UNIVERSITY OF NAIROBI

COMPARISON OF THE VISUAL AND INTERNATIONAL PROSTATE SYMPTOM SCORE IN THE EVALUATION OF PATIENTS WITH BENIGN PROSTATIC ENLARGEMENT AT THE KENYATTA NATIONAL HOSPITAL

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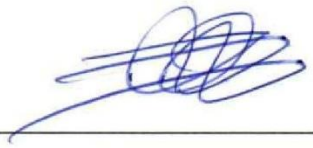
Mmed Urology

This dissertation is submitted in partial fulfillment of the requirements for the award of the Master of Medicine degree in Urology.

May 2022

STUDENT'S DECLARATION

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

Signed  Date 26/07/21

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DEPARTMENTAL APPROVAL

The proposal for this dissertation had been presented and approved at the general surgery departmental meeting of the University of Nairobi held on 1st July 2021 and was thereafter presented to the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee for approval. The dissertation is hereby submitted for examination with my approval as the Chairman, Department of Surgery.

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ABBREVIATIONS

BPE – Benign Prostatic Enlargement

LUTS – Lower urinary tract symptoms.

AUA-SI – American Urological Association symptom index

IPSS – International prostate symptom score

VPSS – Visual prostate symptom score

WHO – World Health Association

EAU – European Association of Urology

PLESS – Proscar Long Term Efficacy and Safety Study

COMBAT – Combined Avodart and Dutasteride Trial

BPO – Benign prostatic obstruction

BPH – Benign prostatic hyperplasia

Qmax – Peak urinary flow rate

Qave – Average flow rate

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ABSTRACT

Study background

Lower urinary tract dysfunction is a common urological complaint. It is of heterogeneous origin and becomes more prevalent with age. The clinical approach to LUTS features the usage of the IPSS which allows quantification of treatment severity with various discriminant, predictive and evaluation of treatment response roles. The International Prostate Symptom Score (IPSS) is a high-precision instrument that has been validated in multiple languages as a cost-effective tool for the evaluation of lower urinary tract dysfunction. Despite this, its accuracy and consistency are constrained among elderly patients in the developing world where comparatively lower education levels and multilingual societies predominate.

The visual prostate symptom score (VPSS) consists of pictogram-based responses and has been found to provide reliable data in patients who are unable to self-administer the IPSS due to prerequisite literacy/numeracy. However, its usage remains unvalidated in Kenya.

This study, therefore, scrutinizes the applicability of the visual prostate symptom in the evaluation of patients with benign prostatic enlargement by comparing its findings against those of the established gold standard – the IPSS.

Broad objective

The main objective of this study was to determine how accurate and reliable the VPSS is in evaluating lower urinary tract dysfunction by comparing it to the IPSS.

Study design and site

This was a cross-sectional study of patients visiting the urology outpatient clinic at the Kenyatta National Hospital.

Participants and methods

Consenting patients who presented with symptoms of lower urinary tract dysfunction and benign prostatic enlargement were requested to complete written versions of the novel VPSS and the validated IPSS.

Data management

The principal outcome measure was the degree of concordance between scores obtained by VPSS and those obtained by IPSS. This was obtained through data analysis using the 26th version of the SPSS software. Pearson's r value >0.4 was accepted as significant. Data on patient characteristics was also be collected to homogenize patient pools and reduce the influence of known confounders.

Results

This study detected a high degree of correlation between scores obtained using the novel VPSS and corresponding scores obtained by the IPSS. Pearson's r-value was 0.6 for the total scores. The VPSS parameters with the highest fidelity were the nocturia and weakness of stream images respectively. The highest degree of correlation was found among patients who filled the VPSS without assistance. Demographic characteristics of the respondents did not significantly impact the degree of correlation.

Conclusion

The high degree of positive correlation between the novel VPSS and the IPSS supports the role of the VPSS as an adjunct to the clinical evaluation of male patients afflicted with lower urinary tract symptoms. A higher proportion of patients are able to complete the VPSS without assistance compared to the IPSS. While the VPSS has potential for universal application, further validation is needed to justify widespread deployment. By these means, the ageing African male, who is unable to provide precise and consistent responses to the IPSS, can access the recommended severity-based treatment for their LUTS with optimization of the quality of life and minimization of the financial and health-related consequences of inappropriate management

1.0 INTRODUCTION

Symptomatic lower urinary tract dysfunction is one of the commonest diagnoses in the urological clinic. This disease has significant cost implications both for the affected patient and the local health care system. (1). While many patients experience LUTS as a result of prostatic enlargement, the coexistence of these two phenomena does not necessarily indicate a causal relationship(2, 3). BPE progresses gradually, in an age-dependent manner (4). The obstructive effect of BPE on urinary flow can result in serious health complications. These include acute urinary retention, urinary tract dysfunction bladder stones, chronic kidney disease and bother, all of which can severely impact the elderly male patient's quality of life(5).

The International Prostate symptom score is a tool used to produce a quantitative assessment of the severity of LUTS. It consists of 7 questions evaluating the severity of LUTS and a single question evaluating the patient's quality of life. Correctly applied, it is a high precision instrument that allows quantitative assessment of both the severity of the patient's LUTS, response to treatment as well as various other discriminant and predictive roles. Its usage for this purpose has been endorsed by the WHO and multiple society guidelines and its effectiveness has been validated in multiple languages. The IPSS is intended to be a standardized, easy to fill, self-administered inquiry that can be applied at the most basic level of primary health care services provision.

The collection of reliable IPSS data is constrained by inter-individual differences in perception of symptoms and an inability to comprehend and relate to the various written responses, among other challenges. This heterogeneity of data is worsened by errors introduced by 3rd party involvement during the administration of the questionnaire. One of

the ways by which these problems may be mitigated is by the usage of pictogram-based responses, as opposed to written answers, to elicit symptom severity. Image-based measures of symptom severity have since been compiled into a complementary visual prostate symptom score that assesses both storage and voiding symptoms and the extent to which the patient is bothered by his symptoms(6). The VPSS offers a novel opportunity to adapt accurate assessment of lower urinary tract dysfunction to the unique cognitive, ethnic, and educational characteristics of the aging male patient with greater potential for comparison of symptom scores across populations. This study thus attempts to compare the accuracy of the VPSS with the IPSS in the assessment of lower urinary tract symptoms among BPE patients visiting Kenyatta National Hospital.

2.0 LITERATURE REVIEW

2.1 Epidemiology

An estimated 45.2% of the 2008 world population (of 4 billion people) suffer from LUTS. Out of these people, 21.5% had LUTS that were linked to bladder outlet obstruction(7). These numbers were projected to rise by 18.4% in 2018 - driven in part by a higher expected life expectancy. Accordingly, the EPIC study estimated the overall prevalence of LUTS at 62.5%(8). LUTS have a detrimental effect on the quality of life of up to 39% of affected individuals and are the primary reason for consultation in 71.3% of patients seeking healthcare services (9, 10). Other reasons include physician review (14.9%), fear of prostate cancer (8.9%) requests by friends and family (1%). At least half would wish to reduce their likelihood of developing acute urinary retention or requiring surgical management of BPE.

While population-based research has shown a consistently poor correlation between the severity of LUTS and the prostatic volume (10, 11), the Olmstead County study did show that men with prostate volumes greater than 30ml are 4 times more likely than men with volumes less than 30ml to have moderately to severely bothersome LUTS with a correspondingly greater deterioration of their quality of life(12). Clinical research analyzing the long-term benefits of drugs that reduce the size of the prostate has corroborated these findings. For instance, the Proscar Long Term Efficacy and Safety Study (PLESS) established that long term usage of finasteride decreased the prostate size by as much as 18% over 1 year – compared with an increase of 14% for placebo over the same period – with concomitant sustained risk reduction of development of painful urinary retention or need for surgical management by more than 50%(13).

2.2 Evaluation of prostatic size

The healthy prostate of the adult human male is approximately 4cm wide, 3 cm high, and 2-3 cm thick and has an estimated volume of 15-25ml. BPE is a progressive disease with research indicating a consistent pattern of human prostatic growth with age (14-17) with an estimated average change rate of 1.6% per year across all age groups. Symptomatic BPE has a waxing and waning course but few men will have spontaneous long-term remission.

Studies on the natural history of BPE have invariably reported no or weak correlation between LUTS severity and the size of the prostate(18, 19). This may be explained by several factors such as variations in the response of the bladder to obstruction and aging, variable prostatic configuration, a complex interplay between variations in sympathetic tone of prostatic smooth muscle and the relative proportions of stromal and glandular tissue in the prostate. Indeed, the term lower urinary tract symptoms was first published in the British Medical Journal in 1994 as a means of appreciating the heterogeneous origin of LUTS – as opposed to such terms as “prostatism” or “clinical BPH” which were born of a spurious diagnostic association between lower tract dysfunction and prostatic enlargement (2) and consequent inappropriate prostate ablation without sufficient exclusion of other causes of LUTS.

Paradoxical to these perspective-shifting measures in the modern practice of LUTS management is the fact that later population-based studies have identified larger prostatic volumes as risk factors for BPE-related surgery and acute urinary retention while interval increase in the size of the prostate in men with LUTS has been established as a measure of disease progression(20). Determination of prostatic volume thus plays a significant role in

treatment selection and follow-up for these patients. Based on these findings, the EAU guidelines on the management of non-neurogenic male LUTS provide for a rational, patient-benefit based approach with management tiers based on prostate size.

All male patients with LUTS should undergo digital rectal examination for assessment of (inter alia) the prostate size. This is a largely inaccurate method of determination of prostate size with errors leaning towards underestimation of larger prostatic volumes - as compared to estimates obtained from trans-rectal ultrasonography(21) with greater variability in studies involving multiple examiners. At a minimum, DRE has been proven to provide sufficient discrimination of prostate sizes of <50ml from those >50 ml (15, 21). In addition, studies have shown that the utilization of 3D sizing models such as the one illustrated below provide DRE-based estimates of the prostatic size that show comparable reliability and correlation with transrectal ultrasonography of the prostate (TRUS)(22, 23).

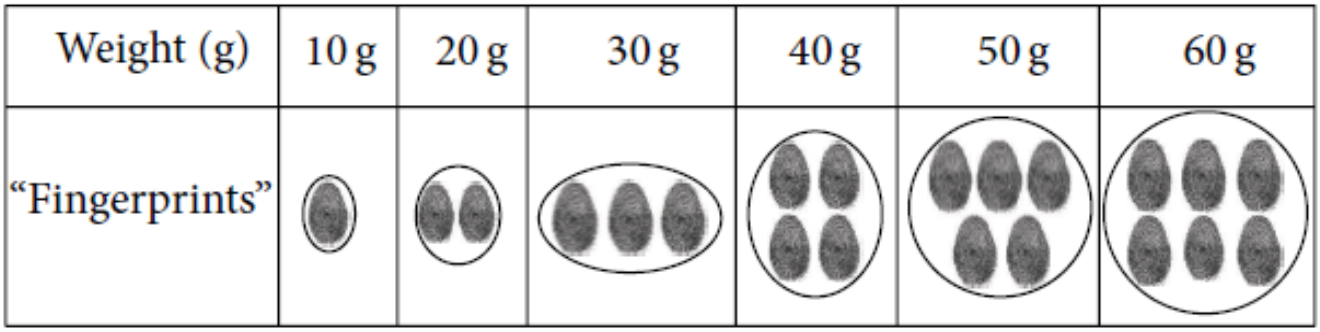


Fig 1: Scaled schematic for the standardization of prostate size estimation by DRE. Reis et al 2013(24)

There are no statistically significant differences between prostate volume estimations obtained by trans-abdominal ultrasound and those obtained by TRUS with r-values as high as 0.967 reported with experienced sonographers and a mean difference of 8.4 +/- 10.5mls (25, 26)

2.3 Advent of the IPSS

The VPSS and IPSS represent an attempt to codify subjective lower urinary tract symptoms into more objective, quantifiable numbers. The original version of the IPSS was devised in 1992 by Barry et al as the American Urological Association symptom index (27). The AUA-SI was designed against a background of multiple innovations in the field of surgical treatment of BPE and a boom of up to 400,000 prostatectomies performed annually for BPE with an annual cost of treatment of $3.5 Billion in the United States alone. There was a need to develop non-invasive methods of comparing how the outcomes of new medical therapies compared to more traditional modalities of treatment such as prostatectomy. In particular, it was found that while a minority of patients underwent prostatectomy for such absolute indications as recurrent urinary retention, treatment-refractory urinary tract infections, biochemical renal insufficiency, or significant visible hematuria, the vast majority of patients (91%) underwent surgical operations to relieve bother from urinary symptoms and improve their quality of life(28). This means that while more objective outcome measures such as uroflowmetry have been used to compare the efficacy of treatment modalities, an IPSS and quality of life score cannot be omitted from decisions regarding rational treatment modality selection.

The IPSS has since been found to be indispensable in the evidence-based selection of BPE patients who are at high risk for disease progression and thus benefit from combined medical therapy as opposed to monotherapy and those patients with symptoms that are refractory to medical management who might then be considered for surgery. The overall effect has been a reduction in surgery-related costs. For example, there is reduced reliance

on the relatively more morbid surgical treatment with absolute TURP rates in the USA declining from 227,000 surgeries in 2003 to less than 100,000 surgeries in 2009.

The figure below summarizes the English version of the IPSS.

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

	None	1 time	2 times	3 times	4 times	5 times or more	**Your score**
Nocturia Over the past month, many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning?	0	1	2	3	4	5	

Table 1: English version of the IPSS

Quality of life due to urinary symptoms	Delighted	Pleased	Mostly satisfied	Mixed: Equally satisfied / dissatisfied	Mostly dissatisfied	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that?	0	1	2	3	4	5	6

Table 2: Quality of Life score

2.4 The VPSS

While it is clear that the IPSS has played a revolutionary role in the low-cost assessment of BPE/LUTS, it has likewise become increasingly clear that poorly educated patients are less likely to accurately complete the IPSS. McDiarmid et al (1998) concluded that a minimum grade 6 reading level (by American standards) was required to successfully fill the AUA-SI(29). Further studies found a negative correlation between education level and symptom misrepresentation with greater heterogeneity of frequency and urgency data. The experience of Ogwuche et al provides a typical example of challenges hampering the utilization of the IPSS in developing communities(30). Out of 70 patients enrolled, 34.3% did not understand spoken English and of the remainder, 74.3% could not read English. This is particularly troubling in the African setting given that the findings of Ogwuche and Sarma et al also point to a tendency for greater LUTS severity among black men compared to white men (even after adjustment for age, level of education, income, and marital status) with less reported bother for any level of LUTS severity(31). While the IPSS has been translated and validated for use in many languages, this does not fully address the challenge of the multilingual and multicultural population, a defining characteristic of most African societies.

In developing countries, there are high levels of illiteracy. Furthermore, the majority of men affected by BPE/LUTS are in their sixth to eighth decade and often have cognitive and visual impairment that further limits their ability to fill the form. Such patients are more likely to misrepresent their symptoms, which exposes them to the risk of inappropriate diagnosis and treatment with the associated financial implications and treatment-related adverse effects(32). When such patients are requested to fill the IPSS form there is a

documented tendency to seek further clarification of the questions or assistance in completing the form from the doctor, nurse, or available family members and caregivers. This might further distort the information collected, either by miscommunication or by the introduction of bias by the 3rd party interpreters who may place undue influence on the patient to answer in a particular way – especially considering the intimate nature of such discussions - or due to misinterpretation the patient's responses. Such problems are compounded if different interpreters are assisting the patient during successive hospital visits since there will be increased intra-individual variability in IPSS parameters that is not a result of the patient's native pathology.

To address these challenges, van der Walt et al devised a visual prostate symptom score consisting of four pictograms representing weak stream, nocturia and frequency (4). An additional pictogram depicts the quality of life of the patient in regards to their urinary symptoms. These series of pictograms are simpler and easier to understand, with a reportedly higher proportion of patients of limited education able to complete the form without assistance(33). In addition, there is a high degree of correlation between severity measures obtained by IPSS and those obtained by VPSS (33, 34). There was also a significant negative correlation between the patient's assessment of their urinary stream and both Qmax and Qave figures obtained on uroflowmetry from a study conducted at Windhoek Central Hospital in Namibia that focused on a population with a greater diversity of language and reduced formal education(35). This means that validated VPSS parameters are an acceptable substitute in select patients and may even be used as single-item queries to rapidly assess lower urinary tract dysfunction in busy referral centers with a high turnover of patients.

Guzelsoy et al (2018) established that while VPSS had no superiority to IPSS, it was the best method to exclude bias in elderly patients (36). Significant correlation has also been demonstrated between VPSS and IPSS (r=0.845), Qmax (r=0.681), and urethral diameter (r = -0.552) as well as a reduction in time taken by almost 50% among men with urethral stricture (37).

In East Africa, validation of the VPSS was most recently attempted by Stothers et al in 2017(38). This study compared LUTS severity measures obtained by IPSS (translated into the dominant local language - Runyankole) and those obtained by VPSS in rural Uganda. While the outcomes in terms of the degree of correlation were comparable to previous studies, this study also allowed patients to offer comments on clarity and suggestions on how the VPSS might be improved. For instance, regardless of the level of education, the weak stream image was the most recognizable while QoL and nocturia images were reportedly less clear with a larger number of patients requiring assistance before completing these parts of the form. Some of the improvements suggested included increased black/white contrast for nocturia, increased image size for nocturia and frequency, and the use of additional images to allow the patient to report urgency.

From the foregoing, the IPSS and VPSS have an integral role to play in cost-effective evaluation, treatment selection, and longitudinal follow-up of patients who suffer LUTS as a result of BPE. However, their development requires careful matching of the tool to the social, cultural, cognitive and linguistic characteristics of the elderly patient to acquire the desired information while minimizing errors caused by lack of comprehension or filtering of information through non-constant 3rd parties. Of the two tools, the VPPS may have greater potential for global usage and standardization of the data derived thereof because

image-based responses require less translation to apply to different populations. However, such universal adoption must be preceded by exhaustive validation in diverse environments.

2.5 Study justification

2.5.1 Context

Lower urinary tract dysfunction is a pervasive disorder that has a debilitating effect on the patient's quality of life and threatens the life-preserving functions of the kidneys in some cases. Despite this, cost-effective diagnosis and follow-up of such patients is challenging since there are no cause-specific symptoms. Moreover, lower urinary tract symptoms have a complex multifactorial etiology and it is uneconomical to fully investigate each of these causes for every patient. Objective quantification of the patient's symptoms, particularly in terms of response to treatment, has faced similar constraints. To address some of these challenges, the AUA-SI was developed and subsequently adopted by the WHO as a vital adjunct to the clinical evaluation of these patients. This International Prostate Symptom Score quantifies 7 symptoms that most frequently complicate the natural history of lower tract dysfunction. These include frequency, nocturia, urgency, weakness of stream, straining, intermittency and urinary tenesmus. A rational approach to treatment selection is bolstered by an additional quality of life score that weighs the extent to which the LUTS patient is bothered by his symptoms and allows selection of the appropriate modality of treatment.

2.52 Rationale of this study

Despite these strides, adoption of the self-administered IPSS among LUTS patients has been limited by time constraints, language barrier, and a lack of numeracy and/or literacy among elderly, affected patients seeking assistance at KNH. To mitigate these problems we

query the suitability of the new visual prostate symptom score in the assessment of BPE-associated LUTS in patients who are unable to self-administer the IPSS.

2.6 Study question

How accurate and reliable is the VPSS in quantifying LUTS in BPE patients at KNH?

2.7 Broad Objective

To compare VPSS and IPSS scores among BPE patients presenting with LUTS at KNH.

2.8 Specific objectives

1. To determine the VPSS and visual quality of life scores of BPE patients presenting with LUTS at KNH.
2. To determine the IPSS and quality of scores of BPE patients presenting with LUTS at KNH.
3. To establish the degree of correlation between severity scores obtained by VPSS and those obtained by IPSS.

2.9 Secondary objective

1. To evaluate the influence of age and level of formal education on the patient's ability to complete the VPSS without assistance.

3.0 METHODOLOGY

3.1 Study design

This was a cross-sectional study of BPE patients presenting with LUTS at KNH.

3.2 Study site

The study was carried out at the Kenyatta National Hospital Urology outpatient clinic (UOPC). The UOPC is currently held at clinic no. 24 within the Kenyatta National Hospital outpatient complex during working hours from Monday to Wednesday.

3.3 Study population

This study recruited patients with suspected bladder outlet obstruction secondary to BPE. This is because the natural history of this disease is prolonged and relies heavily on the IPSS for patients on long-term therapy. Accordingly, male patients aged over 50 years who presented with lower urinary tract symptoms and who had clinical or radiological evidence of BPE were included.

While it is possible to obtain evidence of a causal relationship between an enlarged prostate and LUTS, (ie increased urethral resistance) this requires demonstration of reduced flow in the presence of adequate detrusor pressure by utilizing the voiding cystometry. This is rarely performed in a research setting due to the invasiveness of the procedure. Moreover, the EAU has defined specific conditions under which extra-prostatic causes of lower urinary tract dysfunction may be tolerably excluded before the initiation of medical and surgical treatment.

3.4 Inclusion criteria

Patients with the following characteristics were recruited into the study:

1. Male patients aged over 50 years.
2. Patients who presented with lower urinary tract symptoms to the urology outpatient clinic. Ie Urinary urgency, frequency, nocturia, weakness of stream, straining, intermittency, and incomplete voiding.
3. Patients with benign enlargement of the prostate as detected by digital rectal examination.
4. Patients who had provided informed consent to be recruited into the study.

3.5 Exclusion criteria include:

1. Patients in resting pain or altered level of consciousness.
2. Patients who had used urethral catheters over the past month.
3. Those with neurological deficits or who had been diagnosed with neuropathic bladder.
4. Patients who had already undergone surgical management of TURP in the past.
5. Those who had undergone previous pelvic surgery.
6. Patients aged below 50 years or above 80 years.

3.6 Sample size determination

Sample size was determined using Cochran's formula as follows:

$$n_0 = Z^2p(1-p)/e^2$$

Where:

- n_0 = Sample size.

- Z = Standard normal deviation for a confidence interval of 95%
- p = Estimated proportion of the population affected by LUTS. (EPIC study)
- e = Acceptable margin of error between true proportion and the sample proportion

$n_0 = ((1.96)^2 (0.625) (0.375)) / (0.05)^2 = 360$ patients

3.7 Sampling procedure

Convenience sampling was done for all patients presenting at the urology outpatient clinic who matched the inclusion and exclusion criteria and who consented to be included in the study in writing.

3.8 COVID precautions

Temperature checks using non-contact thermometers were used to screen all participants in the study. All interactions were performed in a well-ventilated room with strict maintenance of 1.5m social distance between participants. Hand sanitizer and handwashing stations were availed to all participants. Contact between research assistants and subjects was limited to essential visits self-generated by the patient for purposes of seeking health care in the clinic or as per the recommendations of the EAU for those patients qualifying for conservative management and medical therapy.

3.9 Recruitment, consenting and data collection

A detailed medical and physical examination is recommended for each elderly male patient presenting with lower urinary tract symptoms to the urology outpatient clinic which is currently held at clinic no. 24 within the Kenyatta National Hospital outpatient complex. Data collectors included the principal researcher and research assistants drawn from undergraduate and post-graduate students of surgery who had the privilege of attending to patients at the

clinic and had been trained by the principal investigator. Patients matching the exclusion criteria were then be excluded based on the findings thereof.

Informed consent was then be sought from patients matching the inclusion criteria once the clinical encounter has been concluded.

Consenting study participants were then requested to fill printed versions of the IPSS and VPSS unaided.

3.10 Independent and dependent variables

Subject characteristics of interest were the patient's age, occupation, level of education, and marital status. The subjects' prostate symptom scores as elucidated by IPSS and VPSS were also captured.

Variables of interest are as summarized below:

Table 3: Study variables

Independent variables	**Dependent Variables**
Demographic data 1. Age a. <65 years b. >65 years 2. Level of Education a. Not attended school b. Primary school c. High school d. College e. University	Ability to complete questionnaires: • With assistance • Without assistance. IPSS Scores 1. Frequency 2. Urgency 3. Nocturia 4. Weakness of stream 5. Intermittency 6. Straining 7. Urinary tenesmus. 8. QoL score VPSS Scores 1. Frequency 2. Urgency 3. Nocturia 4. Weakness of stream & intermittency 6. QoL score

3.11 Data management and quality assurance

This entire team strove to abide by the highest standards of data handling and security. Subjects were assigned unique serial numbers to protect their identities. The hard copies of the information provided were kept under lock and key. The patients' right to confidentiality was protected at all stages of the study.

The data was checked for errors and completion. IPSS entries, in particular, were verified by the principal investigator by cross-referencing entries and dates against the participant's

permanent record at KNH before payment of the prescribed fee (see budget under section 9 below) to the research assistant.

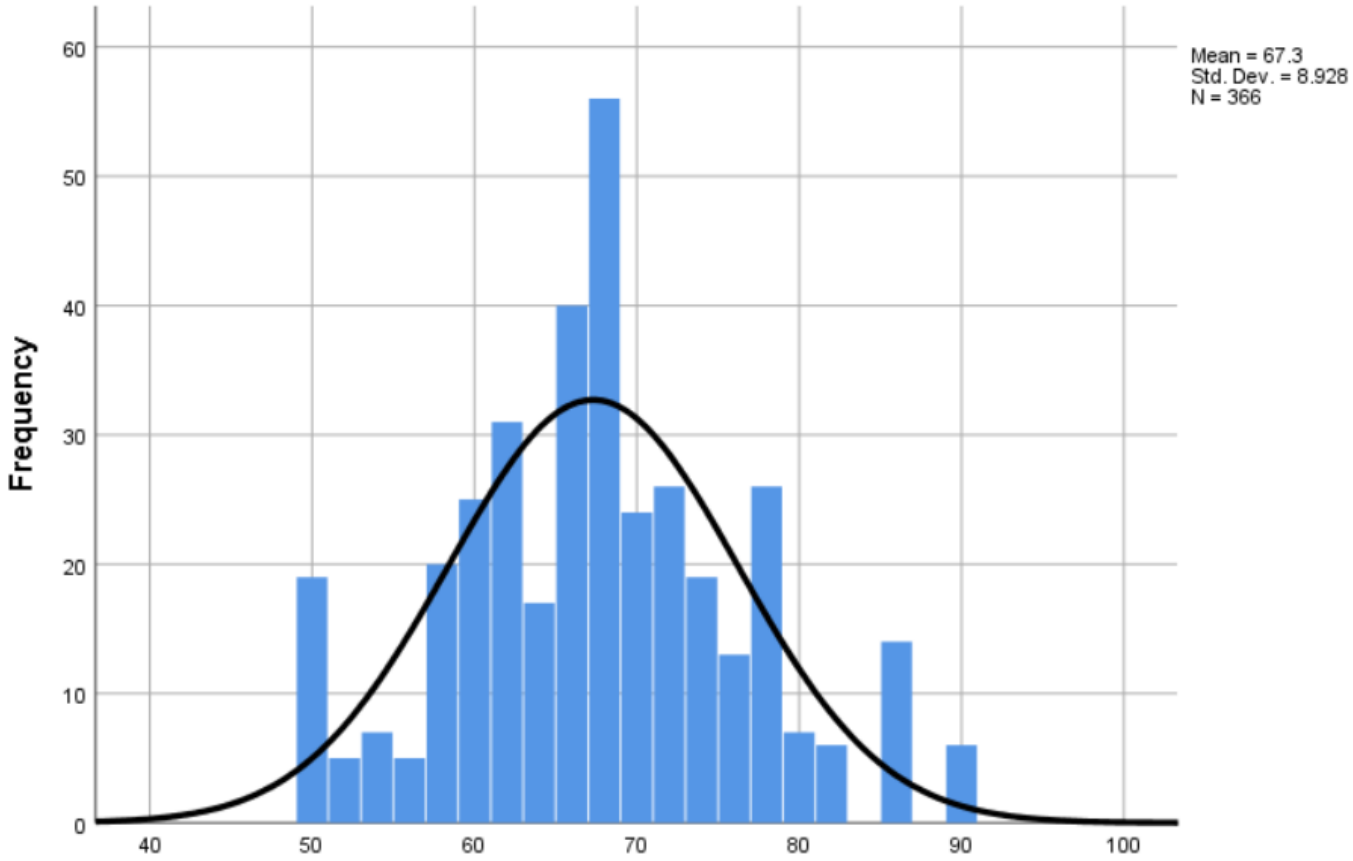
The data was then coded (by assigning numerical values to continuous variables) and then entered into SPSS version 26 for analysis. The association between patient demographics and the ability to complete either questionnaire shall be analyzed using Chi-square (critical p-value = 0.05).

The degree of correlation between corresponding parameters of the IPSS and VPSS was analyzed using Pearson's correlation coefficient (39). Pearson "r" greater than 0.4 would indicate significant correlation. The proportion of patients requiring assistance with individual questions or forms of the questionnaire was recorded with particular attention to those who felt that current pictograms were difficult to comprehend or not representative of their problems and those who offered suggestions on improvement.

4.0 RESULTS

A total of 342 respondents were recruited into the study. 26 patients were excluded on the basis of age. The histogram below shows the age distribution of the respondents.

Fig 8: Histogram of age distribution of respondents



The majority (210 patients) were aged below 65 years of age representing 61.4% of the total. Most of the patients (320 men) were married.

We analyzed whether there was significant association between age and the patient's ability to complete the VPSS and IPSS. The patients were divided into two groups; those aged below 65 years and those aged above 65 years. The cross-tabulation of these variables is shown below:

Table 4: Age * IPSS COMPLETION Cross tabulation

		IPSSCOMPLETION		
		No	Yes	Total
Age	65 years and above	138	72	210
	Less than 65 years	60	72	132
Total		198	144	342

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	13.648[a]	1	.000		
Continuity Correction[b]	12.829	1	.000		
Likelihood Ratio	13.629	1	.000		
Fisher's Exact Test				.000	.000
N of Valid Cases	342				

The p-value obtained from the analysis of expected and measured outcomes of whether or not age affected a respondent's ability to self-administer the IPSS questionnaire was 0.00. This suggests significant association between age and ability to fill the IPSS. 52.17% of patients aged below 65 years were able to complete the IPSS without being assisted as compared to 34.29% of those aged above 65 years.

Table 5 - Age * VPSS COMPLETION Cross tabulation

Count

		VPSSCOMPLETION		
		No	Yes	Total
Age	65 years and above	96	114	210
	Less than 65 years	54	78	132
Total		150	192	342

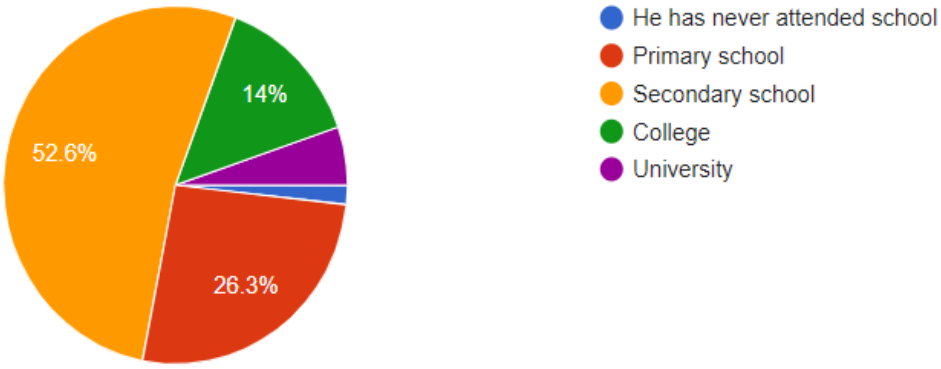
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.760[a]	1	.383		
Continuity Correction[b]	.577	1	.447		
Likelihood Ratio	.762	1	.383		
Fisher's Exact Test				.434	.224
N of Valid Cases	342				

The p-value obtained from the analysis of age versus the respondent's ability to self-administer the VPSS was 0.383 which was much higher than our threshold of 0.04. This suggests that there may not be significant association between the patient's age (and associated physical incapacity) and the patient's ability to complete the VPSS. However, 54.29% of patients above 65 years and 59.09% of patients below 65 years were able to complete the VPSS without being assisted.

There was a higher uptake of formal education than has been reported in previous studies with 247 respondents having studied at least up to the secondary school.

Fig 9 – Level of education of respondents



The table below illustrates the level of education the various respondents achieved as well as the relative proportion of patients who were able to complete the VPSS and IPSS without being assisted.

Fig 9 – Clustered Bar Count of Level of Education by IPSS completion

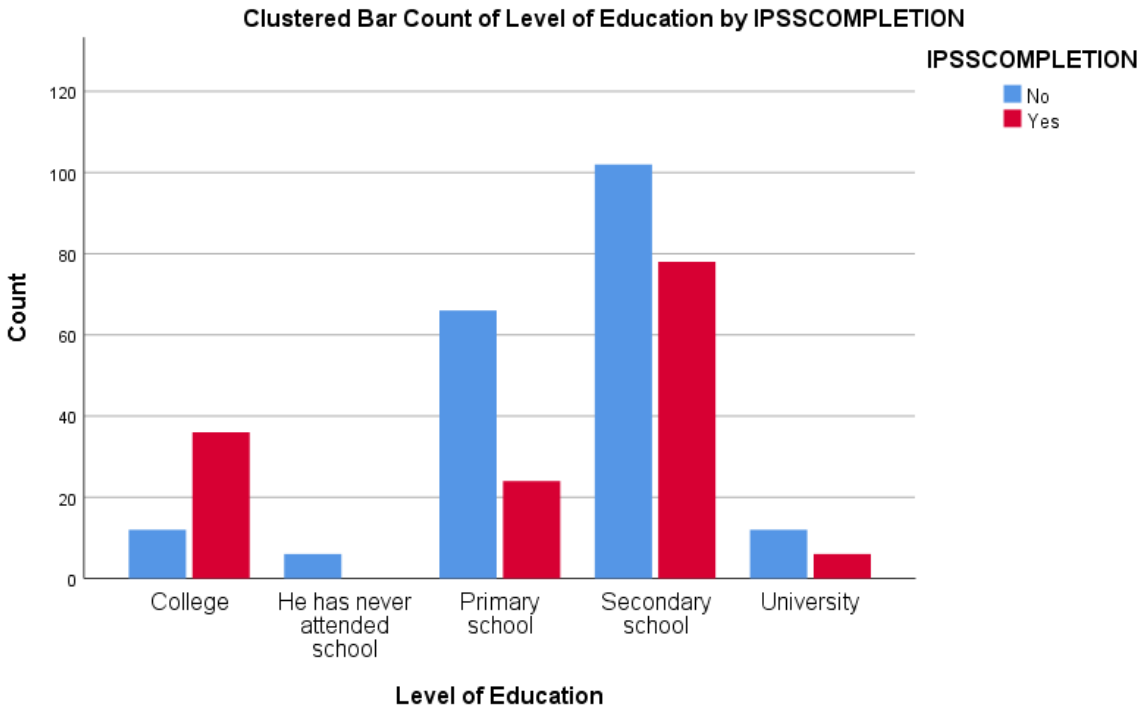
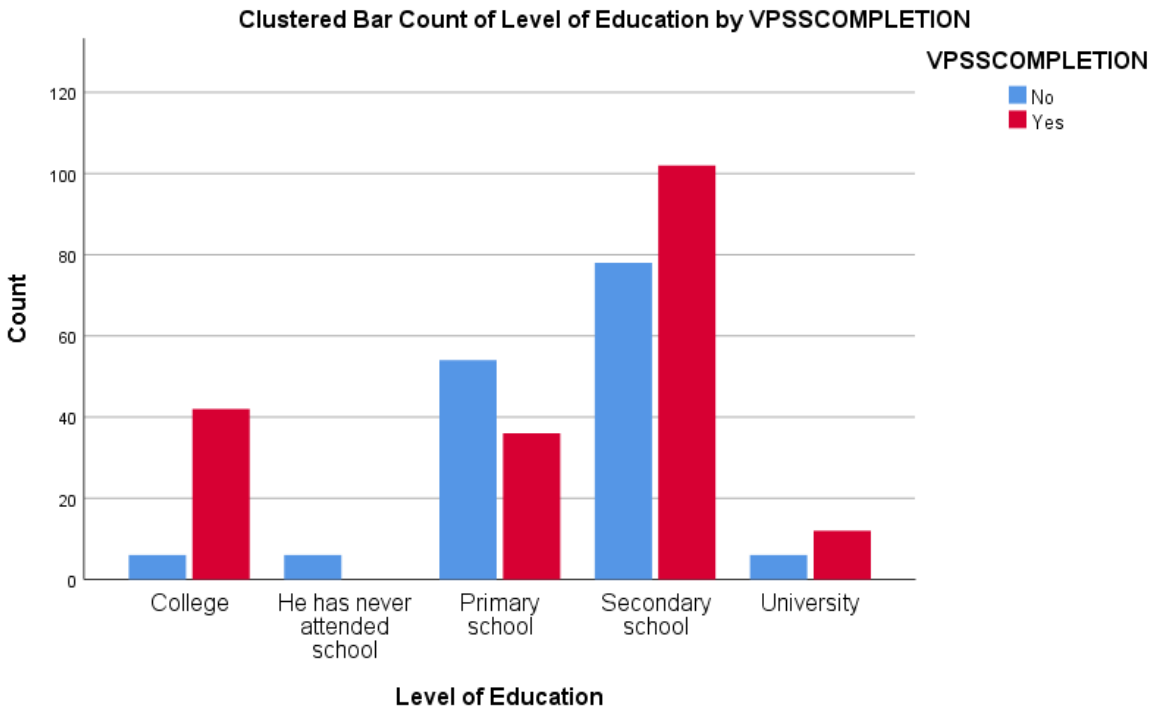


Fig 9 – Clustered Bar Count of Level of Education by VPSS completion



From the foregoing, it is possible to establish a number of relationships. A greater number of respondents were able to self-administer the VPSS (192 patients) compared to the IPSS (143 patients) across all categories of education. This represents an increase of 14.3% of the total number of respondents. Secondly, a higher level of education was found to correspond to a higher proportion of successful completion of both the VPSS and IPSS.

All of the respondents reported lower urinary tract symptoms with an average IPSS of 17.27. Likewise all of the patients had enlarged (estimated volume>30cc) prostates with a median prostate size of 50cc. There was no significant correlation between prostatic size and the severity of lower urinary tract dysfunction as detected by IPSS (Pearson's r-value of 0.018).

Table 6 – Pearson's correlation of prostate size and LUTS severity (Total IPSS)

		Prostate size	IPSS TOTAL
Prostatesize	Pearson Correlation	1	.018
	Sig. (1-tailed)		.372
	N	342	336
IPSSTOTAL	Pearson Correlation	.018	1
	Sig. (1-tailed)	.372	
	N	336	336

A greater number of respondents were able to fill the VPSS without assistance, compared to the IPSS.

As encouraging as these results are, at first glance, a closer analysis of the degree of correlation between those scores obtained by VPSS against those obtained by the gold standard (IPSS) is called for. This was obtained by calculating two-tailed Pearson's correlation coefficients for VPSS parameters and their corresponding parameters on the IPSS scores.

Overall, there was high degree of correlation between the total IPSS and VPSS(r=0.608). The impact of demographic characteristics on the degree of correlation was also studied. The results are as summarized in the table below.

Table 4: Pearson's correlation coefficients of VPSS and IPSS scores

Parameter	**Total (n=342)**	**Above 65 years (n=210)**	**Below 65 years (n=132)**	**Unaided patients (n=192)**	**Assisted patients (n=150)**	**Primary school (n=144)**	**Secondary & above (n=246)**
Frequency	r=0.447	r=0.481	r=0.439	r=0.479	r=0.442	**r=0.532**	r=0.414
Urgency	r=0.381	r=0.366	r=0.411	**r=0.644**	r= -0.118	r=0.370	r=0.393
Nocturia	**r=0.817**	**r=0.837**	**r=0.780**	**r=0.927**	**r=0.720**	**r=0.901**	**r=0.780**
Weakness of stream	**r=0.563**	**r=0.648**	r=0.452	**r=0.607**	**r=0.513**	**r=0.662**	**r=0.554**
Quality of life	**r=0.662**	**r=0.672**	**r=0.656**	**r=0.781**	**r=0.547**	**r=0.547**	**r=0.692**

There was a uniformly high degree of correlation between the visual (Likert) and written quality of life scores with Pearson's r values exceeding 0.5 across all demographic groups. The nocturia image was the most easily interpretable image to the respondents as it registered the greatest consistency with the IPSS nocturia score compared to the other parameters. Similar findings were evident in the high degree of correlation between the weakness of stream image and its IPSS counterpart. Conversely severity scores derived from the frequency and urgency series of images were the least consistent with the corresponding IPSS severity scores with r-values <0.4.

5.0 DISCUSSION

A lesser proportion of respondents (42.11%) were able to complete the IPSS without assistance as compared to 56.14% of patients who were able to complete the VPSS. Some of the respondents cited poor vision as the reason for this deficiency though a lack of formal education and cognitive decline with age were also apparent handicaps. Indeed a significant association was found between age and ability (or inability) to fill in the IPSS without assistance. In addition, a higher proportion of patients were able to perform unaided completion of the IPSS in each advancing formal education stratum. These findings are comparable to others in this field and serve to underline the need for an alternative means of assessment of LUTS severity among older, less educated patients who experience difficulty with the IPSS. There was no significant association found between age and ability to complete the VPSS unaided.

Some studies have demonstrated a difference in health seeking behavior among married patients who seek urological consultation with less severe scores or with associated sexual dysfunction. The number of single respondents in this study (9 widowed and 3 separated from their partners) were too few to further analyze this relationship.

While the enlarged prostate is an important cause of lower urinary tract dysfunction in this age group (men aged 50 to 80 years) and one of the defining characteristics of this study population, there was no significant correlation between prostatic size and LUTS severity (r-value = 0.018). Simply put, it is possible for a patient to experience severely bothersome symptoms with a smaller prostate and less bothersome symptoms with prostatomegaly, due to the complex interplay of forces that produce lower urinary tract dysfunction. A more objective standard for comparison of LUTS severity would be uroflowmetry or urethral

resistance as derived from pressure flow studies. These investigations were not available at Kenyatta National Hospital during the study duration.

There was a high degree of positive correlation between severity scores obtained by VPSS and those obtained by IPSS (r=0.608). This means that scores derived from each tool are varying in tandem with one another.

The visual/Likert quality of life score in particular demonstrated high correlation (r>0.5) with the written quality of life score across all demographic groups. This degree of correlation remains consistently high despite the influence of other independent variables and peaks among those patients with a high level of education. This means that the Likert scale is an accurate means of estimating the degree of bother due to lower urinary tract dysfunction.

The nocturia (r>0.78) and weakness of stream images (r>0.452) also exhibited high correlation with corresponding IPSS scores. This suggests that these images were recognizable and easily interpretable by the patient. Another possible reason is that unlike the other parameters of lower urinary tract dysfunction, the patient need only recall the number of times they wake up to urinate to accurately assign themselves a score. The other IPSS parameters are inherently more subjective and require a slightly better grasp of numeracy to allow standard interpretation that is uniform universally. This suggests the need for validation of the VPSS against more objective measures of lower urinary tract dysfunction, such as urethral resistance as detected by pressure-flow studies. However, such means currently remain beyond the reach of most public health facilities in Kenya.

Scores derived from the urgency and frequency (respectively) series of images were the least consistent with the corresponding IPSS severity scores. This calls for further alteration of these series of images to make them more recognizable to the respondents The r-value of the

urgency scores among patients who had been assisted to fill the VPSS was particularly poor at -0.118. This nonsensical inverse relationship highlights the detrimental effects of 3rd party associated errors. Overall, there was a high degree of correlation between the VPSS and IPSS scores of patients who filled the VPSS form **without assistance**. Particularly high r-values in excess of 0.5 were seen in four out of five parameters among those patients who did not require assistance to complete the VPSS. From the table, we may then infer that of all studied independent variables (age, level of education, et cetera), the ability of the patient to fill in the VPSS without assistance is the most important factor determining accurate and representative completion of the VPSS form, in a manner consistent with the severity of their lower urinary tract dysfunction as determined by the IPSS. Ideally all efforts should be made to ensure the patient fills the prostate symptom score without assistance.

6.0 CONCLUSION

The VPSS shows great potential as a universally applicable adjunct to the IPSS in estimating the severity of lower urinary tract dysfunction. It offers an alternative means of assessment in LUTS patients who are unable to fill the IPSS without assistance. This is demonstrated by the high degree of correlation between VPSS and IPSS scores. It must be emphasized however, that the IPSS is the validated gold standard and remains one of the premier tools of evaluation of LUTS patients.

Selective application of the VPSS according to demographic characteristics of the patients (eg age and level of education) appears to have less role in ensuring accuracy than ensuring that patients complete the score without 3rd party interference, which is to be encouraged.

While this comparison of VPSS and IPSS scores has demonstrated high correlation in this group of patients, some of the series of images (particularly the frequency and urgency images) require further alteration to become more recognizable and interpretable by the ageing male.

Lastly, further validation is needed, particularly against more objective measures of lower urinary tract dysfunction, before recommendations can be made on widespread non-proofed utilization of the VPSS in patient care.

7.0 RECOMMENDATIONS

The validated IPSS remains a vital tool in the evaluation of men with lower urinary tract dysfunction. Some LUTS patients may lack the prerequisite literacy and numeracy to accurately complete the IPSS in a manner that reflects the true severity of their disease. In an ideal environment, the patients who are unable to understand the IPSS should not be assisted to complete the IPSS because the data obtained may contain 3rd party associated errors.

For these patients, the VPSS may be a valuable adjunct in the assessment of the severity of their disease. More patients are able to understand and fill the VPSS without assistance. Usage of the VPSS in patient care should be preceded by the design of more easily interpretable images particularly those assessing urinary frequency and urgency. Lastly the VPSS requires validation against more objective measure of lower urinary tract dysfunction (such as pressure flow studies) to justify widespread deployment for this purpose.

8.0 CONCEPTUAL FRAMEWORK

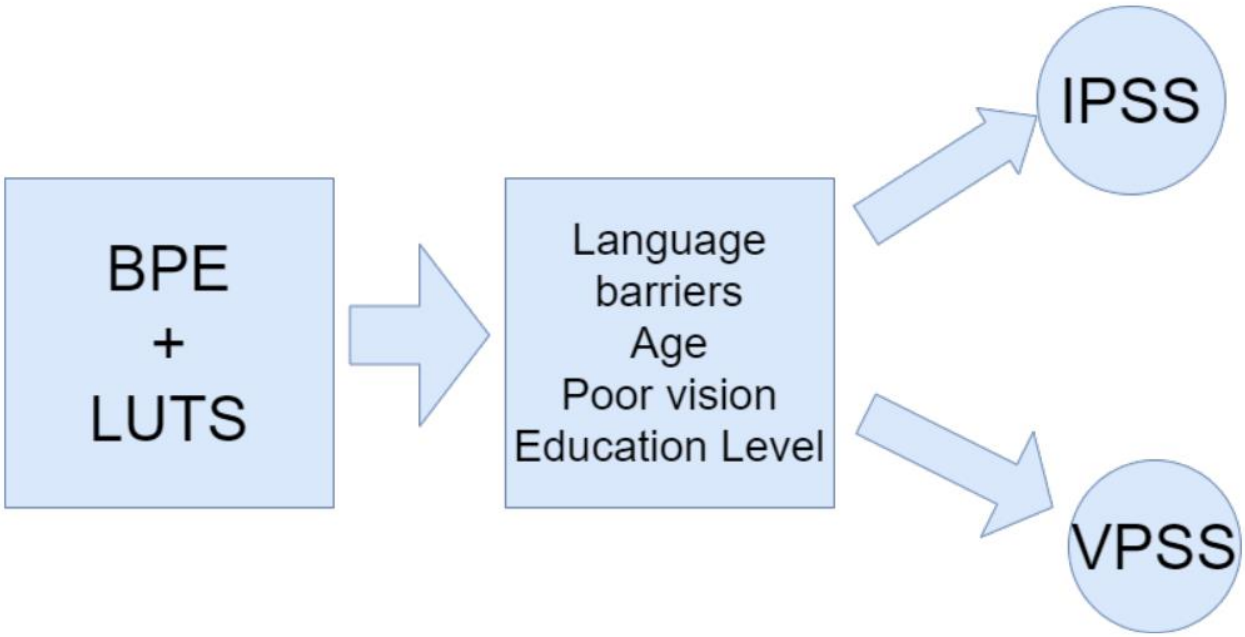


Fig 7 – Conceptual framework

9.0 STUDY RESULTS DISSEMINATION

The findings of this study shall be published in medical journals and presented at scientific conferences. A copy of the same shall also be made available to the electronic repository of the University of Nairobi and the KNH administration.

13.0 ETHICAL CONSIDERATIONS

Permission to perform this research was obtained from the KNH-UON ethics and research committee and KNH administration. Informed, written consent was then obtained from each potential study subject. No financial incentives were offered to patients and no coercion was used to induce patients to participate in the study – participation was on a purely voluntary basis. Care of the highest attainable standard was offered to all patients

regardless of their decision concerning participation in the study, in accordance with the Kenyatta National Hospital mandate.

The principal researcher has no conflict of interest to declare.

11.0 STUDY LIMITATIONS

In this study, the ability to complete the VPSS form without assistance and the degree of correlation of their responses to those of the IPSS has been used as quantifiable measures of their ability to comprehend the VPSS. Inferences drawn from these metrics might be tainted by prior exposure to the forms, ie the patient might remember the questions from a previous encounter. This recall bias was reduced by asking the subject to complete the VPSS before the IPSS, changing the order of the IPSS questions, and by only including those patients with no prior exposure to the VPSS. However, it may not have been completely eliminated, given that KNH is a tertiary referral facility

LUTS are a progressive illness with an age-dependent prevalence. Old age is also a risk factor for cognitive disturbances and poor vision that might confound the subject's ability to comprehend the written part of the inquiry, at a minimum. Accordingly, the data collection tools featured large scripts and images.

Correlation between peak flow rate and IPSS score has been found in clinical research assessing the efficacy of treatment modalities for BPE. While such urodynamic parameters would form a more objective standard against which to compare symptom severity per VPSS, such tools are unavailable in most public health facilities in Kenya.

In this study, a majority of patients were unable to fill the IPSS without being assisted. While this underlines the need for a more patient friendly assessment tool, it also means that the

gold standard utilized in this comparison is marred by 3rd party errors. However, this is a systematic error. With higher respondent numbers, this error may be further nullified by comparing the scores of patients who are able to fill both the VPSS and IPSS without assistance.

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