The Relationship Between Prostate Volume and Prostate Specific Antigen in Benign and Malignant Prostatic Lesions

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***Abstract*- BACKGROUND**: Men often have prostatic lesions especially with advancement in age above 50 years. Lesions of the prostate are common health problems globally with prostate cancer said to be the second commonest malignancy in men. Prostate Specific Antigen (PSA) is a nonspecific marker but very sensitive for prostatic lesions. Benign and malignant prostatic lesions cause appreciable enlargement of the gland and significant rise in PSA. Transrectal ultrasonography is a readily available and affordable imaging modality for evaluating the prostate.

AIMS AND OBJECTIVES: This study aimed at evaluating the relationship between prostate volume and PSA in patients who had prostatic lesions in Abakaliki.

MATERIALS AND METHODS: It was a cross sectional study done within eight months in which seventy-four males within the age range of 45 to 89years who were suspected to have prostatic lesions either on digital rectal examination (DRE) or increased PSA were evaluated using transrectal ultrasound. The ultrasound machine used for the study was Medison Accuvix A30 and all the patients later had 12 core biopsy.

Data analysis was done using Statistical Package for Social Sciences (SPSS) version 20. Results were presented in charts, tables and scatter diagrams. T-test was used to compare the means of continuous variables. To test for relationships, Pearson's correlation analysis was used and p-values ≤ 0.05 were considered significant. Linear regression was also used to show the relationship between dependent and independent variables.

RESULTS: The histology results revealed that forty-nine patients had benign prostatic hyperplasia while twenty-five patients had adenocarcinoma of the prostate.

The mean (±SD) prostatic volume was significantly lower in benign prostatic lesions when compared with malignant lesions (79.70±62.10ml verses114.40±69.50 ml, p=0.032).

The mean (±SD) PSA was significantly higher in patients with malignant lesions compared to those with benign lesions (84.90±135.80ng/ml verses 17.90±32.00ng/ml, p=0.002). Similarly, a significant difference was noted in the mean (±SD) PSA density of these two groups (0.82±1.17ng/ml^2 versus 0.27± 0.51ng/ml^2, p=0.006).

There was significant positive correlation between PSA and Prostate volume in benign lesions (r=0.356; p=0.012) but there was no significant correlation in malignant lesions (r=0.136; p=0.516).

CONCLUSION: In benign lesions, prostate volume correlates well with PSA in a positive trend. Therefore, PSA may be used as a close alternative to prostatic volume when selecting patients for 5α reductase inhibitor therapy where there is no facility to assess the prostatic volume.

***Index Terms*-** Transrectal ultrasound, Prostate volume, Prostate specific antigen, prostate specific antigen density, prostatic lesions.

I. Introduction

Lesions of the prostate often occur in men as they get older usually fifty years and above.[i]The lesions could be benign or malignant. The benign ones include benign prostatic hyperplasia (BPH) and prostatitis while the malignant ones comprise mainly the prostate cancer and very rarely metastasis to the prostate. Prostate cancer is the second commonest malignant tumour and the sixth commonest cause of cancer-associated deaths in adult male worldwide.[i]

Since 1980, the measurement of the PSA level is the most useful screening tool for prostatic lesions. Prostate Specific Antigen (PSA) is a serine protease with molecular weight of 34000 which is produced by ductal and acinal epithelial cells of normal, hyperplastic, and malignant tissues of the prostate.[ii] It is a marker which is organ specific that is often raised in prostatic lesions, PSA value more than 4ng/ml gives a high index of suspicion for prostatic lesion.[iii,iv] Because the serum level of PSA is raised in both benign and malignant diseases of the prostate, it is therefore nonspecific for screening prostate cancer. Lesions with PSA values of 0-4ng/ml are more likely to be benign while those with values >10ng/ml are more likely malignant.[2,v]Prostate specific antigen (PSA) when considered alone has 4.6% cancer detecting rate, 32% positive predictive value and low specificity for prostate cancer (CaP).[vi]

Transrectal ultrasound (TRUS) is a relatively affordable, well tolerated and widely used imaging tool for the prostate. Transrectal ultrasound could be considered an extension of the urologist's finger for early detection of prostate cancer.[vii] TRUS has been used in morphological analysis such as measurement of prostate volume, study of echotexture, illustration of tissue

elasticity, administration of treatments like brachytherapy and monitoring of cryotherapy in prostate cancer management.[4]

It is a common knowledge that both benign and malignant prostatic lesions can present with high PSA level. Stamey et al[3] noted that the serum PSA of cancerous tissue appears to be thirty times more than the normal prostatic epithelial tissue and ten times that of BPH. From the result of simple prostatectomy series, the authors calculated that each gram of BPH and CaP elevated the serum PSA by 0.3ng/ml and 3.5ng/ml respectively.[3]Most patients with prostate cancer have PSA values more than 20ng/ml while those with benign lesions have lesser PSA values.[viii] However, the sensitivity and specificity of PSA alone in differentiating malignant from benign lesion is poor especially in patients with PSA <20ng/ml.[ix]Another study done by Ekeke et al[x] noted that most patient with PSA >10ng/ml have advanced cancer. Prostate cancer has also been found in individuals with normal PSA levels meaning that normal PSA does not translate to absence of cancer and there is no absolute level of PSA that signifies prostate cancer.[xi]

Udeh et al[xii] did a study in Nigerian men from 45 to 99 years of age and noted a statistical difference in PSA between BPH and CaP with mean PSA of 13.71 ± 17.46 and 49.86 ± 41.49 ng/ml for BPH and CaP patients respectively. Although there was statistical difference in mean PSA between CaP and BPH, the mean prostate volume was not significantly different in the two groups. This implied that the difference in PSA could not be explained by the volume of the prostate; rather, the distortion in the basement membrane could be the likely explanation. Their challenge was that in our environment, most patients present to the clinicians only when they are symptomatic.

In 1992, the concept of PSA density (PSAD) was introduced to correlate PSA and prostate volume. This was based on the knowledge that most PSA is produced by prostate epithelial cells and cancer cells produce more PSA per unit volume than benign cells. Prostate specific antigen density (PSAD) was obtained by dividing the total serum PSA with prostate volume, as determined by transrectal ultrasound measurement using the formula; volume = length x width x depth x 0.52.[xiii] Benson et al[xiv] noted that the mean PSAD for prostate cancer (CaP) was 0.581ng/ml^2 while that for BPH was 0.044ng/ml^2 ($p< 0.002$) and no patient with BPH had a PSAD of more than 0.117ng/ml^2 suggesting that PSAD could help to distinguish between CaP and BPH in men whose PSA levels are between 4 and 10 ng/ml. However 6 out of 61patients used in the study with PSAD less than 0.1 had cancer. Other studies have been done to ascertain the relationship between prostate volume and PSA. The correlation was so significant that PSA level could represent an acceptable proxy for prostate volume measurement when selecting candidates for 5-α-reductase inhibitor therapy. Jozo et al[xv] observed that increased prostate volume correlated with increased level of total and free PSA in serum ($p < 0.001$). A similar result was obtained by Putra et al[xvi] in Indonesian men with BPH, they noted that PSA was significantly correlated with prostate volume ($r = 0.26$, $P < 0.0001$) and both increased with age. Similar study done in Nigeria by Udeh et al[xvii] showed that in Nigerian men with biopsy proven BPH, the volume of the prostate was significantly correlated with serum PSA. The maximum PSA value recorded in their study was 35ng/ml with a mean PSA of 12.44±15.49 ng/ml while the maximum prostate volume recorded was 223.82ml with mean prostate volume of 72.79± 44.38ml. The correlation between prostate volume and PSA was 0.3365 based on the Pearson's correlation coefficient with $p<0.05$.[xvii]

The aim of this study was to evaluate the relationship between prostate volume and PSA in various prostatic lesions which will help in monitoring and follow-up of patients with prostate disease.

II. METHODOLOGY

STUDY DESIGN

This was a cross–sectional study to evaluate the relationship between the prostate volume and PSA of benign and malignant lesions of the prostate in patients who were suspected to have prostatic lesions that presented in surgical outpatient and Radiology department of Alex Ekwueme Federal University Teaching Hospital Abakaliki (AEFETHA).

III. STUDY AREA

The study was conducted at AEFUTHA, a tertiary institution in Ebonyi State. The surgical outpatient department serves a large number of patients coming from Abakaliki, Afikpo and suburban areas. The population of Ebonyi state is about 2.39million and men account for about 1.16million.[xviii]

STUDY POPULATION

The participants for the study were men with abnormal digital rectal examination findings or raised PSA who presented in surgical outpatient and Radiology of AEFETHA. Participation was voluntary.

IV. STUDY DURATION

The study period was 8months.

INCLUSION CRITERIA

1. Men who had abnormal prostate findings on DRE.
2. Men who had increased serum PSA level > 4.0ng/ml.
3. Patients that had prostate biopsy with available result.

EXCLUSION CRITERIA

1. Patients who declined consent.
2. Participants with anal fissure or stenosis and uncooperative patients.
3. Normal individual with no suspected prostatic lesions.
4. Patients whose prostate biopsy result were not available.
5. Patient on 5-α-reductase inhibitor treatment.
6. Patient who are on urinary catheter.

EQUIPMENT

The machine used for the prostate scan was Accuvix A30 (MEDISON LV Korea 2013) with transrectal probe of 5 - 9 MHz.

TECHNIQUE

All transrectal ultrasonography in this study were done only by a Radiologist to eliminate inter observer variability. To avoid bias, the Radiologist was not aware of the patient's histology report before the scan.

Positioning: Having explained the procedure and obtained consent, the patient was positioned in a left lateral position with both knees flexed. The patient's privacy was maintained during the procedure.

Preparation of the probe and insertion: Before the insertion of the transducer, digital rectal examination (DRE) was done to ensure there was no contraindication to the procedure such as anal stenosis and fissure. Double condom sheaths were used to cover the probe for protection. Contact jelly was poured into the sheath to establish good contact with the probe and remove air interface for better transmission of sound waves. K-Y jelly was used to lubricate the sheathed probe which was then introduced into the anus and gently angled posteriorly with respect to the curve of the rectum.

Scanning: The prostate was evaluated in both longitudinal and transverse planes for morphology. Transverse scan was done beginning from the bladder base at the level of seminal vesicles to the apex of the prostate while the longitudinal scan was done by moving the probe from right to left lateral parts of the gland. Before the transrectal scan, the patient was asked to empty his bladder. The sonographic measurement of the prostatic volume is shown in figures 1below.

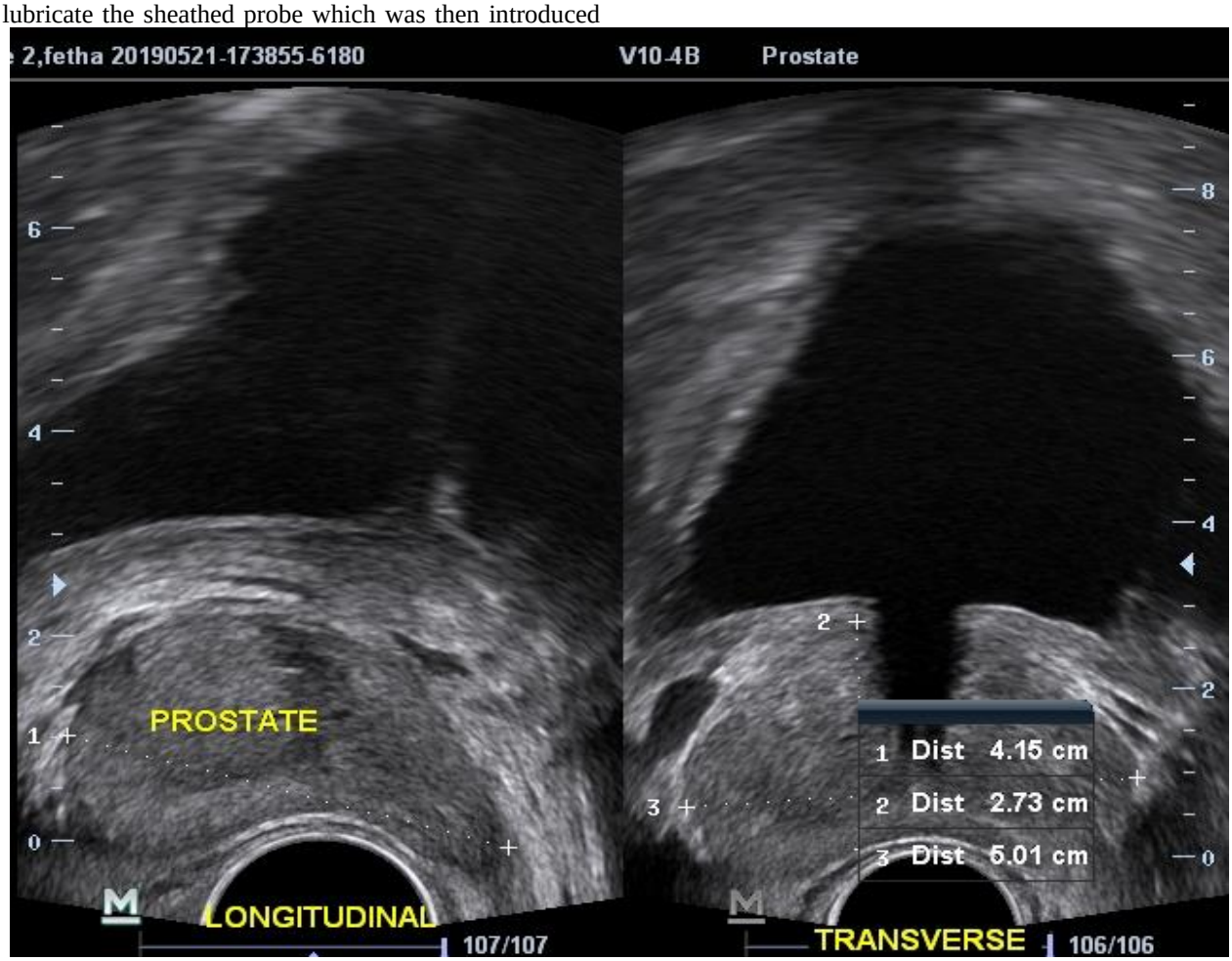


Figure 1: Longitudinal and transverse views of Transrectal ultrasound showing the measurement of the prostate volume.
D1= Superio-inferior diameter.
D2 = Anterio-posterior diameter.
D3 = Transverse diameter.

V. PSA ASSAY

Blood samples of patients were collected and analyzed in the hospital laboratory by the Lab. Scientist. To assay for PSA, TECO (ELISA) kit was used.

VI. PROSTATE BIOPSY

Each participant underwent digitally directed 12-core prostate biopsies which was done by Urologist in the theatre. The Samples collected were sent to the Pathologist for histology reports. The biopsy results were collected later and recorded in the data sheet.

VII. DATA ANALYSIS

The data analysis was done with Statistical Package for Social Sciences (SPSS) for windows version 20 package. The reults were presented using tables and charts. Statistical tests were considered significant at p-value ≤ 0.05.

The data was summarized using descriptive statistics like percentage, frequency, mean and standard deviation. Student t-test and Chi-squared test were used to compare continuous and categorical variables. The test for relationship between variables was done using Pearson's correlation analysis.

VIII. RESULTS

The study was conducted on 74 adult male patients within the age range 45 – 89years with average age of 68.1± 8.5 years who had prostatic lesions. The modal age group was 61– 75years which accounted for 45(60.8%) of the participants. The age group 76-89years recorded the least number 14 (18.9%) of the participants.

Majority 70(94.6%) of the participants were Igbo while just a few of them 4(5.4%) were from other tribes of Nigeria. Seventy two (97.3%) of them were Christians.

Twenty seven (36.5%) participants were farmers, 23(31.1%) were retirees, 10(13.5%) were civil servants, 8(10.8%) were traders while 6(8.1%) were artisans.

Fifty seven (77.0%) of the studied population had formal education while 17(23%) did not receive any formal education.

These demographic variables (age, ethnicity, religion, occupation, marital status and highest level of education) are shown in table 1 below.

Table 1: The demographic variables of the study population

Demographic	Frequency	Percentage (%)	Cumulative percentage (%)
Age Group			
45 – 60years	15	20.3	20.3
61 – 75years	45	60.8	81.1
76 – 89years	14	18.9	100.0
Ethnicity			
Igbo	70	94.6	94.6
Others (Efik, Yoruba)	4	5.4	100.0
Religion			
Christianity	72	97.3	97.3
Traditionalist	2	2.7	100.0
Occupation			
Farmer	27	36.5	36.5
Retiree	23	31.1	67.6
Civil Servant	10	13.5	81.1
Trader	8	10.8	91.9
Artisan	6	8.1	100.0
Marital Status			
Single	3	4.0	4.0
Monogamous	44	59.5	63.5
Polygamous	26	35.1	98.6
Widower	1	1.4	100.0
Highest Level Of Education			
Informal education	17	23.0	23.0
Primary education	25	33.8	56.8
Secondary education	7	9.4	66.2
Tertiary education	25	33.8	100.0

From the study, 49(66.2%) participants had benign lesions while 25(33.8%) participants had malignant lesions. No patient had prostatitis or metastasis to the prostate as shown in table 2 below.

Table 2: The histology reports of the participants

Prostatic lesions	Frequency	Percentage (%)	Cumulative percentage (%)
Prostatitis	0	0.0	0.0
Benign prostatic hyperplasia (BPH)	49	66.2	66.2
Metastasis	0	0.0	66.2
Adenocarcinoma	25	33.8	100.0

There was significant difference in the mean (±SD) prostate volume of benign (79.70±62.10ml) and malignant (114.40±69.50 ml) lesions (p=0.032). The mean prostate volume was 34.70ml larger in malignant than benign lesions.

The mean (±SD) PSA for malignant lesions was 84.90±135.80ng/ml while that of benign lesions was 17.90±32.00ng/ml which was significant (p=0.002). The mean PSA was 67.00ng/ml lower in benign than malignant lesions.

The mean (±SD) PSA density was significantly higher in malignant lesions (0.82±1.17ng/ml^2) compared to the benign lesions (0.27± 0.51ng/ml^2) with p=0.006.

The details of the prostate volume, PSA and PSA density values are shown in table 3.

Table 3: Measurements of PSA, prostate volume and PSA density in benign and malignant lesions

Parameters	Benign (n=49)		Malignant (n=25)		Mean Diff	t-test	df	P-value
	Range	Mean ±SD	Range	Mean ±SD				
PSA (ng/ml)	0.20-134.00	17.90±32.00	0.50-613.40	84.90±135.80	67.00	3.30	72	0.002
Prostate volume (ml)	15.60-292.60	79.70±62.10	36.10-298.20	114.40±69.50	34.70	2.18	72	0.032
PSA density(ng/ml^2)	0.00-3.36	0.27± 0.51	0.01-4.82	0.82±1.17	0.55	2.83	72	0.006

There was significant positive correlation between PSA and Prostate volume in benign lesions (r=0.356; p=0.012) but there was no significant correlation in malignant lesions (r=0.136; p=0.516). This is shown in table 4 below.

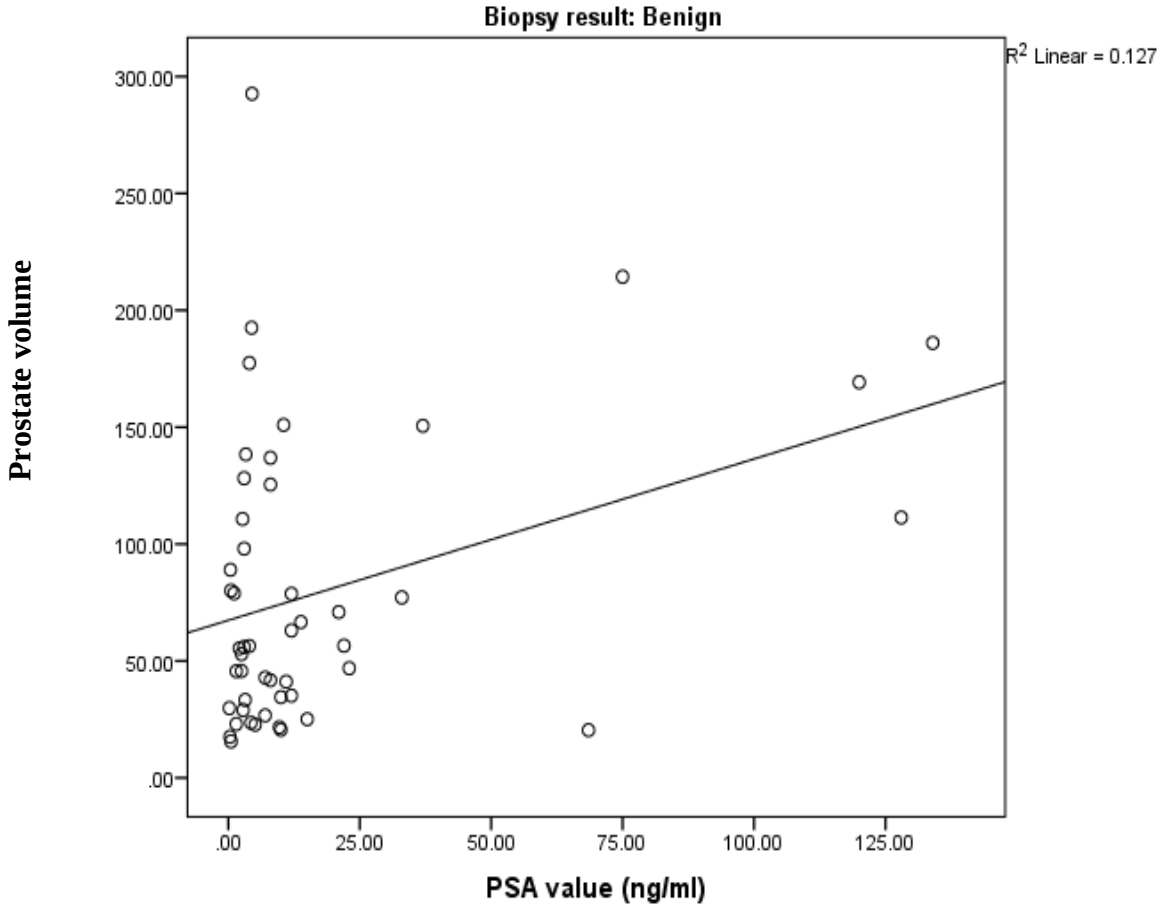
Table 4: The correlation between PSA and prostate volume in benign and malignant lesions

		Prostrate Volume	
		Benign	Malignant
PSA value (ng/ml)	Pearson Correlation	0.356	0.136
	P-value	0.012	0.516
	N	49	25

There was a direct relationship between PSA and prostate volume (r=0.356) in benign lesions. As the prostate volume increases, the PSA also increases.

Majority of PSA in benign lesion clustered below 25.00ng/ml while prostate volume clustered below 100.00ml. This is illustrated in figure 2 below.

Figure 2: A scatter plot with trend line of relationship between PSA and prostate volume in benign lesions.



IX. DISCUSSION

Seventy-four adult male aged 45 to 89years with prostatic lesions were recruited for the study.

The modal age group was 61-75years which represented 60.8% of the studied population.

In 2011, Anunobi et al[xix] noted a modal age group of 60-69years with a mean age of 67years for prostatic lesions which agreed with the present study. Other studies carried out in Pakistan and Nigeria observed similar mean age and modal age group with none contradicting this current study. This might imply that prostatic lesions could be part of aging processes.[xx,xxi] Out of the total number of people recruited for the study, benign prostatic hyperplasia (BPH) accounted for 49(66.2%) while prostate cancer (CaP) accounted for 25(33.8%) which agreed with the common knowledge that BPH is the commonest prostatic lesion in adult males. Nwafor et al[20] noted that in Nigeria men, BPH accounted for 62.8% and was distantly followed by CaP that accounted for 29.3% of histology results which was similar to findings in this study. However, Aslams et al[21] quoted a much higher proportion for BPH 42(87.5%) as against CaP 6(12.5%). This difference might be due to geographical variation because their study was done in Pakistan.

A significant statistical difference was noted in the mean prostate volume in benign (79.7±62.1ml) and malignant (114.40±69.50ml) lesions (p=0.032). The larger volume seen in malignant lesions might be because most patients presented late with advanced cancer which had invaded the surrounding structures. It might also be due to the difference in the number of participants with benign and malignant lesions (49 versus 25) used for this study. Udeh et al[17] showed no statistical difference in the mean prostate volume of these two groups. Conversely, Al-Khalil et al[xxii] noted an inverse relationship between prostate volume and the incidence of CaP.

There was significant difference between the mean PSA of patients with benign (17.90±32.00ng/ml) and malignant (84.90±135.80ng/ml) prostatic lesions with p-value=0.002. Although the PSA values in these two conditions were elevated compared to the normal value of ≤4.0ng/ml, it was markedly higher in malignant lesions.[11]The study done by Stamey et al[iii] noted a similar exceedingly higher PSA value in CaP than in BPH. Another study done in Nigeria by Udeh et al[12] noted a statistical significant difference in PSA value between BPH and CaP in favour of CaP which also agreed with the findings of this index study. The difference in PSA level between these two prostatic lesions could be attributed to distortion of the basement membrane

of prostatic epithelium by prostate cancer resulting in higher production of PSA.[12] Though Ekeke et al[7] observed that most patient with PSA >10ng/ml had advanced prostate cancer, this might not be generally true since BPH could also give such high PSA values.

A statistical significant difference was noted in the mean PSA density (PSAD) in benign (0.27± 0.51ng/ml^2) and malignant lesion (0.82±1.17ng/ml^2) with p-value = 0.006. This agreed with the common knowledge that cancer cells produce more PSA per unit volume than benign cells. A study done in New York by Benson et al[xiv] observed that the mean PSAD for prostate cancer (CaP) was significantly higher in malignant prostatic lesions than in BPH (0.581ng/ml^2 versus 0.044ng/ml^2, p < 0.002) and no patient with BPH had a PSAD of more than 0.117ng/ml^2 suggesting that PSAD could help to distinguish between CaP and BPH in men whose PSA levels are between 4 and 10 ng/ml. Although their result agreed with that of present study, the values were much lower. This might be due to racial differences. Bastola et al[xxiii] stated that PSA density was a better predictor of prostate cancer in Chinese men with PSA levels of 4-10 ng/ml. They noted that 88.9% of patients with malignant prostatic lesions had PSA density > 0.15 ng/ml/cm^3 which was significantly higher compared to those with benign lesions (p=0.02). They also observed that at a cutoff of 0.134 ng/ml/cm^3, the sensitivity and specificity of PSA density in detecting prostate cancer were 90 %and 33.7%, respectively.

There was significant correlation between PSA and Prostate volume in benign lesions(r=0.356, p=0.012) while malignant lesions did not show any significant correlation (r=0.136, p=0.516). This might be because most PSA was produced by prostate epithelial cells and cancer cells cause distortion in the basement membrane and produce more PSA out of proportion compared to the prostate size.[7]It might also be due to variation in the number of participants with benign and malignant lesions in this index study. A Study done in Bosnian and Herzegovina men by Jozo et al[15] observed that increased prostatic volume correlated with increased level of total and free serum PSA (p < 0.001) but their work did not specify whether in benign or malignant prostatic lesions. Putra et al[16] did a study in Indonesian men with BPH, they noted that PSA was significantly correlated with prostate volume (r = 0.26, p< 0.0001) which was similar to the findings in this study. Another study done in Nigeria by Udeh et al[xvii] in men with biopsy proven BPH, gave a similar result of significant positive correlation between prostate volume and serum PSA. Similarly, Benson et al[14] noted that the relationship between PSA and prostate volume in BPH was so significant that PSA level could represent an acceptable proxy for prostate volume measurement when selecting candidates for 5-α-reductase inhibitor therapy. Stamey et al[iii] observed that PSA was strongly correlated with volume of prostate cancer (r= 0.70) and bivariate and multivariate analyses of their study indicated that cancer volume was the primary determinant of serum PSA levels. Their observation was not in agreement with the finding of this present study. This variation might be due to larger number of patients with CaP in their study when compared with the present study (102patients verses 25patients).

X. CONCLUSION

There is a positive relationship between prostate volume and PSA in benign prostatic hyperplasia. Therefore, both parameters can be used interchangeably in assessment and monitoring patients with BPH especially in selecting patient for 5 α- reductase inhibitor treatment. PSA density is a useful tool in differentiating benign from malignant prostatic lesions.

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