PROSTATE VOLUME MEASUREMENT BY SUPRAPUBIC AND TRANSRECTAL ULTRASONOGRAPHY IN THE ASSESSMENT OF BENIGN PROSTATIC HYPERPLASIA PATIENTS: A CROSS SECTIONAL STUDY.

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DECLARATION

I, Dr Malemo Kalisya, hereby declare that this work is original and has never been presented in any institution of learning either in partial or total fulfillment for the requirements of the award of any degree. The contributions used in this manuscript are appreciated and their sources quoted. I therefore present it for the award of the degree of Master of Medicine in Surgery of Makerere University.

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DEDICATION

This work is dedicated to my wife Stéphanie Bake, my son Daniel Hakim Malemo, my daughter Daniella Ishara Malemo who so tirelessly cheered me on through the academic path.

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LIST OF ABBREVIATIONS

3AGU: Genito Urinary Ward.

3BES : Surgical emergency ward

BPH: Benign Prostatic Hyperplasia

COU: Church of Uganda or Anglicans.

DRE: Digital Rectal Examination

IPSS: International Prostatic Symptom Score

LUTS: Lower Urinary Tract Symptoms

PI: Principal investigator

PSA: Prostatic Specific Antigen

SOPD : Surgical Outpatient Clinic

SPSS: Statistical Package for Social Science

SPUS: Suprapubic Ultrasonography.

TAUS : Transabdominal Ultrasonography

TRUS: Transrectal Ultrasonography

TURP: Transurethral resection of prostate

TUUS: Transurethral ultrasound

OPERATIONAL DEFINITIONS

• **Prostatectomy**: surgical removal of part or whole of prostate gland.

• **Symptomatic BPH**: obstruction to urinary flow due to BPH, which after evaluation will have an IPSS of eight and above.

• In the whole text **suprapubic ultrasonography (SPUS)** is the same as transabdominal ultrasonography (TAUS).

• **Size of the prostate** means volume of prostate unless otherwise defined. The preoperative volume by SPUS or TRUS is calculated from the 3 dimensions of the prostate, ie transverse, anteroposterior and longitudinal diameters.

• **Volume of enucleated adenoma**: In order to be able to compare same units, the weight of enucleated prostatic adenoma was converted in its calculated volume: calculated volume (ml) = weight(g) of enucleated prostate adenoma because the density of prostate is equal to one.

• **Hemoglobin level**: amount of the oxygen carrying pigment in the red blood cells

• **Hematocrit**: measure of the proportion of red blood cells to the total blood volume.

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ABSTRACT

Title: Prostate volume measurement by suprapubic and transrectal ultrasonography in the assessment of BPH patients.

Objective: To compare preoperative volumes of the whole prostate as measured by SPUS, TRUS and the correlation between preoperative volume and weight of enucleated adenoma of the prostate among patients with BPH.

Methods: A Cross Sectional Study involving 50 patients who presented with symptomatic BPH and an IPSS> 20 with histological confirmation of BPH were included using a consecutive sampling. The volume of the whole prostate was estimated by a Radiologist using two modalities SPUS and TRUS on each patient during the same session. Open prostatectomy was done and the weight of the enucleated prostatic adenoma measured using an electronic weighing machine. Analysis included paired t test of means and mean of differences, sensitivity, specificity, positive and negative predictive values and Bland-Altman analysis of the degree of agreement between the two methods.

Results: The mean age was 69.94 years (range 51 to 91). The mean volume of the prostate by SPUS and TRUS were respectively 95.89±51.38 ml and 95.98±51.55 ml. The mean of the differences between the prostate volume estimates by the two methods was 0.09 ml (95% CI: -2.07 to + 1.89) and was not statistically significant (p= 0.93).The correlation coefficient between preoperative volume of prostate estimates by SPUS and by TRUS was strong (r= 0. 98, p-value< 0.001). Bland and Altman analysis confirmed the strong degree of agreement between SPUS and TRUS. The sensitivity, specificity, positive and negative predictive values of the SPUS to detect prostate volume ≤ 80ml were both over 95%. The mean difference between the volume of the enucleated adenoma and the

preoperative volume of the whole prostate estimated by SPUS and TRUS were 12. 39ml (95% CI: 7.89 16.88, p< 0.001) and 12.47ml (95% CI: -8.17 33.12, p< 0.001) respectively.

Conclusion: The study has shown that SPUS is as accurate as the TRUS in assessing preoperative volume of prostate among symptomatic BPH patients. Suprapubic ultrasonography has excellent sensitivity and specificity for assigning patients to TURP relative to TRUS as gold standard. Suprapubic ultrasonography prostate volume estimates are highly correlated with the volume of the enucleated prostatic adenoma.

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CHAPTER ONE

1.1. Introduction & Background

Symptomatic benign prostatic hyperplasia (BPH) is the most common neoplastic condition in men worldwide and constitutes a major public health problem in both developed and developing countries (1). Benign prostate hyperplasia is found in 50% of men in their 50s and 80% of men beyond 70 years (2). In some African countries, lower urinary tract symptoms due to BPH occur in one third of men over 60 years of age (3). One study from Saudi Arabia showed that workload due to treatment of benign prostatic hyperplasia is increasing and estimated currently to be 20-40% of the whole urological workload (4). In Uganda, prevalence of the disease is not known. But data from Mulago Hospital Urology Unit shows that symptomatic BPH is the leading cause of admissions with 177 cases of BPH out of 742 (24 %) of admissions on the ward between January 2005 and June 2006 (5).

Mortality and morbidity due to complications of BPH is still high in developing countries. A systematic overview of worldwide trends in mortality from benign prostatic hyperplasia (BPH) over the past four decades shows a decrease in some countries, in part due to the introduction of TURP (6). It is expected that the widespread use of TURP will decrease the morbidity and mortality due to BPH in African countries (7).

The volume of the prostate is a key element in determining the choice of surgical approach, the response to treatment , outcomes after surgery and to some extent involved in the severity of symptoms(8). Several modalities of estimating prostate volume exist. According to the literature, there is a strong correlation between prostate volume measured by TRUS and the real prostate weight in specimens excised operatively or in cadavers. Although it is accepted that the TRUS is superior to suprapubic ultrasonography (SPUS) in the evaluation of the

prostate, SPUS seems to offer many advantages in the measurement of prostate dimensions since it is non-invasive, more available in Uganda, less cumbersome for patients and quick. Therefore, the purpose of this study is to assess the diagnostic accuracy and agreement of suprapubic ultrasonography (SPUS) in relation to transrectal ultrasonography (TRUS) in the measurements of prostate volume among patients with symptomatic benign prostatic hyperplasia.

1.2. Problem Statement

Symptomatic BPH contributes approximately 24% of hospital admissions to the Urology ward in Mulago Hospital. This is the single largest contributor to workload in the Urology unit.

With the introduction of endoscopic prostatectomy (TURP), Urologists need an accurate way of knowing the exact volume of prostate in order to assign patients to TURP (if the prostate volume is less than 80ml) or to open prostatectomy(if the prostate volume is more than 80mL).

There are many methods for estimating prostate volume. Some of them have shown limitations: they are either expensive, not available in most of the hospitals in Uganda (TRUS, Cystoscopy, MRI) or inaccurate (DRE).

The gold standard TRUS is not readily available in practice in Uganda and there are only thirty trained Radiologists in Uganda who can perform the examination. It is discomforting, especially in patients with anal diseases such as hemorrhoid, anal fissure, and anal fistula, as well as patients with a low pain threshold. However SPUS is available with a larger number of trained radiographers, sonographers as well as the Radiologists who can perform the examination, but its accuracy is unknown in Uganda. Also the accuracy of SPUS is still controversial.

1.3. Justification of the study

Accurate prostate volume estimation is critical in morbidity and mortality containment. It contributes to better decision-making for both non surgical and surgical treatment of patients with BPH. It avoids unnecessary surgical intervention and encourages more investigation for patients who present with symptoms of lower urinary tract obstruction but with an otherwise ultrasonographicaly normal volume of prostate. It may help in investigating other causes of urinary obstruction.

It forms a basis for prediction of postoperative outcomes and complications. This allows for fore planning and efficient utilization of hospital resources.

SPUS is hoped to become a suitable alternative to TRUS if it is established that it provides comparable accuracy for prostate volume estimation.

1.4.Research Questions

(1) Is there any difference between prostate volume measured by SPUS and TRUS?

(2) What is the correlation between preoperative prostate volume measured by SPUS and TRUS and the weight of enucleated adenoma in patients with BPH?

1.5. Research Objectives

1.5.1. General Objective

To assess the accuracy of measurement of prostatic volume by SPUS and TRUS among patients with BPH at Mulago Hospital.

1.5.2. Specific objectives

(1) To compare the mean prostate volumes measured by SPUS and TRUS among patients with BPH.

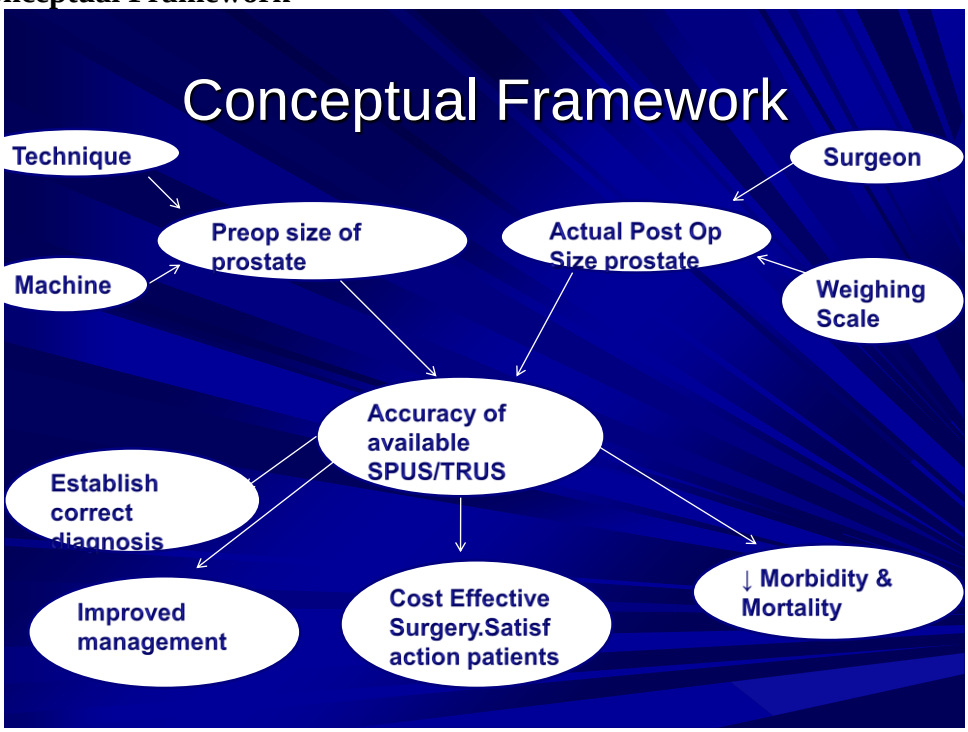
(2) To assess the sensitivity, specificity, negative and positive predictive values of SPUS as a guide in assigning patients in TURP surgery compared to gold standard TRUS using a cut off of 80mls of preoperative volume.

(3) To determine the correlation between the weight or volume of enucleated prostatic adenoma and the preoperative volume of the whole prostate measured by SPUS and TRUS among symptomatic BPH patients.

1.6. Research Hypothesis

1. There is no difference in the mean preoperative prostate volumes measured by SPUS and TRUS among BPH patients in the study population.
2. The sensitivity and specificity of SPUS in relation to TRUS to estimate prostate volume are high.
3. There is a strong correlation between the preoperative volume of the prostate as determined by either SPUS or TRUS and the volume of the enucleated prostatic adenoma among symptomatic BPH patients in the study population.

1.7. Conceptual Framework



CHAPTER TWO

LITERATURE REVIEW

Symptomatic BPH is a worldwide disease of the aging men and constitutes an increasing health problem in both developing and developed countries. The weight of the prostate is around 20g between 20-30 years. The mean prostatic weight increases after the age of 50 (2).

The prevalence of histologicaly diagnosed prostatic hyperplasia increases from 8% in men aged 31 to 40 years, to 50% in men aged 51 to 60 years, to more than 80% in men older than age 80 years (2, 9). In some African countries, lower urinary tract symptoms due to BPH occur in one third of men over 60 years. This pathology constitutes a public health problem (3). The workload due to benign prostatic hyperplasia is increasing and estimated currently to be 20-40% of the whole urological workload. In Uganda, prevalence of the disease is not known. Data from Mulago hospital Urology Unit fall in similar ranges , showing that symptomatic BPH is the leading cause of admissions with 177 cases of BPH out of 742 (24%) of admissions on the ward between January 2005 and June 2006 (5).

The volume of the prostate is an important element determining the choice of surgical approach, the response to some treatment and outcomes after surgery (8). Transrectal Ultrasound has been established as the gold standard modality for assessing the volume of prostate. Unfortunately it has been of limited use in Urology practice in Uganda due to its limited availability and discomfort for patients. Also it needs a lot of preparation and trained personnel who are not available. There is a need for a more accessible, easier to perform and comfortable modality of assessing the volume of the prostate. One of them is suprapubic ultrasound (SPUS) (8). Preliminary studies show that SPUS compares well with TRUS in estimating prostate volume (8, 10), but controversy abounds.

Relationship between ultrasonographic volume and weight of prostate

In this paragraph we are giving the relationship between the volume of the whole prostate by ultrasound and the weight of prostate.

Ultrasound gives the volume of the prostate using the ellipsoid formula calculated from the 3 dimensions of the prostate: Volume= 0.523 ×width (cm) ×height (cm) ×length (cm) will be measured**.**

The weight of prostate (in grams) equals the volume (in ml) because the density of the prostate approximates one (11, 12).

Clinical significance of preoperative volume of the prostate estimation

In Clinical practice, prostate volume estimation is very important to guide the Clinician in many ways.

(1) It *predicts* the deterioration of symptoms such as the risk of acute retention of urine.

(2) Prostate volume determines the choice of the medical treatments : α-receptor blockers or 5α- reductase inhibitors . It is used to assess the response to medical treatment of BPH.

(3) It determines the choice of surgical approach.

First, it determines the type of surgical approach either TURP or open prostatectomy. When the obstructing tissue of prostate is estimated to weigh more than 50 g, serious consideration should be given to an open procedure rather than TURP (13, 14). In many Urology Centers, TURP is not possible for prostate weighing more than 80-100g (15, 16). Open prostatectomy is preferred for bigger prostates. One recent study conducted in Lithuania (17) involving

patients with histological confirmation of benign prostatic hyperplasia , showed that in open prostatectomy of BPH, 97 % (74g out of 76g) of the weight of the adenoma measured by preoperative TRUS was enucleated but 90% at TURP. This shows that residual prostatic tissue left at open prostatectomy is insignificant.

Whether prostate volume predicts the deterioration of symptoms, in particular the risk of acute retention of urine and need for surgical intervention is a subject of controversy. Although most hospital-based studies have shown a poor correlation between prostate size and both symptoms and flow rate, more recent community-based studies report a useful correlation. The Olmsted study showed that the odds of having moderate to severe LUTS were 1.5 times higher for men with prostates of 30 mL and 3.5 times higher for men with prostates of 50 mL (18). Prostate volume, clinical symptoms, and peak urinary flow demonstrate the progressive nature of BPH (19). The Olmsted County Study and the Baltimore Longitudinal Study of Aging using repeat ultrasound measures in a 7-year period found that average prostatic growth rates were 1.6% yearly in men between ages 40 and 79 years and that the yearly percent growth of the prostate depends on baseline volume, in that the larger the prostate at baseline, the greater the percent of growth every year thereafter. They concluded that, while prostate volume correlates poorly with symptoms and urinary flow at any given time point, the larger the prostate, the greater the likelihood of future clinical deterioration (20).

Preoperative volume or calculated weight of the prostate is key predictor of postoperative outcomes. A study (21) done in UK by Kirollos in 2003 showed that prostate weight was the most important measurable factor in determining blood loss after TURP. Blood loss, the need for transfusion, the amount of blood transfused, and the duration of surgery, catheterization, and hospital stay were all related to prostate size (22).

Prostate volume is used for planning of nonsurgical therapy and for following up the response to treatment. Accurate and reliable measurement of prostate volume is crucial for the management of prostate diseases. Response to certain types of BPH therapy depends on actual prostate weight or volume. Therefore, it is important to have a simple way to accurately determine the size of the prostate (8, 23, 24) .

Methods of Prostate volume estimation

Several modalities have been used to estimate the dimensions of the prostate including DRE, SPUS, TRUS, TUUS, urethrocystoscopy and MRI. MRI and TRUS are the most accurate, but MRI is not always available and is very expansive (25). TRUS is considered the gold standard in estimating the size of the prostate (14). It compares well with MRI in estimation of the size of prostate. DRE and urethrocystoscopy tend to overestimate small and underestimate large glands over 40ml (26). A review of articles showed that DRE underestimated prostate volume (20).

Due to the poor acceptability of TRUS by patients, SPUS is regaining more interest and some published data suggest that SPUS offers an alternative to the gold standard TRUS since it compares well with TRUS (8, 10, 27-29). It is easier, more available and more comfortable for patients (8). However other studies (30, 31) found SPUS to be inaccurate and controversy still abounds.

One of the studies showing SPUS to be inaccurate for the estimation of prostatic volume and weight was done by Blanc in 1998 including 196 patients (30). He found SPUS to give the same volume and weight with TRUS in only 27% of cases. On the other hand the study showed that prostatic volume and weight measured with SPUS are overestimated in about 50% of cases. But Kanao et al. in 2004 found that ultrasound underestimates the weight of the prostate by 21g (31).

In contrary, some other studies (24, 32-34) found SPUS to be comparable with the gold standard TRUS and to postoperative weight of the prostate in BPH. In the preoperative evaluation of the prostatic size SPUS is rapid, simple and noninvasive and gives preoperative information for prostatectomy. In the following paragraph we will summarize some of them. Such studies have not been carried out in Uganda.

In Greece, 1994, Prassopoulos and colleagues prospectively compared the reliability of SPUS to TRUS in 95 patients with BPH (24). According to the results of this comparative study, SPUS appears to be as reliable as TRUS in assessing the size of the prostate and may be used effectively in the evaluation of patients with BPH, as it is less cumbersome, better tolerated, and a widely available examination technique. Similar conclusions were drawn by Hevdik (35).

Studies in African countries are scarce. However, in Nigeria, one comparative study comparing SPUS to TRUS in the assessment of prostatic volume found a good correlation between the two (26). But this study did not compare the calculated weight by ultrasound to the postoperative weight and recommended that such a study should be carried out. A strong correlation has been reported between prostate volume measured by TRUS and the real weight of prostatic biopsies excised operatively or in cadavers (5, 13, 14, 25, 30, 36).

In Uganda, SPUS is readily available and has been used. To our knowledge no study has assessed its accuracy for the preoperative assessment of the prostatic volume in patients with symptomatic BPH.

CHAPTER THREE

METHODS

3.1. Study Design

This was a cross sectional study.

3.2. Study Setting

The study was conducted in the Genito-Urinary Unit (GUU) of Mulago hospital, a National Referral and Teaching Hospital, with a bed capacity of 1500beds. The hospital is located in Kampala, the capital city of Uganda. It provides diagnostic, curative, rehabilitation, and preventive services for the whole country and neighboring countries. Patients seen in Mulago Hospital are referred from regional referral hospitals all over Uganda, from other hospitals in Kampala and from other countries. Some patients are self referred.

The Genito-Urinary Unit of Mulago hospital has a team of six dedicated Urology Surgeons and a well trained nursing staff. Both open prostatectomy and endoscopic prostatectomy (TURP) are offered in the Mulago GUU. Its service-units include an Outpatient Clinic and 3A Genito-Urinary ward with a capacity of 40 beds. The bed occupancy rate averages 110%.

The Clinical Hematology, Chemistry Laboratories, and Radiology Department of Mulago Hospital offered the appropriate investigations in the research. The histopathology laboratory of Department of Pathology, Makerere College of Health Sciences carried out the histology of the prostatic biospsies.

3.3. Target population

All patients with BPH who sought treatment at Mulago hospital during the study period.

3.4. Accessible population

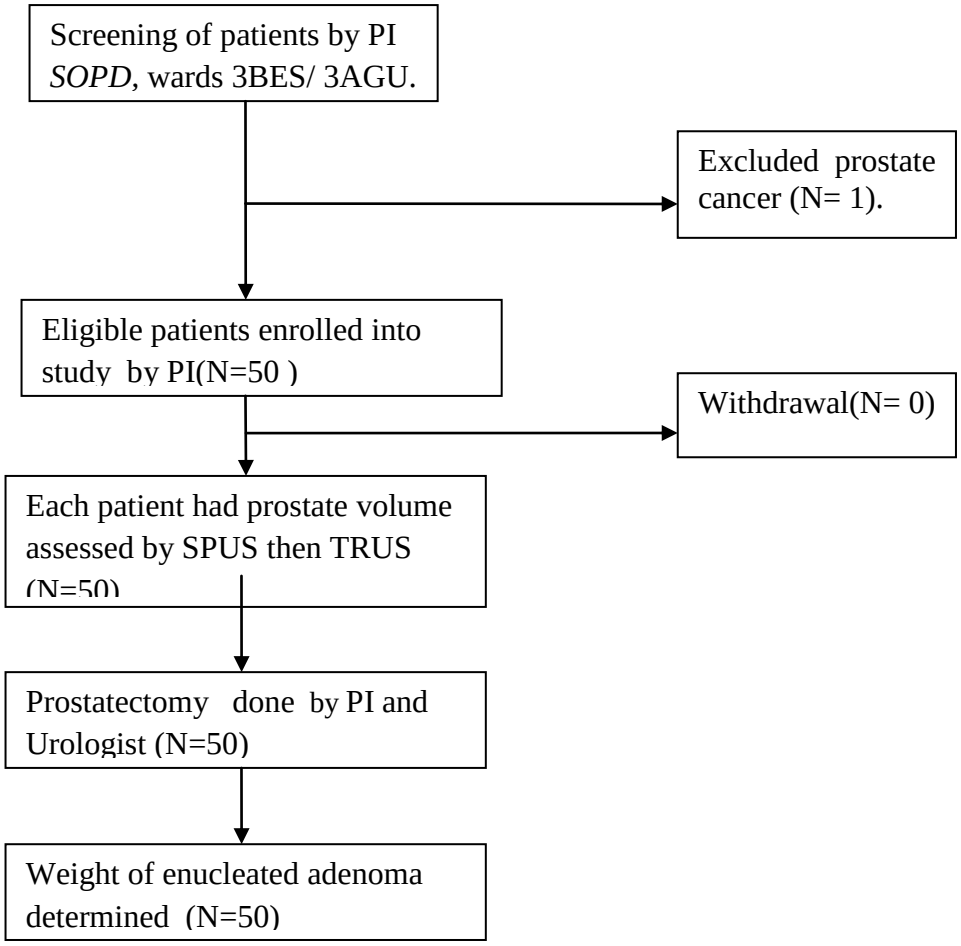
All patients with symptomatic BPH who attended Urology Surgical Outpatient Clinic, 3BES or the GUU of Mulago hospital during the study period.

3.5. Study Population

All patients with symptomatic BPH who attended SOPD, 3BEM or the GUU of Mulago hospital who met eligible criteria and consented.

3.6. Assessment and Flow of Patients

Upon consultation at the Urology Surgical Outpatient Clinic of Mulago Hospital, the patients were assessed by taking the history of presenting complaints and confirming the obstructive uropathy as elicited by LUTS. Patients were assessed during their evaluation before the decision to operate on them was taken. Other patients who presented as emergencies with acute urinary obstruction, hematuria, obstructive uropathy or other complications were recruited from the emergency ward (3BES) or from 3AGU ward and examined. Under general examination they were assessed for presence or absence of pallor, dehydration, pedal edema, temperature and BMI. Systemic examination was then done, including urogenital examination; plus a DRE for enlargement, firmness, nodularity, tenderness, and mobility of the rectal mucosa over the prostate. Investigations included hematological tests (complete blood count), renal function tests, serum electrolytes. PSA levels were assessed for any patient found to have an enlarged nodular prostate and biopsies were then taken. Radiological investigations included SPUS and TRUS. The Principal Investigator took active part in patients' assessment. The informed consent was obtained and those who accepted to participate were enrolled into the study.



3.7. Inclusion Criteria

• All patients admitted to the Urology unit of Mulago hospital, who were above the age of 50 years, with a diagnosis of symptomatic BPH having an IPPS of 8 and above and consenting to participate in the study were enrolled.

• All patients with symptomatic BPH and who were fit for surgery.

3.8. Exclusion criteria

Patients were excluded from the study if after clinical assessment they had a hard and nodular enlarged prostate on DRE and a PSA level above 4ng/ml.

3.9. Surgical Procedures

All patients were assigned to open prostatectomy, due to the fact that TURP is not regularly done in the study setting; even though some could benefit better from TURP (those with volumes ≤ 80ml). Besides, open prostatectomy leaves lesser amount of residual prostate tissue than TURP**.**

3.9.1. Transvesical Prostatectomy

With the patient in supine position on the operative table, under general or spinal anesthesia, and after preparing and draping him in the standard sterile fashion, a urethral catheter Gauge 22 was introduced aseptically into the bladder, filled to approximately 250ml with saline then removed. A vertical midline incision from below the umbilicus to the pubis symphysis was made. Dissection between the laterally retracted rectus abdominis was made and the prevesical space opened into extraperitoneally. Two stay sutures were placed in the anterior bladder wall, and a vertical cystotomy made up to 1cm proximal to the bladder neck, allowing visualization of the bladder neck and prostate. The superior bladder edge was retracted cranially and the inferior portion distal to the trigone caudally to display the posterior bladder neck. The two ureteric orifices were protected as the bladder neck mucosa was incised just distal to the trigone, over the prostate circumferentially. Using sharp and blunt dissection, a plane was developed between the adenoma and the prostatic capsule. Gentle blunt digital dissection was performed. Completion of the remaining dissection both posteriorly and circumferentially around the prostatic apex and urethra was done by gentle blunt digital dissection. The urethra was transected close to the apex of the prostate. Following gross enucleation of the adenoma, the prostatic fossa was inspected and removal of any remaining adenoma done to make sure the whole adenoma was removed. Using figure-

of-8 sutures, the prostatic arteries at the 5- and 7-o' clock positions were ligated to achieve hemostasis. A 22F, 30-ml, 3-way Foley catheter passed per urethra was inflated to prevent retraction into the prostatic fossa. Bladder irrigation was started. Full thickness closure of the bladder was done, through the serosa using a double layer of interrupted 2/0 Vicryl suture. Incision wound was closed in layers.

3.9.2. Modified retropubic prostatectomy

With the patient in supine position on the operative table, under general or spinal anesthesia, and after preparing and draping him in the standard sterile fashion. A vertical midline incision from below the umbilicus to the pubis symphysis was made. Dissection between the laterally retracted rectus abdominis was made and the prevesical space opened.

Through gentle blunt dissection the adenoma was exposed in the retro pubic space. The lateral pedicles were identified at the prostate-vesical junction, and transfixed with two figure-of -8 Vicryl 2/0 sutures on 1/2 circle, atraumatic needle. The dorsal vein complex tributaries were transfixed with figure-of -8 Vicryl 0 sutures on 1/2 circle, atraumatic needle. Through a transverse incision, one (1) cm superior to the bladder neck- adenoma junction, the bladder was opened to expose the adenoma. Enucleation was done breaking through the anterior and posterior commissures to enucleate the adenoma. The prostatic fossa was inspected and removal of any remaining adenoma done to make sure the whole adenoma was removed. Using Vicryl 2/0 and Allis clamps holding the posterior edge of the bladder neck, a haemostatic running suture was placed around the bladder neck from the 3 o' clock, via the 6 o'clock, to the 9 o' clock positions, uniting the bladder mucosa and the prostatic capsule. A 22F, 3 way Foley catheter passed per urethra was inflated in the prostatic fossa. Bladder

irrigation was started. The bladder wound was closed using a double layer of running 2/0 Vicryl suture and incision closed in layers.

3.10. Variables

3.10.1. Independent variable

These were dichotomous: type of ultrasonographic technique, either SPUS or TRUS

3.10.2. Dependent variables

Continuous: preoperative prostate volumes by SPUS and TRUS (mean volume in ml, mean in differences of volumes) and the volume of enucleated prostatic adenoma specimens after prostatectomy.

3.11. Sample size estimation

Objective 1: In order to obtain the sample size required to answer objective 1, the sample size estimation was based on the t-test formula for comparing two means in an analytical study with dichotomous and continuous variables is:

$\mathbf{N= 4\ S^2\ x\ [\ (Z_\alpha + Z_\beta)^2\ ] \div E^2(37,38)}$, where, **N**- total number of subjects required, $\mathbf{Z_\alpha}$- Standard normal deviate for $\boldsymbol{\alpha}$ (0.05) = **1.96** and $\mathbf{Z_\beta}$- Standard normal deviate for β (1-power) **.** We decided to use a higher power of 95% to minimize type β error.

E- Effect Size (minimum expected difference in the mean values of the key outcome variables i.e. difference in preoperative volume of prostate by SPUS versus TRUS).

S- Estimated Standard Deviation of the key outcome variables. E&S were obtained from previous studies.

From a previous study (8) E=3.7ml, S= 3.3ml. Using power 95%, and α= 0.05, we used the table of standard normal deviates. The findings are reported with a 95% confidence level and the sample has a power of 95% to detect a effect size of E (3.7ml) and above.

Z_{α}- Standard normal deviate for **α** (0.05) = **1.96**

Z_{β}- Standard normal deviate for **β** (0.05) = **1.96**

The formula gives $N1= [4x (3.3.)^2 x (1.96+1.96)^2] \div (3.3.)^2$ = **49** subjects

Objective 2: Since the sample was collected as continuous but was categorized later to assess for sensitivity, specificity and diagnostic accuracy of determining subjects with prostate volume below 80mls we did not find it necessary to recompute the sample size for this objective.

Objective 3: The sample size was determined using the formula for estimating sample size using coefficient correlation, r (for a study with a combination of continuous dependent and continuous independent variable)(37):

$N = [(Z_{\alpha} + Z_{\beta})/ C^2] + 3$, Where $C = 0.5 \times \ln [(1+r)/(1-r)]$

A two sided alpha of 0.05 ($Z_{\alpha} = 1.96$) and a Beta of 0.1 ($Z_{\beta} = 1.645$), r =0.69

The results have a 95% confidence and a power of 0.90 to detect a correlation of r= 0. 69 (28). The estimated sample size was **18 subjects**. We considered the highest value of 49 as the sample size. The sample size was further increased by 10% to account for anticipated withdrawal or failure to complete the surgical procedures, the estimated sample size of subjects to be enrolled was planned to be 49+ 5 patients = 54 subjects.

3.12. Data Management

3.12.1 Data collection methods

Simple consecutive sampling was used until we reached our sample size. Patients with BPH fit for prostatectomy were recruited for the study. For each patient both SPUS and TRUS were done to estimate the volume of the whole prostate by one of two trained Radiologists.

One standard machine was used for scans because different machines may have different sensitivities.

After open prostatectomy, the weight of the removed prostatic adenoma was measured by the researcher or his assistant immediately before it dried.

Data was collected using a pre-coded questionnaire and cleaned. The role of the PI during data collection was to assess and recruit patients, inform them about the research, give them an explanation about the procedures, answer all the questions of patients, obtain their consent, collect data, participate in prostatectomy as the second surgeon, weigh the prostatic tissue, send enucleated specimens to histopathology and follow up patients during the postoperative period.

3.12.2. Data analysis and presentation

Data was coded and entered using EXCELL and transferred to STATA version 11.0 for analysis.

Using STATA11.0 software package, the collected data was checked for accuracy, correctness and completeness by the Principal Investigator.

Data was then saved and backed up into two different storage devices by the PI in order to avoid loss or damage.

Categorical data was presented in form of frequencies and percentages using tables, graphs or pie charts. Continuous data was computed for means with standard deviations, 95% confidence interval, medians with interquartile ranges.

Assessment for prostate volume as determined by SPUS and TRUS was done to determine whether data was normally distributed, positively or negatively skewed. If normally distributed the mean volumes using the two modalities of TRUS and SPUS were compared using the student's t tests or the Wilcoxon Rank test. The mean differences, confidence interval as well as the standard deviations were computed. If the data was skewed the medians were used to compare the medians of the volumes by TRUS and SPUS among symptomatic BPH patients. Correlation and Bland- Altman Analysis of the agreement between the two tests SPUS and TRUS was also done. A p value of <0.05 was considered significant.

The sensitivity, specificity, predictive and negative predictive values of SPUS in relation to TRUS using a cutoff preoperative volume of 80ml were determined.

The mean of preoperative volume of the prostate using the two modalities of TRUS and SPUS was compared to the weight or volume of enucleated prostatic adenoma. The mean difference between volume of prostate by SPUS and the weight or volume of enucleated prostatic adenoma as well as the mean difference between the volume by TRUS and weight or volume of adenoma were determined .

The correlation between prostate volume measured by SPUS, TRUS and the weight or volume of enucleated prostatic adenoma was analyzed. We used the Spearman's rank correlation test for the degree of correlation.

Bland-Altman Analysis was also done to complete the assessment of agreement between preoperative and postoperative volume estimates. These were done with the help of two Biostatisticians.

3.12.4. Quality control

- The study was supervised by a Senior Consultant Urologist and Senior Lecturer
- Pretesting of the questionnaire was done before the study was carried out
- The ultrasonography scans were done by either of two trained radiologists using the same machine.

3.13. Ethics

- Ethical approval was sought for and obtained from the Department of Surgery and the Makerere University Faculty of Medicine Research and Ethics Committee.
- The participants were given detailed explanation of the study and an informed consent was sought and obtained before enrollment into the study.
- Those refusing to participate were not discriminated against.
- The researcher was available to answer any question from participants.

3.14. Data Dissemination Plan

The findings of this research are to be published in a peer reviewed journal and made available to :

The Prof. Kyalwazi Memorial Library in the Department of Surgery

The Albert Cook Memorial Library in Mulago Medical School

The Makerere University Main Library.

CHAPTER FOUR
RESULTS

A total of 50 patients who presented with symptomatic BPH and an IPSS> 20 with histologically confirmed BPH were included using a consecutive sampling. One patient had prostatic cancer and was excluded from the study.

4.1. Demographic and Clinical characteristics

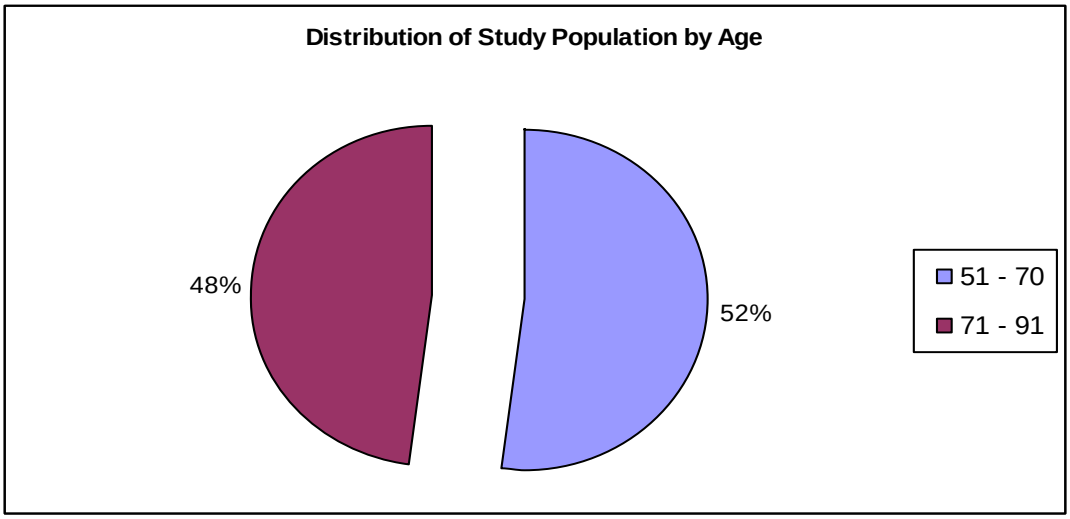


Fig 1: Distribution of the Study population by age

Fifty two percent (52%) of patients' age was between 51-70 years, 48% between 71-91 years. The mean age was 69.94 years (range 51 to 91) and the median was 70 years (IQR 63 to 76 years).

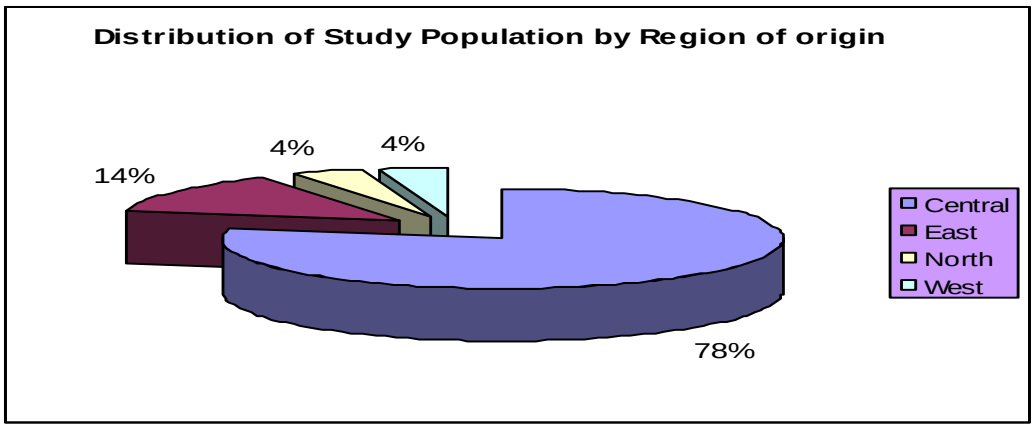


Fig 2: Distribution of Study population by Region of origin

Most (78%) from the participants were from the Central part of Uganda, 14% from the Eastern while the Northern and Western regions had an equal number of participants of 4% each.

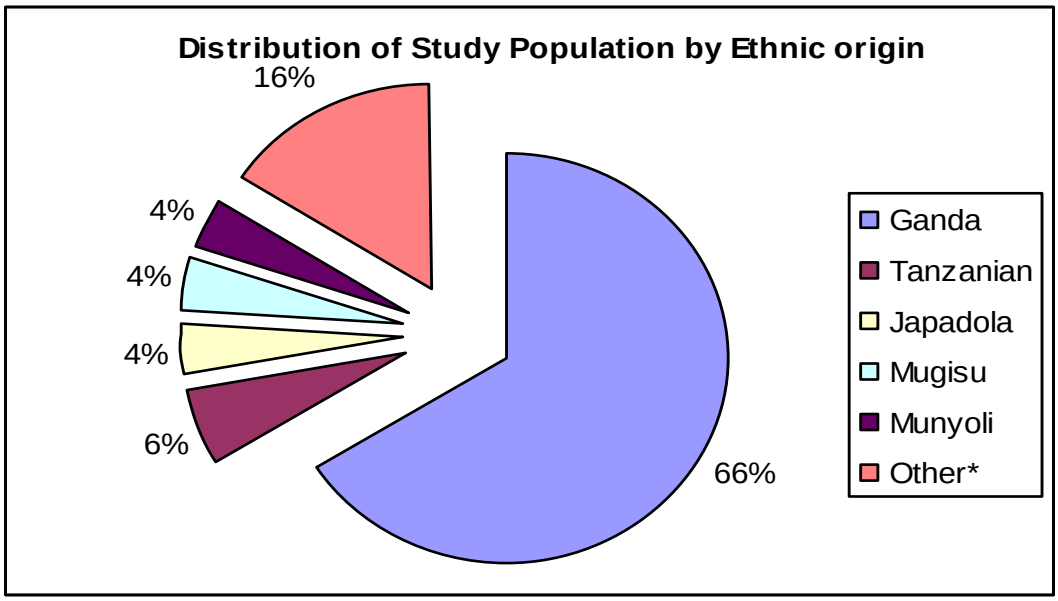


Fig 3: Distribution of Study population by Ethnic origin

The Ganda ethnic group formed 66% of the participants, Tanzanians 6%, Japadola, Bagisu and Banyoli had an equal proportion of 4% and the others* 16% was formed by the following ethnic groups: Alur, Basoga, Kiga, Lango, Madi, Nkole, Nyeri and Sudanese.

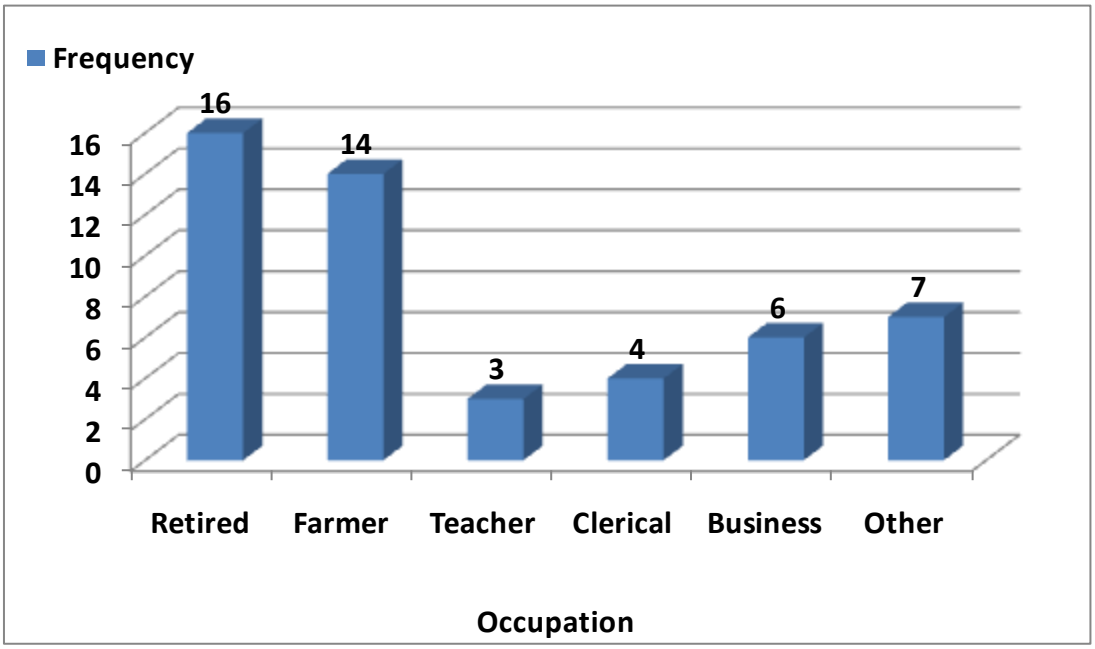


Fig 4: Distribution of Study population by occupation

Retired 16/50(32%), farmers 14/50(28%) formed the majority of the occupations.

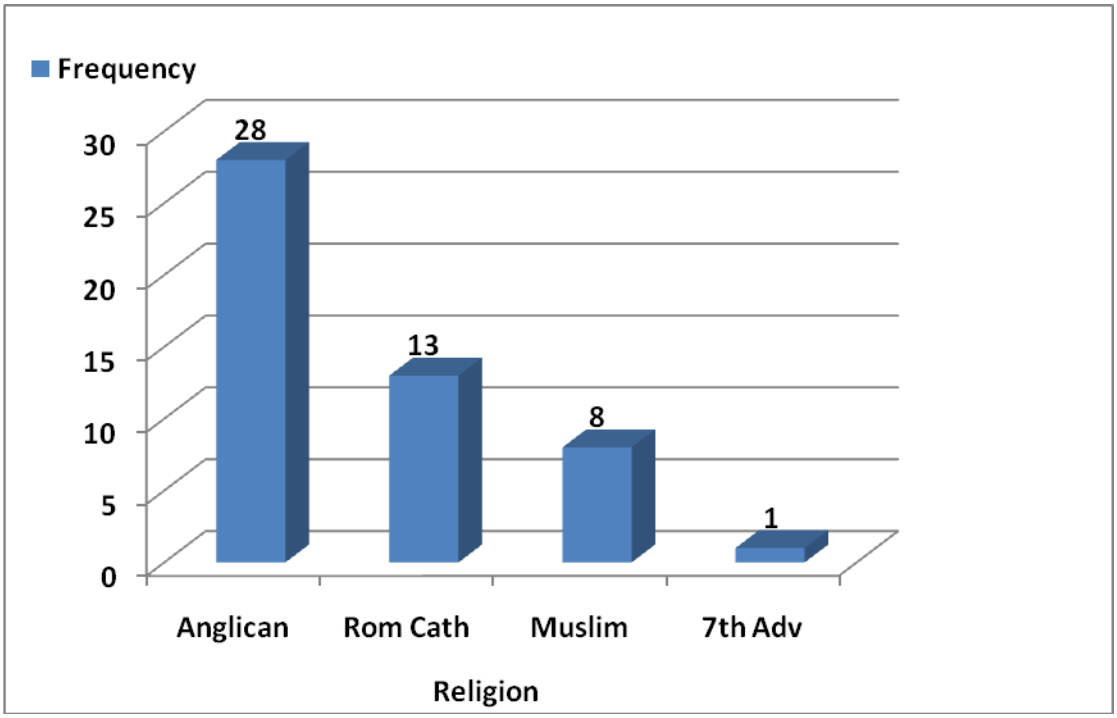


Fig 5: Distribution of Study population by religion
Most, 28/50(56%) of participants were Anglicans, 13/50(26%) were Roman Catholics, 8/50(16%) were Muslims and 1/50(2%) were from the Seventh Adventist Church (SDA).

Table I: Baseline clinical characteristics of Study population

Characteristic	Value
Body Mass Index [kg/m^2], mean (SD)	24 (2.66)
Normal (<25 kg/m^2), N (%)	37 (74)
Overweight (≥ 25kg/m^2), N (%)	13 (26)
Hemoglobin, mean (SD)	12.6 (1.45)
Blood pressure, mean (SD)	
Diastolic	76 (12.52)
Systolic	134 (17.60)

Clinical characteristics indicate that this was mainly an elderly population that had normal body mass index, hemoglobin levels, diastolic pressure and pre-hypertension systolic blood pressure.

4.2. Comparison of Suprapubic Ultrasonography and Transrectal Ultrasonography in the Estimation of Preoperative Prostate Volume.

Table II: Statistics of preoperative volumes (ml) of prostate by SPUS and TRUS of patients with BPH.

Factor	SPUS (Mean±SD)	TRUS (Mean±SD)	Difference (95% CI)	P Value
Volume (ml)	95.89±51.38	95.98±51.55	-0.09 (-2.07 – 1.89)	0.93*

**Computation of p value based on Paired t-test.*

The mean of the differences between paired estimates of prostate volume by TRUS and SPUS was 0.09 ml and was not significant (p=0.93, CI: -2.07 to 1.89).

In order to assess the agreement between SPUS and TRUS for preoperative prostate volume measurement we used the method of Bland and Altman.
As a first step the prostate volume measurements by SPUS were plotted against TRUS measurements, together with the line of equality **(Fig 6).**Qualitatively there appear to be a strong linear correlation and high degree of agreement between the 2 methods. We calculated the correlation coefficient between the 2 methods. The Spearman's Rank correlation coefficient was r= 0.98 (p< 0.001).

Next we created a Bland and Altman plot of the difference between measurements versus the mean of the measurements which is more informative **(Fig 7).** The bias of SPUS relative to the TRUS was 0.09 ml (CI -2.1 to 1.9, p= 0.93). The limits of agreement between the methods were: upper limit 13.6 ml (95% CI 10.1- 17.0) and lower limit -13.8ml (95%CI -17.2 to -10.3) **(Table III).**

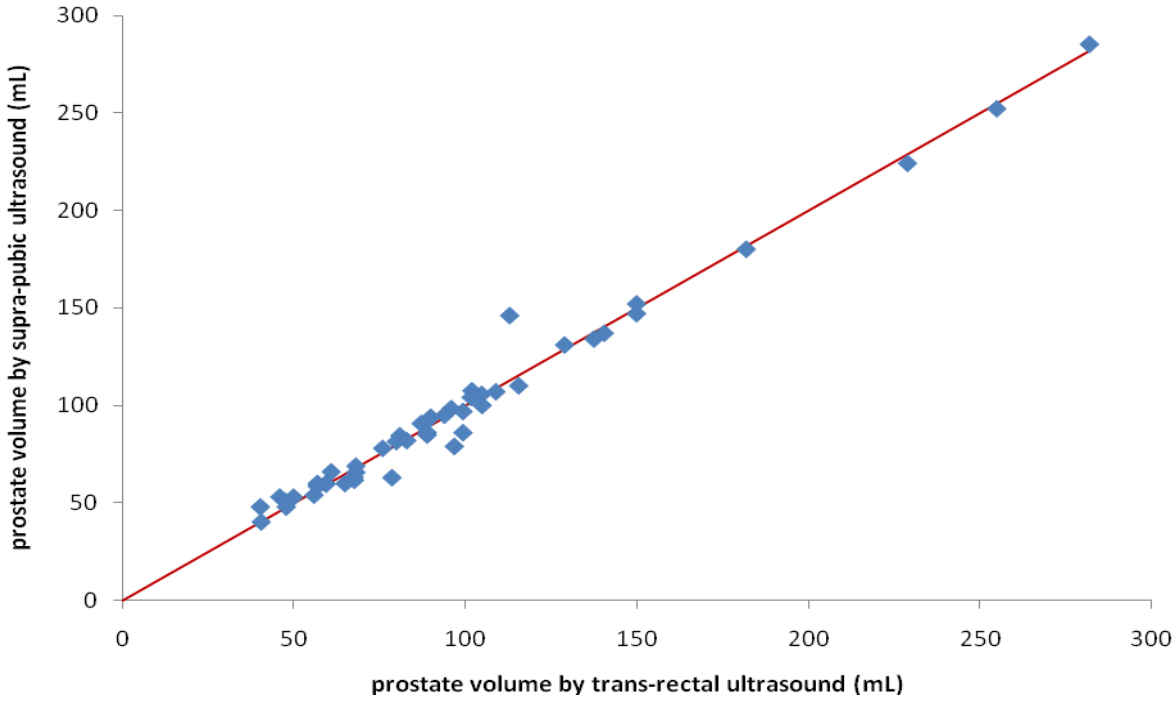


Fig 6: Volume measurements by SPUS plotted against TRUS measurement, correlation together with the line of equality. A strong linear correlation (Spearman's Rank correlation coefficient was r= 0.98 (p< 0.001) and high degree of agreement between the 2 methods.

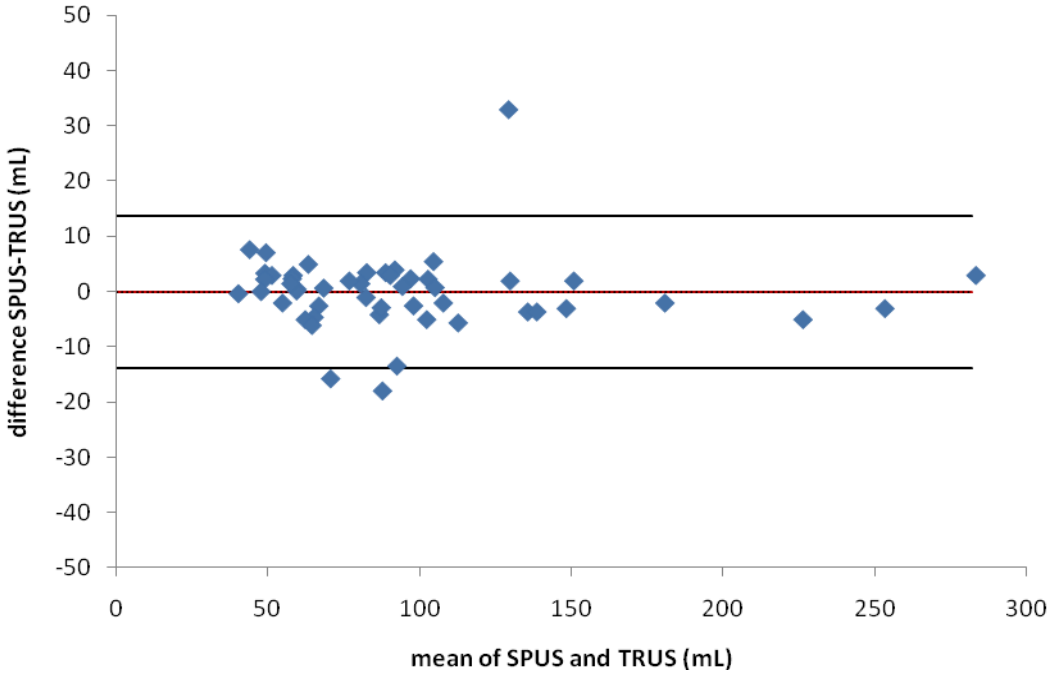


Fig 7: Bland and Altman plot of the differences between measurements against the mean of the measurements. The line passing at mean of differences (bias) is close to zero. The limits of agreement between the methods were: upper limit 13.6 ml (95% CI 10.1- 17.0) and lower limit -13.8ml (95%CI -17.2 to -10.3)

Table III: Statistical parameters of limits of agreement between the methods.

Factor	**Estimate (ml)**	**95 %CI**
Mean of Differences SPUS-TRUS	-0.09	-2.07 1.89
Upper limit of agreement	13.8	10.1 -17.0
Lower limit of agreement	-13.8	-17.2 -10.3

The difference between SPUS and TRUS is statistically and clinically insignificant since the limits of agreement are less than 20ml.

Table IV: Prostate volumes (in ml) by BMI and age categories.

Factor	SPUS Mean (SD)	TRUS Mean (SD)	Difference(SD)	Pvalue
BMI				
<25	81.65 (25.66)	81.60 (79.99)	0.05(7.49)	0.98
≥25	136.44(79.99)	136.91 (80.62)	0.47(2.98)	0.60
Age-category				
50-70	98.45(58.40)	97.19(57.79)	1.26(8.17)	0.37
71-91	93.13(43.62)	94.67(45.02)	1.54(5.19)	0.32

There remained no statistical difference between preoperative volume of prostate by SPUS and TRUS in both BMI and age categories of patients (p values> 0.05).

4.3. Sensitivity and Specificity of SPUS Relative to TRUS as Gold Standard

A prostate volume less than of 80ml is an indication for TURP. Using the cut off of 80mLs, we examined the ability of the SPUS to correctly assign patients to TURP, relative to TRUS as the gold standard imaging modality. The test performance characteristics were expressed as sensitivity, specificity, positive and negative predictive values (Table Va, Vb).

Table Va: Basis of Calculation for Sensitivity and Specificity of SPUS to detect prostate volume < 80ml in relation to TRUS.

	Prostate volume estimates by TRUS		
Prostate volume estimates by SPUS		**≤ 80ml**	**>80ml**
	≤ 80ml	21(95.45%)	01(3.57%)
	>80ml	01(4.55%)	27(96.43%)
		22	28

Of the 22 prostates measured as < 80ml by TRUS, SPUS found the same in 21 patients and missed one. The sensitivity of SPUS to detect prostate volumes ≤ 80ml is 21/22=95.45% . Of the 28 prostates volumes which were not less than 80mL by TRUS, SPUS detected the same in 27, giving a specificity of 27/28=96.43% .

Table Vb: Sensitivity, Specificity, Positive predictive value, Negative predictive value of SPUS to detect prostate volume < 80ml in relation to TRUS .

SPUS/TRUS	
Sensitivity	21/22 (95.5%)
Specificity	27/28 (96.4%)
Positive predictive Value	21/22 (95.5%)
Negative predictive value	27/28 (96.4%)

The accuracy of SPUS in relation to TRUS was high.

4.4. Correlation between suprapubic ultrasonography prostate volume estimates and the volume of enucleated prostatic adenoma

Table VI: Correlation between volume of prostate by SPUS (preop. volume SPUS) and the volume of enucleated prostatic adenoma (volume adenoma).

	Volume adenoma Mean±SD	**Preop volume Mean±SD (TRUS)**	**Preop volume Mean±SD (SPUS)**	**Correlation coefficient***	***Pvalue**
Overall	83.51 (52.48)	95.98 (51.55)	95.90(51.4)	0.90	<0.001
<25 (Normal Weight)	69.10(26.55)	81.60(25.17	81.65(25.66)	0.87	<0.001
≥25 (Overweight)	124.5(81.68)	136.91(80.62)	136.44(79.99)	0.96	<0.001
Age : 50-70	82.76(55.45)	97.19(57.79)	98.45(58.40)	0.84	<0.001
Age: 71-91	84.32(50.24)	94.67(45.03)	93.13(43.62)	0.96	<0.001

**Spearman's correlation between supra-public ultrasound volume estimate and volume of enucleated prostatic tissue.*

* The overall correlation between the preoperative volume of prostate by SPUS and the volume of enucleated prostatic adenoma was statistically significant ($r = 0.90$, $p < 0.001$). This correlation was higher among the overweight patients ($r = 0.96$, $p < 0.001$) and the elderly ($r = 0.96$, $p < 0.001$).

The mean difference between preoperative volume of the whole prostate by SPUS and the volume of surgically enucleated prostatic adenoma was 12.39g and statistically significant (95% CI 7. 89 to 16.88, $p < 0.001$).

Table VII: Correlations coefficients between preoperative volume by SPUS, TRUS and with volume of enucleated adenoma.

Factor	Correlation Coefficient	P Value
Preoperative Volume SPUS Versus TRUS	0.98	<0.001
Preoperative Volume SPUS Versus Volume Adenoma	0.90	<0.001
TRUS Versus Volume adenoma	0.92	<0.001

The correlation between preoperative volume of prostate by TRUS and postoperative volume of enucleated adenoma was slightly stronger ($r=0.92$, $p<0.001$) than between SPUS and postoperative volume of the enucleated adenoma ($r=0.90$, $p<0.001$).

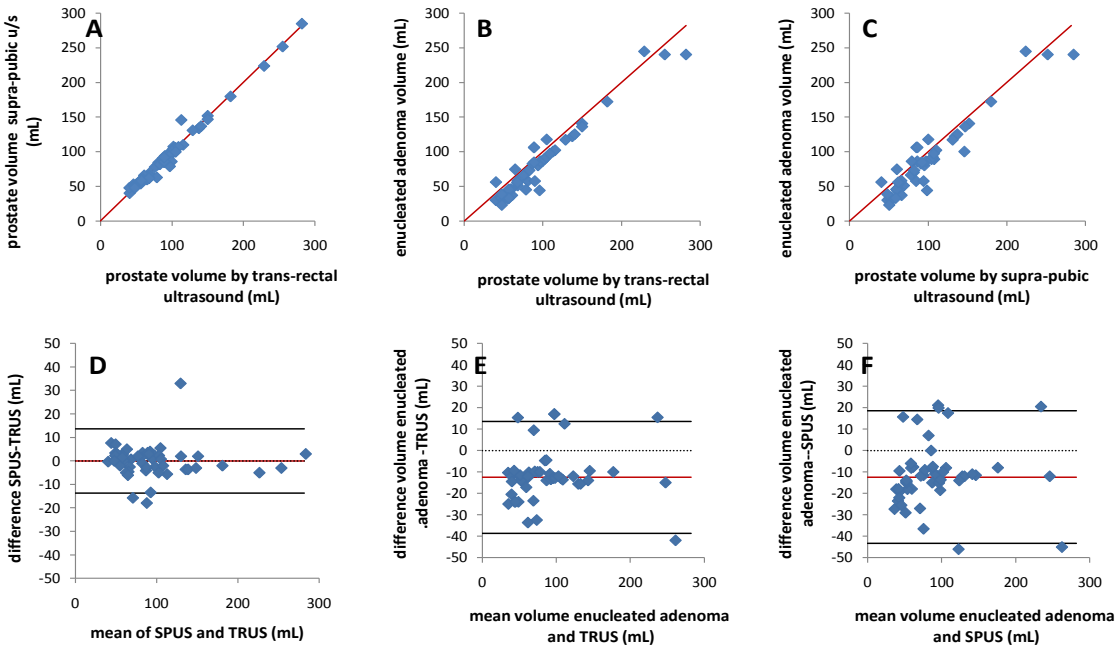


Figure 8. Correlation (**A** to **C**) and Bland-Altman (**D** to **F**) plots for two-way comparisons of SPUS, TRUS and volume of enucleated adenoma. Despite an apparent excellent correlation between all three measures of prostate volume (**A** to **C**), agreement analysis between enucleated prostatic adenoma volume and either ultrasound method demonstrates bias and variability between the upper and lower limits of agreement (**E** and **F**). The agreement between SPUS and TRUS is comparatively strong and unbiased (**D**).

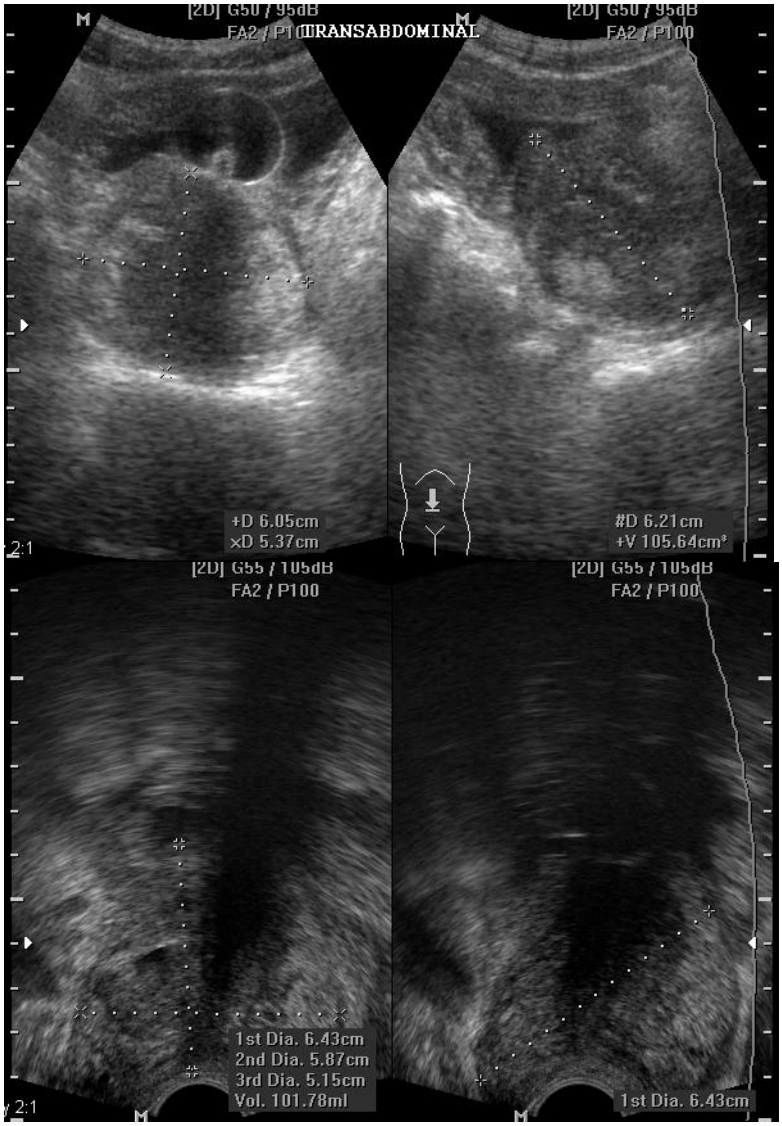


Plate 1: Prostate volume of one of the patients being measured by SPUS then by TRUS .

Plate 2: Prostate volume of one of the patients being measured by SPUS then by TRUS .

Plate 3: An enlarged prostate from one of the study patients being weighed by an electronic weighing machine, weighing 141.0g. The preoperative volume estimation was 152ml by SPUS and 150ml by TRUS.

CHAPTER FIVE

5.1. DISCUSSION

The study purpose was to determine the accuracy of suprapubic ultrasonography compared to transrectal ultrasonography in estimating preoperative prostate volume as well as to determine the correlation between the two preoperative ultrasonographic prostate volume estimate methods and the volume of surgically enucleated prostatic adenoma.

50 patients with LUTS and an IPSS> 20 with histological confirmation of BPH were included using consecutive sampling. Most of previous studies we found have used similar methods and similar sample sizes varying from 23 to 100 patients with BPH (10, 12, 15, 25, 30).

5.1.0. Demographic and Clinical Description of the Study Population

Socio-demographic Characteristics

The mean age was 69.94 years (range 51 to 91) and the median was 70 years (IQR 63 to 76 years). The study is in agreement with the fact that benign prostatic hyperplasia is a disease of the ageing men, rare before the age of 40 and almost never observed in men under the age of 30 years (39). Older age is a significant risk of clinical progression of BPH disease and peak in prostate volume at 60–69 years is documented (39, 40). A linear relationship between prostate volume and age was found in the Baltimore Longitudinal Study of Aging (20). The mean age of patients with severe BPH who underwent surgery in different studies was similar across continents, in the range of 60-70 years (12, 26).

Most, 82%, of the participants were Christians and 16% were Muslims (41). Although religion is a risk factor of benign prostatic hyperplasia (40), this may reflect the distribution of the Ugandan population by religions, with a predominance of Christians in Uganda (85.1%) compared to Muslims (12.1%). The similar distribution of our study population with the real distribution of the population may suggest that our sample was representative of the population of Kampala.

Most, (78%) of the participants were from the central part of Uganda. The location of the study setting in the Central region of Uganda (Mulago hospital) may explain this finding. Most (66%) were from the Ganda tribe. It is well known that to an extent the volume of prostate varies with social characteristics, family history, ethnicity and geographical factors, smoking, sexual activity, religion, alcohol use and hepatic cirrhosis, diet and obesity, lifestyle, hypertension and other factors (42).

Clinical characteristics

Fifty patients with LUTS and an IPSS> 20 with histologically confirmed BPH were included. The mean hemoglobin level was 12.59 mg/dl(range 11.5-13.6), mean diastolic pressure 75.58 mmHg(range 60-110) and mean systolic pressure 134.12 mmHg(110-188). This was mainly an elderly population that had normal hemoglobin levels, diastolic pressure and pre-hypertension systolic blood pressure.

The mean BMI was 23.89 kg/m^2 (range 19.37-36.51) and median BMI 23.31kg/m^2 (IQR 22.49-25.6) .Only 26 % of the participants were overweight. The mean prostate volume in this study is significantly higher among overweight patients than patients with BMI < 25 kg/m^2 (136.9 ml versus 81.6 ml). Obesity and diet are well documented risk factors for BPH; studies have reported positive correlation of body mass index with prostate volume. One of the studies is the Baltimore Longitudinal Study of Aging which showed that obesity,

fasting plasma glucose, and diabetes were associated with prostatic enlargement (43). Obesity increases peripheral aromatization of testosterone with a resulting increase in the estrogen/testosterone ratio, inflammation and oxidative stress; factors that have been associated with BPH (40, 43). Also, obesity may interfere with prostate volume measurement by SPUS. In general the BMI of the participants in our study was around *normal* with a mean of 23.89 kg/ m^2 (range 19.37-36.51). This overall normal BMI might have contributed to the good accuracy of the ultrasonographic estimations by SPUS.

Overall prostate volumes found in our study are among the highest: the mean prostate volumes by SPUS and TRUS were respectively 95.98mL (range 40.3-285) and 95.98 ml (range 46-282) and the mean volume of enucleated adenoma was 83.51ml(range 23-244.5) The prostate volumes reported by previous studies are different and inferior in general as compared to our study. A Systematic Review including 16 high quality studies and 12 158 patients found that the mean volumes reported in the literature varied from 33.9-61.0 ml (44). We postulate that this may be due to delay in seeking professional help due to numerous factors that impede access to healthcare.

5.1.1. Comparison of Suprapubic Ultrasonography and Transrectal Ultrasonography in the Estimation of Preoperative Prostate Volume.

The mean volume of the prostate by SPUS and TRUS was respectively 95.89±51.38 and 95.98±51.55 ml. This difference was not statistically significant (p= 0.93). The correlation coefficient between preoperative volume of prostate estimates by SPUS and by TRUS was significant (r= 0. 98, p-value< 0.001). We accept the null hypothesis stating that the mean of

differences between paired estimates is equal to zero. The estimates by the two methods are close.

There is paucity of studies that compare suprapubic to transrectal ultrasonography in prostate volume estimation in the East Africa region . However, our findings are in agreement with previous studies which have demonstrated that preoperative volume estimated by the two methods SPUS and TRUS were close and in strong correlation. A study conducted in Nigeria on 100 patients found a similar small difference between the preoperative volume by SPUS and TRUS, with only 0.49cc of difference (26). In Netherlands in 2004, a similar study found a mean difference of 1ml between volumes of prostate by SPUS and by TRUS using a sample size of 100 patients (10). Other studies found different values between prostate volumes by SPUS and TRUS. Wolff et al. in 1995 found a difference in means of prostate volume between SPUS and TRUS of 10g (29) and Kim in 2008 found 8ml of difference (8).

We think these variations of mean differences may be explained in part by the difference in BMI and experience of Radiologists used in each study. Obesity has been shown to make suprapubic measurement of prostate volume difficult. In our study, most of patients had a normal BMI. We think this made SPUS volume estimation easy and may explain the high accuracy of SPUS.

The level of training and the experience of Radiologist affects quality of estimations. In one study (8) experienced examiners had the highest correlation ($r = 0.967$) and the significantly smallest difference (5.4 ± 3.9 ml) compared to the beginner and the trained examiners. In contrast, another study found no statistically significant differences between two different transabdominal devices nor between different observers (10). The two Radiologists we used had similar training but different duration of experience. The Senior had 3 years of experience and the Junior six months of experience. In our study a sub-analysis of the mean of

differences by Junior (1.56 ± 14. 74ml) versus the mean difference by Senior (0.28± 3.22ml), there was no statistical difference due to experience of Radiologist (p =0.47).

Our study found a strong correlation (r =0.98, p< 0.001) between the preoperative volume of prostate using suprapubic ultrasonography and transrectal ultrasonography. Similar strong correlations between prostate volume by SPUS and TRUS have been reported by previous studies (24, 30-32). Previous studies found that suprapubic measurement of prostate volume had a good correlation with the measurements performed by TRUS, and thus, there was no need for the discomforting TRUS (7, 8, 45). And this strong correlation is reported across different continents, both in developed and developing countries. In contrast, in Netherlands, Chung and colleagues (10) found a lower correlation of 0.84.

In the analysis of agreement between two clinical methods Bland and Altman (46) proved that the use of correlations alone was misleading, and clearly showed that the analysis should include but go beyond correlations for the following reasons : (1) Correlation measures the strength of a relation between two variables, not the agreement between them . (2) A change in scale of measurement does not affect the correlation, but it certainly affects the agreement. (3) Correlation depends on the range of the true quantity in the sample. If this is wide, the correlation will be greater than if it is narrow. (4 Data which seem to be in poor agreement can produce quite high correlations.

This methodological paper has been cited more than ten thousands times by researchers assessing the agreement of two clinical methods like it is the case in our study. This is why we added Bland and Altman analysis **(Fig 6, 7, 8)** which confirmed the strong degree of agreement between SPUS and TRUS. Many urologists agree that patients from 80-100mLs can all be assigned to TURP. As a consequence, the only difference of clinical importance is a difference above 20mLs between SPUS and TRUS since it would affect the surgical

technique (15, 16). Bland –Altman analysis showed that the upper and lower limits of agreement are less than 20mL (**Table III**). Since the discrepancy of preoperative prostate estimated volume by SPUS compared to TRUS estimates is less than the limit of clinical significance 20mLs, the two tests are interchangeable.

5.1.2. Sensitivity and Specificity of SPUS Relative to TRUS as Gold Standard

Urologists need to accurately estimate the volume of prostate in order to assign patients to TURP or to open prostatectomy. The study assessed the ability of SPUS to assign patients to TURP based on the sensitivity and specificity of SPUS compared to the gold standard TRUS in detecting a prostate volumes ≤ 80ml. The sensitivity, specificity, positive and negative predictive values of the SPUS to detect prostate volume was both over 95%. The accuracy of SPUS to split patients in two groups, those with prostate volume ≤ 80ml and those with prostate volumes > 80ml was high. Surgical approach can comfortably be chosen based on SPUS estimation.

In our study only one over twenty-two prostates measuring less than 80ml by TRUS and one over twenty-eight prostates volumes measuring 80ml and above by TRUS were missed by SPUS. In all categories of prostates volumes, SPUS was as accurate as TRUS. Previous studies have showed that correlation between TRUS and SPUS is weak in small prostates and becomes stronger in prostates bigger than 50ml (47). Some unpublished data and experts report that TRUS is less accurate with very big prostates and that SPUS is superior to TRUS for very big prostates. In contrary, Kim and Kim reported that larger prostates might make the dimension measurements difficult on SPUS, especially because of the difficulty in determination of the caudal end of the prostate (8). The same study (8) also showed that only experienced radiologists are able to detect the caudal part of the prostate in big prostates. We think that the high correlation of measurements for both small and large prostates in our study

were due to the highly trained radiologists who performed the examinations and a fairly normal BMI of most of the patients.

5.1.3. Correlation between suprapubic ultrasonography prostate volume estimates and the volume of enucleated prostatic adenoma

When comparing the calculated volume of the enucleated adenoma to the preoperative volumes of the whole prostate estimated by SPUS we found a significant difference of 12. 39ml or 12.39g (95% CI: 7.89 16.88, p< 0.001). The difference between the preoperative volume of prostate by TRUS and the volume of enucleated adenoma and was 12.47ml and significant (95% CI: 8.69 16.26, p< 0.001). The Bland- Altman analysis of agreement between enucleated prostate volume and either ultrasound method demonstrates a similar difference . Kanao et al. in 2004 compared the volume of the whole prostate and the weight of the enucleated adenoma on 23 Japanese patients with BPH and found a difference of 21g between preoperative prostate volume and volume of enucleated adenoma (31). Differences in samples may partly explain the differences in results.

The Spearman's correlation coefficient between the volume of enucleated adenoma and the pre operative prostate volume estimated by SPUS was (r=0. 90, p=< 0.001). However this correlation was slightly weaker compared to the correlation between the volume of the enucleated adenoma and preoperative volume by TRUS which was (r=0. 92, p<0.001).

The findings of this study are similar to previous reports that in patients with benign prostate hyperplasia, there is a strong correlation between the measurements of prostate volume measured by SPUS and the real prostate weight in excised specimens (47). In 1992, Osca conducted a cross-sectional study using SPUS in 88 Spanish patients undergoing retropubic adenomectomy. The correlation coefficient between preoperative and post-operative prostatic gland weight measures was r = 0.91 (33). In Lithuania, a correlation of 0.92 was found

between volume of prostate and weight of enucleated adenoma (17). In contrast, Chen found lower correlations (r= 0.77) between preoperative estimated weight of the prostate and TURP specimens in a study on 40 patients with BPH in Taiwan (12). This is expected since at TURP it is more difficult to remove all the adenoma, yet in open prostatectomy the residual adenoma is insignificant (13).

5. 2. STUDY LIMITATIONS

• The fact that the assessment of the prostate volume using the Ultrasound was done by the same radiologist may have introduced an Investigator bias. This is likely to have been minimal since a high level of correlation is observed when the ultrasonographic results are compared to the actual post operative weight which was measured by a different researcher after the prostatectomy.

•The outcomes might be surgeon dependent to an extent. Despite this, the results were not very different since all the operating clinicians were experienced urologists. Also an effort was done throughout the study to remove the whole adenoma at surgery.

5.3. CONCLUSIONS

This study has shown that SPUS is as accurate as the TRUS in assessing preoperative volume of prostate among symptomatic BPH patients.

Suprapubic ultrasonography has excellent sensitivity, specificity, positive and negative predictive values for assigning patients to TURP relative to TRUS as gold standard.

Suprapubic ultrasonography prostate volume estimates are highly correlated with the volume of the enucleated prostatic adenoma.

These findings indicate that the SPUS is an effective alternative to TRUS for assessment of volume of prostate as it is an accurate and quick technique for assessing prostate volume prior to surgery. Also, it is non invasive, accepted by patients, more comfortable than TRUS. It can be safely used in clinical practice especially where TRUS is not available.

5.4. RECOMMENDATIONS

•A larger and multicentric study can be undertaken with the prostate volume estimation being done by two radiologists, one for SPUS another for TRUS with blinding of all the radiologists, surgeons and principal investigator.

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APPENDICES

APPENDIX I. Timeline

Activity	Month							
	Oct	Nov	Dec	Jan	Feb	March	Apr	May
Proposal approval	x	x	x					
Planning field work, training			x					
Data Collection			x	x	X	x	x	
Data Analysis							x	x
Report writing & Dissemination								x

APPENDIX II. CONSENT FORM IN ENGLISH

Title of the Study: Prostate volume measurement by suprapubic and transrectal ultrasonography in the assessment of BPH patients. A Cross Sectional Study.

Principal Investigator (Researcher): Dr Malemo Kalisya (0775 288 601)

Introduction:

Dr Malemo Kalisya a graduate student of the Department of Surgery, Makerere College of Health Sciences is carrying out a study to compare prostate volume measurement by suprapubic and transrectal ultrasonography in the assessment of BPH patients in Mulago hospital.

This study is being conducted as a partial fulfillment for the award of the degree of Master of Medicine (Surgery) for the Principal Investigator (PI) Dr Malemo Kalisya. Before agreeing to participate in the study, you must understand its purpose, its benefits, risks to you and what is expected of you as a volunteer in this study.

Purpose of the study.

To compare preoperative and postoperative prostate volumes measured by two different modalities among symptomatic BPH patients.

The study will improve the assessment and management of patients with symptomatic BPH.

Description of the research procedure

You will be requested to give information about your identification, family structure, social behavior, your past and present health status. Your answers will all be recorded on a questionnaire and then you will be examined. Blood investigations, biospies and ultrasound will be conducted. The volume of your prostate will be measured preoperatively by 2

different ultrasonography techniques the same day by a trained Radiologist. The first technique (suprapubic ultrasound) consists of putting the probe on the lower abdomen and in the second (transrectal ultrasound) the probe of the ultrasound is inserted in the rectum. You will then be operated on using open prostatectomy on a different day. This surgery involves making an incision below your umbilicus, through your urinary bladder and removal of the diseased part of your prostate. The actual postoperative weight of the prostatic adenoma removed will be compared with the preoperative one.

There will be no change in the treatment ordinarily planned for you and you will not be required to stay in hospital after you have recovered from your illness for the sake of this study.

Risks to the participant

You will not be required to take any medication or undergo any treatment that is not usually indicated for therapy. All examinations, investigations and treatments that will be given are in accordance with recommended standards. Some questions and examinations might cause you some discomfort. I have understood that there may be excessive blood loss to me during or after surgery, wound sepsis at the incision site, and urinary incontinence following surgery.

Benefits to the participant

You will benefit by having major surgery done on you and having some investigations done at no cost.

You will not be charged to participate in this study. You will not be paid to participate in this study. You will be followed-up on the ward or outpatient. We will help ensure that you get the necessary investigations and treatment**.**

Confidentiality

Information obtained from you will be handled in a confidential manner, and will be accessible only to the principal investigator, or other people involved in the study and faculty research and ethics committee if need be, or released as required by law.

Voluntariness

Your participation in this study is voluntary and out of your own free will. You can withdraw your participation from this study at any time without any penalties or losing any benefits that you are otherwise entitled to.

Questions about the study

If you have any questions about the study you are free to ask questions or seek clarifications about the study at any time without hesitation or fear from the principal investigator Dr Malemo Kalisya (0775 288 601).

Questions about your rights as a participant

If you have questions about your rights as research participant please contact the chairman faculty of medicine research and ethics committee Dr C. Ibingira (0772 437 351).

Statement of Consent

I have read/listened to the contents of this consent form and certify that the research described and in which I am to participate has been fully explained to my satisfaction.

Volunteer/ Next of kin's name……..……

Signature /thumb print……date……

Name of Witness……

Signature/thumb print…….date……..

I have explained nature of this study and am convinced the patient has understood it.

Investigator signature……..date…….

APPENDIX III. CONSENT FORM IN LUGANDA

Title of the Study: **Prostate volume measurement by suprapubic and transrectal ultrasonography in the assessment of BPH patients**.

Akulira okunoonyereza: Dr Malemo Kalisya (0775 288 601)

Ennyanjula:

Nze Dr Malemo Kalisya, asoma diguli eyokubili mu by'okulongoosa abalwadde mu e Makerere College of Health Sciences. Noonyereza mu kugerageranya obuneene bw'akanuusi akazibikila omumwa gw'akawago mu balwadde abalina obuzibu mu kufuyisa okuletebwa ensanjalavu nga egezze mu balwadde abatanalongosebwa wamu nabo abamaze okulongoselebwa mu dwaliro lye Mulago.

Okunoonyereza kuno kwekumu kubisanizo ebyetagisa okumaliliza diguli yange eyokubiri mu by'okulongoosa abalwadde.

Nga tonasalawo kankubulire ebikwatagana n'okunoonyereza kuno. Bw'onokiriza okwetaba mukunoonyereza kuno ojja kusabibwa okusayininga oba okuteka ekinkumu kyo ku kiwandiiko.

Omulamwa oba ekigendererwa mu kunonyereza kuno

Twagala okugerageranya obuneene bw'akanuusi akazibikila omumwa gw'akawago mu balwadde abalina obuzibu mu kufuyisa okuletebwa ensanjalavu nga egezze mu balwadde abatanalongosebwa wamu nabo abamaze okulongoselebwa.

Ebinagobererwa mu kunonyereza kuno

Ojja kusabibwa okwogera kubikukwatako mu bulamu bwo, mu makaago ne ebyobulamu byo ebyemabega.

By'onaddamu bijakuwaandiikibwa oluvanyuma okebelebwe. Ojakujibwaako omusaayi, oluvanyuma okebelebwe mu sikaani oba kativvi.

Obunene bwakanuusi bugya kupimibwa oba okukebelebwa abasawo abakugu mu sikaani(kativi) zabika bibiri kulunaku lwelumu. Sikaani y'okulubuto ney'emabega. Oluvannyuma olongosebwe akanuusi nga bayita ku kawago ko musulo. Obunene bwakanuusi bujja kugerageranyizibwa nga tebunalongosebwa wamu n'obo obumaze okulongoselebwa.

Obujjanjabi tebuja kukyuukamu okuva bwabulijjo eli obulwadde buno era tolina kusigala wano olw'okunoonyereza kuno nga omazze okufuna obujjanjabi.

Obuzibu mu kunoonyereza kuno:

Tojja kukilizibwa kufuna bujjanjabi bulala bwona, obutalina kuwebwa okusinzila ku bulwadde bwo. Okukebelebwa, okunoonyereza n'obujjanjabi by'onoofuna byona byamutindo omulungi. Oyinza obutawulira bulungi oluvanyuma lwokubuzibwa ebibuuzo ebimu n'okukebelebwa.

Ntegedde nti nyinza okufilwa omusaayi nga nongosebwa oba oluvanyuma, okutana kw'ekiwundu n'otiriika omusulo oluvannyuma lw'okulongosebwa.

Byono'ganyulwa mukunonyereza:

Okulongosebwa wamu n'okukebelebwa byona togenda kubisasulira. Togenda kusasulibwa oba okusasulira kwetaba mu kunoonyereza kuno.

. Ojja kwekebejjebwa oluvannyuma lw'okulongosebwa ward nokuvawabweru . Tujja kufuba okulaba nga okebelebwa n'okufuna obujjanjabi obwetagisa.

Okukuuma ebyaama ebikukwaatako:

Ebiwandiiko ebiriko ebikukwatako bigenda kukumibwa bulungi mukifo ekyekusifu nga kyaakyaam era elinya lyo lya kuwebwa e namba enakozesebwanga mu kunonyereza

Ddembe lyo okugaana okwetaba mu kunoonyereza kuno:

Okwetaba mukunoonyereza kuno kwakyeyagalire. Olina eddembe okugaana okwetaba mu kunoonyereza kuno oba okukuvaamu ekisera kyona. Bino byona tebigenda kutabula bujjanjabi bwolina kufuna mu dwaliro lino.

Ebibuuzo

Bwoba olina ebibuuzo byona ebikwatagana no kunoonyereza kuno ekiseera kyona, labagana ne Dr Malemo Kalisya (0775 288 601).

Bwoba olina ebibuuzo byona ebikwatagana ne ddembe lyo mukunoonyereza kuno labagana ne Dr. Charles Ibingira, Faculty of Medicine, College of Health Sciences, Makerere University, P.O.Box 7072, Kampala. ku simu eno 0772437351

Ekiwandiiko eky' okukiriza:

Mbulidwa ne ntegera bulungi ebikwatagana no'kunonyereza kuno abakukulira nga teli muzibu bujja kuntukako era nsazeewo okukwetaba mu kyeyagarire era manyi nti nsobola

okukusazaamu ekisera kyona nga kino tekigenda kutabula bujjanjabi bwenina kufuna mu dwaliro lino.

Omukono oba ekinkumu kyange wamanga kiraga nti nzikiriza kyeyagalire.

Erinya / Ely'omujjanjabi…….

Sayini oba ekinkumu ……..

Ennaku z'omwezi ……

Mbulide ne nyinyonyora byona ebigendererwa by'okunoonyereza kuno eri agengenda okukwetabamu bulungi okusinzira kukumanya kwange era akiriza nga simukase.

Erinya / Omunoonyereza …….

Sayini oba ekinkumu ……..

Ennaku z'omwezi …….....……

APPENDIX IV: QUESTIONNAIRE

Title: Prostate volume measurement by suprapubic and transrectal ultrasonography in the assessment of Benign Prostatic Hyperplasia patients.

A. DEMOGRAPHIC CHARACTERISTICS

1. Date of interview……DATE
2. Name……IDNo……..IDNO
3. Age (years)……AGE
4. Tribe……TRIB
5. District of Residence……DISTR
6. Religion……..REL
7. Occupation……OCC

B. CLINICAL INDICES

HISTORY

1. Urinary Retention……..UR
2. Hematuria……...HEMAT
3. Recurrent UTIs……..RUTI
4. Incomplete emptying: Over past month or so, how often have you had a sensation of not emptying your bladder completely after finishing urinating (0=none, 1=1 in 5, 2=<1/2 of the time, 3= 1/2 of the time, 4= > 1/2 of the time, 5= always)……
5. Frequency : Over past month or so, how often do you have to urinate again less than 2 hours after you finished urinating……..

6. Intermittency: Over past month or so, how often have you stopped and started again several times when you urinated……

7. Urgency: Over past month or so, how often have you found it difficult to postpone urination……

8. Weak stream: Over past month or so, how often have you had a weak urine stream……..

9. Straining: Over past month or so, how often have you had a push or strain to begin urination……

10. Nocturia : Over past month or so, how many times during a single night did you usually get up to urinate, from the time you went to bed until the time you got up in the morning……

11. Mild symptom score (0-7)……MILSCORE

12. Moderate symptom score(8-19)……..MODSCORE

13. Severe symptom score (20-35)……SEVSCORE

EXAMINATION

14. Sick looking……SICK

15. Not sick looking……..NSICK

16. Weight(Kg) ……..WT

17. Height (m) …….. …. HT

18. Blood pressure ……SYST……..DIAST

19. Pulse rate ……PRATE

20. DRE findings: ….....

……

…….DRE

INVESTIGATIONS

21. Preoperative volume of prostate by SPUS (mL)……VOLSPUS

22. Preoperative volume of prostate by TRUS (mL)……...VOLTRUS

23. Biopsy results……. BPSY

24. Preoperative hemoglobin level (g/dl)…….PREHB

25. Weight of enucleated adenoma……POWT

APPENDIX V: BPH IPSS QUIZ

This validated questionnaire is used to assess the severity of symptoms based on the International Prostatic Symptom Score (IPSS). The Score varies from 0-35 marks.

Over the past month or so:

(1). How often have you had a sensation of not emptying your bladder completely after finished urinating? 0 – Not at all 1-Less than 1 time in 5

2- Less than half the time 3-About half the time

4- More than half the time 5- Almost always

(2). How often do you have to urinate again less than 2 hours after you finished urinating? 0 – Not at all 1-Less than 1 time in 5

2- Less than half the time 3-About half the time

4- More than half the time 5- Almost always

(3).How often have you stopped and started again several times when you urinated?

0 – Not at all 1-Less than 1 time in 5

2- Less than half the time 3-About half the time

4- More than half the time 5- Almost always

(4). How often have you found it difficult to postpone urination?

0 – Not at all 1-Less than 1 time in 5

2- Less than half the time 3-About half the time

4- More than half the time 5- Almost always

(5). How often have you had a weak urine stream?

0 – Not at all 1-Less than 1 time in 5

2- Less than half the time 3-About half the time

4- More than half the time 5- Almost always

(6).How often have you had a push or strain to begin urination?

0 – Not at all 1-Less than 1 time in 5

2- Less than half the time 3-About half the time

4- More than half the time 5- Almost always

(7). How many times during a single night did you usually get up to urinate, from the time you went to bed until the time you got up in the morning?

0– Non 1-1 time 2- 2 times 3- times 4- 4 times 5- 5 times.

APPENDIX VI. RADIOLOGICAL PROCEDURES FOR SPUS AND TRUS

Ultrasonographic examination of the prostate was performed using Sonoace Medison 9900. A 3.5MHz curvilinear probe was used for SPUS and a biplane transrectal probe 4-9MHZ for TRUS. Examination was performed with a full bladder for SPUS, which was determined as the patient was having a desire to micturate, but not with a severe discomfort. Measurements were performed in the supine position during SPUS .The patient then emptied the urinary bladder .The post micturition volume was measured and TRUS examination was performed in the left lateral position. The transverse (width), craniocaudal (length) and anteroposterior (height) dimensions of the whole prostate were measured using both methods. The craniocaudal and anteroposterior dimensions were measured in the sagittal plane, and the transverse dimensions measured in the transverse plane. The longest dimension from the base of the prostate to the apex was measured for the craniocaudal dimension. The longest distance between the anterior-posterior prostate margins that crosses the trace of carniocaudal measurement at an acute angle was measured for anteroposterior dimension. The longest dimension between the right and the left lateral margins where the prostate was observed widest was measured for transverse dimension. All measurements were performed at the same session. The volume of the prostate was calculated by using the ellipsoid formula: Volume= 0.523 ×width (cm) ×height (cm) ×length (cm). The ultrasonic machine, based on the above dimensions, automatically computed the volume of prostate gland.