologic emergency resulting to erectile dysfunction and greatly influenced by duration of symptoms (4). The results of our study indicated that duration of symptoms was inversely associated with the occurrence of ED, p value 0.001. As duration of symptoms increases, the IIEF reduces with patients who took longer to present to hospital, with a worse ED scores. Multiple studies have shown that the longer the duration of priapism, the worse the outcome. Ugwumba F.O et al found that the interval between onset of symptoms to presentation to a health facility ranged from 6 hours to 28 days with only 20% presenting within 12 hours (mean of 96 hours). ED occurred in 46.6% of these patients with 33.3% having severe ED unresponsive to PDE5 inhibitors. This prove that time interval between the onset of symptoms and presentation for medical intervention impacts on the outcome of management.

From our study the commonest causes of priapism were idiopathic (26.92%), Chronic myeloid leukemia (25.64%), Sickle cell disease (17.95%) and use of anti-psychotics at 14.10%. These results build on existing evidence and similar to studies by Dilip K et al (2016) in a prospective institutional study on outcome and erectile function following treatment of priapism that found out idiopathic causes were the highest at 26%. Patient populations with Sickle cell disease (SCD) have shown to be affected with greater frequency relative to the general population (17). Conversely, three different studies in Nigeria found Sickle Cell Disease, use of local aphrodisiac *(bura-ntashi)* and use of antipsychotic medications as the commonest causes of low flow priapism (17-19).

Priapism has been described as a genuine erectile dysfunction in which erection persists without any sexual stimulation (3). This study confirmed that the prevalence of erectile dysfunction is high among patients with priapism. The prevalence of ED after occurrence

of priapism was 100% as compared to 74.4% before priapism. However, ED occurred in varying categories after onset of priapism with majority having severe ED (59%). This high prevalence of erectile dysfunction among patients with priapism is in line with several studies (10,25).

The objective of management of all patients with priapism is to achieve detumescence as soon as possible and retain erectile function and this data would assist medical personnel in mitigating ED in such patients. Patients treatment and management for priapism should be prompt after diagnosis. Unfortunately, part of the treatment aimed at correcting priapism have the potential complication of erectile dysfunction. In our study, majority of participants underwent T shunt (Lue), 51 (65.4%), Winter, 13 (16.7%), Ebbehoj, 5 (6.4%), Aspiration, 5 (6.4%), Burnett, 2 (2.6%) and Conservative 2 (2.6%) as treatment methods. Distal shunts (cavernoglanular) were prioritized in treatment of patients. Phil HS. *et al,* indicated that the rate of success for distal shunts was 66-77% while for proximal shunt is 50% (6). However, if distal shunting procedures failed, proximal shunting procedures would be warranted.

This study established that aspiration was not associated with occurrence of severe erectile dysfunction as a method of treatment for priapism. Bivariate analysis was done to compare other methods with aspiration to assess the risk of severe ED, and it was evident that surgical procedure T shunt, Winter and Burnett were significantly associated with severe erectile dysfunction as compared to Ebbehoj and conservative methods. Dilip K. et al, reported that the rates of ED occurring were 81.9% and 80% for distal and proximal shunts respectively. Studies suggest that acute penile prosthesis implantation would be the best

treatment method post ED after priapism with 96% rate of satisfaction of patients (12). However, its majorly unavailable and out of reach for most of our patients.

It is worthwhile to note that the interpretation of these study findings had some limitation. Firstly, this was a cross-sectional study making it susceptible to selection bias, missing data and measurement errors that resulted to exclusion of some participants. The small sample size on this study also limited its wide applicability. Patients with priapism may not present to the hospital for financial reason and social stigmatization and this explained the small size of our data. Hence, a well-designed prospective study would establish the pattern of priapism occurrence and the associated complications of erectile dysfunction without a doubt.

5.1 CONCLUSION

In Kenya and our region, we have inadequate data regarding the incidence of priapism and erectile function outcomes following management for priapism. This study establishes there is a high burden of priapism and subsequent ED rates in the country. Associated risk factors are late presentation and use of T shunt, Winter and Burnett methods for treatment of ED after priapism.

It is therefore recommended that public health interventions measures are required to inform patients on need to recognize the problem among males and early referrals to appropriate treatment centers. Health care professional as well need to be informed on the appropriate management techniques that would mitigate occurrence of ED.

In Kenya, penile prosthesis which has more satisfactory outcomes in post priapism patients with ED is not readily available and is way out of reach for many Kenyans. This would

also inform the basis for development of protocols for advocating for availability of prosthesis at affordable cost.

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STUDY BUDGET AND BUDGET JUSTIFICATION

Particulars	**Details**	**Amount (Ksh)**
Submission to Ethics fee	1 doc. * Ksh. 2000	2,000
Stationery	20 pages/ patient * 100 patients * Ksh 10	20,000
Binding charges	20 manuscripts * 100 Ksh. / manuscript	2,000
Research Assistants 1 (file retrieval)	100 files * Ksh. 100/file	10,000
Research Assistants 2 (data collection and entry)	100 patients * Ksh. 500/file	50,000
Statistician		40,000
Contingencies		20,000
Fare for patients	80 patients * Ksh. 500	40, 000
Airtime		20,000
Total		**204,000**

Budget Justification

Research fee is based on the required figure for submission to ethics department

Stationery fee is based on cost of printing the questionnaires and informed consent which was as follows.

Cost per page printing Ksh 10 * 20 pages/ patient * 100 patients

= 20,000

Binding of document services = 20 manuscripts * Ksh. 100/manuscript

= 2000 Ksh.

Research assistants

Cost of file retrieval = 80 files * Ksh. 100/file = 8,000

Cost of data collection+ data entry = 80 files * Ksh. 500/file = 40,000

Statistical analysis

Cost of statistician = 40,000

patients fare

80 patients x Ksh 500 = 40,000

ANNEXES

Appendix 1: Informed Consent Form

Informed consent form for the study on 'Erectile Dysfunction Rates and Associated Factors due to Priapism in Adult Patients at The Kenyatta National Hospital.'

Name of Principal Investigator: Dr Patrick Muigai

Name of Organization: University of Nairobi.

Contact Details

1. Principal Investigator: Dr Patrick Muigai – 0725498090

2. Lead Supervisor: Professor Ndaguatha – 0722314533

3. KNH – UoN ERC - 0799495829

This informed consent form has two parts:

- Information sheet (to share information about the study with you)
- Certificate of consent (for a signature if you choose to participate)

Part I: Information Sheet

Introduction

I am… .....a medical doctor undertaking studies at the University of Nairobi, Department of Surgery, Urology Unit. I am conducting a study on 'Erectile Dysfunction Rates and Associated Factors due to Priapism in Adult Patients at The 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 is to identify the rate of erectile dysfunction and the factors contributing to erectile dysfunction in patients after management for priapism. The information gathered will assist the medical personnel in anticipating, managing and mitigating erectile dysfunction in such patients.

Type of Intervention

This study will involve your participation as an individual. It will take about 10 minutes over the phone and we will ask you questions pertaining to your erectile function before and after treatment for priapism.

Participant Selection

You are being invited to take part in this study having been treated for priapism not longer than ten years ago.

Voluntary Participation

Your participation in this study is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services, you receive during the follow up clinics at the KNH will continue and nothing will change.

Procedures

We are inviting you to take part in this research project. If you accept, you will be asked to respond to a few questions that the research assistant/I will administer to you. You will be asked a few questions by the research assistant or myself. If you do not wish to answer any of the questions included in the study, you may skip them and move on to the next question. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except our data analyst will have access to the data.

Duration

The data collection process for the study will only be taken once. However, if we have a follow up question we may give you another call.

Risks

In case in the course of the survey you feel uncomfortable talking about some issues, you are at liberty not to answer any question or take part in the discussion; that is also fine. You

do not have to give us any reason for not responding to any question, or for refusing to take part in the study.

Benefits

Your participation is likely to help us find out more about how to improve the management of priapism and reduce the rate of erectile dysfunction.

Reimbursements

You will not be provided with any incentive to take part in the study.

Confidentiality

The study will be conducted face to face from a private room. We will not be sharing information about you to anyone outside of the study team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key.

Sharing the Results

Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and the hospital where you attend the clinic before it is made widely available to the public. The results will be presented at the department of Surgery, University of Nairobi as part of the fulfilment of the master of Urology. Subsequently, the results will be published so that other interested people may learn from the study.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your access to the services offered at the K.N.H.

Who to Contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact the principal investigator on the following number: Dr Muigai on

0725498090 and KNH-ERC on 0799495829. This proposal has been reviewed and approved by the Kenyatta National Hospital – University of Nairobi Ethics Review Committee; the committees' task it is to make sure that research participants are protected from harm**.**

Part II: Certificate of Consent

I have been invited to participate in the study **Erectile Dysfunction Rates and Associated Factors due to Priapism in Adult Patients at The Kenyatta National Hospital'**. The foregoing information has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily verbally to be a participant in this study

Name of Participant_____

Signature of the participant _____

Date_____(Day/Month/Year)

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands. I 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 consent has been given freely and voluntarily.

Name of person taking the consent _____

Signature of the person taking the consent_____

Date_____(day/month/year)

Swahili Version of the Consent Form

Fomu za idhini kwa kujihusisha kwa utafiti kuhusu shida za uume zinazotokana na 'priapism'

Jina la mpelelezi mkuu: Dkt. Patrick Muigai

Jina la shirika: Chuo kikuu cha Nairobi

Jina la mdhamini: Hospitali kuu ya Kenyatta

Mawasiiano

1. Mpelelezi Mkuu: Dkt. Patrick Muigai – 0725498090

2. Msimamizi Mkuu: Profesa Ndaguatha – 0722314533

3. KNH – UoN ERC - 0799495829

Hii fomu ya idhini ina sehemu mbili:

- Karatasi ya habari (kueleza habari kuhusu utafiti nawe)
- Cheti cha idhini (saini iwapo unachagua kushiriki)

Sehemu ya kwanza. **Karatasi ya habari**.

Dibaji

Mimi ni Dkt Patrick Muigai, aliye mwanafunzi katika chuo kikuu cha Nairobi. Nitawapa maelezo na kuwaaalika kuhudhuria katika utafiti huu. Kabla ya kuamua, uko na uhuru wa kuulizia ufafanuzi zaidi kutoka kwa yeyote kwa starehe zako. Fomu hii ya idhini/ ridhaa huenda ikawa na maneno ambaye huyaelewi. Tafadhali niulize usipoelewa tunaavyopitia habari name ntachukua muda wangu kukueleza. Vilevile, kama una maswali baadae waezaniuliza mimi, ama wenzangu hapa.

Madhumuni/ nia ya utafiti

Ugonjwa huu sanasana husababisha madhara yanazofanya upotovu wa uume wako. Sehemu ambazo huadhiriwa kwa urahisi ni kama sehemu za uzazi za akina baba (penis); hizi sehemu za uzazi zinapodhuruwa, inaweza sababisha baba kuwa tasa. Kwa sababu hii, na ili tuweze kujua kiwango cha madhara haya kwa miili zenu, tungependa kupata mbinu za kuboresha huduma ambazo tunapeana. Tunaamini unaweza kutusaidia kwa kutuambia kile ujuacho kuhusu hali yako baada ya kutibiwa kwa ile shida ya priapism.

Aina ya kuingilia kati

Huu utafiti utahusisha ushiriki wako kibinafsi. Utachukua dakika ishirini tu.

Uchaguzi wa mshirika

Unaalikwa kushiriki katika huu utafiti kwasababu tunahisi kama wakuu wa wanachama nyumbani kuwa wawezachangia mengi kwa kuelewa kwetu na kujua mazoea ya afya mtaaani.

Ushiriki wa hiari

Ushirika wako katita utafiti huu ni kwa hiari yako mwenyewe. Ni chaguo lako kushiriki au kutoshiriki. Ukichagua kutoshiriki, huduma zote unazopokea kliniki ya mkononi zitaendelea, hakuna kitakachobadilika.

Utaratibu

A. Tutakuuliza utusaidie kujua zaidi kuhusu juu ya afya yako baada ya kupata tiba ya priapism. Tunakualika kujiunga na hi mpango huu wa utafiti. Ukikubali, utaulizwa kujibu maswali machache nitakayokuuliza.

B. Utajaza fomu ya utafiti ambayo nitapeana na tutasanya au waweza kujibu dodoso wewe mwenyewe, ama ukisomewa na unawezasema kwa sauti jibu unalotaka niandike chini. Kama hautaki kujibu swali lolotekatika utafiti,wawezaenda kwa swali jingine. Habari itakayopeanwa ni siri, jina lako halitanakiliwa kwa fomu, ni baaadhi tu ambao watakutambua na hakuna mwengine ila mkaguzi wa takwimu (data) atakayeafikia utafiti wako.

Hatari

Japo kwa katika utafiti hutahisi vizuri kuongelea swala Fulani, hautalazimishwa kujibu swali lolote au kujihusisha na majadiliano/mahojiano/utafiti kama huhisi kufanya vile na ni bora pia. Huna lawama ya kutupatia sababu ya kutojibu swali lolote lile, au kwa kukataa kujihusisha na utafiti.

Faida

Hakutakua na faida za moja kwa moja kwako wewe lakini kuhudhuria kwako huenda kukatusaidia kujua mengi kuhusiana na jinsi ya kuboresha kupeana huduma za afya katika jamii yako.

Kulipia

Hutapewa malipo ya na mna yoyote kuchangia utafiti.

Siri

Huu utafiti utakavyofanyika katika jamii huenda ikavutia watu na iwapo uutahudhuria,wawezaulizwa maswali na baadhi ya watu katika jamii. Hatutapeana habari kukuhusu nje ya kundi letu. Habari ambayo tutachukua kutokana na huu utafiti itaekwa kibinafsi. Habari yoyote kukuhusu itakuwa na nambari badala ya jina lako. Watafiti pekee ndio watakaojua nambari yako na haitafikiwa na yeyote tu.

Kugawana matokeo

Hakuna kile utakachotwambia kitajadiliwa na yeyote yule nje ya kundi hili la utafiti, na hakuna kitakachoidhinishwa jina lako. Ujumbe ambao tutapata kutokana na huu utafiti tutajadili nawe na jamii kabla iwe huru kwa watu wengine. Kila atakayeshiriki atapokea maelezo kiufupi ya majibu. Pia kutakua na mikutano ndogo katika jamii na hii itawasiliswha kutokana na mikutano, tutachapisha majibu ndiposa wengine walio na na hamu waweze kujifunza kutokana na utafiti.

Haki ya kukataa au kujitoa

Sio lazima ushiriki katika utafiti huu kama huna nia ya kufanya hivo, na kuchagua kutoshiriki haitadhuru kuopokea huduma zinazopeanwa katika kliniki za mkononi kwa njia yoyote ile.

Wa kuwasiliana nao

Ikiwa una swali lolote, unaweza ukauliza sasa hivi ama baadae. Kama una nia ya kuuliza baadae unawezawasiliana nasi kupitia wafwatao: Dkt. Patrick 0723500674 ama KNH-

UON ERC kwa nambari 0799495829 Hili pendekezo la utafiti limepitiwa na kukubaliwa na bodi ya chuo kikuu cha Nairobi pamoja na Hospital kuu ya Kenyatta; chanzo chao ni kuhakikisha kwamba washiriki wa utafiti wanalindwa kutokana na madhara.

Sehemu ya pili: Cheti cha idhini/ridhaa

Nimealikwa kushiriki katika utafiti kuhusu mambo yanayochangia upatikanaji wa huduma za afya. Nimepitia habari ifuatayo, ama nimesomewa. Nimekua na nafasi kuuliza maswali kuihusu na maswali yoyote ambayo nmeulizwa nimeyajibu kadri ya ufahamu na utoshelezi wangu. Ninaidhini kibinafsi kuwa mshirika katika stadi hii kwa njia ya simu.

Jina la uchapishaji la mshirika……

Saini ya mshirika ……

Tarehe ……

Wasilisho la mtafiti/mwenye kuchukua idhini.

Nimemsomea kitaratibu karatasi ya habari huyu mwenye uwezo wa kushiriki, na kwa kadri ya uwezo wangu nimehakikisha kwamba huyu mshirika ameelewa, Nathibitisha kuwa mshirika alipewa nafasi ya kuuliza maswali kuhusu utafiti huu, na maswali yote aliyouliza mshirika yamejibiwa kisawasawa na kwa kadri ya uwezo wangu. Nathibitisha kwamba huyu hajalazimishwa kupeana idhini na idhini imepeanwa bure na kwa kujitolea.

Jina la uchapisho la anayechukua idhini……..

Saini ya anayechukua idhini……..

Tarehe …….

Appendix 2: Study Questionnaire

Study Title: Erectile Dysfunction Rates and Associated Factors due to Priapism in Adult Patients at The 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)

1. Serial number…….
2. What is your age in years..... ?
3. What was your age when you were treated for priapism? _____
4. What is your highest attained level of education *(tick as appropriate)?*

Primary ☐

Secondary ☐

Tertiary (College/University) ☐

The IIEF -5 Questionnaire

Six months Prior to diagnosis of priapism (*circle as appropriate)*

1. How do you rate your confidence that you could get and keep an erection?	Very low 1	Low 2	Moderate 3	High 4	Very high 5
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5

3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated your partner?	Almost never of never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	Extremely difficult 1	Very difficult 2	Difficult 3	Slightly difficult 4	Not difficult 5
5. When you attempted sexual intercourse, how often was it satisfactory for you?	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5

Total Score: _____

1-7: Severe ED 8-11: Moderate ED 12-16: Mild-moderate ED
17-21: Mild ED 22-25: No ED

Six Months after Treatment for Priapism *(circle as appropriate)*

1. How do you rate your confidence that you could get and keep an erection?	Very low 1	Low 2	Moderate 3	High 4	Very high 5
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5
3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated your partner?	Almost never of never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult

	1	2	3	4	5
5. When you attempted sexual intercourse, how often was it satisfactory for you?	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
	1	2	3	4	5

Total Score: _____

1-7: Severe ED 8-11: Moderate ED 12-16: Mild-moderate ED 17-21: Mild ED 22-25: No ED

Section II: Information to be extracted from the file (*tick as appropriate)*

1. Date of admission____

2. Duration of symptoms prior to presentation at KNH in hours

- <24 hours
- 24 – 48 hours
- 48 – 72 hours
- 72 – 96 hours
- Over 96 hours

3. Management prior to admission at KNH

- Therapeutic Aspiration +/- irrigation
- Surgical shunting

4. Type of priapism

- Ischemic
- Non ischemic
- stuttering

5. Management at KNH

- Therapeutic Aspiration +/- irrigation
- Shunting

6. Type of shunting

- Proximal Shunting
- Distal shunting

7. Distal corpora-glanular shunts

- Winter
- Ebbehoj
- T-shunt (Lue)
- Al-Ghorab
- Burnett

8. Proximal Shunts

- Quackels

- Sacher
- Grayhack
- Barry

7.(i) Repeat shunting

- Yes
- No

(ii) If yes to (i) above which method was used? _____

8. what was the final identifiable cause of the priapism?

- Sickle cell disease
- Chronic myeloid leukemia
- Psychiatric disorders
- Medications (name the medication)
- Drugs of abuse (name the drug)
- Others (specify the cause)

9. Comorbidities

- Diabetes Mellitus Yes / NO
- Hypertension Yes / NO
-
- Others (specify) Yes / NO
-

10. Others

- History of smoking Yes / NO
- History of alcoholism yes / NO

KIAMBATISHO CHA PILI: DURUSU HOJAJI HII

MADA: Ukadiriaji wa Ugonjwa wa Kutosimika na Hali iletayo Usimikaji wa muda mrefu miongoni mwa wagonjwa katika hospitali ya Kenyatta

Tarehe…….

Saa…….

Sehemu ya 1: (***Itaendeshwa na mtafiti. Atawapa wahusika watakaotoa majibu kwenye hojaji hii. Tafadhali weka alama ifaavyo kwenye kijisanduku)***

Nambari ya siri…….

1. Umri wako… .....?
2. Ulikuwa na umri wa miaka mingapi ulipoanza kutibiwa ugonjwa wa usimikaji wa muda mrefu? _____
3. Kiwango cha masomo *(Weka alama ifaayo)*

Shule ya Msingi ☐

Sekondari ☐

Chuoni ☐

IIEF -5 Hojaji

MIEZI SITA KABLA YA KUANZA MATIBABU YA KUTOSIMIKA

(*Tumia mduara kujibu)*

1. Unakadira vipi uwezo wako wa kupata usimikaji na kuweza	**Chini zaidi**	**Chini**	**Kadri**	**Juu**	**Juu Zaidi**

kuendeleza kusimika?					
	1	2	3	4	5

2. Unaposisimua mwili wako kupitia kunyegezwa mathalani unapoguzwa sehemu zako za siri, uwezo wako wa usimikaji huwa vipi kabla ya kujamiana?	Uwezo haupo	Uwezo huwepo kiasi mathalani chini ya nusu ya muda wa kujamiana	Uwezo huwepo mathalani nusu ya muda wa kujamiana	Uwezo huwepo mathalani zaidi ya nusu ya muda wa kujamiana	Uwezo huwepo sana wakati wote
	1	2	3	4	5

3. Wewe huwa una uwezo gani wa kusimika wakati wa kufanya mapenzi?	Uwezo haupo	Uwezo huwepo kiasi mathalani chini ya nusu ya muda wa kujamiana	Uwezo huwepo mathalani nusu ya muda wa kujamiana	Uwezo huwepo mathalani zaidi ya nusu ya muda wa kujamiana	Uwezo huwepo sana wakati wote

	1	2	3	4	5

4. Wakati unapofanya mapenzi, unakumbana na changamoto kuendeleza usimikaji?	Nina tatizika sana	Nina ugumu sana	Nina Ugumu	Nina Ugumu kiasi	Sitatiziki hata!
	1	2	3	4	5

5. Ulipojihusisha katika kitendo cha ngono, uliridhika vipi?	Hata sikuridhika	Niliridhika kiasi mathalani chini ya nusu ya	Niliridhika wakati mwingine mathalani nusu ya	Niliridhika sana mathalani zaidi ya nusu ya	Niliridhika kila wakati

		muda wa kujamiana	muda wa kujamiana	muda wa kujamiana	
	1	2	3	4	5

ALAMA

1-7: UGONJWA WA KUTOSIMIKA UPO JUU

8-11: UGONJWA WA KUTOSIMIKA NI WA KIWANGO CHA KADRI YA JUU

12-16: UGONJWA WA KUTOSIMIKA NI WA KADRI KIASI

17-21: UGONJWA WA KUTOSIMIKA NI WA KADRI

22-25: UGONJWA WA KUTOSIMIKA HAUPO

MIEZI SITA BAADA YA MATIBABU YA KUTOSIMIKA (*Tumia mduara kujibu*)

1. Unakadira vipi uwezo wako wa kupata usimikaji na kuweza kuendeleza kusimika?	Chini zaidi	Chini	Kadri	Juu	Juu Zaidi
	1	2	3	4	5

2. Unaposisimua mwili wako kupitia kunyegezwa mathalani unapoguzwa sehemu zako za siri, uwezo wako wa usimikaji huwa vipi kabla ya kujamiana?	Uwezo haupo	Uwezo huwepo kiasi mathalani chini ya nusu ya muda wa kujamiana	Uwezo huwepo mathalani nusu ya muda wa kujamiana	Uwezo huwepo mathalani zaidi ya nusu ya muda wa kujamiana	Uwezo huwepo sana wakati wote
	1	2	3	4	5

3. Wewe huwa una uwezo gani wa kusimika wakati wa	Uwezo haupo	Uwezo huwepo kiasi mathalani chini ya nusu ya	Uwezo huwepo mathalani nusu ya	Uwezo huwepo mathalani zaidi ya nusu	Uwezo huwepo sana wakati wote

kufanya mapenzi?		muda wa kujamiana	muda wa kujamiana	ya muda wa kujamiana	
	1	2	3	4	5

4. Wakati unapofanya mapenzi, unakumbana na changamoto kuendeleza usimikaji?	Nina tatizika sana	Nina ugumu sana	Nina Ugumu	Nina Ugumu kiasi	Sitatiziki hata!
	1	2	3	4	5

5. Ulipojihusisha katika kitendo cha ngono, uliridhika vipi?	Hata sikuridhika	Niliridhika kiasi mathalani chini ya nusu ya muda wa kujamiana	Niliridhika wakati mwingine mathalani nusu ya muda wa kujamiana	Niliridhika sana mathalani zaidi ya nusu ya muda wa kujamiana	Niliridhika kila wakati

	1	2	3	4	5

ALAMA

1-7: UGONJWA WA KUTOSIMIKA UPO JUU

8-11: UGONJWA WA KUTOSIMIKA NI KIWANGO CHA KADRI YA JUU

12-16: UGONJWA WA KUTOSIMIKA NI WA KADRI KIASI

17-21: UGONJWA WA KUTOSIMIKA NI WA KADRI

22-25: UGONJWA WA KUTOSIMIKA HAUPO