INTERNATIONAL PROSTATE SYMPTOMS SCORE AMONG PATIENTS WITH SYMPTOMATIC PROSTATE ENLARGEMENT AT MTRH-ELDORET

By

Olunga Osundwa Richard.

A thesis submitted to the School of Medicine in partial fulfillment for the requirements of the degree of Master of Medicine in General Surgery of Moi University

DECLARATION

Declaration by Student

This thesis is my original work and has not been presented for an award of a degree in any other University. No part of this thesis may be reproduced without prior written permission of the author and/or Moi University.

Signature…….....Date …….....……

Olunga Richard Osundwa

REG. NO. SM/PGGS/04/12

Declaration by Supervisors

This thesis has been submitted with our approval as University supervisors;

Signature…….....Date …….....……

Dr. Pius Musau

Senior Lecturer Moi University.

Signature…….....Date …….....……

Dr. Florentious Koech

Senior Lecturer Moi University.

DISCLOSURE

The candidate neither received nor expects to receive any financial benefits from this research.

Signature…….....Date …….....……

Olunga Richard Osundwa.

REG. NO. SM/PGGS/04/12

DEDICATION

I dedicate this work to all urologists who have endeavored to make the ‘water’ flow among our patients.

I also dedicate this work to my beloved wife Joy Mideva for her great support and encouragement.

ACKNOWLEDGEMENTS

I would like to thank my supervisors Drs. Florentius Koech and Pius Musau for their guidance in development of this thesis. I thank Ujenzi foundation for their support towards my Masters of Medicine training. I also thank my colleagues and family for their support and contributions.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

A.U.A	American Urological Association.
AUR	Acute Urinary Retention
B.O.O	Bladder Outlet Obstruction
BPH	Benign Prostate Hyperplasia
Ca	Cancer
CPPS	Chronic Pelvic Pain Syndrome
CRI	Chronic Renal Insufficiency
CUR	Chronic Urinary Retention
DHT	Dihydrotestosterone
DI	Detrusor Instability
DRE	Digital Rectal Examination
IPSS	International Prostate Symptoms Score
IPSS-E/S	International Prostate Symptom Score- Emptying/Storage
LUTD	Lower Urinary Tract Disease
LUTS	Lower Urinary Tract Symptoms
MTRH	Moi Teaching and Referral Hospital
OAB	Overactive Bladder
PRV	Postvoid Residual Volume.
PSA	Prostatic Specific Antigen
QOL	Quality Of Life
SPSS	Statistical Package for Social science

TRUS	Transrectal Ultrasound
UTI	Urinary Tract Infection

OPERATIONAL DEFINITIONS AND TERMS

Irritative symptoms: Symptoms of overactive bladder such as urgency with or without urge incontinence, with frequency and nocturia.

Irritative symptoms: Symptoms of overactive bladder such as urgency with or without urge incontinence, with frequency and nocturia.

Medical Treatment: Any intervention other than prostatectomy, includes pharmacotherapy.

Medical Treatment: Any intervention other than prostatectomy, includes pharmacotherapy.

Obstructive symptoms: Symptoms due to blockage of the bladder outlet such as straining at micturition, weak stream, intermittency and incomplete emptying of the bladder.

Obstructive symptoms: Symptoms due to blockage of the bladder outlet such as straining at micturition, weak stream, intermittency and incomplete emptying of the bladder.

ABSTRACT

Background: The International Prostate Symptoms Score (IPSS) is a validated, well-designed and extensively studied scale for quantifying Lower Urinary Tract Symptoms (LUTS) to diagnose prostate disease, and may predict the severity of the disease, patient's quality of life, size of the prostate and suggest the modality of management for the condition. Despite the high morbidity attributed to prostate related disorders, there has been no local study which relates IPSS with sociodemographic factors, diagnosis and care at Moi Teaching and Referral Hospital (MTRH)

Study setting -This study was carried out at MTRH, Eldoret Kenya, in the urology clinic, laboratories and surgical wards.

Study design: This is a hospital based cross-sectional descriptive study.

Objective: To describe the IPSS score and its correlation with socio-demographics, clinical diagnosis, size of prostate, mode of treatment and histological diagnosis of patients seen at MTRH urology clinic with LUTS due to prostate enlargement.

Sample size: One hundred and four (104) patients were recruited in this study.

Sampling Technique: Patients presenting with Lower Urinary Tract Symptoms due to prostate enlargement who consented were consecutively enrolled until the desired sample size was achieved.

Data Collection & Handling: The patients' biodata, IPSS score, most bothersome symptom, prostate size, mode of treatment and histological diagnosis were collected using interviewer administered structured questionnaires, clinical examination surgical operations and laboratory investigation results. The data was entered in Microsoft Excel and later exported to SPSS® version 24 of Windows® for analysis.

Results: One hundred and four patients were recruited in this study. The age of the patients ranged between 46 and 88yrs with a mean age of 69±9 years. On digital rectal examination, the size of the prostate was either mild (19%), moderate (55%) or grossly enlarged (26%). Using the transabdominal ultrasound examination prostate size ranged from 30 to 173 cm^3, with a mean prostate volume of 76.4±28 cm^3. The mean duration of the symptoms before seeking medical help was 10±6 months. In terms of most bothersome symptoms, 36% of the patients had a weak stream while 33% had straining at micturition. While none of the patients presented with mild IPSS cores, majority (70%) presented with a severe IPSS score with the rest presenting with a moderate IPSS scores. Most (80%) of the patients had poor quality of life. Histologically, most of the prostate masses were benign (70%).

In the results, we focused on the key issue of IPSS and its impact; the duration of the symptoms, most bothersome symptoms and effect on QOL.

Conclusion: Patients with LUTS due to prostate enlargement tend to present late. Patients with high IPSS score are likely to have larger prostate size, benign histological structure of the gland and poor quality of life.

Recommendation: IPSS should be used both as a screening tool, diagnostic tool and for follow up of patients with LUTS due to prostate enlargement.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

The prevalence of lower urinary tract symptoms (LUTS) in men increases with age. LUTS affects 5 to 60% of males aged 40 years and above and greatly affects quality of life (Eckhardt *et al*., 2001; Liao *et al.,* 2011). It is a common feature in patients with prostate enlargement because of the anatomic position of the prostate relative to the bladder and urethra. The prostate is a periurethral gland and any changes in its size will directly affect the caliber of the urethra resulting in lower urinary tract symptoms. The International Continence Society has classified LUTS as bladder storage symptoms, sensation or voiding symptoms and post-micturition symptoms (Abrams *et al*., 2002). The specific symptoms include frequency, urgency, nocturia, difficulty in initiating urination, a sense of incomplete bladder emptying, decreased force of stream and interruption of stream. All these symptoms are related to benign prostate hyperplasia (BPH) which is the main etiology of lower urinary tract symptoms in males.

In general, prostate diseases comprise of BPH, prostate cancer and prostatitis, which make up to 80%, 18% and 2% respectively (Lee et al., 2004). Voiding symptoms usually result from bladder outlet obstruction at the level of the prostate. The obstruction can be caused by increase in prostate volume and or increased smooth muscle contraction in the prostate, bladder neck and urethra. Storage symptoms such as nocturia, urgency, increased daytime frequency, and urinary incontinence have complex etiology such as stimulation of the androgen receptor (AR) in the bladder, especially subtype α_{1D}-AR, which predominates human detrusor (Price, 2001).

BPH is the main problem affecting quality of life in men older than 50 years and is histologically diagnosed in up to 90% of men over 85 years (Berry *et al*., 1984). Up to 14 million men in USA have symptoms of BPH (Ajayi *et al*., 2013). Three quarters of patients in their 8th decade have a histological diagnosis of benign prostate enlargement (Ngugi and Byakika, 2007).

The American Urological Association (AUA) guidelines established that evaluating symptom severity with a symptom score is an important part of assessment of male LUTS. This association devised the IPSS in 1992 and originally lacked the 8th QOL question, hence its original name; The American Urological Association symptoms score (AUA-7). The current IPSS is an eight question (seven symptom questions and one Quality of life question), reproducible, validated tool designed to screen for, track symptoms, determine severity, suggest management and assess response to therapy of the symptoms of prostate enlargement (Liao *et al.*, 2011). No study has been done in our setting or the region to determine how our patients with prostatism relate to IPSS. This study therefore sought to correlate IPSS with age of patients, duration of symptomatology, treatment modality and histological diagnosis.

1.2 Problem Statement

Lower urinary tract symptoms (LUTS) are prevalent among men over 40years; affecting approximately 40% of these men and greatly impacts negatively on the quality of life (Patel and Parsons, 2014). Prostate related LUTs account for 30 – 40% of patients seen at urology clinic in MTRH. In 2016, a total of 131 patients with symptomatic prostamegally were seen at MTRH urology clinic. LUTS denote the presence of a varied range of prostate disease including benign prostate enlargement, prostate cancer or prostatitis. Benign Prostatic Hyperplasia is the most commonly occurring neoplastic condition in the aging human male (Parsons, 2011; Hosseini *et al*., 2007). Prostate cancer and prostatitis (acute bacterial prostatitis, chronic bacterial prostatitis) can present with LUTs, presenting mainly with the irritative symptoms (Price, 2001). Prostate Enlargement related disorders including BPH and prostate cancer accounts for the high percentage of patients visiting urology clinics and admitted in the male surgical wards. These patients have equally been forced to change their lifestyles due to the associated complications. This current state of morbidity burden and economic strain, necessitates the need for early diagnosis and appropriate intervention. IPSS is a useful tool in assessment, diagnosis and prognosis of prostate disease. While the IPSS is a cheap reliable tool in diagnosis and monitoring response to treatment of prostate disease, its role in our set up is largely unknown and a study in this area would help bridge the knowledge gap on our patient care in MTRH.

1.3 Research question

What is the IPSS score among patients presenting with symptomatic prostate enlargement at MTRH and how does it correlate with clinical diagnosis, size of the prostate, histological diagnosis and mode of treatment?

1.4 Justification

With the control of communicable diseases and longevity of life, prostate enlargement related disorders are a highly prevalent disease in the elderly men, bearing a significant burden of disease and negative socioeconomic impact. There is very little data from the region and the rest of the African Continent to guide evidence-based medicine, resource planning and effective health care delivery in the setting of a developing country. Frequent comorbidity with potential prostate disease adds complexity to the management of male LUTS.

There is equally very little data on the rate of utility of IPSS, an internationally validated tool in the diagnosis and management of Lower Urinary Tract symptoms due to prostate enlargement. This knowledge will go a long way in ensuring early diagnosis, and can guide both the primary clinician and the urosurgeon on the mode of treatment for the specific Prostate enlargement conditions. This study provides baseline data on the presentation of patients with prostate enlargement at MTRH. It also explores the role of IPSS in early diagnosis and subsequent management of patients with LUTS due to prostate enlargement.

1.5 Significance of the study

LUTs are a common problem among patients presenting to urology clinic. These symptoms are usually either due to overactive bladder or bladder outlet obstruction (prostate enlargement and urethral conditions like strictures). Since OAB Symptoms comprise the same symptoms as storage LUTs in prostatism and most men with OAB do not experience incontinence, men with storage LUTS are often misdiagnosed to having clinical BPH. IPSS can be utilized in clinical diagnosis of the possible causes of prostate enlargement such as BPE and Prostate cancer in the clinic. It can also be employed in establishing the severity of LUTS due to prostatism and subsequently initiation of correct and timely management and monitoring response to therapy. This study sheds light on our patient symptomatology, clinical findings and interventions and will form a baseline on understanding patients with prostatism in our country and region.

1.6. Objectives

1.6.1 Broad Objective

To describe the IPSS score and its correlation with clinical diagnosis, size of prostate, mode of treatment and histological diagnosis of patients seen at MTRH urology clinic with LUTS due to prostate enlargement

1.6.2 Specific Objectives

1. To describe the socio-demographic characteristics of patients presenting with LUTS due to enlarged prostate
2. To determine the IPSS score of the patients attending the urology clinic of MTRH with LUTs due to prostate enlargement.
3. To correlate IPSS scores with clinical diagnosis, size of prostate and mode of treatment and histological diagnosis for prostate enlargement

1.7 Scope of the study

This study focused on the patients presenting with LUTS due to Prostate enlargement at urology clinic in MTRH, assessment of their prostate size, clinical diagnosis, their IPSS scores, mode of treatment and histological diagnosis. It also included how the IPSS relates to specific LUTs, clinical diagnosis, prostate size, mode of treatment and histological diagnosis.

CHAPTER TWO: LITERATURE REVIEW

2.1 Overview of Lower Urinary Tract symptoms and IPSS

The International prostate symptoms score (IPSS) is a guideline tool designed for rapid clinical diagnosis and subsequent follow up and management of patients with Lower Urinary Tract Symptoms. The IPSS is a derivative of the American Urological Association symptoms index. The AUA symptom index is based on a questionnaire used in assessing patients with specific lower Urinary Tract Symptoms (LUTs) due to either Bladder outlet obstruction (BOO) or Overactive Bladder (OAB). The IPSS consist of seven AUA symptoms question that can be divided into obstructive/emptying symptoms (incomplete emptying, intermittency, weak stream and straining) and irritative/ storage symptoms (frequency, urgency and nocturia).

Several studies have noted that men with LUTs, secondary to OAB were being misdiagnosed as having clinical BPH (Ignjatovic, 2001; Kuo, 2002; Lee et al., 2004;). It therefore became necessary to establish a guiding framework to improve clinical non-invasive diagnosis of BPH and other causes of Prostatism.

2.2 Epidemiology of lower urinary tract symptoms and prostate enlargement

Lower Urinary symptoms arise from outlet obstruction at the bladder neck. The aetiology of LUTS is multifactorial involving many different processes that eventually lead to obstructive uropathy. LUTs in elderly men were traditionally attributed to the enlarging prostate.

Although the enlarged prostate can contribute to the onset of LUTS in proportion of men over 40 years of age, other factors are of equal importance. There are suggestions that

LUTS may be linked to the prostate (BPH-LUTS), bladder (detrusor overactivity-overactive bladder syndrome, detrusor underactivity) or kidney (nocturnal polyuria) (Chapple & Roehrborn, 2006). Because of the great prevalence of BPH in elderly men, which is as high as 40% in men in their fifth decade and 90% in men in their ninth decade, the IPSS categorizes these LUT symptoms into obstructive and irritative (Roehrborn, 2005). The irritative symptoms arise later due to the effect of initial obstruction and subsequent urine stasis.

The increase in growth of peri-urethral prostate results in obstruction of the prostatic urethra hence LUT symptoms consistent with bladder outlet obstruction. BPH is a common condition among older men, generating considerable morbidity and health care costs. Lower urinary symptoms associated with clinically detectable prostate enlargement are presumed to be caused primarily by BPH (Sciarra et al., 1998). Various theories have been postulated to explain molecular etiology of BPH. These include;

i. Dihydrotestosterone (DHT) Hypothesis: It's been observed that functioning testes are required for the development of BPH and that with aging there is a shift in prostate androgen metabolism favoring the prostatic accumulation of DHT. DHT is believed to be the major androgen stimulating prostate growth and formation (Moore, 1947; Campbell, 2005).
ii. Another theory is based on stromal-epithelial interaction in growth and maintenance of the prostate. This theory postulates that the aetiopathogenesis of BPH is based on the initial stromal-epithelial induction that results in subsequent migration of epithelial cells hence formation of new glandular elements (Chapple & Roehrborn, 2006).

iii. LUTs, including bladder storage, voiding symptoms, and postmicturation dribbling, represent a common condition in elderly men and were traditionally related to an enlarged prostate (Alessandro et al., 2005). However recent studies have shown that while prostate growth leading to bladder outlet obstruction may contribute to the development of LUTs, other factors originating from the bladder, such as detrusor overactivity, detrusor underactivity and inflammatory processes may be equally relevant (Roosen et al., 2009).

2.3 Pathophysiology of LUTS

It has historically been assumed that the pathophysiology of LUTS in men is definitely the result of bladder outlet obstruction associated with prostate enlargement. Such that prostate enlargement, results in bladder outlet obstruction, with urinary retention, straining with voiding, weak stream and frequency. The observation that prostate enlargement, bladder outlet obstruction, and LUTS are all age-dependent has been interpreted to indicate that these phenomena were causally related, but there is insufficient evidence for this (Lepor, 2005). Undoubtedly, some men's prostate enlargement causes obstruction and symptoms.

Since OAB symptoms comprise the same symptoms as storage LUTs in BPH and most men with OAB do not experience incontinence, men with storage LUTS are often misdiagnosed with clinical BPH. The cause of OAB symptoms may be due to bladder dysfunction such as detrusor overactivity or impaired detrusor contractility, or occur in combination with BOO (Oelke & Descaueaud, 2012).

The clinical manifestations attributed to BPH include LUTS, impaired bladder emptying (PVR), acute urinary retention (AUR), detrusor instability (DI), urinary tract infection (UTI), chronic urinary retention (CUR), chronic renal insufficiency (CRI), and hematuria. Historically, it has been thought that these signs and symptoms resulted from bladder dysfunction arising from BOO due to the enlarged prostate. Prostatic enlargement promoted BOO due to dynamic and static factors. Smooth muscle hyperplasia contributed to the dynamic obstruction and the generalized hyperplasia of both stromal and epithelial elements contributed to the static obstruction. Bladder outlet obstruction predisposed directly to AUR. Long-term BOO also promoted bladder dysfunction, which was manifested by poor contractility or detrusor instability. The incomplete bladder emptying resulting from impaired bladder contractility caused LUTS, UTIs, CUR, and CRI. The detrusor instability also contributed to LUTS.

The medical therapies widely used today for treatment of BPH are targeted to diminishing bladder outlet obstruction in order to reduce prostate volume and relax prostate smooth muscle tension. Clinical data demonstrate that androgen suppression and α-blockade relieve and increase urinary flow rates in men with BPH; these data have been used to support the hypothesis that the pathophysiology of “prostatism” is due to bladder outlet obstruction.

2.5 Role of IPSS in diagnosis and treatment of prostate enlargement

IPSS was designed to be self-administered by the patient with speed and ease in mind. Additionally, IPSS can be performed multiple times to compare the progress of symptoms and the severity over months and years. The IPSS uses seven questions (AUA-7) that relate to the associated symptoms; Classification ranges from mild (0 to 7) to moderate (8 to 19) or severe (20 to 35). Patients with moderate or severe symptoms require treatment. In addition, the IPSS includes a quality of life score as a single 7-point scale question asking the patient how he would feel if he were to spend the rest of his life with his current urinary condition (Johnson et al., 2012).

It has been documented that the IPSS is a simple and useful method of the first line physicians especially those who have no diagnostic equipment (Liao et al., 2013). In that study results, using the IPSS to guide initial treatment for males with LUTs was safe and results in satisfactory outcome. In Kenya, Campbell did a study on the high rates of prostate symptoms among Ariaal men from Northern Kenya. He wanted to determine the prevalence and possible determinants of symptomatic BPH in a subsistence population. The IPSS was administered to men among the Ariaal community. He established that 72% of men over 50 years had moderate to severe LUTs hence high rates of LUTs compared to industrial populations (Campbell, 2005). Larger and longer placebo-controlled studies are still needed to confirm the role of IPSS-E/S in male LUTs (Oelke & Descaueaud, 2012).

For prostate cancer, the shortage of sensitive, specific, cost beneficial and easily-used screening tools for diagnosing this disease is obvious and tangible. Logically, it is clear

that using this kind of screening tools like the IPSS by the health care providers and the elders themselves could lead to the earlier diagnosis of the disease and the reduction of the disease induced problems and the costs as well. One of the important features of a screening tool is its sensitivity and specificity. Several authors reported that a lot of the elderly had urination problems, but that only small percentages of them consulted physicians (Roehrborn, 2005).

CHAPTER THREE: METHODOLOGY.

3.1 Study site

This study was conducted at the urology clinics, histology laboratory, operation theatres and the surgical wards of Moi Teaching and Referral Hospital's (MTRH), Eldoret – Kenya. MTRH hospital is the second largest referral hospital in Kenya. It serves the greater Western Kenya region representing about 40% (approximately 16.2 million people) of the country's population. It also serves Eastern Uganda and parts of Southern Sudan.

MTRH also serves as a teaching hospital for Moi University School of Medicine.

3.2 Study Design

This was a hospital based cross-sectional descriptive study where patients seen at the Urology clinic with Lower Urinary Tract symptoms due to prostate enlargement were subjected to the IPSS tool, initiated on appropriate treatment and underwent either Trucut or excisional biopsy for histological diagnosis.

3.3 Study Population

This included male patients who presented with LUTs due to prostate enlargement at Moi Teaching and Referral Hospital (MTRH) during the study period (January -December, 2016).

3.4 Sample size

The sample size was determined by the use of Eng (2003) statistical formula for descriptive studies:

$$n = \frac{4\sigma^2(z_{crit})^2}{D^2}$$

Where

n = Desired sample size

:σ

= is the assumed SD for the group, which was 0.13 based on the previous study by Campbell, 2005.

Z_{crit} = The standard normal deviate set at 1.96 which corresponds to 95% confidence level.

D = is the total width of the expected CI of 95% which is 0.05.

Therefore, in substitution:

$n = \frac{4(0.13)2*(1.96)^2}{(0.05)^2}$ = 103.87

A sample size of 104 was therefore selected for this study.

3.5 Sampling technique

Consecutive sampling was used to recruit participants into this study until the calculated desired sample size was achieved. These were adults who presented to the urology clinic at MTRH between January and December 2016, with Lower Urinary Tract Symptoms secondary to Enlarged Prostate.

3.6. Study variables

The dependent (outcome) variable was the lower urinary tract symptoms. The independent variables included demographic characteristics, clinical and histological diagnosis and mode of treatment.

Table 1: Variables used in the study

VARIABLE	MEASURE
Age	Years
IPSS	Score
Clinical Diagnosis	Incidences
Histological Diagnosis	Incidences
Mode of Treatment.	Surgical or medical

3.6 Eligibility Criteria

3.6.1 Inclusion Criterion

- All consenting adult male patients presenting with lower urinary tract symptoms with confirmed enlarged prostate on DRE

3.6.2 Exclusion criteria

- None consenting patients.
- Patients already on medication associated with LUTS such as antidepressants, diuretics, bronchodilators and antihistamines.
- All patients who have already undergone surgical operation for LUTs related disorders.
- Co-morbidity eg urethral strictures, urinary bladder tumors.

3.7 Study procedures

Patients with lower urinary tract symptoms due to prostate enlargement attending the urology clinic were requested to participate in the current study. Those who consented were enrolled into the study upon meeting the inclusion criteria. The management of the patients was according to the standard hospital protocol. The investigator took the patient's biodata and a comprehensive medical history of current and past illnesses as well as duration of LUTs and use of medications.

These patients were subjected to Digital Rectal Examination (DRE) to clinically determine the presence of prostate enlargement. The prostate was considered enlarged if the examiner's finger gets over the prostate with difficulty or it cannot get over the prostate at all. The principal investigator performed all the Digital Rectal Examinations.

Subsequently transabdominal kidney, ureter, bladder- prostate ultrasounds were done by qualified sonographers. This included the scan of the prostate for its volume. Biopsy of the prostate was obtained from patients using a prostate biopsy gun, after standard procedural analgesia and prophylactic antibiotics. The collected sample was later subjected to microscopic examination and histological diagnosis established. The histological procedures were performed and interpreted by the qualified clinical pathologist in conjunction with the principal investigator and laboratory technician. All laboratory investigations were carried out at the MTRH laboratory. Clinical, ultrasound, histological findings were entered into a structured questionnaire.

3.8 Data Management

3.8.1 Data Collection and management

Data collection was done through an interviewer administered structured questionnaire based on the IPSS tool. This method was used because men of all literacy levels were included in this study. It wasn't possible for all men to read and respond appropriately on their own. Medical records were also reviewed for determination of clinical findings as well as performance of biopsies for determination of histological diagnosis. The collected data included demographic, clinical and histological characteristics. All filled questionnaires were checked for completeness and coded accordingly and stored in lock

and key data cabinets and the database was pass-worded. The data was entered in MS Excel database at the end of each day for storage and backup before exporting to SPSS.

3.8.2 Data Analysis and presentation

Descriptive Statistics such as continuous data were analyzed and summarized as means and median, with standard deviation and interquartile ranges, respectively using SPSS version 24 for Windows®. Categorical data were presented in the form of frequency tables and charts. The inferential Statistics for continuous data employed the Student's T-test to compare means while linear regression was used to control for confounders. For binary data, chi square test was used for analysis while logistic regression was used to control for confounders.

3.9 Ethical considerations

This study was carried out after approval by the Institutional Research and Ethics Committee (IREC) of MTRH and Moi University School of Medicine and permission from MRTH management. A written informed consent was obtained from the participant to be included in this study. Confidentiality was maintained throughout the study by using passwords for the database and limiting its access only to principal investigator. Patients' identity was concealed as this data was coded. Interviews were carried out in a consultation room which ensured privacy and convenience. All participants received the same level of care awarded to all other patients irrespective of their participation. There were very minimal anticipated risks to the participants attributable to this study except the physical pain of biopsy and discomfort associated with sample collection. Patients with LUTS were informed of their results and managed accordingly. There was no

conflict of interest in this study. The results of this study will be made available to the Moi Teaching and Referral Hospital and may be presented in professional conferences.

CHAPTER FOUR: RESULTS

One hundred and four cases were recruited in this study. Fifteen patients had been excluded because of incomplete data and their data was not used in the final analysis of this study.

4.1 Participant demographic characteristics

The patients ages ranged between 46 and 88 years, with mean age (with SD) of the participants was 69±5 years. Participants of this study originated from the Nyanza, Western and Rift Valley regions of Kenya, which constitutes the main catchment areas for MTRH. They were predominantly retired workers and farmers.

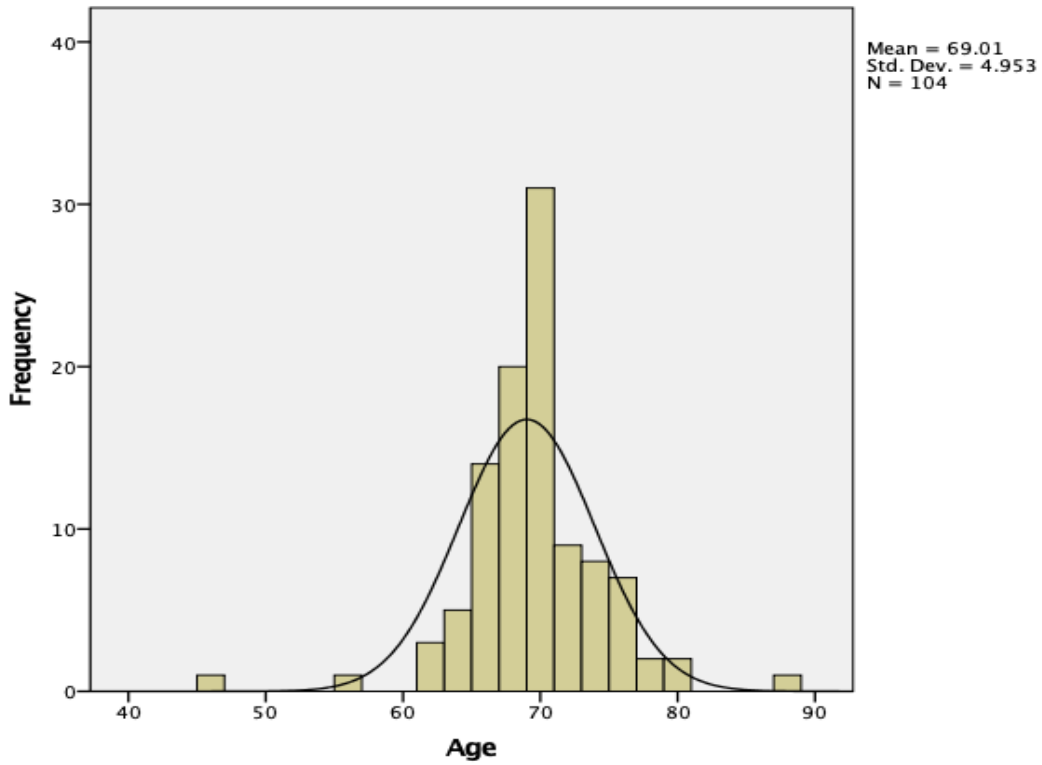

Figure 4.1: A histogram showing the distribution of LUTS in different age groups

4.2 Clinical presentation and diagnosis

Most patients presented with complaints of weak stream (36%) and straining (33%). The mean duration of symptoms was 10±6 months, with the median and mode of 6 months. Using the question on quality of life, most (80%) of the patients had poor quality of life. On digital rectal examination, the size of the prostate was mild, moderate or grossly enlarged in 20%, 57% and 27% of the cases respectively. Majority of the patients (70%) presented with a severe IPSS score with the rest presenting with a moderate IPSS.

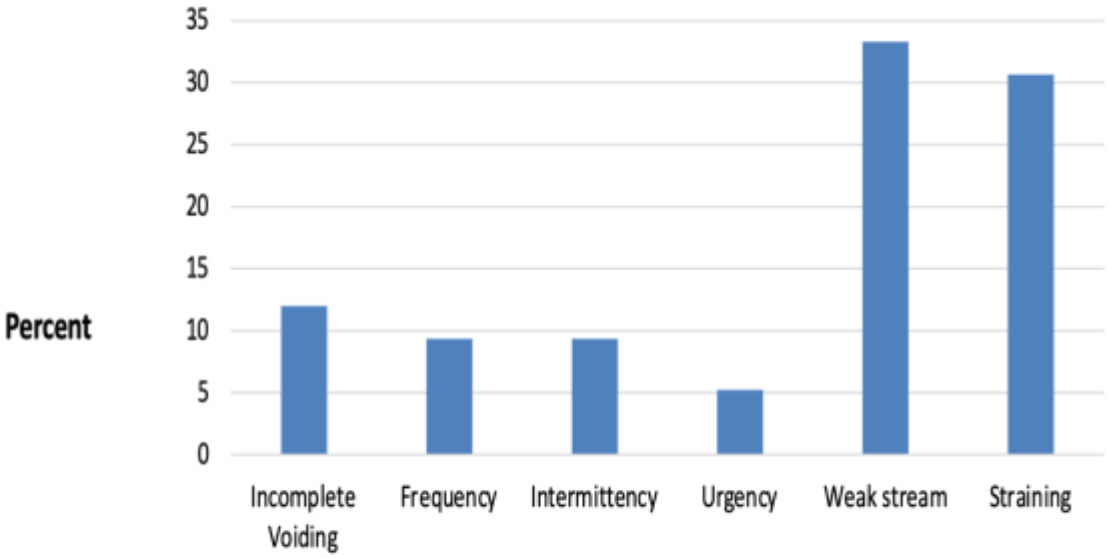

Figure 4.2: A bar chart showing the most bothersome symptom.

Using the transabdominal ultrasound examination, the mean prostate volume was 76.4±28 cm^3, with a range of 30 to 173 cm^3. Using the bivariate regression model, the size of the prostate by clinical examination correlated positively with their ultrasound sizes ($p<0.001$).

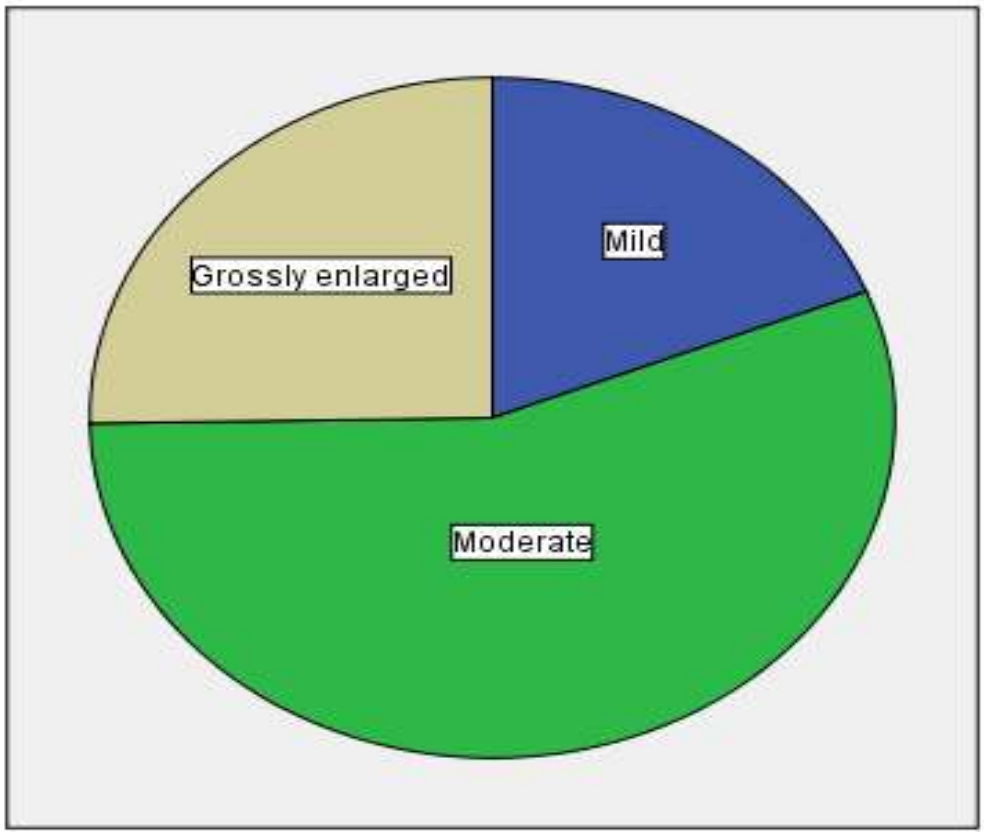

Figure 4.3: A pie chart showing different proportions of the prostate size

Table 2: The correlation between prostate size on DRE and on Ultrasound.

Prostate size	Mean Volume	Correlation significance p
Mild	60±24	0.001
Moderate	68±25	0.003
Grossly Enlarged	101±32	0.004

After the routine processing of the biopsy materials for light microscopy, the prostate mass slides were examined by the qualified pathologist. Most of the prostate masses had features suggestive of benign prostate enlargement (70%), while the rest had features of prostate malignant change.

4.3 Management of LUTS secondary to Enlarged Prostate.

Almost a third (30%) of the patients were medically managed, while the rest were surgically managed. Medical management of the tumor included pharmacotherapy, hormonal therapy or a combination of both. Some of the pharmacotherapeutic agents included Tamsolusin and Dutasteride. While orchiectomy was the method used in hormonal manipulation. Surgically, the prostates were either resected by TURP (N = 4) or by open prostatectomy (N = 66).

4.4 Correlations between IPSS with multiple parameters.

There was no correlation between the IPSS and the age of the patients (P=0.82) or the duration of symptoms (p=0.59). The IPSS correlated positively with the size of the prostate (Correlation coefficient of 0.260, p=0.012).

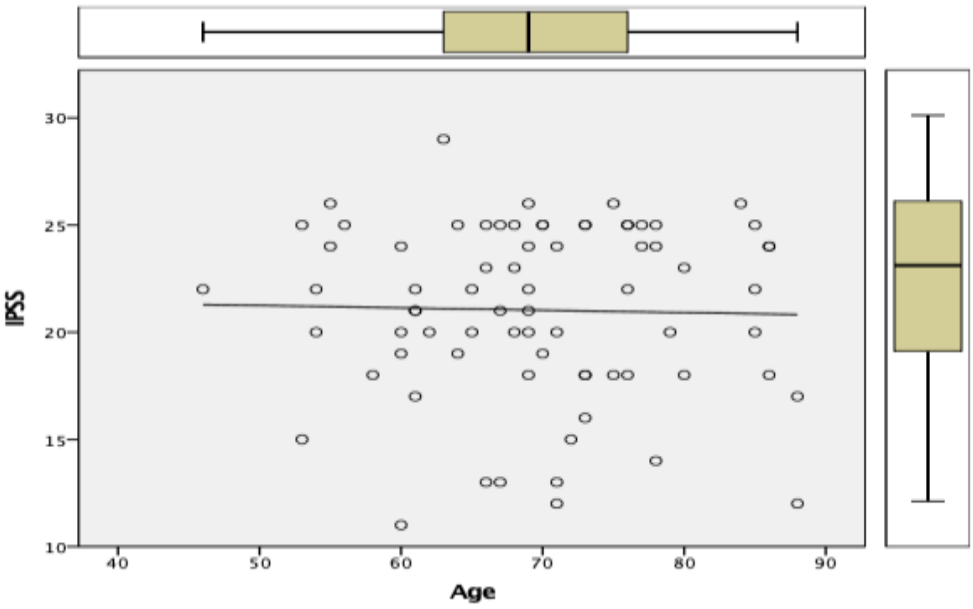

Figure 4.4: A scatter plot showing the correlation between IPSS with patient's age

Moderate and severe IPSS correlated positively with weak stream and straining (P=0.05). IPSS correlated positively with benign histological organization of the tumor (p=0.05); the higher the IPSS the more likely it is to be benign prostate hyperplasia. Although the histological organization of the tumor did not have any significant correlation with the size of the tumor (Table 3, Figure 4.5).

Table 3: Correlation of IPSS with other parameters.

	IPSS	P value
Parameter	Standardized correlation coefficients	
Prostate volume	0.260	0.012
Most Bothersome Symptom	0.043	0.671
Duration of symptom	-0.57	0.590
Histological Organization	0.197	0.050

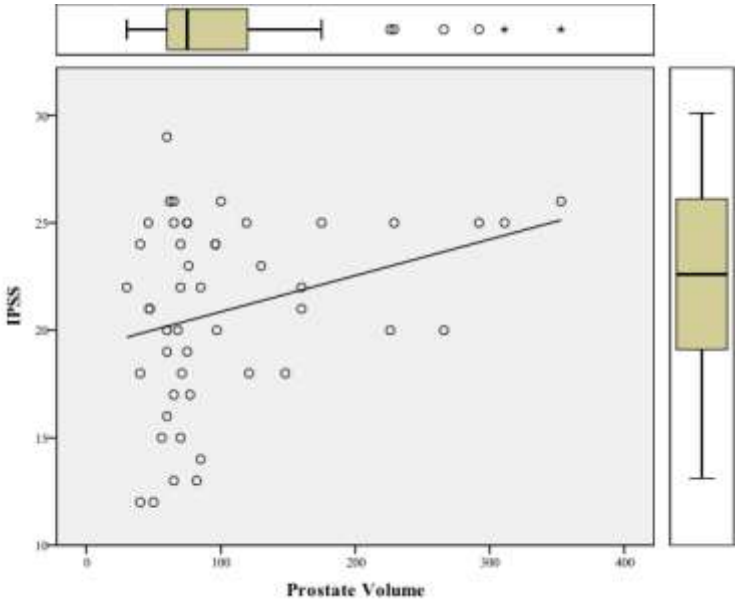

Figure 4.5: Scatter plot showing a linear correlation between IPSS score and prostate volume.

CHAPTER FIVE: DISCUSSION

5.1 Overview and Socio demographic characteristics of patients

This was a crossectional descriptive study used to assess the overall sociodemographic features, presentation and correlation of IPSS with clinical diagnosis, histology and size of the prostate of patients presenting with LUTS secondary to enlarged prostates at MTRH.

In the current study, the mean age of the patients presenting with LUTS due to enlarged prostate was 69 years. This is consistent with observations from other populations, that prostate disease increases with age; the mean age of presentation of patients with prostate enlargement in the Nepalese, Korean and Japanese populations was 67.5yrs, 69.5yrs, 69.5yrs and 67 yrs respectively (Agarwal et al., 1998; Oh et al., 1998; Tsukamoto et al., 2007; Fujimora et al., 2012).

Other studies have shown that BPH, the major cause of LUTS is a progressive disease; a European study on men with mild IPSS scores showed that 31% of these men eventually progressed from the mild symptoms group to the moderate symptoms or severe symptoms after 48- months follow up (Djavan et al., 2002)

However, there was no correlation between the age of the patients with the IPSS score. This observation is similar to the findings of Ganpule et al., (2004) who did not find any correlation between the age of the patients with the IPSS scores in some sample of 2406 Indian patients with LUTS due to prostate enlargement.

5.2 Lower urinary tract symptoms and diagnosis of prostate disease

In the present study, patients were assessed using the IPSS tool and determined that most of them (70%) had severe obstructive symptoms with poor quality of life. A study done in Nigeria among patients with BPH found 46% with severe IPSS scores (Amu, et al., 2012).

In a population study done in Saudi Arabia among men over the age of 40years it was found that 58% had mild IPSS scores and only 4% had severe IPSS scores (Mostafa, et al., 2014).

In agreement with previous population studies, patients responded to all the IPSS questions without any difficulty, in spite of their educational, age and cultural differences (Neto et al., 1997). Assessing the LUTs in men >50 by the IPSS test, could lead to early diagnosis and even prevention of disease, and will help the health care providers and the patients to be aware of the disease status (Vogelzang, 2006).

5.3 Estimation of prostate volume and its role

It was found that the average prostate volume measured by digital rectal exam to be moderate. On transabdominal ultrasound examination, the average size of the prostate volume in the present study was 76 cm^3. In as much as the prostate volume on digital rectal examination had a linear correlation with the ultrasound findings, the transabdominal ultrasound prostate volumes were slightly larger than the anticipated figures on clinical examination. In a previous study, Palmerola et al (2012) described that abnormal DRE has a sensitivity of 44%, specificity of 68%, with a positive predictive value (PPV) of 46%, with a negative predictive value (NPV) of 67% for detecting prostate disease. The prevalence of DRE-detected enlarged prostate in Ghana was 62.3%

with the prevalence of moderate to severe LUTS (IPSS>/=8) at 19.9%; prevalence of IPSS>/= 8 and an enlarged prostate on DRE was 13.3% (Chokkalingam et al., 2012). Therefore, the role of DRE in examining enlarged prostates for whichever pathology cannot be over emphasized.

An estimation of prostate volume is very useful, it helps to decide upon the appropriate therapy and assist in the interpretation of serum PSA level for the presence of cancer (Stone et al., 1991; Lee et al., 1992). Previously, some authors used transabdominal ultrasonography to measure prostate size while others used the transrectal ultrasound (TRUS) exam to assess the size of the prostate with conflicting results (Stone et al., 1991; Stravodimus et al., 2009). Some authors have described the TRUS to be more accurate than the transabdominal scan, while others have found no difference between the two methods (Chung et al., 2004; Ajayi et al., 2013).

There was no correlation between the prostate volume and the mode of management of the patients in our center. Other studies have strongly linked the volume of the prostate to the treatment modality applied, especially in medical treatment (Stone et al., 1991; Lee et al., 1992; Emberton et al., 2003; Nickel, 2003). In the present study, very few patients benefitted from isolated medical treatment of their enlarged prostates. Statistically, this small number was therefore insignificant, suggesting that the size of the prostate was necessarily not used to decide whether to manage the condition primarily through surgery or by medical treatment. For those patients who were eventually surgically managed; the patients with relatively small size (<100cc) prostates were managed by TURP, while the large prostates were managed by open prostatectomy.

5.4 Correlation of IPSS with prostate volume

There was a strong correlation between the IPSS score and the volume of the prostate in the current study, this agrees with another study, Bosch et al., 1995. However, Agarwal et al (2008), did not find any relationship between the IPSS score and the prostate volume in a Nepalese population. In another study, Franciosi et al., (2007) did not find any correlation between the prostate volume and the IPSS score. The variance between the current study and those of Agarwal (2008) and Franciosi (2007), maybe related to the difference in the patient response to the IPSS questions, as well as the difference in duration of symptoms before seeking medical care

In general, there is a noted association between prostate volume and male LUTs (Liao, 2011). Specifically, studies have related large prostate volume to incomplete voiding and nocturia (Agarwal et al., 1998). Studies showed that 25 – 50% of men with BPH have LUTs and 48-53% of men with LUTs have proven Bladder Outlet Obstruction (B.O.O) due to BPH or other urethral conditions (Eckhardt et al., 2001).

5.5 Correlate IPSS scores with histological diagnosis

In the current study, IPSS score correlated positively with the histological organization of the prostate. Higher IPSS scores correlated positively with benign prostate disease. This could partly be skewed because of the larger number of benign prostate enlargement cases compared to the cancerous ones. Ngugi and Byakika (2007), found that 76% of the specimen from patients with prostate enlargement in a Kenyan sample were benign. Hosseini et al (2011), in a study similar to ours, in an Iranian sample demonstrated that mild IPSS score had a sensitivity and specificity of 78% and 59.4%, respectively, to predict prostate disease. IPSS scores had a linear correlation with the benign prostate

enlargement. Other studies have documented that the correlation between IPSS and objective noninvasive parameters of lower urinary tract dysfunction is low (El Din et al., 1995; Bosch et al., 1995), discounting it as a useful tool in decision making (Agarwal et al., 2008). Sciarra et al., (1998), seem to suggest that IPSS has an even stronger association with objective measures in older patients, further strengthening the role of the IPSS in diagnosis of lower urinary tract obstruction.

5.6 Correlation of IPSS with mode of treatment for prostate enlargement

In this study, the IPSS did not have any correlation to the mode of management of the prostate. In the current study, most patients with enlarged prostates were managed surgically. This included open prostatectomy and TURP. Very few patients benefitted from medical management because they presented late with severe symptoms on the IPSS score, making them not eligible for medical management. Traditionally, medical treatment of enlarged prostates ranges from use of drugs such as tamsolusin, dutasteride and other pharmacological agents such as saw palmito berry (Wilt et al., 2003).

CHAPTER SIX CONCLUSION AND RECOMMENDATION

6.1 Conclusions

1. In our setting, patients with prostate disease present to the hospital late, around six months after onset of their symptoms.
2. Majority of the patients with prostamegally in our setting present with straining at micturition and weak stream as the most bothersome symptoms.
3. Majority of the patients with prostatism come with moderate to severe IPSS scores due to their late presentation.
4. A high IPSS score predicts the larger prostate size and benign histological structure of the prostate gland.

6.2 Recommendations.

IPSS should be widely used both by the primary clinician and the urosurgeon for screening, diagnosis and follow up of patients with LUTS secondary to prostate enlargement.

REFERENCES

Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A. (2002). Standardization Subcommittee of the International Continence Society. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. *Neurourol Urodyn* 21, 167-178.

Agarwal CS, Chalise PR, Bhandari BB. (2008). Correlation of prostate volume with international symptom score and quality of life with men with benign prostatic hyperplasia. Nepal Medical College Journal. 2008. 10: 104 -7.

Ajayi I, Aremu A, Olajide A, Bello T, Olajide F, Adetiloye V. (2013). Correlation of transrectal and transabodominal ultrasound measurement of transition zone volume with post-operative enucleated adenoma volume in benign prostatic hypertrophy. *The Pan African medical journal*. 16: 149

Benson MC, W.I., Pantuck A, Ring K, Kaplan SA, Olsson CA, Cooner WH. (1992). Prostate specific antigen density: a means of distinguishing benign prostatic hypertrophy and prostate cancer. *J Urol* 147: 815-6.

Berry SJ, Coffey DS, Walsh PC, Ewing LL. (1984). The development of human benign prostatic hyperplasia with age. *The Journal of urology* 132, 474-479.

Bosch JLHR, Hop WCJ, Kirkels WJ, Schroder FH. (1995). The International Prostate Symptom Score in a community-based sample of men between 55 and 74 years of age: prevalence and correlation of symptoms with age, prostate volume, flow rate and residual urine volume. BJUI. 75: 622 – 630.

Campbell B. 2005. High Rate of Prostate Symptoms Among Ariaal Men From Northern Kenya. Prostate. 62: 83-90.

Chapple CR, Roehrborn CG. (2006). A shifted paradigm for the further understanding, evaluation, and treatment of lower urinary tract symptoms in men: focus on the bladder. *Eur Urol* 49, 651-8.

Chung HF, de Vriesa SH , Raaijmakersa R et al. 2004. Prostate Volume Ultrasonography: The Influence of Transabdominal versus Transrectal Approach, Device Type and Operator. European Urology 46: 352–356.

Eckhardt MD, van Venrooij VG, Boon TA. (2001). Symptoms, prostate volume, and urodynamic findings in elderly male volunteers without and with LUTS and in patients with LUTS suggestive of benign prostatic hyperplasia. *Urology* 58, 966-971.

El Din EK, Kiemeney LA, De Wildt MJ, Debruyne FMJ, Dela Rosette JJM. (1996). Correlation between uroflowmetry, prostate volume, postvoid residue, and lower urinary tract symptoms as measured by the international prostate symptom score. Urology. 48: 393 - 397.

Emberton M, Andriole GL, de la Rosett J, et al. (2003). Benign prostatic hyperplasia: a progressive disease of aging men. Urology. 61: 267–273.

Eng J. (2003). Sample Size Estimation: How Many Individuals Should Be Studied? Radiology. 227:309–313

Franciosi M, Koff WJ, Rhoden EL. (2007). Correlation between the total volume, transitional zone volume of the prostate, transitional prostate zone index and lower urinary tract symptoms (LUTS). Int Urol Nephrol. 39(3):871-7.

Fujimura T, Kume H, Nishimatsu H, Sugihara T, Nomiya A, Tsurumaki Y, Miyazaki H, Suzuki M, Fukuhara H, Enomoto Y, Homma Y. (2012). Assessment of lower urinary tract symptoms in men by international prostate symptom score and core lower urinary tract symptom score. BJU Int.109(10):1512-6.

Ganpule AP, Desai MR, Desai MM, Wani KD, Bapat SD. (2004). Natural history of lower urinary tract symptoms: preliminary report from a community-based Indian study. BJU Int. 94(3):332-4.

Godley PA, Carpenter WR. (2007). Case-control prostate cancer screening studies should not exclude subjects with lower urinary tract symptoms. *J Clin Epidemiol* 60, 176-80.

Homma Y, Kawabe K, Tsukamoto T *et al.* (1997) Epidemiologic survey of lower urinary tract symptoms in Asia and Australia using the International Prostate Symptom Score. *Int J Urol* 4: 40 6.

Hosseini M, Seyed A S, Alinaghi S, Mahmoodi M. (2011). Sensitivity and Specificity of International Prostate Symptom Score (IPSS) for the Screening of Iranian Patients with Prostate Cancer. Acta Med Iran. 49:451-5.

Hosseini SY, Danesh AK, Parvin M, Basiri A, Javadzadeh T, Safarinejad MR, Nahabedian A. (2007). Incidental prostatic adenocarcinoma in patients with PSA less than 4 ng/ml undergoing radical cystoprostatectomy for bladder cancer in Iranian men. Int. braz j urol. 33: 167-173.

Ignjatovic I. (2001). Symptoms and urodynamics after unsuccessful transurethral prostatectomy. *Int Urol Nephrol* 32, 655-658.

Jemal A, S.R., Ward E, Murray T, Xu J, Smigal C, Thun MJ. (2006) Cancer statistics, 2006. *Cancer J Clin* 56, 106-30.

Johnson TV, Abbasi A, Ehrlich SS, Kleris RS, Owen-Smith A, Raison CL, Master VA. (2012). IPSS quality of life question: a possible indicator of depression among patients with lower urinary tract symptoms. Can J Urol. 19(1):6100-4.

Karayi MK, Markham AF. (2004). Molecular biology of prostate cancer. Prostate Cancer Prostatic Dis. 7:6-20.

Kimball FA, B.A., Carter DB, Walsh PC. (1984). Benign prostatic hyperplasia: Etiological considerations. in New Approaches to the Study of Benign Prostatic Hyperplasia. Alan R. Liss, Inc, New York. Vol. 14 (ed.,) 1-25 .

Kuo HC. (2002). Analysis of the pathophysiology of lower urinary tract symptoms in patients after prostatectomy. *Urol Int* 68, 99-104.

Lee F, Littrup PJ, Loft-Christensen L et al. (1992). Predicted prostate specific antigen results using transrectal ultrasound gland volume: differentiation of benign prostatic hyperplasia and prostate cancer. Cancer 70: 211-20.

Lee JY, K.H., Lee SJ, Koh JS, Suh HJ, Chancellor MB. (2004). Comparison of doxazosin with or without tolterodine in men with symptomatic bladder outlet obstruction and an overactive bladder. *BJU Int* 94, 817-820.

Lepor H. 2005. Pathophysiology of Lower Urinary Tract Symptoms in the Aging Male Population. Rev Urol. 2005; 7(Suppl 7): S3–S11.

Liao CH, Chung SD, Kuo HC. (2011). Measurement of International Prostate Symptom Score Subscores in Male Lower Urinary Tract Symptoms. 65: 552-8

Mettlin C, L.P., Kane RA, Murphy GP, Lee F, Chesley A, Badalament R, Mostofi FK. (1994). Relative sensitivity and specificity of serum prostate specific antigen (PSA) level compared with age-referenced PSA, PSA density, and PSA change. *American Cancer Society National Prostate Cancer Detection Project*.

Moore RA. (1943). Benign hypertrophy of the prostate. A morphological study. *J Urol* 50, 680-710.

Moore RA. (1947). Benign hypertrophy and carcinoma of the prostate. In Twombly, (Oxford Press, London and New York). 543 -545.

Neto NR, de Lima LP, de Andrate EFM, Apuzzo F, da Silva MB, Davidson IM, Moises MJ, Chamna EJ, Bogado H. (1997). Latin american study on patient acceptance of the international prostate symptom score (IPSS) in the evaluation of symptomatic benign prostatic hyperplasia. Urology. 49: 46-49.

Ngugi PM, Byakika B. (2007). Histology of specimens taken by prostatectomy and needle biopsy. East Afr Med J. 84(8):363-6.

Nickel JC. (2003). Benign Prostatic Hyperplasia: Does Prostate Size Matter? Rev Urol. 5(Suppl 4): S12–S17.

Norman RW, Nickel JC, Fish D, Pickett SN. (1994).'Prostate-related symptoms' in Canadian men 50 years of age or older; prevalence and relationships among symptoms. *Br J Urol* 74: 542 50.

Oelke M, Bachmann A, Descaueaud A, EMberton M, Gravas S, Michel MC et al.(2012). Guidelines on the management of male lower urinary tract symptoms (LUTS), incl. benign prostatic obstruction (BPO). European Association of Urology.

Oh BR, Kim SJ, Moon JD, Kim HN, Kwon DD, Won YH, Ryu SB, Il Park YI. (1998). Association of Benign Prostatic Hyperplasia with Male Pattern Baldness. Urology. 51: 744–748.

Okamura K, U.T., Nagahama K, Maruyama S, Mizuta E. (2002). "Quality of life" assessment of urination in elderly Japanese men and women with some medical problems using International Prostate Symptom Score and King's Health Questionnaire. *Eur Urol* 41, 411-9.

Okamura K, U.T., Nagahama K, Maruyama S, Mizuta E. (2002). The relationships among filling, voiding subscores from International Prostate Symptom Score and quality of life in Japanese elderly men and women. *Eur Urol* 42, 498-505.

Palmerola R1, Smith P, Elliot V, Reese CT, Mahon FB, Harpster LE, Icitovic N, Raman JD. (2012). The digital rectal examination (DRE) remains important - outcomes from a contemporary cohort of men undergoing an initial 12-18 core prostate needle biopsy. Can J Urol. 19(6):6542-7.

Parsons JK. (2011). Lifestyle factors, benign prostatic hyperplasia, and lower urinary tract symptoms. Curr Opin Urol. 21:1–4.

Patel ND, Parsons JK. 2014. Epidemiology and etiology of benign prostatic hyperplasia and bladder outlet obstruction. Indian J Urol. 30(2): 170–176.

Pinnock C, Marshall VR. (1997). Troublesome lower urinary tract symptoms in the community: a prevalence study. *Med J Aust* 167: 7.

Plante M, Corcos J, Gregoire I, Belanger ME, Brock G, Rossingol M. (1996). The international prostate symptom score: Physician versus self-administration in the quantification of symptomatology. Urology. 47: 326 – 328.

Price D. (2001). Potential mechanisms of action of superselective adrenoceptor antagonists. *European urology* 40, 5-11.

Roehrborn CG. (2005). Benign prostatic hyperplasia: An overview. Rev Urol. 2005; 7(Suppl 9): S3–S14.

Roosen A, Chapple CR, Dmochowski RR, Fowler CJ, Gratzke C, Roehrborn CG, Stief CG, Andersson KE. (2009). A refocus on the bladder as the originator of storage lower urinary tract symptoms: a systematic review of the latest literature. *Eur Urol* 56, 810–20.

Rosenberg MT, S.D., Kaplan SA, MacDiarmid SA, Newman DK, Ohl DA. (2007). A practical guide to the evaluation and treatment of male lower urinary tract symptoms in the primary care setting. *Int J Clin Pract* 61, 1535-1546.

Sagnier PP, Girman CJ, Garraway M. (1996). International comparison of the community prevalence of symptoms of prostatism in four countries. *Eur Urol* 1996; 29: 15 20.

Sciarra Al, D'Eramo G, Casale P, Loreto A, Buscarini M, Di Nicola S, Seccareccia F, Di Silverio F. (1998). Relationship among symptom score, prostate volume, and urinary flow rates in 543 patients with and without benign prostatic hyperplasia. 1998. 34: 121 – 128.

Stone NN, Ray PS, Smith JA et al. (1991). Ultrasound determination of prostate volume: comparison of transrectal (ellipsoid v planimetry) and suprapubic methods. J Endourol 5: 251-4.

Stravodimus KG, Petrolekas A, Kapetanikis T, Vourekas S, Koritsiadis G, Adamakis I, Mitropoulos D, COnstantinides C. (2009). TRUS versus transabdominal ultrasound as a predictor of enucleated adenoma weight in patients with BPH: a tool for standard preoperative work-up? Int Urol Nephrol. 41(4):767-71.

Swyer GI. (1944). Post-natal changes in the human prostate. *J Anat* 78, 130-14.

Tsukamoto T, Masumori N, Rahman M, Crane MM. (2007). Change in International Prostate Symptom Score, prostrate-specific antigen and prostate volume in patients with benign prostatic hyperplasia followed longitudinally. Int J Urol. 14(4):321-5.

van Haarst EP, H.E., Newling DW, Schlatmann TJ. (2005). A cross-sectional study of the international prostate symptom scores related to age and gender in Dutch adults reporting no voiding complaints. *Eur Urol* 47, 334-9.

Vogelzang NJ. (2006). Comprehensive Textbook of Genitourinary Oncology, Lippincott Williamsand Wilkins, Philadelphia, PA. pg 345.

Wilt TJ, Mac Donald R, Rutks I. (2003). Tamsulosin for benign prostatic hyperplasia. Cochrane Database Syst Rev. (1):CD002081.

APPENDICES

Appendix I: Consent Form

STUDY TITLE: THE INTERNATIONAL PROSTATE SPECIFIC SYMPTOM SCORE IN PATIENTS PRESENTING WITH LOWER URINARY TRACT SYMPTOMS AT MTRH- ELDORET.

INVESTIGATOR - DR OLUNGA RICHARD OSUNDWA.

P.O BOX 5880-30100,

ELDORET, KENYA.

Purpose of Study: The major objective of this study is to help in early diagnosis and subsequent intervention of patients with lower urinary symptoms due to Prostate Enlargement so as to enable them lead a normal life.

I _____of PO BOX_____,
telephone_____

Hereby willingly give informed consent to participate in the above mentioned study which is being conducted at MTRH. The study has been fully explained to me by Dr Olunga Richard Osundwa (or his assistants) in a language and terms I can understand. I was assured that no injury or harm will come to me as a result of involvement in this study. It was elaborated that participating in this study is voluntary and that I am at liberty to withdraw at any point should I wish to do so without prejudice to my right of treatment at MTRH. I was further reassured that principles of medical ethics; autonomy, justice, beneficence and non-maleficence will be fully adhered to in this study.

Name of participant_____
Signature_____
Date_____

Appendix II: Fomu Ya Kukubali

MADA YA UTAFITI: THE INTERNATIONAL PROSTATE SPECIFIC SYMPTOM SCORE IN PATIENTS PRESENTING WITH LOWER URINARY TRACT SYMPTOMS AT MTRH- ELDORET.

MTAFITI - DR OLUNGA RICHARD OSUNDWA.

P.O BOX 5880-30100,

ELDORET, KENYA.

Kiini cha utafiti: Lengo kuu la huu ni kusaidia katika utambuzi wa mapema na kutibu kwa mtawalia wagonjwa na walio na maambukizi ya kibofu na dalili za maambukizi ya sehemu za mkojo inayotokana na uvimbe wa “prostate” ili kuwawezesha kuishi maisha ya kawaida.

Mimi _____

S.L.P_____, Nambari ya Simu_____

Najitolea kwa hiari yangu mwenyewe kutoa kibali cha kujihusisha katika utafiti uliotajwa hapo juu inayoendelezwa katika MTRH. Nimepokea maelezo ya tafsili kuhusu utafiti huu kutoka kwa Dr Olunga Richard Osundwa (au watafiti wasaidizi wake) katika lugha, kanuni na masharti ninayoelewa vyema. Nimehakikishiwa kuwa, sitadhurika kamwe kutokana na kujihusisha kwangu katika utafiti huu. Ilibainishwa kuwa kujihusisha katika utafiti huu ni kwa hiari na nina uhuru wa kujiondoa wakati wowote ule bila ya kuhujumiwa hasa kuhusu haki yangu ya kupokea matibabu katika MTRH. Zaidi ya hayo, nilihakikishiwa kuwa, kanununi zote za maadili ya utabibu,uhuru, haki, na manufaa zitazingatiwa katika utafiti huu.

Jina la Mhojiwa_____

Sahihi _____

Tarehe _____

Jina la shahidi _____

Sahihi _____

Tarehe _____

Appendix III: Questionnaire
Data Collection Sheet (Questionnaire)

MTRH Clinic: _____ Date:

_____

Participant's

Code_____

IP NO._____

Address_____ Phone

no._____

Type of referral: Self ☐ ☐

Another facility specify_____

D.O.B_____ Weight_____

Occupation (current / previous).

_____

Residence. _____

Previous History of Urine Retention. _____

Clinical Diagnosis:

_____

Duration of symptoms:

_____

Size Of Prostate. _____

Histological Diagnosis: _____

Previous Medical Therapy: _____

Current/Final Mode of Treatment.

_____

IPSS SCORE: _____

Appendix IV: International Prostrate Symptom Score (I-PSS)

Patient Name:_____ Date of Birth:_____ Date Completed_____

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 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

other comments:_____

Appendix V: IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2014/191
Approval Number: 0001425

25th June, 2015

Dr. Olunga Richard,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
25 JUN 2015
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Olunga,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"International Prostate Symptom Score among Patients with Lower Urinary Tract Symptoms due to Prostate Enlargement at MTRH- Eldoret"

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1425*** on 25th June, 2015. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 24th June, 2016. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

Appendix VI: Hospital Approval (MTRH)

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
P. O. Box 3
ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

25th June, 2015

Dr. Olunga Richard,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"International Prostate Symptom Score among Patients with Lower Urinary Tract Symptoms due to Prostate Enlargement at MTRH-Eldoret".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

DR. JOHN KIBOSIA
DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM

Appendix V: Timelines

	Feb-15	Mar-15	June-15	Aug-15	Oct- 15	Jan-16	Jan- 17	Mar-17	May- 17	Aug- 17	Dec-17
Developing proposal(Intorduction,Literature review & Methodology)											
Presenting proposal to supervisors											
Developing data collection tools											
Proposal Submission to IREC											
Piloting data collection tools											
Finalisation of data collection tools											
Data collection											
Data entry, coding and cleaning											
Interim analysis											
Final Analysis											
Thesis write up(results, discussion)											
Notice of intent to submit											
Mock defence											
Submission of Thesis for Examination											
Thesis defence											
Graduation											

Appendix VI: Budget

ITEM.	KSH.
Four reams of plain paper @ ksh 500/=	2,000
Pens, Pencil, Rubber, Folder	1,000
Two Computer Flash Disks	4,000
Printing Research Proposals.	2,000
Printing Thesis, 4 copies.	12,000
Binding Thesis	5,000
Research Assistants @ 3,000 p.m	18,000
I.R.E.C fee	1,000
Data Handling.	20,000.
Biopsy/histology @1500/	150,000
TOTAL	213,000.00.