CORRELATION BETWEEN POSTVOID RESIDUAL URINE VOLUME AND LOWER URINARY TRACT SYMPTOMS AS MEASURED BY INTERNATIONAL PROSTATE SYMPTOM SCORE IN PATIENTS WITH BENIGN PROSTATE ENLARGEMENT IN KNH

THIS DISSERTATION IS PRESENTED AS PARTIAL FULFILLMENT FOR THE AWARD OF THE DEGREE OF MASTERS OF MEDICINE IN UROLOGY AT THE UNIVERSITY OF NAIROBI.

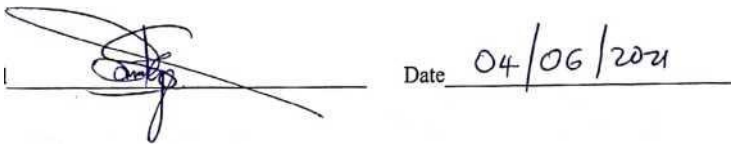
BY DR. SAMUEL MATHENGE MAINA

H58/88364/2016

STUDENT'S DECLARATION

I, Dr. Samuel Mathenge Maina, do declare that this dissertation is purely my own original work and has not been presented, to the best of my knowledge, for a degree in any other university.

Dr. Samuel Mathenge Maina



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ABBREVIATIONS

AUA- American Urological Association

AUR- Acute Urine Retention

5ARI- 5 Alpha Reductase Inhibitors

BOO- Bladder Outlet Obstruction

BPE- Benign Prostatic Enlargement

BPH- Benign Prostatic Hyperplasia

DRE- Digital Rectal Examination

ERC- Ethics and Research Committee

IPSS- International Prostatic Symptom Score

KNH- Kenyatta National Hospital

KUB- Kidney Ureter and bladder ultrasound

LUTS- Lower Urinary Tract Symptoms

OAB- Overactive Bladder

PVR- Post Void Residual Volume

PSA- Prostatic Specific Antigen

SPSS- Statistical Package for Social Sciences

TZ- Transitional zone

UDS- Urodynamic Study

UON- University of Nairobi

UTI- Urinary Tract Infection

EAU- European Association of Urology

AUA- American Association of Urology

OPERATIONAL DEFINITIONS

Post void residual volume (PVR): The amount of urine remaining in the bladder after a voluntary void measured in milliliters (mls).

Benign Prostate Enlargement (BPE): Non- malignant enlargement of the prostate gland with resultant narrowing of urethra and lower urinary tract symptoms(LUTS).

Lower Urinary Tract symptoms (LUTS): A group of urinary symptoms which can be classified as obstructive or voiding and triggered by bladder outlet obstruction by an enlarged prostate, urethral stricture, or urinary tract infection.

International Prostate Symptom Score (IPSS): Validated questionnaire used to assess severity of LUTS.

ABSTRACT

Background: Post Void Residual Urine Volume **(**PVR) is a widely used diagnostic tool for assessment of Benign Prostatic Enlargement (BPE) due to its procedural simplicity, availability and cost. However, its diagnostic accuracy in determining severity of Lower Urinary Tract Symptoms (LUTS) and threshold of what constitutes significant PVR has long been in contention. This study sought to establish the diagnostic accuracy and clinical value of PVR in determining severity of LUTS amongst BPE patients.

Objective: To determine the correlation between PVR and severity of LUTS as measured by IPSS.

Materials and Methods: The study was a cross-sectional analytical study where 67 patients undergoing treatment for BPE at Kenyatta National Hospital (KNH) Urology clinics were recruited into the study by consecutive sampling. Data collected was patient's International Prostatic Symptom Score (IPSS) and PVR. The severity of LUTS was assessed and categorized with the validated IPSS score questionnaire into mild, moderate and severe LUTS. PVR was assessed using trans-abdominal bladder ultrasound after micturition. This was done as part of the routine Kidney Ureter and bladder ultrasound (KUB) ultrasound. The data obtained was entered into SPSS version 24 software for analysis. Bivariate analysis was done to determine the association between PVR and IPSS score and correlation between the two done using Spearman's Rho correlation Test. A p value of 0.05 and confidence interval of 95% was used to determine significance of collected data.

PVR was categorized into groups based on IPSS score to determine the PVR ranges for mild, moderate and severe IPSS. Receiver operating curves (ROC) were used to determine to cut-

off values for specific classifications of PVR based on IPSS score. Further bivariate analysis using Chi square test was done to assess association between categories of IPSS and categories of PVR.

Results:

67 patients were recruited into the study. The average age was 66 years. PVR mean was 112mls with a range of 0- 1011mls. Average prostate volume was 69.4cc range 10- 235cc. Mean IPSS score was 18, range 0- 35. There was a positive correlation between IPSS and PVR; this was found to be statistically significant (p value <0.001). Using Receiver operating curve (ROC), PVR cutoff values for mild, moderate and severe LUTS were established at 24mls, 111mls and 345 mls respectively.

1.0 CHAPTER ONE:

INTRODUCTION

Benign Prostatic Enlargement (BPE) is a common condition that afflicts the aging male and it is characterized by the prostate gland enlarging and the urethra narrowing with resultant Lower Urinary Tract Symptoms (LUTS), both obstructive and irritative symptoms. Prevalence increases with age and approaches 80% by age of 80 years [1]. Post-void residual volume (PVR) is the urine that remains in the bladder after a voluntary void [2]. PVR can be evaluated via Bladder Ultrasound or sterile catheterization, but ultrasound is widely favoured due to its non- invasiveness [3].

PVR is among the recommended investigation for initial evaluation for LUTS secondary to BPE [4]. Urologists in their routine clinical practice frequently rely on PVR to assess LUTS secondary to BPE due to its procedural simplicity, availability and affordability [5][6][7][8].

However, there has been conflicting evidence on the diagnostic accuracy of PVR in determining severity of LUTS and the threshold of significant PVR. In a study by J. L. H. Ruud Bosch, weak correlations were also found between PVR and the total IPSS symptom score ($r = 0.25$, $P < 0.05$). Kolman C. *et al.,* found that Postvoid residual urine had a statistically significant relationship with severity of symptoms. In another study by Rule, A.D., *et al*., a rapid increase in PVR slope was more likely in men with a baseline IPSS> 7 (age adjusted odds ratio [OR]1.6, 95% CI 1.0 to 2.5). Hammers *et al*. did not find any relationship between International Prostate Symptom Score (IPSS) to an abnormal PVR in men aged over 50 years with LUTS [9][10][43].

There exists a lack of accord of what constitutes a post-void residual volume that is elevated significantly, or at what point elevations in PVR start to contribute to urinary problems. No PVR threshold for treatment decision has been established. Available data is conflicting. In a

study by Matthias Oelke et al., using a PVR threshold of 50 mL, the diagnostic accuracy of PVR measurement has a positive predictive value of PPV of 63% and a negative predictive value (NPV) of 52% for the prediction of LUTS [11][12][42].

The purpose of this study was to determine the relationship between severity of LUTS and PVR. The study also sought out to determine the threshold/ cut-off values of PVR indicating mild, moderate and severe LUTS.

2.0 CHAPTER TWO:

LITERATURE REVIEW

2.1 BPE- Definition, Epidemiology, Evaluation & Management

Benign Prostatic Enlargement (BPE) is marked by the prostate gland enlarging and the urethra narrowing with resultant Lower Urinary Tract Symptoms (LUTS). Global prevalence of BPE varies from 20-62% in men over 50yrs. Results from South Africa indicate prevalence of over 50% in adult males of 60yrs and above [13]. BPE affects majority of men older than 80 years old and more than 50% of those older than 60 years, and is a major cause of LUTS [14][15].

Hanno et al. [1] found that BPH histologic evidence to be present in around 65% of men aged between 60-70 years, and in almost 80% of older men aged between 70-80 years. A study of autopsies done showed that there was 8% BPH prevalence in life's 4th decade and as high as 80% in the 9th decade. BPH is identified by increased number of epithelial and stromal cells in the periurethral transitional zone of the prostate and thus accurately referred to as hyperplasia [16].

BPE is considered to be a progressive disease characterized by the patient's symptoms deteriorating over a period. The goal of evaluating patients with LUTS secondary to BPE is to be able to ascertain the patients who are at risk of the disease progressing so that their disease management can be optimized. Evaluation for BPH includes a detailed history, objective assessment of LUTS with validated questionnaires, assessment of upper urinary tract and prostate size [17]. Tests recommended for the disease evaluation in men suffering from symptoms that are moderate to severe (IPSS 8-35) include the flow rate of urine, PVR urine, and pressure-flow urodynamic studies [16]. Findings from the evaluation have an impact on management decisions.

LUTS is usually divided into two categories which are voiding also known as obstructive and storage also known as irritative symptoms. Symptoms of voiding are a weak urine stream, a terminal dribble, hesitancy when urinating, urgency to urinate, intermittency, and the incomplete emptying of the bladder. Storage symptoms include frequency, urgency, nocturia and urge incontinence. BPE causes LUTS by two mechanisms:

a) Direct Bladder Outlet Obstruction (BOO) from the enlarged prostate -Mechanical Obstruction.

b) An increased smooth tone of the muscle and prostrate resistance -Dynamic Obstruction.

Management of BPH aims to improve lower urinary tract function, prevent development of complications and alleviate bothersome LUTS. Options in the management of BPH include watchful waiting for mild to moderate symptoms and surgical or medical therapy for symptoms that range from moderate to severe. Indications for surgical therapy include renal failure, urine retention, recurrent urinary tract infections, obstructive uropathy, gross hematuria, and bladder calculi [17].

Medical therapy with 5 alpha reductase inhibitors (5ARI) and alpha blockers are the first-line choice of treatment for patients suffering from moderate-to-severe LUTS secondary to BPH. TURP is the gold standard surgical procedure for the management of LUTS due to BPE [17].

Patients with coexisting BPE and overactive bladder (OAB), additional therapy with anticholinergic is indicated. However, patients should be screened for elevated PVR before commencing anticholinergic therapy to be able to prevent acute urine retention (AUR). Anticholinergic therapy should not be used in patients showing PVR > 200 mL, those whose Qmax is < 5 mL/s, or to the patients who have portrayed a history of an acute urinary retention requiring catheterization [17].

2.2 PVR Definition & Measurement

PVR is defined as the urine that remains in the bladder especially after a voluntary void and works as a non-invasive diagnostic tool for evaluating voiding dysfunction and Detrusor dysfunction [18][19]. There are two methods of evaluating for PVR that is Sterile catheterization or Bladder Ultrasound. Bladder Ultrasound is a noninvasive method that is both accurate and simple [3]. Urethral catheterization measures the PVR directly and regarded as the standard in the determination of PVR [20].

Bladder ultrasound is convenient as it is non-invasive and efficient. It is thus the most widely used method for evaluating PVR among the hospitalized population and also among the vulnerable population [18].

Sterile catheterization is the gold standard for measuring PVR, however, this procedure is associated with several disadvantages such as causing the patient with discomfort, being time-consuming, and having a risk of urinary tract infection (UTI) and trauma to the urethra [18]. Therefore, bladder ultrasound is the most convenient and widely used method in clinical practice to determine PVR [18].

2.2.1 PVR Cut-Off Values

Parameters for interpreting the results of PVR testing are not standardized or well evaluated. There is no standard for what constitutes a clinically significant PVR. A PVR of more than 100 mls, or > 1/3 of bladder capacity, is considered incomplete emptying [21][18].

Values of 50 mL or less are considered to be normal. On the other hand, values of 100 mL and above are accepted as meaningful high residual urine [22][23]. Studies have concluded that the normal volume range of residual urine is between 0.09 mLs-2.24 mLs, with a mean of

0.53 mL. About 78% of healthy men have PVRs of < 5 mL, and 100% of healthy men have PVRs < 12 mL [24] [25].

A study by Bosch, J.L.H. Ruud in Netherlands showed an increase in mean PVR with the age of the person to almost 0.65 mL [19]. However, there isn't an accord of what constitutes an elevated PVR, or at what point elevations in PVR start to contribute to urinary problems. Available data is conflicting [11][12].

More research is required to define pathologic urine retention and to quantify PVR urine volumes precisely [27]. There is an on-going discussion that it can be more meaningful clinically to describe PVR more of a percentage of the capacity of the bladder rather than it being an absolute number.

2.2.2 PVR Significance

Urodynamic study (UDS) is the recommended standard for clinical assessment of BOO in BPH patients. However, UDS has significant limitations in terms of invasiveness, availability, cost, and morbidity. Therefore, Urologists in their routine clinical practice frequently rely on PVR to assess LUTS secondary to BPE due to its procedural simplicity, availability and cost [5][6][7][8].

PVR is among the recommended investigation for initial evaluation for LUTS secondary to BPH. The others are: Medical history, Physical examination, Digital Rectal Examination (DRE), IPSS score, Urinalysis, Serum Creatinine, PSA, Uroflowmetry and Urodynamic studies (UDS) [28][8][16]. PVR is an important diagnostic and prognostic test for assessing LUTS secondary to BPH [29].

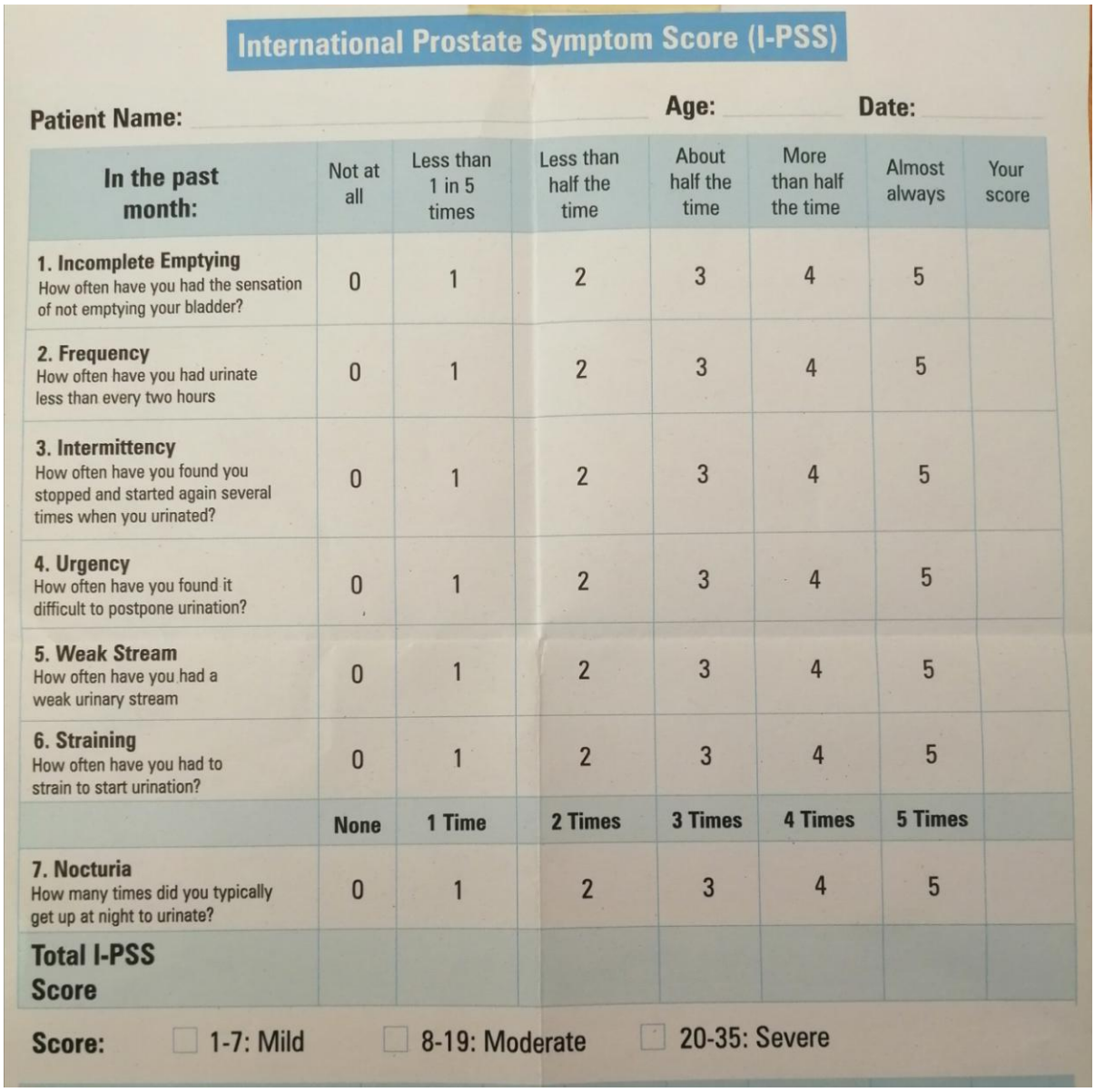
An elevated PVR was shown to be a critical risk factor for progression and was therefore used in the identification of patients that are at a high risk of LUTS/BPE progression. Other risk factors for progression were poor maximum flow rate (Qmax) and increased symptom severity [18][30][31].

From the Medical Therapy of Prostatic Symptoms (MTOPS) study, increasing PVR has been found to predict AUR occurrence. The control patients who didn't develop AUR during the follow up are considered to have a stable PVR while those who developed AUR are considered to have an increasing PVR [32].

Elevated PVR is associated with UTI and upper urinary tract damage. Severely elevated PVR (>300 mL) increases the risk of UTI, renal insufficiency and dilation of the urinary tract. An elevated or increasing PVR has been postulated as a possible indication for surgical intervention. [16]

PVR has been used to monitor and predict outcomes. Studies from the urodynamic results of operative treatment for BPH have shown that PVR reduces significantly surgical treatment. Abrams et al. [33] showed in a study where 152 men were treated using transs urethral resection of the prostate (TURP), there was a decrease in the mean PVR value from 106 mls to 28 mls. It was also reported by Neal et al. [34] that there is a decrease in the average PVR value from 196 mls to 67 mls in a study conducted on 207 patients.

2.3 IPSS Score



International Prostate Symptom Score (I-PSS)

Patient Name: _____ **Age:** _____ **Date:** _____

In the past month:	Not at all	Less than 1 in 5 times	Less than half the time	About half the time	More than half the time	Almost always	Your score
1. Incomplete Emptying How often have you had the sensation of not emptying your bladder?	0	1	2	3	4	5	
2. Frequency How often have you had urinate less than every two hours	0	1	2	3	4	5	
3. Intermittency How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
4. Urgency How often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5. Weak Stream How often have you had a weak urinary stream	0	1	2	3	4	5	
6. Straining How often have you had to strain to start urination?	0	1	2	3	4	5	
	None	**1 Time**	**2 Times**	**3 Times**	**4 Times**	**5 Times**	
7. Nocturia How many times did you typically get up at night to urinate?	0	1	2	3	4	5	
Total I-PSS Score							

Score: ☐ 1-7: Mild ☐ 8-19: Moderate ☐ 20-35: Severe

Fig. 1

The IPSS, Fig. 1, is a useful tool used for subjective assessment of BPE patients. It assesses degree of LUTS and quality of life. The use of IPSS is highly recommended as the instrument to be used for symptom scoring of the baseline of severity in men suffering from LUTS to determine and monitor treatment plan. IPSS is a self-administered questionnaire that quantifies the symptom's severity from BPE. It consists of 4 questions related to obstructive

symptoms- Straining, weak stream, intermittency, incomplete bladder emptying and 3 questions related to irritative symptoms- frequency, urgency and nocturia. There is an 8th question concerning quality of life in relation to urinary symptom. Each of the question ranges from 0-5 points which produces a total score of 0-35.

. The IPSS score is categorized as:

a) Mild symptoms: 1-7 points
b) Moderate symptoms: 8-19 points
c) Severe symptoms: 20-35 points.

2.4 Correlation between IPSS and PVR

PVR and IPSS are both widely used diagnostic parameters for assessing LUTS. However, there has been conflicting evidence on the accuracy of PVR in determining severity of LUTS, and the threshold of significant PVR. In a study by HA Lammers et al, did not find any relationship between IPSS and PVR [35].

Another study by Ezz el Din K Et al, a weak relationship between IPSS as measured by LUTS and PVR [36]. Kolman C et al., found that Postvoid residual urine had a statistically significant relationship with severity of symptoms [37]. Barry et al. [z] Demonstrated that reduced symptom score was significantly related to decreased PVR and improvement of uroflowmetry [38]. In another study, there is a weak relationship between PVR and other relationships with a correlation coefficient that ranges from 0.1-0.3. The poor baseline correlations shown in the above series shows that there is an unreliability of the use of PVR as a single dependent parameter as a BOO indicator [8].

In the AUA Outcome Study, there was a significant relationship between elevated PVR and low flow rates, but doesn't have a correlation with the IPSS. Thus, large PVR may occur in

patients showing low symptoms [39]. In the BPH Treatment outcome pilot study (BTOPS), equally poor relationship between baseline PVR and symptom score was found [9].

2.5 PVR Pathophysiology

High PVRs results from inadequate evacuation of the bladder. It can be caused by BOO, bladder hypocontractility, and in rare cases, a large bladder diverticulum [18]. Differentiation of the causes is impossible without a pressure-flow study. However, interpretation of significant PVR in favor of isolated benign prostatic obstruction (BPO) has been proposed in numerous studies [40].

2.6 Study Justification

Urologists in their routine clinical practice frequently rely on PVR to assess LUTS secondary to BPE due to its procedural simplicity, availability and cost. PVR has been shown to be a predictor of BPH progression, development of Acute Urine Retention, UTI and risk of Upper Urinary Tract Damage. An elevated or increasing PVR has been postulated as a possible indication for surgical intervention.

However, there has been conflicting evidence on the accuracy of PVR in determining severity of LUTS, and the threshold of significant PVR [24]. There is a need for more data on normative values of PVR volume. The purpose of this study is to demonstrate how closely PVR reflects severity of LUTS, and the threshold/ cut- off values of PVR level indicating mild, moderate and severe LUTS.

2.7 Study Question

What is the relationship between PVR and severity of LUTS as measured by IPSS in patients presenting with BPE in KNH?

2.8 Null Hypothesis

There is no correlation between PVR and LUTS in patients with BPE.

2.8 Objectives

2.8.1 Broad Objective

To assess the correlation between PVR and severity of LUTS as measured by IPSS.

2.8.2 Specific Objective

- To determine the PVR of patients with BPE in KNH.
- To determine the LUTS of patients with BPE in KNH as measured by IPSS.
- To assess the correlation between PVR and LUTS in patients with BPE in KNH.

2.8.3 Secondary Objective

- To evaluate PVR cut-off for mild, moderate and severe LUTS as categorized by IPSS

3.0 CHAPTER THREE:

METHODOLOGY

3.1 Materials and Methods

3.1.1 Study Design

The study was a cross- sectional analytical study.

3.1.2 Study Site

The study was carried out at the Kenyatta National Hospital Urology clinics. KNH is a teaching hospital for the University of Nairobi, Faculty of Medicine. Three urology clinics run per week by three different firms on Monday, Tuesday and Wednesday at clinic 24.

3.1.3 Study Population

Study included all patients undergoing treatment for BPE at KNH urology clinics.

3.1.4 Inclusion Criteria

The study included all patients undergoing medical treatment for BPE by virtue of symptomatology, DRE, PSA, imaging (ultrasound and MRI) and prostatic biopsy findings.

3.1.5 Exclusion Criteria

a) Patients with prior surgical intervention for BPE

b) Patients with neurogenic bladder

c) Patients with Over Active Bladder (OAB)

d) Patients with bladder diverticulum.

3.2 Sample Size Determination

Selection was via non-randomized consecutive sampling of eligible patients until the desired sample size was achieved. Fischer's formula was used.

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

- Z: statistic for a level of confidence for the level of confidence of 95%, which is conventional, Z value is 1.96)
- P: Prevalence of DRE- detected and symptomatic BPE in West Africans is 13.3%.[41]
- d: precision. (Corresponding to effect size, considered 0.05 to produce good precision and smaller error of estimate)
- n= Sample Size

$$n = \frac{(1.96)^2 \times 0.133 \times 0.827}{(0.05)^2}$$

$$n = \frac{3.84 \times 0.143}{0.0025}$$

n= 169

3.3 Sampling Procedure

Consecutive sampling was done for all patients who met the inclusion criteria in KNH Urology clinics.

3.4 Ethical Consideration

1. Ethical approval was sought from the department of surgery (UON) and KNH Ethics and Research Committee before commencing the study.
2. Counselling was done prior to consent to give the patient background information in the study.
3. Patient who accepted to consent to the study had their data handled with confidentiality and were allowed to drop out of the study on their own volition if need be.
4. Raw data was destroyed pending completion of the study.
5. Those that declined to participate in the study were not denied treatment.
6. The study participants did not incur any extra financial costs related to the study.
7. The principal investigator did not obtain any monetary benefit from the study.
8. The results will be published to allow other medical practitioners to benefit from the findings of the study.

3.5 Recruitment of Study Participants

Before commencement of the study and upon approval of the protocol by the KNH-UON ERC and the KNH research committee, research assistants were briefed on BPE ,data collection questionnaire (IPSS score). They were also familiarized on the consenting procedure and confidentiality.

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

Patients who met the inclusion criteria were recruited into the study. After consenting, a questionnaire, the International Prostate Symptom Score, was then issued to the study participant to fill. Those who could not read and write were assisted to fill the questionnaire. PVR was captured from the KUB ultrasound which is part of routine evaluation for BPE and was done by a dedicated sonographer to minimise observer error.

3.6 Data Variables

The variables evaluated in this study were: Age (years), Total IPSS score, PVR(mls), and Prostate volume (cc).

Independent Variable	**Dependent variables**
Age(years)	PVR(mls)
IPSS score	
Prostate size/ volume	

3.7 Data Collection and Storage

Demographic data and IPSS score was captured using the structured IPSS questionnaire (Appendix 2).

Post-void (PVR), and Prostate size was recorded from patient's Kidney ureter & bladder ultrasound report (KUB) which is done as routine evaluation for BPE (Appendix 1).

Data collected was tabulated and entered in tally sheets (Appendix 3) and collated using spread sheets on excel.

3.8 Data Analysis

Data collected was entered into tables. Data was then be analyzed using SPSS version 24.

Demographic clinical data that was continuous was analyzed and presented as means with standard deviations or as medians with interquartile ranges, while those that were categorical were analyzed and presented as frequencies and proportions.

Bivariate analysis using Student's t test was done to determine the association of PVR, age, and prostate size with IPSS score and correlation between these done using Spearman's Rho correlation co-efficient.

PVR was categorized into groups based on IPSS score to determine the PVR ranges for mild, moderate and severe IPSS. Means and SDs was used to determine to cut- off values for specific classifications of PVR based on IPSS score. Further bivariate analysis using Chi square test was done to assess association between categories of IPSS and categories of PVR.

Multivariate analysis using ordinal logistic regression was used to determine the influence of age, prostate size and IPSS score with categories of PVR. Results of regression model was presented in Odds ratios and 95% confidence intervals. A p value of ≤ 0.05 was considered significant statistically.

Data was presented in frequency tables, bar and linear graphs, pie charts and scatter plots as appropriate.

3.9 Confidentiality

Neither participant's name nor hospital number will be recorded on the data tools but will be assigned a research tracking number.

An inventory of participants tracking system will be safely kept by the principal researcher. Confidentiality of the clinical information of the participants will be ensured at all stages of research.

Collected data will always be kept safely by the principal researcher.

4.0 Quality Assurance

The research assistants were trained in handling of data to improve quality of data collected. The study protocol and methodology was adhered to. Cleaning and duplication of data was done before data analysis and the procedures documented.

4.1 COVID -19 Mitigation Strategy

To guarantee safety of participants and research staff, the following mitigation measures were be taken during the study:

a) Adherence to COVID-19 public health directives and infection prevention control measures as regular hand washing, use of 3-ply mask and social distancing.
b) Screening of participants and research staff for symptoms and temperature checks in the urology clinics and radiology ultrasound unit.

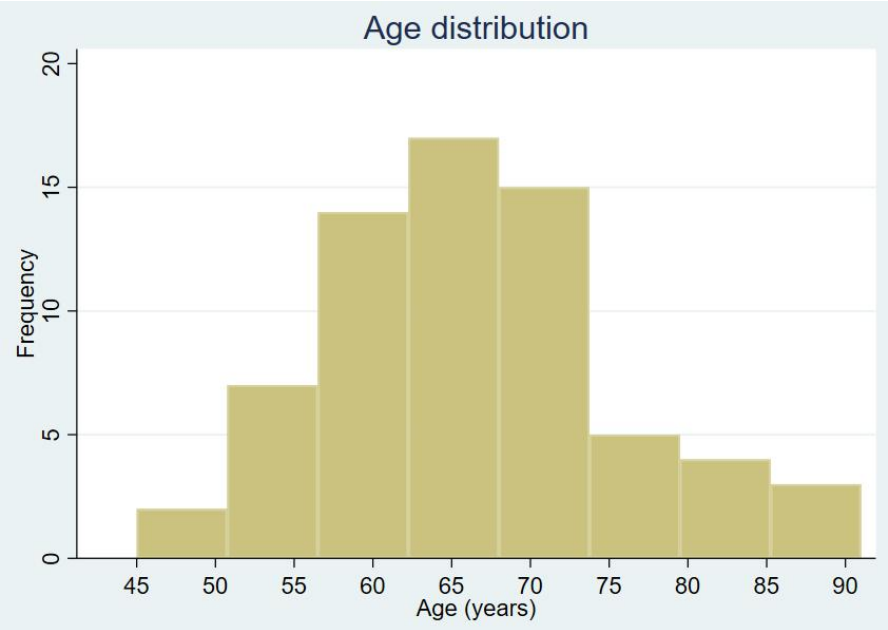
5.1 RESULTS

Seventy-five participants were recruited into the study. However, 8 participants were excluded for failure to meet inclusion criteria and missing records. Therefore, data was analysed for sixty-seven participants.

5.1.1 Age

Mean age of the 67 study participants was 66.1 years, (SD 9.33), median age of 66 years, with a range of 45 – 91 years. The peak age group was 63- 67years as shown in figure 1.

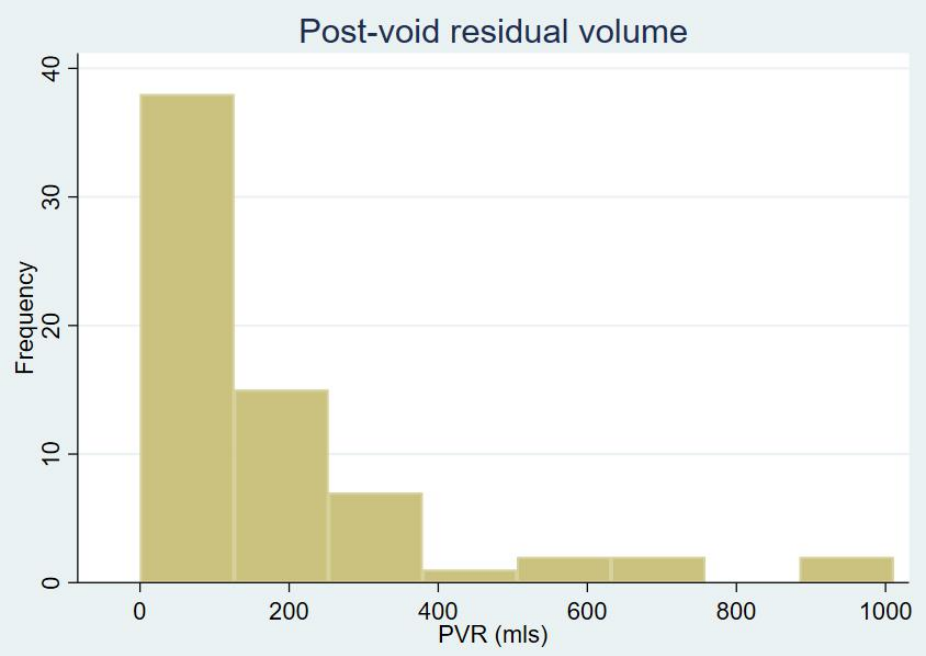
Figure 2:Histogram showing age distribution



5.1.2 Post void residual volume

The median PVR was 112 mls, with a range of 0- 1011mls. 23 patients had PVR >100mls, most of them with severe LUTS as per IPSS score. Figure 2 shows the PVR distribution of patients in the study.

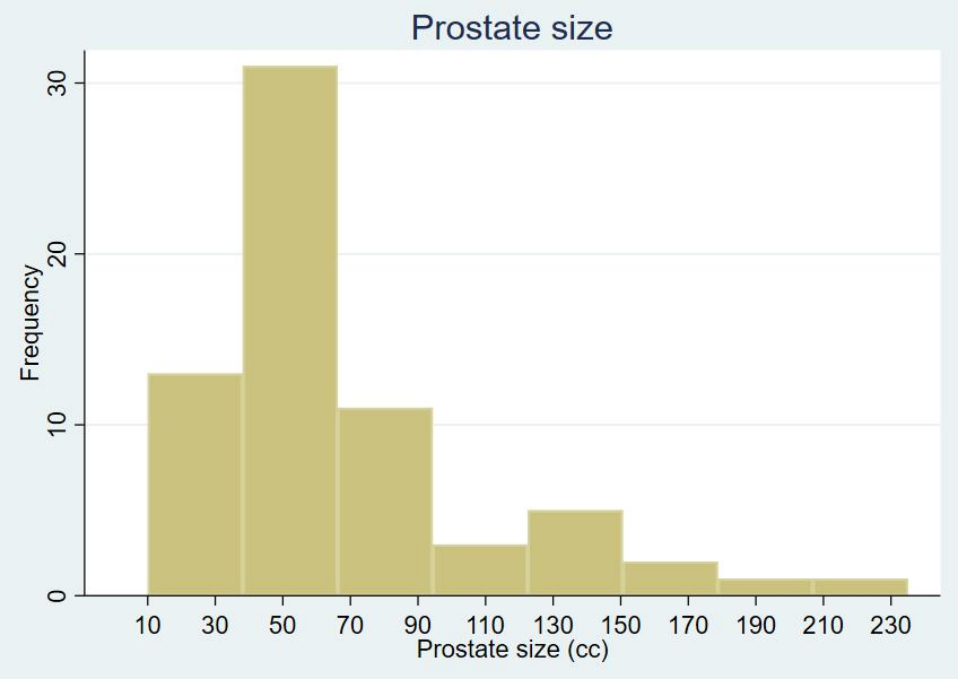
Figure 3:Histogram showing PVR distribution



5.1.3 Prostate volume

Ultra sonographic measurement of the prostate revealed a mean prostate volume of 69.4 cc, (SD 43.2) with a range of 10 – 235cc, Median 57.

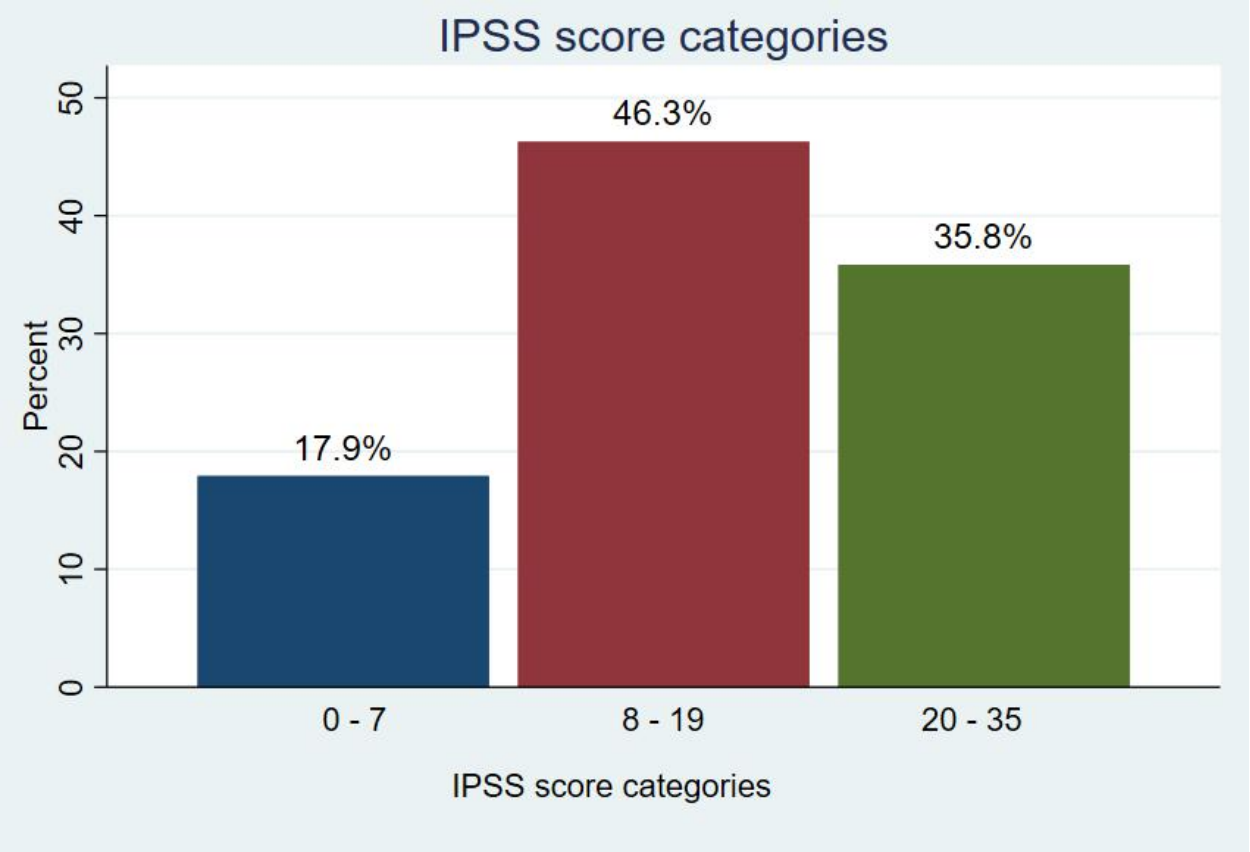
Figure 4:Histogram showing prostate size distribution



5.1.4 IPSS score

The mean IPSS was 18, with a range of 5-35. 12 patients (17.9%) had mild symptoms, 31 patients (46.27%) had moderate symptoms while 24 patients (35.8%) had severe symptoms as illustrated in figure 4.

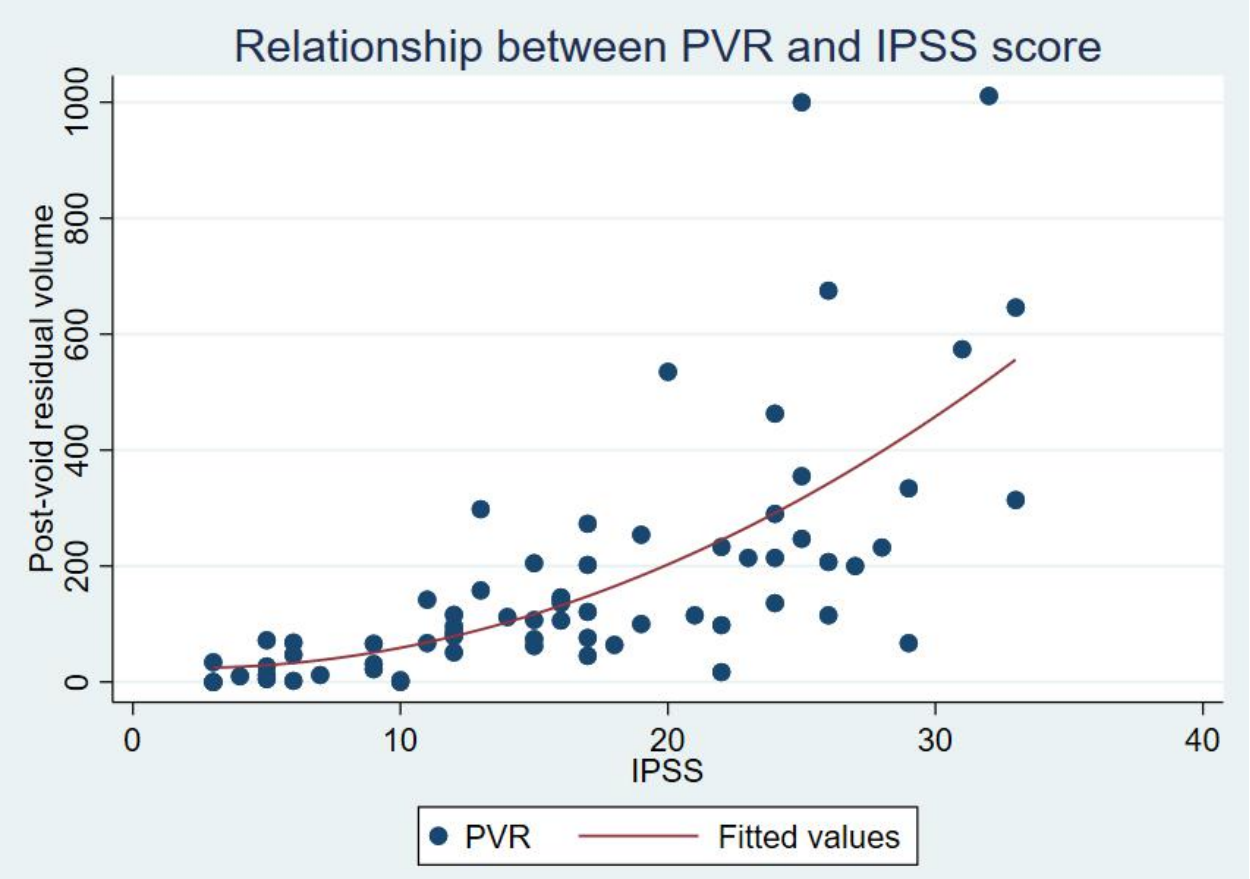
Figure 5: Bar graph showing categories of IPSS score.



5.1.5 Relationship between PVR and IPSS score

There was a positive correlation between IPSS and PVR; this was found to be statistically significant (p value <.001). As IPSS increases, the PVR rises as illustrated in figure 5.

Figure 6. Scatter plot. PVR vs. IPSS

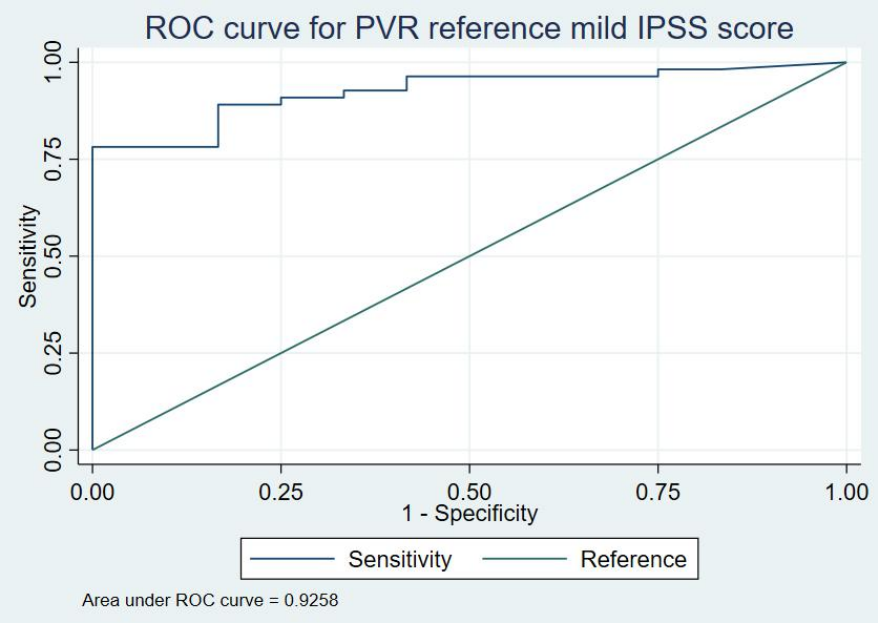


5.1.6 PVR CUTOFF VALUES FOR IPSS CATEGORIES

Cutoff for mild IPSS score

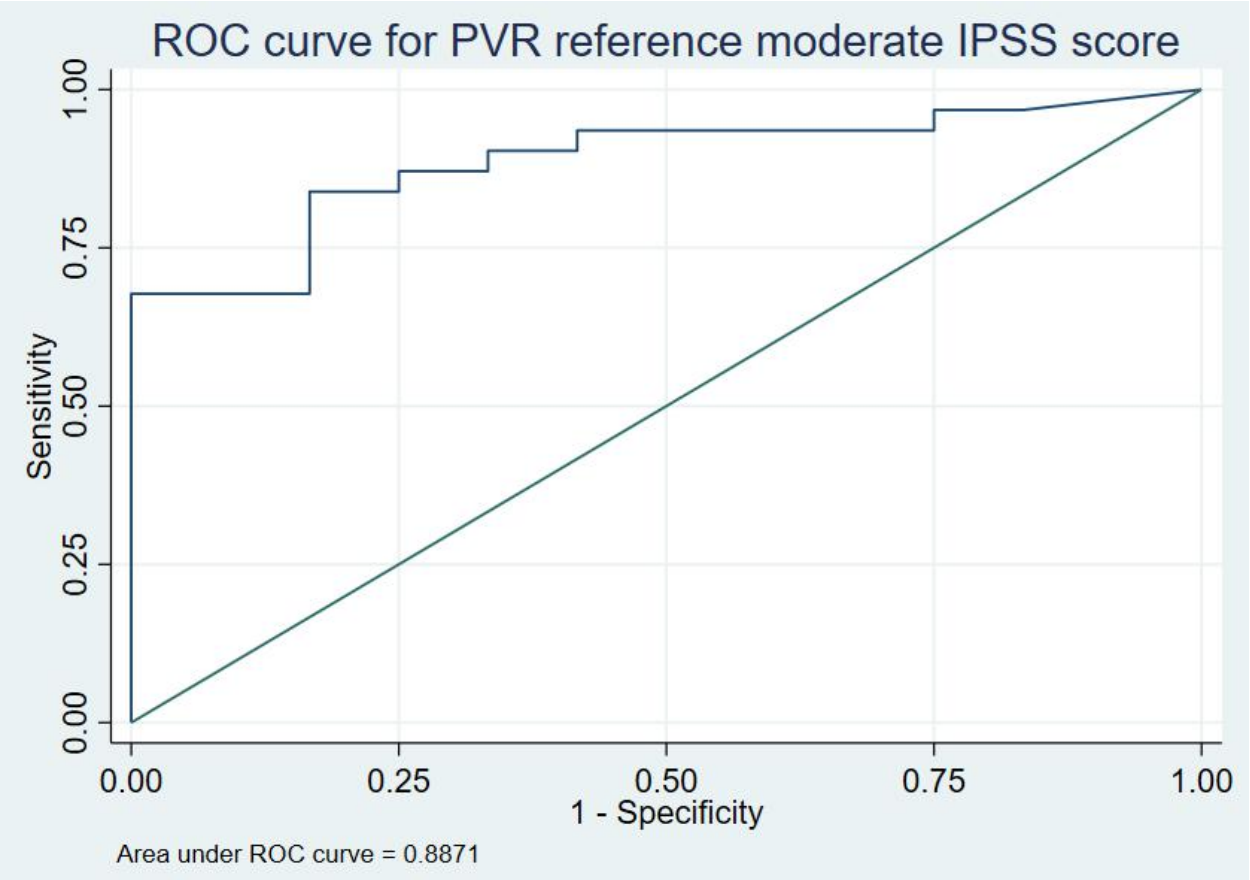
Receiver operating curve (ROC) was used to determine the PVR cutoff values for mild, moderate and severe LUTS as per IPSS. The area under the curve (AUC) was calculated finding of 0.9258. This indicates that the PVR cutoff values have favourable predictive value for patients symptom score.

Figure 7: ROC. PVR Cutoff for mild IPSS



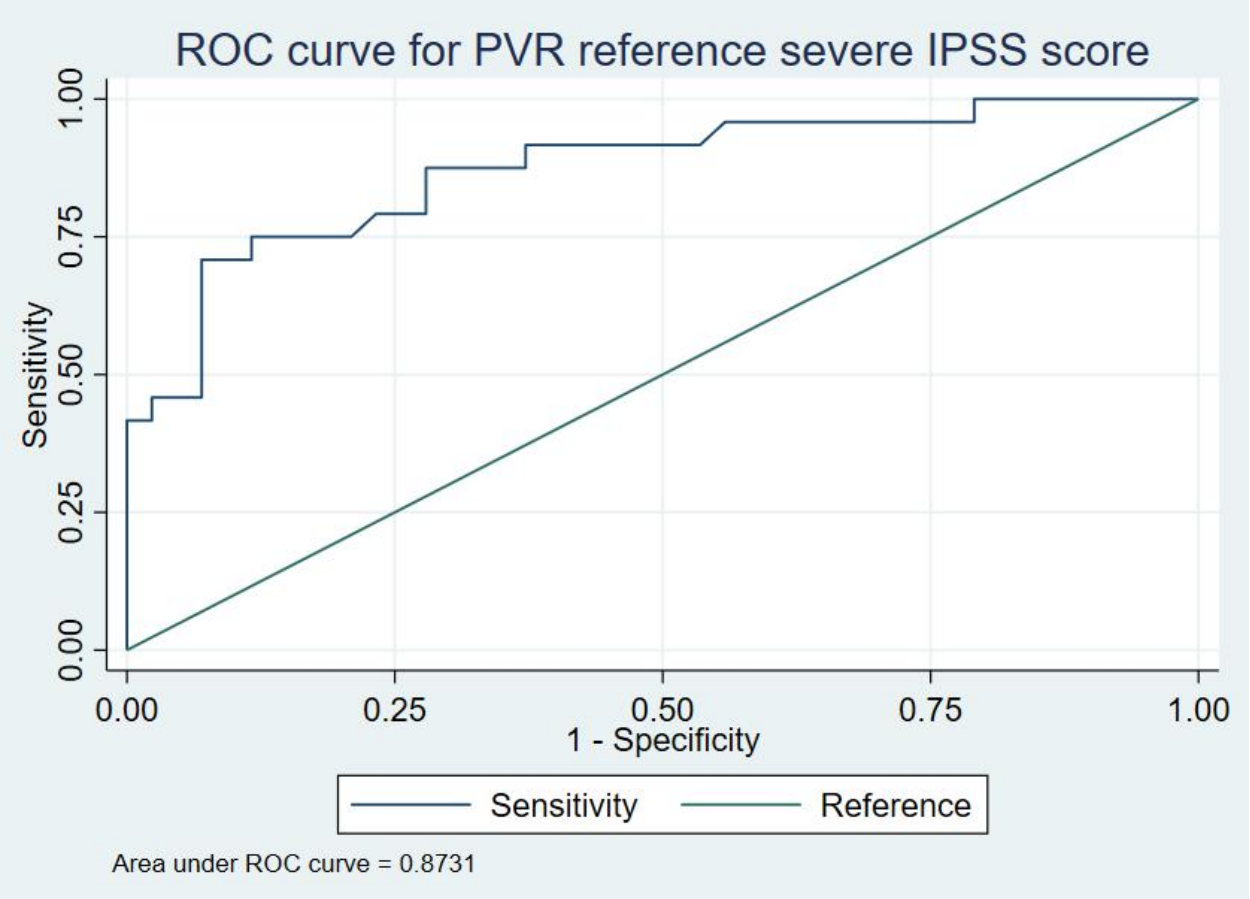
Cutoffs for PVR for moderate IPSS score

Figure 8: ROC. PVR cutoff for moderate IPSS



Cutoffs for PVR for severe IPSS score

Figure 9: ROC. PVR cutoff value for severe IPSS



Summary statistics for PVR Cutoff values varied by IPSS category

IPSS category	Mean	SD	Range	Median
0 – 7	**24.1**	25.9	0 – 72	12
8 – 19	**111.0**	74.0	0 – 298	100
20 – 35	**345**	270.5	17 – 1011	240

6.0 Discussion

Postvoid residual urine volume (PVR), is a noninvasive, reliable and widely used test in evaluation of patients with BPE. However, its diagnostic accuracy in determining severity of LUTS has been in contention.

This study aimed to determine the relationship between PVR and LUTS as measured by IPSS score and the PVR cutoff values for mild, moderate and severe IPSS categories.

A total of 67 patients were evaluated for BPE during the study period. The mean age was 66.1 years. The peak age group was 63-67 years range. The mean age is similar to findings of other studies. Udeh *et al* [44] in Nigeria reported mean age of 65.6 years. Badmus *et al* [45] in Nigeria reported a mean age of 64.4 years. Patients in this study, therefore, appear to be representative of patients with BPE.

Median PVR was 112mls with a range of 0-1011mls. 23 patients (34%) had PVR >100mls. The mean PVR was higher than findings in other studies. In a study by Saafa Hussein *et al*, [46] in Sudan, mean PVR was 69.3 mls +/- 39.8mls. In another study by Lammers HA *et al* [35], PVR >100mls was measured in 27% of cases of which 44% were above 200mls.
The higher PVR finding in the study could be accounted for by poor health seeking behaviour in our set up, where patients seek medical consultation with significant symptoms translating to higher PVR.

In Rotterdam (The Netherlands), a community based data on PVR [9], 372 men enrolled, there was statistically significant increase in PVR with age (p=0.02). Rule *et al* [51], echoed the finding of the Rotterdam study. In the study, a random sample of community dwelling men

(529 men aged 40 -70years) were followed up with a sonographic PVR every 2 years upto 12 years, the median annual change (slope) for the PVR was +2.2% (p=0.03).

PVR is the volume (mls) of urine left in the bladder at the end of micturition. PVR is a consequence of bladder outlet obstruction (BOO) or underactive/ acontractile bladder. BOO occurs due to BPE, urethral stricture or detrusor sphincter dysnergia. Underactive/ acontractile bladder can be from various neurogenic or myogenic causes. Patients with other conditions that could elevate PVR except from BPE were excluded from the study.

Elevated PVR has been associated with progression of symptoms, upper urinary tract damage with obstrucive uropathy, recurrent UTI and acute urine retention (AUR), In a study by Kolman *et al*. [37], men with PVR >50mls at baseline were 3 times as likely to have subsequent acute urine retention with catheterization during 3 to 4 years follow-up; this would require a different prospective study to corroborate the findings.

In the study, the average prostate size was 69.4cc (SD 43.2) with a range of 10-235cc. This is in keeping with a study in Nigeria by Hamza *et al*. [47], whose finding was average prostate size of 64cc. A study in Sudan by Saafa *et al* [46] had comparable findings with mean prostate volume of 78.4cc. A study of Asian population by Kuei *et al* [48] reported mean prostate volume of 40cc. A study in Japan [49] about healthy population reported average prostate size of 18.5 +/- 5.2cc. The normal prostate gland measures 3*3*5cm approximately or a volume of 15 - 25cc. Prostate size increases with age, androgen levels and varies among different race and ethnic groups. A study by Mubenga *et al* [50] in DR Congo found that prostate volume was statistically different among ethnic groups. Prostate size was significantly larger in Lega tribe 55cc range (38-81cc), and smaller among the Havu tribe 20cc range (17-24cc).

In a study by Kolman *et al* [37], an enlarged prostate volume has been linked to an elevated PVR. African race and health seeking behaviour of patients in the study with significant symptoms/ obstructive prostatic enlargement could explain the larger prostate volume among study participants.

The mean IPSS was 18 (Moderate symptoms). 17.9% had mild symptoms, 46% moderate symptoms and 35% had severe symptoms. This is comparable to a study by Hamza et al [47], with mean IPSS 18 +/- 6.93 which was within moderate score on IPSS. The predominance of moderate and severe symptoms among study participants can be attributed to the fact that the study was done in referral hospital urology clinic; where patients are more likely to be referred to the urologist with bothersome LUTS (moderate to severe score on IPSS). A population based study is likely to have patients with mild symptoms as compared to a hospital based study. Ezeanyika et al.[52], in a population based study in Nssuka, Nigeria, on males without symptoms reported 74.65% with mild symptoms, 23.58% with moderate symptoms and 1.77% with severe symptoms. This study participants' higher symptom score could also be attributed to their health seeking behavior. Many men often attribute the changes in urinary pattern as an inevitable consequence of aging and only seek professional care when symptoms become bothersome.

There was a positive correlation between IPSS and PVR; this was found to be statistically significant,(p value <0.001). As IPSS increases, the PVR rises. Several studies have reported contradicting results on the correlation between IPSS and PVR. Hamza *et al.* [47], found significant correlation between PVR and IPSS. Singla *et al*. [53] and Kolman C. *et al*. [10] both reported significant positive correlation between PVR and IPSS. In a study by Saafa *et al.* [46] reported positive significant correlation between PVR and IPSS. Large PVR yielded a significant 2-fold upto 4-fold increased risk of AUR and subsequent Surgical intervention.

Ezz el Din K *et al* [36], in the 1996 found a statistically significant but weak correlation between urinary symptoms measured by IPSS and PVR. Wang JY *et al.*[54] also found a significant correlation between PVR and IPSS, however, in their study with 1295 patients, they noted that it is difficult to predict the severity of symptoms based on PVR. A study by S. Mendez et al. [55] did not find any correlation between PVR and IPSS symptom score.

The conflicting findings on the correlation between PVR and IPSS from different studies could be explained by the fact that occurrence of PVR is not necessarily associated with BPE only, but poor detrusor function/ hypocontractile bladder can also cause an elevated PVR. In this study, we excluded patients with all possible cause of neurogenic bladder to minimize on errors of other contributing factors to PVR.

Receiver operating curve (ROC) was used to determine the PVR cutoff values for mild, moderate and severe LUTS as per IPSS. The area under the curve (AUC) was calculated finding of 0.9258. This indicates that the PVR cutoff values have favourable predictive value for patients symptom score. The PVR cut-off values for mild, moderate and severe IPSS were 24mls, 111mls, and 345 mls respectively.

There has been no consensus among various studies about what volume should be considered a significant or pathological residual volume. Fiala *et al* [56], proposed 100mls of PVR as a pathological value in patients with BPE. AURO guidelines on BPE[57], define as pathological a PVR of more than a third of total bladder capacity but with level 4 evidence. The EAU, AUA and NICE guidelines do not define threshold values for pathological PVR.

7.0 Study Limitations

There are other factors/ conditions that independently influence PVR and IPSS score that were confounding. This include overactive bladder, neurogenic bladder, urethral stricture and bladder diverticulum. To overcome this, such patients were excluded from the study.

Difficulty achieving sample size attributed to third wave of COVID 19 and lockdown that happened during the study duration saw decreased numbers of patients attending urology clinics at our facility.

8.0 Conclusion

In our study, positive correlation was found between IPSS symptom score and post void residual urine (PVR), therefore, PVR can be accurately used as a diagnostic tool to quantify severity of LUTS in patients with BPE.

PVR cut-off values of 24mls, 111mls and 345 mls for mild, moderate and severe IPSS can be used as a guide to quantify LUTS severity.

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APPENDICES

Appendix 1: Data Collection Sheet

Demographic data:

1. Study number.....

2. Patient number.....

3. Age (years).....

4. Occupation.....

5. Residence.....

6. Pre-void residual volume on ultrasound……

7. Post void residual volume on ultrasound……..

8. Prostate size on ultrasound…….……

9.PSA LEVEL…… ……

Appendix 2: International Prostate Symptom Score

Study number:…… **Age**…… **Date**……

In the past month	Not at all	Less than 1 in 5 times	Less than half the time	About half the time	More than half the time	Almost always	Your score
1. **Incomplete Emptying** How often have you had the sensation of not emptying your bladder	0	1	2	3	4	5	
2. Frequency How often have you had to urinate less than every two hours?	0	1	2	3	4	5	
3. Intermittency How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
4. Urgency How often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5. Weak Stream How often have you had	0	1	2	3	4	5	

a weak urine stream?							
6. Straining How often have you had to strain to start urination?	0	1	2	3	4	5	
	None	**1 time**	**2 times**	**3 times**	**4 times**	**5 times**	
7. Nocturia How many times did you typically get up at night to urinate?	0	1	2	3	4	5	
Total IPSS score							

Score: ☐ **1-7: Mild** ☐ **8- 19: Moderate** ☐ **20- 35: Severe**

Appendix 3: Informed Consent Form

This Informed Consent form is for patients in the wards and those attending Urology Outpatient Clinic at KNH.It will be administered to the eligible patients. We are requesting these patients to participate in this research project whose title is: **CORRELATION BETWEEN POSTVOID RESIDUAL URINE VOLUME AND LOWER URINARY TRACT SYMPTOMS AS MEASURED BY INTERNATIONAL PROSTATE SYMPTOM SCORE IN PATIENTS WITH BENIGN PROSTATE ENLARGEMENT IN KNH.**

Principal Investigator: Dr. Samuel Mathenge Maina

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. Samuel Mathenge, a post graduate student in urology at the University of Nairobi. I am carrying out a research to determine relationship between Lower urinary tract

symptoms and Post void residual urine in patients with benign prostatic enlargement at Kenyatta national hospital.

Purpose of the research

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. This study will establish the relationship between Post void residual urine and Lower urinary tract symptoms amongst Benign prostatic enlargement patients at KNH.It will also seek to establish the threshold of Post void residual urine indicating mild, moderate and severe Lower urinary tract symptoms.

Type of Research Intervention

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

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 study 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. Improve diagnostic accuracy and management of BPE.

Risks

There will be invasion of patient privacy during filling of the IPSS questionnaire.

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 University of Nairobi and/Kenyatta National Hospital Ethics Committee, which is a Committee whose task is to make sure that research participants are protected from harm.

Who to contact

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

Principal Researcher:

Dr. Samuel Mathenge Maina,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676 KNH, Nairobi 00202.

Mobile no. 0721 640874

University of Nairobi Supervisors:

Professor, Peter L.W Ndaguatha

MB.ChB, M.MED (Surgery) (UoN), FCS (ECSA), Fellow of Urology (UK)

Professor & Consultant Surgeon and Urologist

Department of Surgery, University of Nairobi.

Dr. Francis Owillah

MBChB, M.Med Surgery (UoN), Cert Urol (KCMC)

Senior Lecturer and Consultant Urologist,

Department of Surgery, University of Nairobi.

If you have any ethical concerns, you may contact:

Secretary, UON/KNH-ERC,

P.O. Box 20723- 00202,

KNH, Nairobi.

Tel: 020-726300-9 EXT 44355

Email: uonknh_erc@uonbi.ac.ke

PART II: Certificate of Consent

I have read the above information, 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_____ Thumb print of participant

Signature of witness _____

Date _____

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 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 4: FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI WA "CORRELATION BETWEEN POSTVOID RESIDUAL URINE VOLUME AND LOWER URINARY TRACT SYMPTOMS AS MEASURED BY INTERNATIONAL PROSTATE SYMPTOM SCORE IN PATIENTS WITH BENIGN PROSTATE ENLARGEMENT IN KNH."

Fomu hii ya makubaliano ni ya wale wanaume ambao wanahudumiwa kwenye kliniki za Urolojia na waliyolazwa katika hospitali ya KNH na wamealikwa kujiunga na utafiti "CORRELATION BETWEEN POSTVOID RESIDUAL URINE VOLUME AND LOWER URINARY TRACT SYMPTOMS AS MEASURED BY INTERNATIONAL PROSTATE SYMPTOM SCORE IN PATIENTS WITH BENIGN PROSTATE ENLARGEMENT IN KNH."

Mtafiti mkuu: Dkt. Samuel Mathenge Maina

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. Samuel Mathenge. Mimi ni daktari ninaesomea urolojia katika Chuo Kikuu cha Nairobi, idara ya upasuaji. Ninafanya utafiti kwa anwani ya, "CORRELATION BETWEEN POSTVOID RESIDUAL URINE VOLUME AND LOWER URINARY TRACT SYMPTOMS AS MEASURED BY INTERNATIONAL PROSTATE SYMPTOM SCORE IN PATIENTS WITH BENIGN PROSTATE ENLARGEMENT IN KNH.".

Lengo kuu la utafiti.

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.

Utafiti huu utapania kuangalia uhusiano kati ya mkojo unaobaki katika kibofu cha mkojo baada ya haja ndogo, na shida ya kupitisha mkojo kati ya wanaume wanao ugua ugonjwa wa uvimbe wa tenzi- kibovu.

Utafiti huu pia utapania kuangalia kiwango cha mkojo unaobaki katika kibofu unadhibitisha ukali wa maradhi.

Aina ya utafiti.

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

Haki ya kukataa utafiti

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

Tandhima ya siri

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

Faida za kushiriki.

1. Utachangia katika kuendeleza umakinifu wa afya ya kisayansi.
2. Kuimarisha tiba ya uvimbe wa tenzi kibofu.

Adhari za kushiriki.

Hakutakuwa na madhara yoyote kwa kushiriki katika utafiti huu, ila kuingiliwa faragha yako unapojibu maswali tutakayo kuuliza.

Anwani za Wahusika

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

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Appendix IV: Fomu Ya Makubaliano Ya Kujiunga Na Utafiti

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_____ Alama ya kidole cha mshiriki

Sahihi la shahidi_____

Tarehe _____

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_____

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