1	Original Research Article
2	Is Serum PSA a Predictor of Lower Urinary Tract Symptom
3	Severity in Nigerian Males 40 Years and above?

4 ABSTRACT

Background: Prostatic diseases are the commonest cause of lower urinary tract symptoms in men worldwide. The most ideal method for assessing symptom severity in men with LUTS currently is the International Prostate Symptom Score (IPSS). Prostate specific antigen (PSA) is widely in use as an indicator of prostatic disease in general. Few studies have been carried out to correlate PSA with symptom severity in men with LUTS.

Aim: To correlate Prostate Specific Antigen (PSA) values with International Prostate Symptom Scores (IPSS) in a screened population of male subjects 40 years and above presenting with symptoms at a medical outreach.

Study Design: Cross sectional descriptive study.

Place and Time of Study: The study was carried out at the University of Calabar, South-South, Nigeria in November 2016

Methodology: Sixty one male subjects were interviewed using the IPSS questionnaires after which blood samples for PSA estimation were collected. PSA values were then correlated with IPSS and Quality of Life (QoL) scores.

Results: Sixty one male patients with mean age 52.03±7.5 years were included in the study. Over 67% of subjects had a PSA value less than 4ng/ml. No statistically significant correlation was found between PSA and IPSS scores or QoL values in the subjects.

Conclusion: This study shows PSA not to be a predictor of prostate symptom severity. More studies need to be carried out to be able to confirm these findings.

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Keywords: International prostate symptom score, Quality of life, Serum PSA, Nigerian males.

7 1. INTRODUCTION

8 Prostatic diseases are the main cause of lower urinary tract symptoms in men. Even though not all 9 men suffer from this condition, about half of those with histological hyperplasia eventually develop 10 bothersome lower urinary tract symptoms (LUTS) [1,2]. Benign prostatic hyperplasia (BPH) is the 11 commonest urologic disease affecting elderly men, causing symptoms in approximately 90% of men 12 over the age of 80 years[3,4]. Prostate-specific antigen (PSA) is produced in the glandular epithelial 13 portion of the prostate gland and is the most widely used screening marker for prostate cancer ever 14 since it was introduced[2]. It also is in wide use as an indicator of prostatic disease in general[1]. 15 Recent data indeed seems to suggest that the use of PSA may have greater potential within the BPH 16 population than in cancer diagnosis[5]. PSA is used as a measure of prostate growth and studies 17 have shown a strong correlation between serum PSA level and age as well as the size of prostate. 18 Thus PSA value increases as a man ages and his prostatic size increases[6,7]. Traditionally, lower 19 urinary tract symptoms were thought to be precipitated by increasing prostate volume because of the 20 bladder outlet obstruction that results[1]. Few studies have been done to correlate PSA with the 21 severity of LUTS as measured by the International Prostate Symptom Score (IPSS). Since 1993 when 22 the IPSS was adopted by the World Health Organization from the American Urological Association 23 Symptom Index (AUASI) it has become one of the most used measures in determining the severity of 24 LUTS and consequently the management choice for patients with BPH[8]. It consists of seven LUTS-25 questions and one quality of life question. The 7 lower

urinary tract symptoms graded are frequency, urgency, nocturia, weak stream, intermittency, straining
and incomplete bladder emptying. A score ranging from zero (with no symptom) to five (with symptom
always present) is assigned. The score therefore ranges between 0 and 35. Subjects are
subsequently classified as having mild (IPSS =0-7), moderate (IPSS= 8-19) or severe symptoms
(IPSS= 20-35) The global impact of LUTS on the quality of life is graded from 0 (delighted) to 6
(terrible) [9]. This study was carried out to correlate PSA with IPSS and QoL in a screened population
of men above 40 years.

33 **2. METHODOLOGY**

34 2.1 Study Design and Materials

This was a cross sectional descriptive study. Subjects were interviewed using standardized questionnaires for IPSS and blood samples were collected for PSA estimation. PSA values were grouped as less than 4ng/ml, 4 to 10ng/ml and greater than 10ng/ml.

38 2.2 Sample size

Male subjects 40 years of age and above who presented at an outreach to screen for prostate cancer at the University of Calabar, South-Southern Nigeria in November 2016 and who had not previously been screened or managed for any prostatic disease were recruited in this study. Subjects already diagnosed with or receiving treatment for prostatic diseases were excluded.

43 2.3 Data Analysis

Data collected was analyzed using the Statistical Package for Social Sciences (SPSS) version 20. Data was summarized as frequencies, percentages, means, and standard deviations and presented in tables and a bar chart. Tests of correlation between PSA and IPSS as well as median QoL were carried out. Statistical significance was set at $p \le 0.001$.

48 2.4 Ethical Considerations

49 Ethical clearance for the conduct of this study was obtained from relevant authorities.

50 **RESULTS**

51 Sixty one apparently healthy males, who met the inclusion criteria, were recruited into the study out of 52 200 men who presented at the outreach. The mean age was 52.03±7.5 years with the age range 53 being 40 to 66 years. About 64% of the subjects were 50 years and above and 80.3% were married.

Over 67% of subjects had a PSA value less than 4ng/ml while 18% had values greater than 10ng/ml.
(Details in Figure 1).



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Fig 1: PSA values of subjects

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59 PSA values were not found to correlate with IPSS scores or median quality of life values in our

60 subjects. (Tables 1 and 2)

61 Table 1: Correlation between PSA and IPSS groups

IPSS	PSA (ng/ml)		
	<4.0	4.0-10.0	>10.0
Mild	35(68.6%)	5(9.8%)	11(21.6%)
Moderate	4(57.1%)	3(42.9%)	0(0.0%)
Severe	2(66.7%)	1(33.3%)	0(0.0%)

62 p value=0.108

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64 Table 2: Correlation between PSA groups and median Quality of Life (QoL) Scores

PSA group (ng/ml)	Median QoL Score	
<4	3.00	
4-10	5.00	
>10	3.00	

65 p value=0.117

67 **3. DISCUSSION**

68 Correlation of PSA with IPSS implies that PSA values can be used to predict the severity of lower 69 urinary tract symptoms in men with prostatic diseases. Even though IPSS cannot be used in making a 70 diagnosis of BPH, it is however ideal in determining and grading symptom severity, assessing 71 response to therapy and detecting symptom progression in patients being managed with watchful 72 waiting[10]. Prostate specific antigen has been documented in several studies to have a linear 73 correlation with prostate volume[11–13]. Despite the traditional association of development of or 74 worsening lower urinary tract symptoms with an enlarging prostate, several researchers have shown 75 that no statistically significant correlation exists between the prostatic volume and symptom 76 severity[14-16]. Only a few studies have been carried out to correlate PSA with IPSS worldwide. In 77 this study, the symptom severity which was assessed using IPSS as well as QoL values were found 78 not to correlate with the PSA. This is in contradistinction to a similar study carried out on 34,857 79 patients in a large-scale Korean screening program by Park et al[17] which demonstrated PSA to be a 80 significant predictor of IPSS. A mild linear relationship was also found to exist between both variables 81 in a study carried out by Lim and Buchan[1] on 833 patients in New Zealand. The common thing 82 between these 2 previous studies was the large sample size. However Tsukamoto et al[18] carried 83 out a similar study on 67 patients in Japan but found no significant correlation between PSA and 84 IPSS. Favilla et al[19] also in their study on 122 patients in Italy as well found no correlation between 85 both variables. Therefore the non-correlation between both variables recorded in our study could be 86 attributed to the weakness of the study accounted for by our small sample size of 61. This is because 87 similar studies by Tsukamoto and Favilla with small cohort of patients like ours recorded similar 88 results. Aside from this, no similar study, from our literature search has been carried out in our own 89 environment, Nigeria. Therefore more studies especially on a larger scale are required to determine 90 whether race or environment could also be determinants in the type of results obtained in our study.

91 4. CONCLUSION

This study has shown PSA not be a good predictor of prostate symptom severity in Nigerian males 40 years and above. In addition the non-correlation of PSA with median quality of life values indicates that PSA cannot be used to predict the quality of life in patients presenting with lower urinary tract 95 symptoms. Further studies are required on a larger scale before the results of this study can be96 generalized for Nigerians.

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UNDER PEER REVIEW

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UNDER PEER REVIEW

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