TO ASSESS UROLOGICAL COMPLICATIONS OF TRANSRECTAL PROSTATE BIOPSY IN KENYATTA NATIONAL HOSPITAL

A DISSERTATION SUBMITTED AS PART FULFILMENT OF THE REQUIREMENTS OF THE UNIVERSITY OF NAIROBI FOR AWARD OF THE DEGREE OF MASTER OF MEDICINE (MMed) IN GENERAL SURGERY.

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DECLARATION

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

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DEPARTMENTAL APPROVAL

This Dissertation has been presented at the Department of Surgery meeting and is hereby approved for presentation to the Kenyatta National Hospital Ethics and Research Committee.

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Special thanks to colleagues in surgery for assistance in data collection and to all patients who voluntarily participated in this study.

Finally, I thank God for the strength that He has given me to complete this study.

DEDICATION

This dissertation is dedicated to my wife Elena and my daughter Milana who have provided the support, love and encouragement to complete this journey.

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To my father Harrison and my late mother Mary who believed in me before I believed in myself.

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LIST OF ABBREVIATIONS

AUA	American Urological Association
BPE	Benign Prostatic Enlargement
EUA	European Association of Urology
DRE	Digital Rectal Examination
IPSS	International Prostate Symptom Score
KNH	Kenyatta National Hospital
PCa	Prostate Cancer
PSA	Prostate-specific Antigen
SHO	Senior House Officer
SIRS	Systemic Inflammatory Response Syndrome
SPSS	Statistical Package for Social Sciences
TRUS	Trans-Rectal Ultra-Sound
UON	University of Nairobi

ABSTRACT

BACKGROUND

The definative diagnosis of prostate cancer is histopatholological proof of neoplastic changes in prostate biopsies. TRUS(Transrectal Ultrasound) guided prostate biopsy is the recommended mode of diagnosis, however in our set up finger guided biopsy remains the most common modality used. Prostate biopsy is a minimally invasive procedure, that is generally performed as an outpatient procedure. The operative complications vary from minor to life threatening, which include infection, bleeding, and urinary retention. Therefore the aim of this study was to assess the complications among patients who underwent transrectal prostate biopsy at Kenyatta National Hospital, and thus form a basis for prophylaxis and treatment.

OBJECTIVE

To assess complications among patients undergoing transrectal prostate biopsy at Kenyatta National Hospital.

STUDY DESIGN

A cross sectional study

SETTING

Kenyatta National Hospital, Minor Theatre and Radiology Department.

PATIENTS AND METHODS

The study was conducted between June 2016 and May 2017, it involved 72 patients with suspected prostate cancer undergoing transrectal prostate biopsy at Kenyatta National Hospital who met the inclusion criteria and gave informed consent . Sample size was achieved by non randomized consecutive sampling.

Patients were followed up postoperatively from day 0 to 14. The presence of the following complications were assessed; infection, bleeding and urinary retention.

RESULTS AND ANALYSIS

Seventy-two patients were recruited into the study. The mean age of males undergoing transrectal prostate biopsy was 71.8 years with a range of 47 to 94 years. Out of the 72 participants, 43 (59.7%) were aged 70 years and above. There were 13 patients with comorbid conditions; hypertension 8 (11.1%) and diabetes 5 (6.9%). The overall rate of transrectal prostate biopsy complications was 62.5 with 32 patients reporting at least one of the complications associated with the procedure. Complications included: haematochezia (31.9%), Urinary tract infection (UTI) (15.3%), orchitis(2.8) and haematuria (12.5%). There were no cases of haematospermia, or urine retention following the procedure. All the complications were self limiting and patients were followed up in the outpatient clinic. All patients made a full recovery within a period of 2 weeks and non required hospital admission.

Data collected was entered and analyzed using Statistical Package for Social Sciences (SPSS) for Windows Version 21. P values were generated using t test for means and x^2 for comparison of proportions. Results were presented in tables, charts and graphs

CONCLUSION,

The results of our study indicated that transrectal prostate biopsy is associated with 62.5% minor complications. Despite the complications, transrectal prostate needle biopsy is a feasible and effective tool in male patients with suspected prostate cancer and can be performed safely in outpatient or office setting. The size of prostate, number of cores, IPSS score, exposure to antibiotics and patient demographics are not risk factors for post-biopsy complications

INTRODUCTION

Prostate cancer (PCa) is Kenya's second commonest male cancer with an incidence of 15.2 per 100,000 and mortality rate of 12.2 per 100,000[1] .Prostate specific antigen (PSA) test and digital rectal examination are used for screening of prostate cancer, however the diagnosis relies on histopathological proof of neoplastic tissue in prostate biopsies. Transrectal ultrasound (TRUS) guided prostate biopsy remains the gold standard for the diagnosis of prostate cancer[2] . At Kenyatta National Hospital, finger guided prostate biopsy remains the most common technique for prostate biopsy. Prostate biopsy is a minimally invasive procedure, as its considered safe and therefore performed as an outpatient procedure

Prostate biopsy complications are mild and self limiting, however life threatening complications do occur. The most common post procedural complications include infection, bleeding and urinary retention[3] . Infection related complications include asymptomatic bacteriuria, UTI(urinary tract infection), epididymo-orchitis and urosepsis[4]. Rates of infection related complications after prostate biopsy have increased in recent years (from 1% to 4%) owing to increased prevalence of fluoroquinolone-resistant pathogens in the rectal flora. In this regard , targeted prophyalaxis after rectal flora swabbing has been shown to be efficacious compared to empirical antibiotic prophylaxis [5].

Bleeding related complications associated with prostate biopsy include hematuria, hematospermia and hematochezia. Hematospermia is the most common at (6.5% to 74.4% of cases), followed by hematuria (up to 14.5% of cases) and hematochezia (2.2% cases)[6].

There is no local data on complications of prostate biopsy. The aim of this study was to determine the prevalence, risk factors and outcome of prostate biopsy complications at KNH. Prostate biopsy being an invasive procedure, patient must receive extensive counseling and informed consent regarding the risks and benefits of this procedure. This study will guide the clinician in objectively taking informed consent and form a basis for prophylaxis and treatment of post biopsy complications.

LITERATURE REVIEW

The development of modern prostate biopsy methods dates back to 1922 when Barringer performed transperineal needle biopsy. Astraldi is credited with carrying out the first transrectal prostate biopsy in 1937.This approach offered more promise of diagnostic accuracy when sampling a prostatic nodule compared with perineal needle biopsy. The TRUS-guided biopsy was described in mid 1980s following the developments in probe technology and biopsy apparatus. TRUS allowed delineation of the prostatic architecture and improved sampling of the prostatic nodule[7].

TRUS-guided biopsy is the standard of care, however finger directed prostate biopsy remains the common method used in resource limited setting. Indications for prostate biopsy are based on suspicious digital rectal exam (DRE) findings and elevated prostate specific antigen (PSA) levels in blood.

According to EUA guidelines 2015 sample sites should be bilateral from apex to base as far posterior and lateral as possible in the peripheral gland. Additional cores are taken from suspected areas by DRE or TRUS. Multiple sampling schemes have been developed in an effort to improve the accuracy of prostate biopsy in the detection of cancer. Six core (sextant biopsy) was the commonly employed sampling technique. However, this method misses about 30% of clinically significant cancers. Because of these error, sextant biopsy has been largely replaced by extended core biopsy. This technique involves obtaining five to seven evenly-distributed specimens from each side. Increasing the number of cores were significantly associated with increased detection of prostate cancer. Another sampling technique that has been described is saturation biopsy which involves extensive sampling of the prostate, obtaining up to 24 core samples. Saturation techniques do not provide increased cancer detection when utilized for first-time biopsy, and is reserved for repeat biopsies[6].

Prostate biopsy is associated with a number of potential complications, both psychological and physical. Bleeding, infection and urine retention have been documented as the possible physical complications.

The rate of complications is difficult to determine as the literature demonstrates significant variability in reported complication. Shittu et al, reviewed 230 patients after transrectal prostate biopsy and noted 26% overall complications, 5.2% of these were hematuria, 10.8 were fever, 5.2 % were urinary tract infection and 0.4% were rectovesical fistula[8]. Sheng-Hui

et al found overall complications of 9.6%. Gross hematuria was present in 4.1%,acute urinary retention 1.7%, UTI 1.4%, hematospermia 1.1%, 0.9% rectal bleeding and anal pain 0.5%[9]. Elabbady et al determined the morbidity and patient tolerance of TRUS-guided biopsy and found that 56.6% of patients did not experience discomfort, while some had mild pain during the procedure. Hematuria was the commonest complication (59.9%) followed by rectal bleeding and hematospermia which occurred in 36.7% and 17.4% of the patients respectively. One major complication was reported, a prostatic abscess which resulted in a temporary urethra-rectal fistula[10]. Complications related to trans-rectal prostate biopsy seem to vary as shown by the studies discussed.

COMPLICATIONS

BLEEDING

Post biopsy bleeding complications include rectal bleeding, hematospermia and hematuria. Enlund et al, reviewed 415 men, and showed 22% had immediate postbiopsy hematochezia, which reduced to 3% at day 3 and 0.5% continued to have hematochezia at day 7, none of the patients required hospital admission or transfusion[11]. Abdelkhalek et al reviewed 42 patients and noted 45% of patients had hematospermia on the 1st week, 20% on the 2nd week, 12.5% on the 3rd week and 2.5% on the 4th week[12].

Berger et al, found no difference in complication rates in relation to the number of cores obtained [2] . Raaijmaker et al, showed a correlation between the volume of prostate and post procedural bleeding, large prostate volume was associated with an increased risk of minor bleeding[13]. There are no clear cut recommendations for anticoagulation during prostate biopsy. Some studies suggested an increase in bleeding duration[14]. Meta-analyses conducted did not show an increase in the risk for severe bleeding, however there was increased risk of minor bleeding, aspirin dosage was not addressed in the meta-analyses[15]. Based on the results of a prospective randomized trial conducted by Giannarini et al, low dose aspirin is no longer an absolute contraindication to prostate biopsy however there is paucity of data on use of warfarin or clopidogrel during prostate biopsy[16].

Management of post biopsy bleeding depends on the severity; severe bleeding may be managed initially by bed rest, fluid resuscitation and blood transfusion. If the initial management fail, options of management include rectal tamponade with an inflated condom,

colonoscopy with injection of epinephrine, angiography with embolization, exploration and suturing[17] .

INFECTION

Transrectal prostate biopsy is the most common modality used for prostate biopsy, it's associated with significant risk of rectal bacteria inoculation into the urinary tract. The infection related complications include: Asymptomatic bacteriuria, fever, symptomatic urinary tract infections (UTIs) and bacteremia [18]. Introduction of rectal bacteria into the bloodstream (bacteremia) may progress to sepsis.

According to EAU guidelines quinolones are the drugs of choice in post biopsy prophylaxis. Increased quinolone resistance is associated with a rise in severe post biopsy infection, resistance is attributed to; fluoroquinolones overuse, under dosage and use in livestock and veterinary practice may lead to development of resistance[20]. Patients with exposure to antimicrobials within 6 months prior to biopsy and hospital workers are at higher risk of development of post biopsy infectious complications[21]. There is no association between the number of core biopsies and infectious complications[2]. Various methods of rectal preparation have been described, povidine-iodine enemas and use of biscodyl suppository the night before the procedure. A Cochrane review comparing antibiotic alone versus antibiotic plus enema and single dose versus multiple dose of quinolone concluded that there is no significant difference in infection rate between the two groups [22].

A study by Griffith et al, to determine the concentrations of levofloxacin in prostate fragments obtained by transurethral resection concluded that concentrations were adequate for an effective treatment for the common pathogens, demonstrating the excellent bioavailability of the drug. They also demonstrated the peak concentration of levofloxacin (500mg) was achieved within the first hour of intravenous administration and 30 to 60 minutes after oral administration[23]

Post procedural infectious complications can be reduced by preoperative evaluation of potential risk factors for infection, such as untreated bacteriuria, a history of recent urogenital infection, bladder stones , and an indwelling urinary catheter[5]. Infections are mostly associated with Gram-negative enterobacteria, especially E.coli, however anaerobic bacteria and enterococci have been identified in some studies[24].

From the foregoing discussion, it's evident that initial appropriate use of prophylactic antibiotics is key to preventing post biopsy complications. Patients must be counseled and

advised to seek medical attention if they experience fever, lethargy, difficulty voiding, testicular swelling or dysuria. Patients with signs and symptoms of sepsis should be immediately initiated on broad spectrum antibiotics and intravenous fluid hydration. Those with history of use of fluoroquinolones prior to biopsy are at increased risk of resistance leading to postbiopsy infection, in this situation empirical antibiotic treatment should exclude a fluoroquinolone[24]. Alternative antibiotics should be used in empirical treatment, Carbapenems has showed minimal resistance and third generation cephalosporins maintains good sensitivity as well[25].

ACUTE URINARY RETENTION

Acute urinary retention is the sudden and painful inability to void despite having a full bladder. Post biopsy urinary retention can be caused by infection or prostatic inflammation. Trauma of the prostate during biopsy or infective process results in swelling of the acutely inflamed gland causing urinary retention[26]. The most common cause of infectious acute urinary retention is acute prostatitis caused by gram-negative organisms, such as Escherichia coli and Proteus species[27]. Risk factors associated with development of urine retention include; large prostate volume, high post void residual volume and a higher international prostate symptom score[13].

Acute urinary retention is a surgical emergency and should be managed by immediate and complete decompression of the bladder through catheterization. Most patients presents within the first 24 hours after the prostate biopsy[26]. Standard urethral catheters are usually inserted, if urethral catheterization is unsuccessful or contraindicated a suprapubic catheter is inserted. Studies have shown that patients treated with alpha-adrenergic blockers (alfuzosin, tamsulosin) for three days starting at the time of catheter insertion have a greater chance of a successful voiding trial without a catheter at two to three days.[28]

STUDY JUSTIFICATION

Prostate biopsy is one of the common urological procedures performed worldwide. Studies conducted in various geographical regions have demonstrated significant variability in overall and specific (bleeding, infection, urine retention) complication rates [9,10,11] . Thus, studies conducted in other parts of the world may not directly translate to our local set up.

In Kenya, there is paucity of data on the prostate biopsy complications, risk factors and their management outcome. The results will help clinicians in predicting patients that are at high risk of post biopsy complication and offer them appropriate prophylaxis and treatment. The data will also help clinicians when taking informed consent from patients undergoing prostate biopsy.

OBJECTIVES

MAIN OBJECTIVE

To assess complications among patients undergoing transrectal prostate biopsy in Kenyatta National Hospital.

SPECIFIC OBJECTIVES

1. To determine the incidence of bleeding, infection and urine retention following prostate biopsy.
2. To determine risk factors associated with prostate post biopsy complications.
3. To determine the outcome of post biopsy complications.

METHODOLOGY

Setting:

The study was carried out in the Urology Clinics conducted by the three urology firms (I,II & III), radiology department Ultrasound room and minor theatre at KNH.

Study population:

The study involved male patients undergoing transrectal prostate biopsy at KNH.

Duration of the Study

1 Year

Study Design: A Cross sectional Study

Sampling Method and Sample size Determination:

Selection was nonrandomized consecutive sampling of eligible patients until the desired sample size was achieved.

The sample size was calculated using formula for cross sectional study[29].

$$n = \frac{NZ^2P(1-P)}{d^2(N-1)+Z^2P(1-P)}$$

n = sample size with finite population correction

Z= standard deviation for the 95th percentile confidence interval 1.96

P= prevalence 26% (overall complications of study done in Nigeria[8])

d= degree of accuracy expressed as a proportion (0.05).

N= Population size 96[30]. Patients undergoing trucut prostate biopsy within 6 months.

$$n = \frac{96*1.96^{2*}0.26(1-0.26)}{0.05^2*(96-1)+1.96^2*0.26(1-0.26)}$$

n = 72

Inclusion Criteria

Patients undergoing prostate biopsy for suspected prostate cancer by digital rectal exam and with elevated PSA were recruited into the study. Only those patients who gave informed consent were included in the study.

Exclusion Criteria

1. Presence of urinary tract infection (patients were treated before the procedure).
2. Patients with bleeding disorders.

Patient Selection

Selection of patient was conducted at the KNH urology outpatient clinics, radiology department and minor theatre. Patients who were seen at Urology clinic and scheduled for prostate biopsy were informed about the research. All patients who met inclusion criteria and voluntarily signed informed consent were recruited into the research.

Patients and Methods:

Consenting male patients with raised PSA and DRE findings suggestive of prostate cancer who had been seen at urology clinic and scheduled for prostate biopsy were recruited. The procedure was conducted in KNH minor theatre and radiology department, by senior house officer or Consultant on call. The patients were counseled and an informed consent was given to undergo the procedure and to participate in the study. Patient were positioned in left lateral position, cleaned and draped. Xylocaine gel was instilled into the rectum and a DRE performed prior to the biopsy. The biopsy was performed using automatic trucut biopsy gun needle 16Ga or 18 Ga. Patients were commenced on prophylactic antibiotics and analgesics Post-biopsy. 3 types of antibiotics were prescribed; ciprofloxacin, levofloxacin and zinnat. The patients were followed up post biopsy from day 0 to 14. All patients were given the principal researcher's phone number for consultation in case of complications. Principal researcher reviewed the patients by phone call within the first 48hours post biopsy. Patients with complains post-biopsy were scheduled for immediate review at our facility. History, clinical examinations and laboratory investigations were performed on symptomatic patients. Patients with no complains were reviewed one week post biopsy in Urology outpatient clinic.

Data Collection

Data was collected using a standard questionnaire administered by the principal researcher and a trained assistant before and after the procedure. Trained assistant was a doctor with qualification of bachelor's degree in medicine.

Patient demographics, clinical findings, laboratory reports, duration and type of symptoms were obtained from both patient and medical records/files. Patients were followed up by phone calls or visits to the clinic for a period of two weeks. Questionnaires were filled in

during phone calls or visits. The questionnaires were checked for completeness and stored securely. Confidentiality was maintained throughout.

Data 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 were expressed as mean, median and mode, while categorical data such as types of complications were expressed as numbers and percentages of the population. At the end of data entry, data was cleaned, verified and entered into MS Excel data sheet and analyzed using Statistical Package for Social Sciences (SPSS) for Windows Version 21. P values were generated using t test for means and x^2 for comparison of proportions. Results were presented in tables, charts and graphs

Ethical Consideration

Ethical approval was sought from the University of Nairobi, Department of Surgery and the KNH Ethics and Research Committee. A pre-consent counseling of the participants was carried out, and then an informed consent obtained from each of the participant prior to enrolment in the study. The guardian /next of kin was required to sign consent on behalf of the participants who could not do so due to their condition. Those who declined participation were not coerced to participate. There was no extra cost incurred for participating in the study. All data was recorded in MS Excel data sheets that were saved under password protection only accessed by the principal researcher and the assistant, confidentiality was maintained throughout.

Patients' hospital file number was included into the data sheet to facilitate easy tracing and capture missed information during data collection.

Any hard copy research data was kept in a safe locked cabinet only accessed by the research team. The raw data collected was destroyed after completion of this study.

RESULTS

Sample characteristics

Seventy-two patients were recruited into the study. The mean age of males undergoing transrectal prostate biopsy was 71.8 years (SD ± 9.1), range 47 to 94 years. Out of the 72 participants, 43 (59.7%) were aged 70 years and above (Table 1). Most 56 (77.8%) of the patients were unemployed, while 16(22.2%) were employed or involved in business or farming.

One-half 36 (50%) of the patients resided in Nairobi county and the remainder were referrals from other counties. There were 13 patients with comorbid conditions including hypertension 8 (11.1%) and diabetes 5 (6.9%).

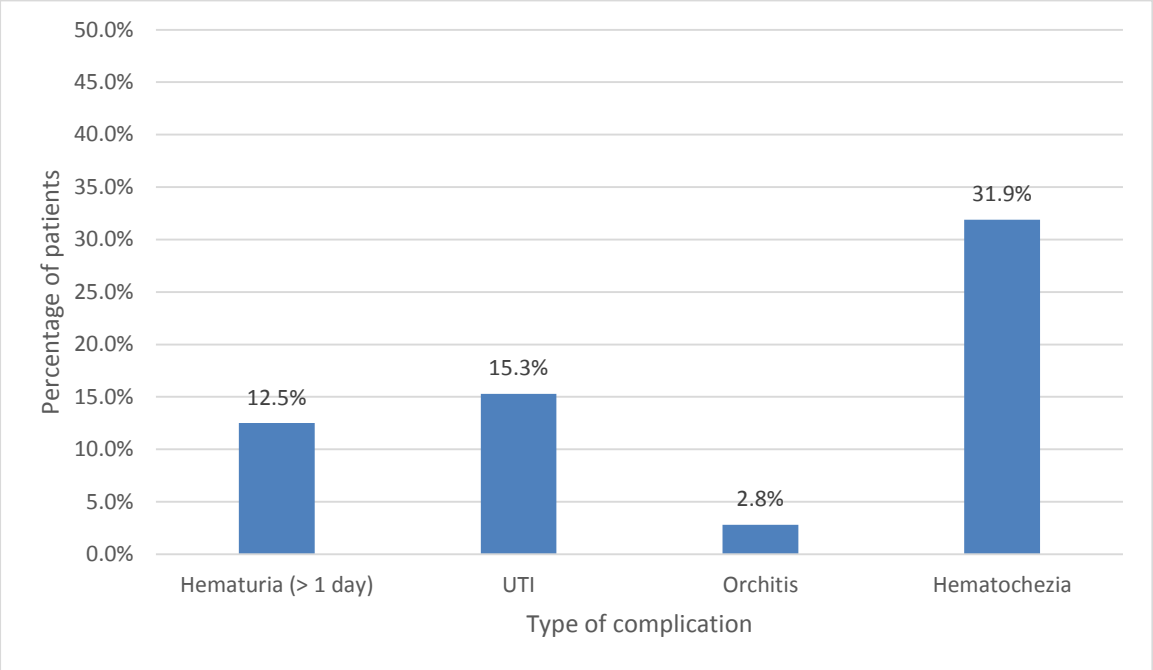
Table 1: Demographic characteristics of patients undergoing trans rectal prostate biopsy in KNH

Variable		**N**	**%**
Age	< 70 years	29	40.3
	> 70 years	43	59.7
Occupation	Unemployed	56	77.8
	Farmer	12	16.7
	Businessman	2	2.8
	Security Guard	2	2.8
Residence	Nairobi	36	50
	Other counties	36	50
Comorbidities	Hypertension	8	11.1
	Diabetes	5	6.9

Complications of transrectal prostate biopsy

The overall rate of transrectal prostate biopsy complications was 62.5% with 32 patients reporting at least one of the complications associated with the procedure. Figure 1 shows the complications that included: haematochezia (31.9%) UTI (15.3%) and haematuria (12.5%). There were no cases of haematospermia, or urine retention following the procedure.

Figure 1: Complications of transrectal prostate biopsy in patients at KNH



Patient age and transrectal prostate biopsy complications

There was no significant association between age and complications associated with transrectal prostate biopsy (Table 2). Haematuria occurred in 13.8% of patients under 70 years and 11.6% of those above 70 years ($p = 0.785$). The frequency of haematochezia was 27.6% and 34.9% in patient below and above 70 years, respectively ($p = 0.515$) and infection occurred in 20.7 and 16.3% of patients in the two age groups ($p = 0.633$).

Table 2: Age and occurrence of transrectal prostate biopsy complications

	Age			
Complication	**< 70 years**	**> 70 years**	**Chi (χ)**	**P value**
Haematuria				
No haematuria	25(86.2)	38(88.4)	0.1	0.785
Haematuria Present	4(13.8)	5(11.6)		
Haematochezia				
No haematochezia	21(72.4)	28(65.1)	0.4	0.515
Haematochezia present	8(27.6)	15(34.9)		
Infection				
No infection	23(79.3)	36(83.7)	0.2	0.633
Infection present	6(20.7)	7(16.3)		

Prostate size and transrectal prostate biopsy complications

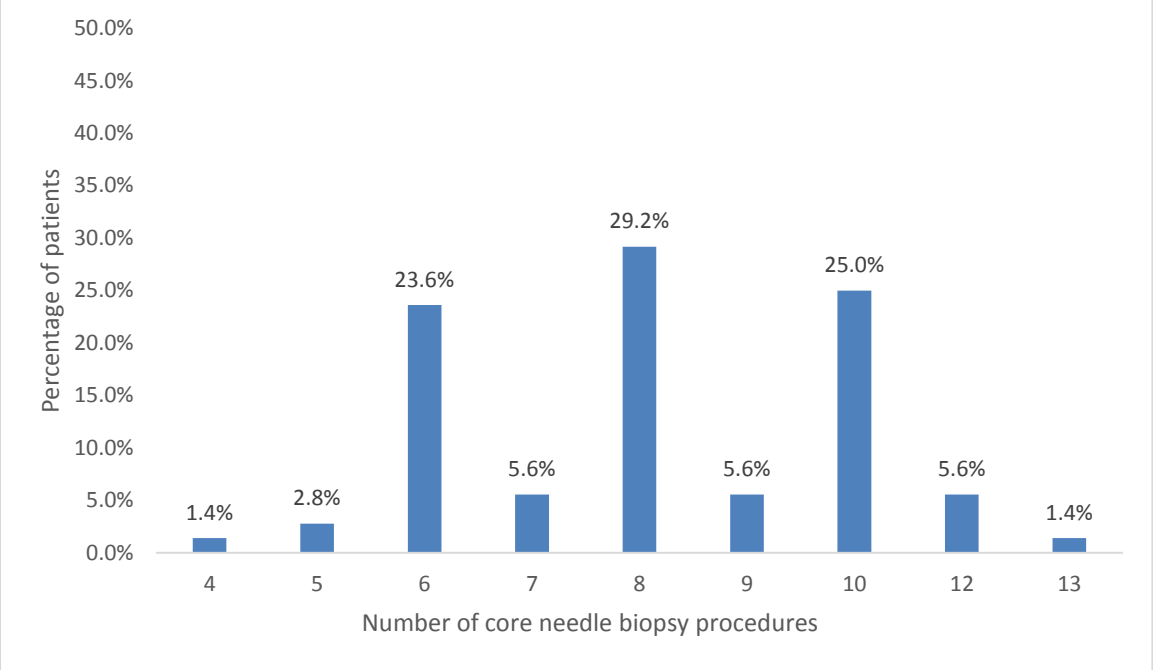
The mean prostate volume was 88.6 (SD ± 47.2) ml, and ranged between 27 and 245 ml. Table 3 shows the association between mean prostate volume and transrectal prostate biopsy complications. There was no significant association between prostate volume and haematuria (p = 0.13), haematochezia (p = 0.086) or infection (p = 0.144).

Table 3: Prostate size and transrectal prostate biopsy complications

		Mean (SD)	Difference (95% CI)	P
Haematuria	Yes	75.1(±21.9)	15.8(-4.0-35.7)	0.13
	No	90.9(±50.1)		
Haematochezia	Yes	76.3(±28.1)	18.4(-2.2-39.1)	0.086
	No	94.7(±53.6)		
Infection	Yes	73.4(±28.2)	17.8(-5.0-40.7)	0.144
	No	91.2(±49.5)		

Core needle biopsy procedures and transrectal prostate biopsy complications

The number of core needle biopsy procedures conducted per patient ranged between 3 and 13 with 29.2% of patients undergoing eight procedures, and 25% and 23.6% undergoing ten and six procedures, respectively (Figure 2).



The number of core needle biopsies performed did not show significant association with transrectal prosate biopsy complications (Table 4). Haematuria complication rate was 10% and 13.5% in patients who had less than 6 procedures and those with more than six procedures, respectively ($p = 0.691$). Haematochezia occurred in 35% and 30.8% of patients undergoing less than 6 procedures and more than 6 procedures, respectively ($p = 0.73$). Infection developed in 15% of patients who had < 6 core needle biopsies and 19.2% of those with > 6 procedures.

Table 4: Number of core needle biopsy and transrectal prostate biopsy complications

	Number of cores performed			
Complication	**< 6 cores**	**> 6 cores**	**Chi (χ)**	**P value**
Haematuria				
No haematuria	18(90.0)	45(86.5)	0.2	0.691
Haematuria Present	2(10.0)	7(13.5)		
Haematochezia				
No haematochezia	13(65.0)	36(69.2)	0.1	0.73
Haematochezia present	7(35.0)	16(30.8)		
Infection				
No infection	17(85.0)	42(80.8)	0.2	0.676
Infection present	3(15.0)	10(19.2)		

IPSS score

The IPPS score in patients undergoing transrectal prostate biopsy ranged from 4 to 34 with a median IPSS score of 20 (interquartile range 15.5 to 26). There were 34 (47.2%) patients with IPSS scores < 20 and 38 (52.8%) patients had scores > 20. IPPS score was not significantly associated with complications (table 5).

Table 5: IPSS scores and transrectal prostate biopsy complications

	IPSS score			
	< 20	**> 20**	**Chi (χ)**	**P value**
Complication				
Haematuria				
No haematuria	30(88.2)	33(86.8)	0	0.858
Haematuria Present	4(11.8)	5(13.2)		
Haematochezia				
No haematochezia	23(67.6)	26(68.4)	0	0.944
Haematochezia present	11(32.4)	12(31.6)		
Infection				
No infection	25(73.5)	34(89.5)	3.1	0.079
Infection present	9(26.5)	4(10.5)		

Comorbidities and complications

There was a significant association between diabetes comorbidity and infection complicating transrectal prostate biopsy ($p < 0.001$), table 6. The rate of infection among diabetics was 80% compared to 13.4% in nondiabetics. Diabetes was not associated with haematuria ($p = 0.054$) or haematochezia ($p = 0.163$).

Hypertension was significantly associated with haematuria with 37.5% of hypertensive patients having this complication compared to 9.4% of non-hypertensives ($p = 0.023$). Hypertension was not associated with haematochezia ($p = 0.655$) or infection ($p = 0.588$).

Table 6: Comorbid illnesses and transrectal prostate biopsy complications

		Hypertension			
Complication		**No**	**Yes**	**Chi (χ)**	**P value**
Haematuria	No haematuria	58(90.6)	5(62.5)	5.1	0.023
	Haematuria Present	6(9.4)	3(37.5)		
Haematochezia	No haematochezia	43(67.2)	6(75.0)	0.2	0.655
	Haematochezia present	21(32.8)	2(25.0)		
Infection	No infection	53(82.8)	6(75.0)	0.3	0.588
	Infection present	11(17.2)	2(25.0)		
		Diabetes			
Complication		**No**	**Yes**	**Chi (χ)**	**P value**
Haematuria	No haematuria	60(89.6)	3(60.0)	3.7	0.054
	Haematuria Present	7(10.4)	2(40.0)		
Haematochezia	No haematochezia	47(70.1)	2(40.0)	1.9	0.163
	Haematochezia present	20(29.9)	3(60.0)		
Infection	No infection	58(86.6)	1(20.0)	13.9	<0.001
	Infection present	9(13.4)	4(80.0)		

Presence of an indwelling catheter

Presence of an indwelling catheter did not significantly increase the risk of complications following transrectal prostate biopsy (table7). Haematuria and haematochezia occurred in 16.7 and 33.3% of patients with indwelling catheters compared to 8.3% (p = 0.285) and 30.6% (p = 0.8) of those without catheters, respectively. Infection rates were 25% in patients without indwelling catheters and 11.1% ibn those with catheters (p = 0.126).

Table 7: Indwelling catheter and transrectal prostate biopsy complications

		Indwelling catheter			
Complication		**Absent**	**Present**	**Chi (χ)**	**P value**
Haematuria	No haematuria	33(91.7)	30(83.3)	1.1	0.285
	Haematuria Present	3(8.3)	6(16.7)		
Haematochezia	No haematochezia	25(69.4)	24(66.7)	0.1	0.8
	Haematochezia present	11(30.6)	12(33.3)		
Infection	No infection	27(75.0)	32(88.9)	2.3	0.126
	Infection present	9(25.0)	4(11.1)		

PSA level

The mean PSA level in patients undergoing transrectal prostate biopsy was 76.2 (SD ± 104.5), and ranged between 3 and 627. Table 8 shows that complications related to transrectal prostate biopsy were not significantly associated with mean PSA level.

Table 8: Mean PSA level according to complications

		Mean (SD)	**Difference (95% CI)**	**P**
Haematuria	Yes	57.0(±58.4)	21.9(-24.8-68.7)	0.37
	No	78.9(±109.6)		
Haematochezia	Yes	86.6(±129.0)	-15.3(-74.0-43.4)	0.613
	No	71.3(±91.9)		
Infection	Yes	57.6(±53.4)	22.7(-18.2-63.5)	0.283
	No	80.3(±112.6)		

Infection rates and drug use

There was no significant association between use of prophylactic antibiotics and infection rates in patients undergoing transrectal prostate biopsy .

	Infection			
	Absent	**Present**	**Chi (χ)**	**P value**
Prophylactic antibiotic				
None	5(55.6)	4(44.4)	5.1	0.161
Ciprofloxacin	44(84.6)	8(15.4)		
Levofloxacin	9(90.0)	1(10.0)		
Cefuroxime	1(100.0)	0(0.0)		
History of drug exposure				
None	57(83.8)	11(16.2)	9.7	0.008
Anticoagulant	2(100.0)	0(0.0)		
Ciprofloxacin	0(0.0)	2(100.0)		

DISCUSSION

Prostate specific antigen (PSA) test and digital rectal examination are used for screening of prostate cancer, however the diagnosis relies on histopathological proof of neoplastic tissue in prostate biopsies. Prostate biopsy remains the gold standard for the diagnosis of prostate cancer[2] . Prostate biopsy is a minimally invasive procedure, as its considered safe and therefore performed as an outpatient procedure. Prostate biopsy complications are mild and self limiting, however life threatening complications do occur. Therefore, clinician must objectively indentify morbidity, complications and patients at risks of post biopsy complications.

In this single institution prospective study, Seventy-two patients were recruited into the study. The mean age of males undergoing transrectal prostate biopsy was 71.8 years with a range 47 to 94 years. Our study population had an advanced age at the time of prostate biopsy in comparison to studies conducted in Nigeria and Egypt which had a study population with a mean age of 63.6 and 67.1 years respectively[8,10]. One-half 36 (50%) of the patients resided in Nairobi county and the remainder were referrals from other counties. There were 13 patients with comorbid conditions including hypertension 8 (11.1%) and diabetes 5 (6.9%). On evaluation of patient demographic data, we did not identify any variables that were associated with the development of a post-biopsy complication. This is consistent with earlier studies[8,9,10,13] .

In this study, the overall rate of transrectal prostate biopsy complications was 62.5% with 32 patients reporting at least one of the complications associated with the procedure. Although direct comparison is difficult due to differences in study population and the biopsy method used, our overall complication rate was high compared with that of shittu et al., 26% and Sheng-Hui et al 9.6%. There were no serious complications requiring admission for inpatient management. These complications can be classified as infective and traumatic complications. Hematochezia was the most common complication at 31.9% followed by UTI, haematuria and orchitis at 15.3%, 12.5% and 2.8% respectively. However, Shittu et al found as the most common complication at 5.2%. There were no cases of hematospermia, or urine retention following the procedure.

Hematochezia of more than 1 day was considered significant, none of the patients required admission or transfusion. In this study hematochezia was high as compared to a study by Enlund et al, which showed hematochezia of 22%. Hematuria was third in prevalence

(12.5%). Several studies have shown significant difference on prevalence of hematuria post biopsy. In studies conducted by Sheng-Hu and elabaddy, hematuria was quoted as low as 4.1% and as high as 59.9%[9,10]. Most patients 63(87.5%) of those who underwent the procedure reported that they were not sexually active due to presence of an indwelling catheter or erectile dysfunction. However, only 4 patients out of 9 who had coitus checked for the presence of hematospermia, this may be attributed to the social cultural practices. There was no correlation between the age of the patient, volume of prostate, IPSS score, PSA levels, presence of indwelling catheter, number of cores and post procedural hematochezia. This is comparable to a studies conducted by Berger et al[2] and Igor et al[26]. However Raaijmaker et al, showed a correlation between the volume of prostate and post procedural bleeding, large prostate volume was associated with an increased risk of minor bleeding[13].

It is difficult from this study to determine accurately the correlation between use of anticoagulants and bleeding complications because only 2 patients 2.8% were on anticoagulants at the time of procedure.

In our study infection was the second most prevalent complication at 18.1%. These patients presented with symptoms of lower urinary tract infection and orchitis. The presenting symptoms were fever, dysuria, frequency and testicular pain. Due to cost implications not all cases were confirmed through laboratory investigations and diagnosis relied on history and clinical examination. All the infective complications were self limiting and responded well to oral antibiotics, patients made full recovery and non required hospital admission.

There was a lot of variation in the type of antibiotics (cephalosporins, Fluoroquinolones) used and duration given ranging from stat doses to 5 day courses. This is due to lack of local bacterial prevalence and resistance profile which is paramount to facilitating antibiotic prophylaxis protocols. In this study patients were given antibiotics after undergoing the procedure. In comparison to other similar studies with lower infection rate, the antibiotics prophylaxis were initiated a day before the procedure[9,10]. The high infection rate can further be explained by a study conducted by Rustom et al[31], in this study the first dose of antibiotic was immediately before the biopsy in the first group and 24 hours prior to biopsy in the second group. The first group had a higher infection rate than the second group. The differing infection rates between the two groups was explained by the pharmacokinetics and bioavailability of antibiotics at the time of biopsy. In the first group the peak plasma concentration was subtherapeutic at the time of biopsy hence the high infection rate.

It is conceivable that size of prostate, number of cores and presence of indwelling catheter cause more frequent infection complication. However, we found no correlation between those factors and complication rate. This has been demonstrated by various studies.[9,28]
Although many studies record no association between diabetes and increase in infection rate in our study there was significant association between the two[26,32]. In our study only 5 patients (6.9%) had diabetes in comparison to the two studies which had a large number of patients with diabetes giving them the advantage of large sample size. This discrepancy may in part be due to the lower number of patients recruited into the study in comparison to the other studies.

Although in the current study all complications were minor and self limiting, studies have reported major life threatening complications necessitating hospital admission. Shittu et al[8], reported recto-vesical fistula in a patient with metastatic disease while Sheng hui et al[9], reported gross hematuria and severe UTI that required admission.

Study Limitation

1. History from patients was subjective. Patients felt embarrassed to answer questions related to sexual life and hematospermia.
2. The costs to conduct investigations for post biopsy complications were high to some patients. Diagnosis relied only on history and clinical examination.
3. The study population with comorbidities and drug exposure was small. A larger sample will have more statistical inference.

CONCLUSION

Our study demonstrates that,

1. The results of our study indicated that transrectal prostate biopsy is associated with 62.5% minor complications. Despite the complications, transrectal prostate needle biopsy is a feasible procedure in male patients with suspected prostate cancer and be performed safely in outpatient or office setting.
2. Size of prostate, number of cores, IPSS score, exposure to antibiotics and patient demographics are not risk factors to post-biopsy complications.

RECOMMENDATIONS

1. There is need to develop local bacterial resistance profile and antibiotic prophylaxis protocols.
2. Further larger multicenter prospective studies are recommended to evaluate diabetes as a risk factor for post-biopsy complications.

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APPENDICES

APPENDIX I : DATA COLLECTION SHEET

Demographic data:

Study number.....

Patient locator form number.....

Age (years) .....

Occupation .....

Residence.....

History:

IPSS……..

Professional qualification of the Doctor performing biopsy (***Tick one***)

Surgical trainee/Registrar ☐

Consultant Surgeon ☐

If a registrar, tick year of study.

Year 1 ☐ Year 2 ☐ Year 3 ☐ Year 4 ☐ Year 5 ☐

Drug history

Exposure to fluoroquinolones: yes ☐ No ☐

If yes Indicate days before biopsy and duration taken……..

On warfarin yes ☐ No ☐

On aspirin Yes ☐ No ☐

Examination:

Vital signs

BP(mmHg)	PR	RR	Temp ^{o}C

Presence of indwelling urethral catheter Yes ☐ No ☐

DRE

findings……

……

……

Investigations

Urinalysis……..……

PSA……..

TRUS: Prostate volume……

Post void residual volume ……

Biopsy method used: TRUS Guided ☐ Blind ☐

Number of cores taken……

Prophylactic antibiotics used ……..

Duration……...

Follow up: Urology clinic ☐ Phone call ☐

POST BIOPSY DAY……

POST BIOPSY PRESENTING SYMPTOMS:

1. Obstructive

	Hesitancy	Straining	Urine retention	Dribbling
Present (X) Absent (0)				
Duration				

2. Irritative [urgency, frequency, or dysuria]

	Dysuria	Frequency	Urgency
Present (X) Absent (0)			
Duration			

3. Bleeding

	Haematuria	Hematochezia	Hematospermia
Present (X) Absent (0)			
Duration			

4. Testicular Pain Yes ☐ No ☐

5. Testicular swelling Yes ☐ No ☐

Examination:

Vital signs

BP(mmHg)	PR	RR	Temp ^{o}C

Investigations

Urinalysis……

…..

CBC

…….

Complications……

……

……..Treatment……

……

…….

Outcome of the complications …….

APPENDIX II: INTERNATIONAL PROSTATE SYMPTOM SCORE (IPSS)

	Not at all	Less than 1	Less than half the time	About half the	More than half the time	Almost always	**Your score**
Incomplete emptying: Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5	
Frequency: Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
Intermittency: Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
Urgency: Over the last month, how difficult have you found it to postpone urination?	0	1	2	3	4	5	
Weak stream: Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
Straining: Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	

	None	1 time	2 times	3 times	4 times	5 times or more	**Your score**
Nocturia: Over the past month, 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	

Total score: 0-7: Mild 8-19: Moderate 20-35: Severe

APPENDIX III: INFORMED CONSENT FORM

TO ASSESS COMPLICATIONS OF TRANSRECTAL PROSTATE BIOPSY IN KENYATTA NATIONAL HOSPITAL.

This Informed Consent form is for surgical male patients attending Urology Outpatient Clinic at KNH, will be administered to the eligible patients or patient's next of kin. We are requesting these patients to participate in this research project whose title is "**TO ASSESS COMPLICATIONS OF TRANSRECTAL PROSTATE BIOPSY IN KENYATTA NATIONAL HOSPITAL**''.

Principal Investigator: **Dr. Muketha Koome**

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

This Informed Consent Form has three parts:

1) Information Sheet (to share information about the research with you).
2) Certificate of Consent (for signatures if you agree to take part).
3) Statement by the researcher/person taking consent.

You will be given a copy of the full informed consent form.

PART I: Information Sheet

Introduction

My name is Dr. Muketha Koome, a post graduate student in General Surgery at the University of Nairobi. I am carrying out a research to determine the is "To assess complications of transrectal prostate biopsy in kenyatta national hospital''.

Purpose of the research

Prostate cancer is one of the most common cancers affecting men older than 40 years of age in Kenya today. The gold standard of diagnosis of prostate cancer is histopatholological proof of neoplastic changes in prostate biopsies. Prostate biopsy being an invasive procedure, is associated with some post procedural complications which can range from minor to major life threatening . Complications include infection, bleeding, and urinary retention. This study seeks to provide data on complications among patients undergoing prostate biopsy and thus form a basis for prophylaxis and treatment.

I am going to give you information and invite you to be a participant in this research. There may be some words that you do not understand. Please ask me to stop 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.

Type of Research Intervention

This research will involve examination of your body and medical records with your doctor's permission [or their representative] to obtain the symptoms of your illness, imaging and laboratory investigation results. A transrectal prostate biopsy will be performed using a 16Ga needle through your anal opening. Before the procedure, you will be given antibiotic and painkiller medication to prevent infection and pain. After the procedure you will be followed up for 2 weeks, during this period the doctor can contact you by phone or request you to come for review in our outpatient clinic.

Voluntary participation/right to refuse or withdraw

It is your choice whether 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 choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital for your condition. You have a right to refuse or withdraw your participation in this study at any point.

Confidentiality

The information obtained will be treated with confidentiality and only be available to the principal investigator and the study team. Your name will not be used. Any information about you 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 that we get from this study will be shared with the policy makers 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:

i. To contribute towards the advancement of health science.
ii. Free on phone consultation.

Risks

Following the biopsy of the prostate you may experience the following:

- Bleeding.
- Pain while passing urine.
- Infection.
- Urine retention.

Cost and compensation

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

This proposal has been reviewed and approved by 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:

1. Principal Researcher:

   Dr. Muketha Koome,

   Department of Surgery, School of Medicine, University of Nairobi

   P.O. Box 19676 KNH, Nairobi 00202.

   Mobile no. 0727581912
2. University of Nairobi Supervisors:

Prof Peter L .W. Ndaguatha

MBCHB, MMED (UON), FCS (ECSA), FELLOW UROLOGY. (UK),

Professor of General Surgery/Urology,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202 KNH, Nairobi, Kenya

Dr. Francis A. Owillah,

MBCh.B, M.MED (Gen Surg.), FCS (ECSA), Cert Urol. (KCMC),
Consultant Urologist/Lecturer,

Department of Surgery, School of Medicine, University of Nairobi,

P.O. Box 19676 KNH, Nairobi 00202.

If you have any ethical concerns, you may contact:

Secretary, UON/KNH-ERC,

P.O. Box 20723- 00202,

KNH, Nairobi.

Tel: 020-726300-9

Email: KNHplan@Ken.Healthnet.org

PART II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

If Non -literate:

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

Print Name of witness_____

Signature of witness _____

Date _____

Thumb print of participant

PART III: Statement by the researcher

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

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to facilitate prophylaxis and treatment of post biopsy complications.

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.

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

Name of researcher/person taking consent ……

Signature of researcher/person taking consent ……

Date…….

APPENDIX IV: FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

COMPLICATIONS OF TRANSRECTAL PROSTATE BIOPSY AS SEEN IN KENYATTA NATIONAL HOSPITAL.

Fomu hii ya makubaliano ni ya wale wanaume ambao wanahudumiwa kwenye kliniki za Urology katika hospitali ya KNH na wamealikwa kujiunga na utafiti **" TO ASSESS COMPLICATIONS OF TRANSRECTAL PROSTATE BIOPSY IN KENYATTA NATIONAL HOSPITAL"**

Mtafiti mkuu: Dkt. Muketha Koome

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

Fomu hii ya makubaliano ina sehemu tatu:

1) Habari itakayo kusaidia kukata kauli
2) Fomu ya makubaliano (utakapo weka sahihi)
3) Ujumbe kutoka kwa mtafiti

Utapewa nakala ya fomu hii.

SEHEMU YA KWANZA: Ukurasa wa habari

Kitambulizi

Jina langu ni Dkt. Muketha Koome. Mimi ni daktari ninaesomea upasuaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, " To assess complications of transrectal prostate biopsy as seen in kenyatta national hospital".

Lengo kuu la utafiti.

Saratani ya tenzi-kibovu ni mojawapo ya saratani kuu zinazowaathiri wanaume walio na umri wa zaidi ya miaka 40, nchini Kenya. Uchunguzi asili wa kufumbua uwepo wa saratani ya tenzi-kibovu mwilini ni kupitia njia ya uchanganuzi wa kina wa nyama-sampuli za tenzi-kibovu utakaofanyiwa katika mahabara ya kisayansi. Sampuli za tenzi-kibovu hufanywa kupitia njia ya kudonadona tenzi hicho kwa kutumia sindano maalum, na huwa kwa kawaida na madhara mbalimbali kwa mgonjwa mengineo yakiwa ni duni hadi yale makuu ya

kuhatarisha. Utafiti huu unadhamiri kuchunguza madhara hayo yanayotokana na kudonadona tenzi-kibovu kwa minajili ya uchunguzi wa kisayansi, hivyo basi kuelekeza uwezekano wa kupewa dawa za kuyazuia au kuyatibu.

Napania kukupa ujumbe kamili kuhusu utafiti huu na hivyo basi kukualika kujiunga katika utafiti. Yapo maneno ya taminolojia ambayo kwayo yatakuwa ngumu kwako 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 au mwuguuzi wako binafsi. Tutaangazia mwelekeo wa ugonjwa wako, madhara husika na vipimo vya mahabara vinavyoambatana nayo. Sampuli za tenzi-kibovu zitapatikana kutokana na sindano maalum ya kudonadona, ambayo itapitishwa kupitia njia yako ya mkundu hadi kwa tenzi chenyewe. Baadaye daktari angependelea kukufuatilia kwa muda wa wiki mbili kupitia njia ya mwasiliano ya simu au kuonekana katika kiliniki.

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.

1. Utachangia katika kuendeleza umakinifu wa afya ya kisayansi.
2. Utapokea mashauriano ya bure kupitia simu ya rununu na Daktari.

Adhari za kushiriki.

1. Ufujaji wa damu
2. Uchungu wa muda unapokojoa
3. Maradhi husika
4. Mkwamo wa mkojo.

Anwani za Wahusika

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

1. Mtafiti Mkuu:
   Dkt. Muketha Koome,
   Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

   SLP 19676 KNH, Nairobi 00202.

   Simu: 0727581912.

2. Wahadhiri wahusika:
   Profesa Peter L.W. Ndaguatha

   MBCHB, MMED (UON), FCS (ECSA), FELLOW UROLOGY. (UK)

   Profesa wa upasuaji / Urology

   Kitengo cha upasuaji, shule ya utabibu, chuo kikuu cha Nairobi

   SLP 19676 KNH, Nairobi 00202.

3. **Dkt. Francis A. Owillah,**

   MBCh.B, M.MED (Gen Surg.), FCS (ECSA), Cert Urol. (KCMC),

   Consultant Urologist/Mhadhiri,

   Idara ya Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

   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: KNHplan@Ken.Healthnet.org

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……