Original Article

Correlation between Prostate Volume Measured by Ultrasound and Symptoms Severity Score in Patients with Benign Prostatic Hypertrophy in Southeastern Nigeria

AE Obiesie, AME Nwofor, CK Oranusi, OO Mbonu

Division of Urology, Department of Surgery, Nnamdi Azikiwe University Awka, Nnewi Campus, Anambra State, Nigeria

Abstract

Background: Benign prostatic hypertrophy (BPH) is a common urological condition in men older than 50 years. It is important in the aetiologies of life-threatening obstructive uropathies. Ultrasound measurement of prostate volume is non-invasive, easily available, and a cost-effective method, useful in assessing bladder outlet obstruction (BOO). The International Prostate Symptoms Score (IPSS) on the other hand objectively assesses symptoms severity in BOO patients. **Aim:** This study was aimed at determining the correlation between ultrasound-measured prostate volume and IPSS in men with BPH. **Patients and Methods:** Following ethical approval from the Nnamdi Azikiwe University Teaching Hospital Ethical Committee, 100 patients who met the inclusion criteria and were diagnosed with clinical BPH were enrolled into the study. They had no other identifiable cause of BOO except BPH after clinical evaluation. The IPSS, Quality of life score (QOL), and prostate volumes were measured. Correlation between prostate volume, IPSS, and QOL were done using SPSS version 20. *P* value <0.05 was considered significant. **Results:** The mean age of patients was 69.3 ± 10.6 years with a range of 48–100 years. The mean prostate volume, IPSS, and QOL were 96.0 ± 70.5 cm^3, 15.63 ± 8.6, and 4.8 ± 1.3, respectively. The highest recorded IPSS was 35 and the lowest was 4, whereas the smallest and largest recorded prostate volumes were 19 cm^3 and 350 cm^3, respectively. Nocturia was the major IPSS subscore. There was a weak positive correlation between prostate volume and IPSS in men with BPH (r = +0.109; P = 0.28) and between prostate volume and QOL (r = +0.072; P = 0.45). There was also a weak positive correlation between patients with only severe symptoms and corresponding prostate volumes (r = +0.122; P = 0.125). The correlation between patients with severe symptoms and their corresponding QOL was strong (r = +0.537; P = 0.135, respectively). These findings were, however, not statistically significant. **Conclusion:** There is a weak positive correlation between prostate volume measured by ultrasound and symptoms severity scores in patients with BPH, although not statistically significant. This may be as a result of the small sample size. A larger sample size may be able to achieve statistical significance.

Keywords: *Benign prostatic hypertrophy, detrusor wall thickness, international prostate symptoms score, median lobe, prostate volume, quality of life*

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Introduction

Benign prostatic hyperplasia (BPH) is a common urologic condition among ageing men. Because of anatomic location of the prostatic growth that characterizes

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Address for correspondence: Dr. AE Obiesie, Division of Urology, Department of Surgery, Nnamdi Azikiwe University Awka, Nnewi Campus Anambra State, Nigeria. E-mail: ea.obiesie@unizik.edu.ng

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BPH (surrounding and adjacent to the proximal urethra), clinical symptoms associated with passage of urine can result.[1] In established BPH, cell proliferation slows down and there is impairment of programmed cell death.[2] BPH in the ageing male is a progressive condition associated with worsening of lower urinary tract symptoms (LUTS) that affect quality of life (QOL) by interfering with normal daily activities and sleep patterns.[3]

Surgical intervention typically reserved for severe symptoms of BPH is more common among African-American (AA) men than Caucasians.[4]

In a study by Udeh *et al*.,[5] to establish the relationship between prostate volume and IPSS in Africans with BPH, no significant relationship was established. In an analysis by Sciara *et al*.[6] in an Italian population, symptom score correlated weakly with prostate volume and age.

A study in Netherlands by Bosch *et al*.[7] showed weak correlation between IPSS and total prostate volume. LUTS arise from the pathology, but seem not to correlate with prostate size. The weak statistical association frequently reported in the literature is mainly the urology clinic-based population from which the patient samples were drawn.[8]

Assessment tools had been developed to predict which group of patients require surgery. Symptoms severity score has been quite useful. Prostate size assessment is currently done as a non-invasive procedure by ultrasound, through two routes: trans-rectal and trans-abdominal. Both have been shown to have similar results.[5] Suprapubic ultrasound is less cumbersome and widely available. Recently, it has been shown that transitional zone volume (TZV) correlates well with symptoms.[5]

The International Prostate Symptoms Score (IPSS) is a modification of the American Urological Association Symptom Index (AUA-SI) that includes a single question assessing the QOL or bothersome score based on the patient's perception of the problem.[9]

Franciosi *et al*.[10] evaluated 223 men with a mean age of 59.3 years and found that there was no significant difference when the TZV and the transitional zone index (TZI) were compared in the groups of men with mild, moderate, and severe symptoms of urinary difficulty. The QOL scores presented progressively worse values as the severity of the LUTS became worse ($P < 0.001$). Overland *et al*.[11] identified a positive weak correlation ($r = 0.176$) between IPSS and prostate volume and negative correlation between IPSS and post void residual (PVR) ($P = 0.278$).

A strong correlation was found between the total symptoms score and the single disease-specific QOL question included in the IPSS ($r = 0.74$; $P = 0.001$). Wang *et al*.[12] in a Chinese survey identified a positive correlation between LUTS and the objective parameters related to BPH.

Lee *et al*.[13] found that prostates of the same volumes were found to have very variable shapes. There are combinations of variably elongated width, height, and lengths. Ezz ell Din *et al*.[14] reviewed 803 consecutive patients with LUTS and/or BPH. They identified a statistically significant but weak correlations between the IPSS and results of uroflowmetry and PVR. There was no correlation between the IPSS and results of prostate volume measurements. Tsukamoto *et al*.[15] reviewed the records of all 67 BPH patients who attended the Urology Clinic of Sapporo Medical University Hospital. Change in IPSS was associated with change in prostate volume PV. In a work by Shi-Jun *et al*.,[16] all prostate parameters were positively correlated with the IPSS, the strongest correlation was associated with the transitional zone length and TZV. Kaplan *et al*.[17] determined if the TZI estimated by transrectal ultrasound TRUS differs among AA, Hispanic, and Caucasian men. The TZI was found to be significantly higher in AA than in either Hispanic or Caucasian men ($P < 0.03$). There was no correlation between the IPSS and either prostate volume or TZV, but there was a moderate correlation with the TZI ($r = 0.29$; $P < 0.01$) regardless of race.

Using the validated Arabic version of IPSS, Arafa *et al*.[18] studied 1851 men aged >40 years in a population in Riyadh Saudi Arabia. They found out that there was a weak but significant correlation between the total IPSS and age, total prostate volume, and prostate specific antigen PSA.

Agrawal and colleagues[19] studied 100 consecutive BPH patients in Nepal. Correlation between prostate volume and age, IPSS and QOL were not statistically significant except for two domains: incomplete emptying and nocturia that appeared to correlate with prostate volume. Nekie *et al*.[20] studied 100 patients and assessed their QOL scores. They found out that only some BPH symptoms influenced the QOL. Incomplete emptying, frequency, poor stream, and nocturia were statistically significant in correlation with QOL. Chalise and colleagues[21] evaluated changes in urinary symptoms and QOL in men following transurethral resection of the prostate (TURP) for BPH. At 3 months follow up, the mean IPSS reduced and QOL improved.

Eckhardt *et al*.[22] evaluated 565 men with BPH and found out that prostate volume and obstruction grade were not, but low detrusor contractility and low bladder

capacity were significantly associated with symptoms and QOL index. Salinus-Sanchez and co-workers[23] studied 189 BPH patients on the waiting list for BPH surgery. They found out that QOL of patients on the waiting list for surgery is poorer than that of the general population of same age. The degree to which the patient is bothered is more important than symptoms score.[24] An enlarged prostate gland was shown to be an independent predictor of treatment intervention, as isolated solitary median lobe enlargement has been reported to cause intractable haematuria and clot retention necessitating surgery in BPH patients.[25,26] Digital rectal examination is an inaccurate determination of prostate size and in fact appears to significantly underestimate the prostate volume.[27] The parameters used to characterize BPH should be considered independently because no predictions about the value of a certain parameter can yet be made by knowing one of the other parameters.[17]

Most of these studies have been done in the Caucasians and other races including blacks in America, where patients present early with small prostate sizes. The results have been applied to the management of patients in our environment. The aim of this study was to establish the relationship between prostate volume and symptoms score in our environment, so as to see if one can use these non-invasive methods to predict the progress of disease or determine best treatment modality.

Methodology

The aim of this study was to determine the correlation between prostate volume as measured by trans-abdominal ultrasound and IPSS in patients with BPH, with specific objectives to determine the relationship between prostate volume, QOL, and other independent variables of IPSS.

This was a prospective cross-sectional descriptive study to determine the correlation between prostate volume measured by ultrasound and IPSS in men with BPH in a referral tertiary hospital in Southeastern Nigeria.

This study was a hospital-based study carried out in the urology outpatient clinics. One hundred new patients presenting with LUTS and >40 years formed the cohort.

Included in the study were all new patients attending urology clinics and with clinical features suggestive of BPH and patients who do not fit into the exclusion criteria. We excluded patients with histories suggestive of other causes of subvesical obstruction other than BPH as well as patients already on treatment for BPH.

Informed consents were obtained before patients were enrolled into this study. These patients presented with LUTS and were physically examined by the researcher. A digital rectal examination was done and PSA values recorded. Patients who met the criteria for prostate biopsies were offered the procedure to rule out malignancy. Study protocols and informed consent were approved by the research and ethical committee of the study center. A written informed consent was obtained from all subjects who met the inclusion criteria before being recruited for the study. Each subject was interviewed by the researchers using a standard proforma. The patients subsequently underwent trans-abdominal ultrasonography of the prostate in a supine position, using the high-resolution prosound 3.5 MHz ALOKA model. The targeted bladder volume was >250 mls and this was achieved when the patient had the urge to pass urine following cosumption of water in the ultrasound room.

The prostate volume was estimated using the prolate ellipsoid formula: antero-posterior (height) × transverse diameter (width) × cephalo-caudal (length) × $\pi/6$.

All trans-abdominal ultrasounds were done by a consultant radiologist, assisted by the researcher.

All answered questionnaires were coded before analysis. The determinant variable was the prostate volume in patients with BPH, whereas the outcome variables in the correlation were the IPSS, IPSS subscores, and QOL.

The severity of these outcome variables was correlated with the prostate volume as measured by ultrasound. Data were analyzed with a multipurpose computer statistical programme - Statistical Package for Social Sciences Version 20 (IBM, SPSS, Chicago, IL, USA). Results obtained were expressed using tables and charts where necessary. Data were subjected to linear regression. Pearson's correlation was used to assess correlation where applicable.

Results

A total of 100 men diagnosed with clinical BPH were studied within this period [Figure 1]. Their mean age was 69.3 ± 10.6 years with an age range of 45–100 years. Sixty-five percent of the patients were in their seventh and eigth decades of life. Prostate

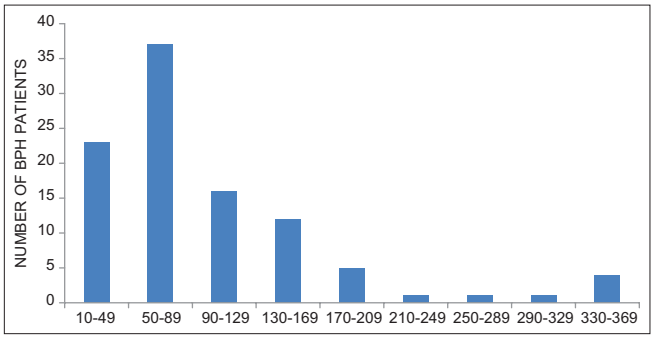

Figure 1: Distribution of Prostate Volume in BPH Patients

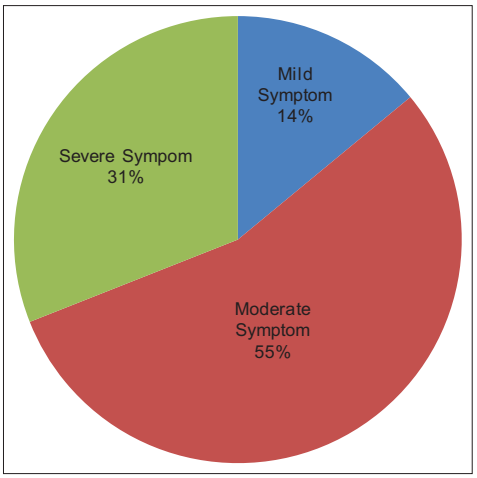

Figure 2: Chart Showing Severity of Symptoms in 100 BPH Patients.

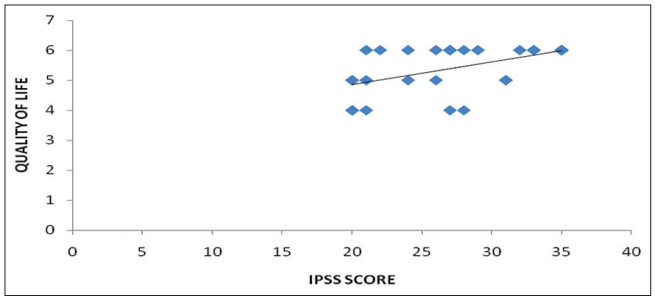

Figure 4: Scatter Diagram with Regression of IPSS on Quality of Life of Patients with Severe Symptom. Interpretation: The figure shows a strong positive correlation between severe IPSS and QOL, $r = +0.537$; $P = 0.135$. The average QOL becomes 3.363 when the IPSS is 0. The impact on QOL per unit increase in IPSS is 0.289. Every unit increase in IPSS brings about an increase in QOL by 0.289. These observations are, however, not statistically significant, $P = 0.135$. Correlation coefficient (r) = +0.109; $P = 0.28$

Table 1: Quality of life distribution amongst BPH patients

QOL Scores	Frequency	Percentage (%)
Delighted (0)	1	1
Pleased (1)	1	1
Mostly satisfied (2)	5	5
Equally satisfied and dissatisfied (3)	8	8
Mostly dissatisfied (4)	15	15
Unhappy (5)	33	33
Terrible (6)	37	37
TOTAL	100	100

volume ranged from 19 to 350 cm^3 with a mean of 95.97 ± 70.52 cm^3, whereas total IPSS ranged from 4 to 35, with a mean of 15.63 ± 8.6. The commonest range of prostate volume was 50–89 cm^3 and commonest IPSS was moderate scores. Figure 1 shows the distribution of prostate volumes in BPH patients.

QOL score ranged from 0 to 6 with frequencies as shown in Table 1. The mean QOL was 4.82 ± 1.3. Most patients

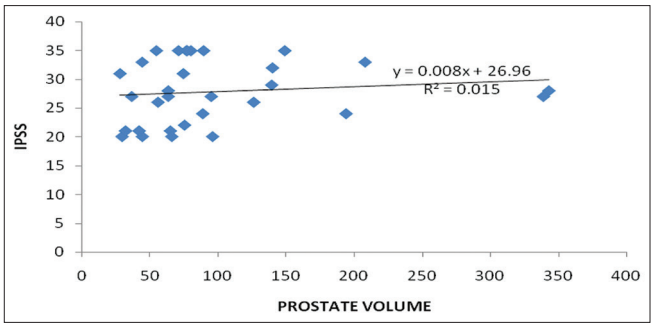

Figure 3: Scatter Diagram with Regression of Prostate Volume and only Severe IPSS. Interpretation: The figure shows a weak positive correlation between severe IPSS and corresponding prostate volume, $r = +0.122$; $P = 0.1.25$. Using the regression equation, it can be seen that the average IPSS becomes 29.96 when the prostate volume is 0. The impact on IPSS per unit increase in prostate volume is 0.015. Every unit increase in prostate volume brings about an increase in IPSS by 0.015. This finding is not statistically significant though, $P = 0.125$. Correlation coefficient (r) = +0.537; $P = 0.135$

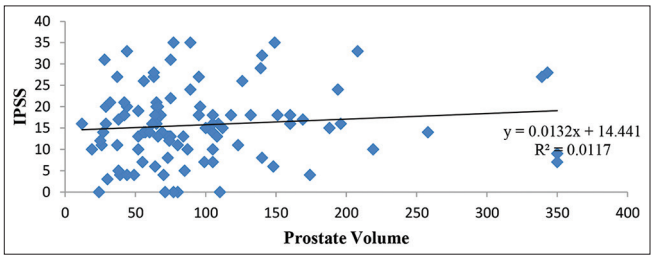

Figure 5: Scatter diagram with regression of Prostate volume on IPSS. Interpretation: The figure shows a weak positive correlation between Prostate volume and IPSS ($r = +0.109$; $P > 0.28$). Making use of the regression equation, $y = a + bx$ (where "y" is IPSS "a" is intercept, "b" is regression coefficient (slope), and "x" is Prostate volume), it can be seen that the average IPSS becomes 14.44 when the prostate volume is zero. Also, the impact on IPSS per unit increase in Prostate volume is 0.0117 (i.e., every unit increase in prostate volume brings about an increase in IPSS by 0.0117). These observations are, however, not statistically significant ($P = 0.28$). Correlation coefficient (r) = +0.072; $P = 0.45$

felt mostly dissatisfied, unhappy, or terrible if allowed to live the rest of their lives the same way it was at presentation.

The smallest prostate volume of 19 cm^3 was recorded in a 67-year-old man with total IPSS of 10 and QOL index score of 2. He scored 3 in each of independent variables of incomplete emptying and straining, whereas the largest prostate volume of 350 cm^3 was recorded in a 63-year-old man with a total IPSS of 7, QOL of 6, and highest independent score of 3 in nocturia.

The mean of the individual parameters of the IPSS as shown in Table 2 were nocturia (3.19/5), frequency (2.51/5), weak stream (2.48/5), urgency (2.18/5), incomplete emptying (2.13/5), intermittency (1.65/5), and straining (1.61/5 Table 2. Nocturia as identified above is one of the earliest symptoms in BPH.

Table 2: The Mean of Individual Sub-scores of IPSS and Frequency of IPSS Score

IPSS Parameters	Mean	Frequency (%)
Nocturia	3.91±1.69	90
Frequency	2.51±2.09	69
Weak Stream	2.48±2.15	67
Urgency	2.18±2.06	62
Incomplete bladder emptying	2.13±1.89	61
Intermittency	1.65±1.75	60
Straining	1.61±1.93	46

IPSS=international prostate symptoms score

Table 3: Mean Values and Correlation of IPSS and Prostate Volume

Parameter	Mean	SD	*n*
IPSS	15.71	8.639	100
Prostate volume	95.97	70.521	100
	Correlation	**IPSS**	**Prostate Volume**
IPSS	Pearson's correlation	1	0.108
	Sig. (two tailed)		0.283
Prostate Volume	Pearson's correlation	0.108	1
	Sig. (two tailed)	0.283	

IPSS=international prostate symptoms score

Table 4: Mean Values and Correlation of Prostate Volume and QOL

Parameter	Mean	SD	*n*
Prostate volume	95.97	70.521	100
QOL	4.82	1.298	100
	Correlation	**Prostate Volume**	**QOL**
Prostate Volume	Pearson's correlation	1	0.072
	Sig. (two tailed)		0.479
QOL	Pearson's correlation	0.072	1
	Sig. (two tailed)	0.479	

QOL=quality of life

Table 5: Mean Values and Correlation of IPSS and Prostate Volume among Patients with Severe Symptoms

Parameter	Mean	SD	*n*
IPSS	27.84	5.51	31
Prostate volume	99.61	78.35	31
	Correlation	**IPSS**	**Prostate Volume**
IPSS	Pearson's correlation	1	0.125
	Sig. (two tailed)		0.504
Prostate Volume	Pearson's correlation	0.125	1
	Sig. (two tailed)	0.504	

IPSS=international prostate symptoms score

Figure 2 shows the distribution of total IPSS in the BPH patients. Mild symptoms were recorded in 14 patients (14%) with a mean prostate volume of 98.3 ± 83.4 cm^3, moderate symptoms in 55 patients (55%), with a mean prostate volume of 94 ± 62.9 cm^3, whereas severe symptoms were seen in 31 patients (31%) with a mean prostate volume of 100 ± 78.2 cm^3.

Table 6: Mean Values and Correlation of Prostate Volume and QOL among Patients with Severe Symptoms

Parameter	Mean	SD	*n*
Prostate volume	27.84	5.508	31
QOL	5.39	0.803	31
	Correlation	**Prostate Volume**	**QOL**
Prostate Volume	Pearson's correlation	1	0.135
	Sig. (two tailed)		0.469
QOL	Pearson's correlation	0.135	1
	Sig. (two tailed)	0.469	

QOL=quality of life

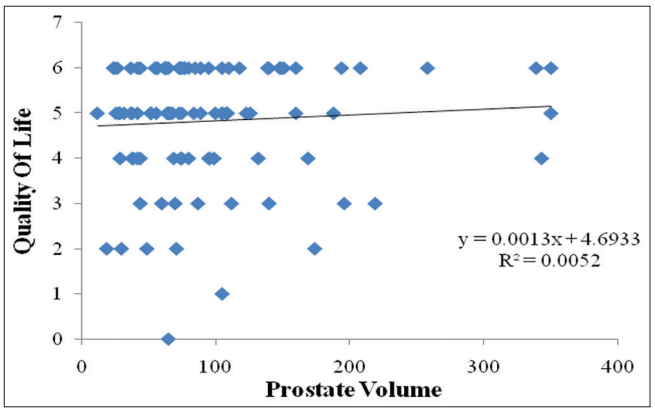

Figure 6: Scatter diagram with regression of Prostate volume on Quality of life. Interpretation: The figure shows a weak positive correlation between prostate volume and Quality of life (r = +0.072; P > 0.45). Making use of the regression equation, $y = a + bx$ (where "y" is Quality of life "a" is intercept, "b" is regression coefficient (slope), and "x" is Prostate volume), it can be seen that the average Quality of life becomes 4.69 when the prostate volume is zero. Also, the impact on Quality of life per unit increase in Prostate volume is 0.0013 (i.e., every unit increase in prostate volume brings about an increase in QOL by 0.0013). These observations are, however, not statistically significant (P = 0.45)

The highest IPSS of 35 were recorded in seven men with a mean prostate volume of 85.4 ± 38.1 cm^3 and mean QOL of 6. All patients with severe scores had a positive correlation with prostate volume and QOL as shown in Figures 3 and 4. In this study, only one patient was delighted with his QOL. He scored 0 with a prostate volume of 65 cm^3. A total of 37 patients felt terrible with their QOL score of 6.

Median lobe was prominent in 19 patients with mean IPSS and QOL of 14.8 and 4.74, respectively. All patients with median lobe had moderate to severe symptoms.

Discussion

The mean age of patients was 69.3 ± 10.6 years with a range of 45–100 years. This is similar to the age group studied in other works.[5,11-13,19,28] The mean prostate

volume in this study was 95.97 ± 70.52 cm^3 with a range of 19–350 cm^3. The commonest range of prostate volume was 50–89 cm^3 as shown in Figure 1. The mean prostate volume identified in this study is very high and similar to the volume recorded by Udeh *et al*.[5] (mean prostate volume of 72.94 ± 44.38 cm^3), and in contrast to the mean prostate volume recorded in other studies done elsewhere.[10,11,14,19,21,28] The American male professional study[17] and the work by Kaplan *et al*.[17] showed that TZI was significantly higher in AA than in the Hispanic or Caucasian men. The higher prostate volume in this study could also be accounted for by the fact that most patients present late to the urology clinics in this part of the world. Most of the works done in other climes never noted the huge prostate sizes regularly seen in clinics in this part of the world.[14-19,21,28] The mean IPSS in this study was 15.6 ± 8.6 [Table 3]. This is lower than the mean IPSS in the works by Agrawal *et al*.[19] and Chalise *et al*.[21] where they recorded mean values of 23.5 and 23.4, respectively. However, these studies identified mainly the IPSS of patients already billed for prostate surgeries, and as such their scores will be likely severe. In this series, all patients were newly diagnosed and may not qualify for surgery. However, the mean score of BPH patients in this study with severe symptoms was 26.8 ± 5.1. This corroborates the above findings.[19,21]

The mean QOL in this study was 4.8 ± 1.3 [Table 4]. This is similar to the findings in other studies.[11,18,19,21,28] This shows that most patients will be mostly dissatisfied, unhappy, or feeling terrible if allowed to live the rest of their lives the way it was when they presented in the clinics. Most of the patients in this study (86%) had moderate to severe symptoms on presentation. Filling phase symptoms notably nocturia and frequency were the most common IPSS sub-score parameters, followed closely by voiding phase symptoms [Table 2]. This is similar to other studies[18-20] and could represent the fact that most patients may identify worsening symptoms at night. Seven patients had individual total IPSS of 35 (maximum) with corresponding poor disease-specific QOL scores. Their mean prostate volume was 85.8 ± 38.1 cm^3. The lowest recorded prostate volume was 19 cm^3 with a corresponding IPSS and QOL scores of 10 and 2, respectively, whereas the corollary was seen in the largest prostate volume of 350 cm^3 who had a terrible QOL score of 6. Figure 4 shows a strong positive correlation between severe IPSS and QOL, r = +0.537; P = 0.135. The average QOL becomes 3.363 when the IPSS is 0. The impact on QOL per unit increase in IPSS is 0.289. Every unit increase in IPSS brings about an increase in QOL by 0.289. These observations are however not statistically significant, but demonstrate that large prostate volumes with high IPSS worsen QOL as shown in this study.

In the scatter diagrams of regression of prostate volume on IPSS and regression of prostate volume on QOL [Figures 5 and 6], there was a remarkable weak positive correlation between prostate volume and IPSS (r = +0.109; P = 0.28). It was seen that the average IPSS becomes 14.44 when the prostate volume is 0. The impact on IPSS per unit increase in prostate volume is 0.0117. Every unit increase in prostate volume brings about an increase in IPSS by 0.0117. These observations are not statistically significant though (P = 0.28). Bosch *et al*.[7] similarly identified a weak correlation (r = 0.19; P < 0.001) between IPSS and prostate volume in his work in a Netherlands population. Sciara *et al*.,[6] Franciosi *et al*.,[10] Overland *et al*.,[11] Wang *et al*.,[12] and Arafa *et al*.[18] identified modest positive correlations between prostate volume and IPSS in their respective works. Their findings were statistically significant. It was noted that in all these works, large number of patients formed their cohorts. Bosch *et al*.[7] studied 502 patients, Overland *et al*.[11] studied 611 men, Franciosi *et al*.[10] studied 223 men, Arafa *et al*.[18] studied 1851 patients, whereas Wang *et al*.[12] studied 1295 patients making it an average of 896 men studied. This is in contrast to other studies with statistically negative correlation where an average of 93 patients were studied.[5,13,14,19] Large sample sizes may have contributed to the improved level of significance of their findings, unlike in this work where 100 men were studied with a finding of positive correlation between prostate volume and IPSS but non-statistically significant observations (P = 0.28) [Tables 5 and 6].

In contrast to findings of this study, Agrawal *et al*.,[19] Udeh *et al*.,[5] Lee *et al*.,[13] Ezz ell Din *et al*.,[14] Veseley *et al*.,[28] and Tsukamoto *et al*.[15] identified that there is no positive correlations between prostate volume and IPSS. Their findings were statistically significant. Most of these works were clinic based. Some were retrospective studies and sample sizes were restricted. Apart from the study by Udeh *et al*.[5] done at Jos Nigeria, others were done in non-African countries. Udeh *et al*.[5] studied 102 men, Tsukamoto *et al*.[15] studied 67 patients retrospectively. Lee *et al*.[13] studied 105 men, whereas Agrawal *et al*.[19] studied 100 men.

The scatter diagram with the regression of prostate volume on QOL [Figure 6] showed a weak positive correlation between prostate volume and QOL (r = +0.072; P = 0.45). The QOL becomes 4.69 when the prostate volume is 0. The impact on QOL per unit increase in prostate volume is 0.0013. Every unit increase in prostate volume brings about an increase in QOL by 0.0013. These observations are however not statistically significant (P = 0.45). Although Agrawal

et al.,[19] Eckhardt *et al*.,[22] and Salinas-Sanchez *et al*.[23] concluded in their works that there was no statistical correlation between prostate volume and QOL, Chalise *et al*.[21] and Seki *et al*.[29] corroborated the findings in this study that there exists a weak positive correlation between prostate volume and either symptoms or QOL score. The scatter diagrams of regression of prostate volume on patients with only severe IPSS [Figure 3], and regression of severe IPSS on QOL [Figure 4], all showed weak positive correlation between the variables compared (r = +0.122, P = 0.125 and r = +0.537, P = 0.135, respectively). It, therefore, implies that if our sample size is larger, findings may be statistically significant.

Conclusion

There is a weak positive correlation between prostate volume measured by ultrasound and symptoms severity scores in patients with BPH. This is not statistically significant. This may be as a result of the small sample size. A larger sample size may be able to achieve statistical significance.

Recommendation

The weak positive correlation between prostate volume and symptom severity scores in this study is not statistically significant. This may be related to the small sample size. It is, therefore, recommended that a larger sample size over a longer period be studied to establish a statistically significant correlation or otherwise.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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