

# Prevalence of clinical symptoms and their effect on quality of life among patients with benign prostatic hyperplasia at a tertiary health facility in Minna, North central Nigeria

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## ABSTRACT

**Background:** Benign prostate hyperplasia (BPH) is increasingly common among older adult males and its treatment has highly variable effect on patient's quality of life. The persistence of clinical symptoms varies widely and also frequently changes in the course of therapy. The severity of symptoms, side effect(s) of drugs, emotional distress and demographic factors have unpredictable impact on patient's quality of life. Furthermore, the persistence of residual clinical symptoms and abnormally high PSA levels remain an ongoing clinical challenge in the management of the disease. This study therefore aims to assess prevalence and severity of symptoms and quality of life of patients with benign prostate hyperplasia.

**Methods:** The study was carried out at Ibrahim Badamosi Babangida specialized hospital Minna, Niger State. The hospital's electronic patient's records were used to identify prospective respondents. The medical information of 443 eligible patients were extracted for analysis. The selected patients were followed up during physician appointments and then administered the EPIC-CP and SF-12 questionnaires to determine prevalence and severity of symptoms as well as quality of life respectively. Data was entered into Microsoft excel and scores calculated according to standard procedures. A subscale score of  $\leq 4$  implied absence or mild symptoms, 5 – 8 (moderate symptom) and 9 – 12 severe symptoms (EPIC-CP), while physical and mental components of quality of life score higher than 50 was satisfactory (SF-12).

**Results:** The mean age of respondents was 65 years and they had been on therapy for 4.9 years. Majority of patients were on Tamulosin monotherapy (63.1%) and Tamulosin / Dutasteride combination therapy (36.9%). The most reported symptoms included sexual dysfunction (96.1%), urinary incontinence (37.6%), urinary obstruction (34.5%) and hormonal symptoms (36%). The quality of life was generally poor and significantly associated with age ( $p=0.042$ ) and PSA level ( $p<0.001$ ). There was significant difference in quality of life based on demographic variables ( $p<0.001$ ).

**Conclusion:** The persistence of high level of sexual dysfunction and urinary symptoms among patients remains a major medical challenge. Quality of life was generally poor and affected by residual symptoms and side effect of drugs.

## Introduction

Benign prostate hyperplasia (BPH) is frequently diagnosed among adult males above 65 years with an estimated 1.4 million new cases annually and 3.8% mortality rate worldwide<sup>1-3</sup>. Recent epidemiological evidence indicate that the highest number of cases are still found in North America, Europe and Oceania region, however it is believed that prevalence is under reported in developing countries<sup>3,4</sup>. It is estimated that by 2040 most of the 2.3 million new cases will be in developing countries<sup>3</sup>. In the

last three decades there have been rising cases of the disease<sup>4,5</sup> with prevalence of between 22.4% and 37.4% among older adults<sup>6,7</sup>.

In high income countries there have been declining number of new cases driven by public health interventions involving screening and availability of new treatments<sup>2,8</sup>. This is in contrast to rising cases in developing countries where public awareness and availability of diagnostic services is encouraging men to seek preemptive screening for the disease<sup>9</sup>. Several studies have also reported rapid rise

in cases of BPH in sub Saharan countries<sup>10,11</sup> and recent projections indicate that an additional 75 million new cases and 17 million deaths will be recorded in the region by 2030<sup>12</sup>.

The rise in prevalence have been attributed to increasing ageing population, rising obesity, unhealthy diets and other risky lifestyles<sup>13,14</sup>. In addition the rise in metabolic diseases in recent decades has added a new layer to the risk of developing BPH<sup>15</sup>. The complex interplay between genetic predisposition and risky lifestyles, smoking, alcohol misuse and chronic urinary tract infections is poorly understood, although they have been reported to be significant contributors to the development of the disease<sup>8,13</sup>.

In many developing countries prognosis after initiation of therapy is highly variable as a significant proportion of patients continue to experience residual symptoms severe enough to affect their quality of life<sup>16-18</sup>. A few studies reported poor long-term prognosis partly because of late presentation at health facilities<sup>19</sup>, poor attitudes toward preventive screening<sup>20,21</sup>, long waiting period before treatment<sup>22,23</sup> and poor access to quality healthcare services<sup>24,25</sup>. Furthermore, poor socioeconomic status of patients<sup>25,26</sup> and disability caused by the disease<sup>27,2</sup> negatively impact on affordability of care, adherence to treatment and clinical outcomes all of which influence prognosis for patients on therapy.

The increasing uptake of screening leading to early detection and treatment has significantly improved long term survival and increased life expectancy<sup>29,30</sup>. However, this comes with challenges with psychological distress<sup>31-33</sup> and poor quality of life<sup>34,35</sup>, although this is not a consistent finding from other studies<sup>34,36</sup>. Benign prostatic hyperplasia is also associated with feelings of “threat to masculinity” due to erectile dysfunction, loss of libido, poor satisfaction with sexual performance which is important to favourable perception of sense of manhood and quality of life<sup>36</sup>.

The relationship between symptoms of the disease, quality of life and psychological distress is not linear<sup>37-39</sup>, as several factors play important roles in determining patient's quality of life<sup>40</sup>. While studies have frequently reported contrasting findings on distress and quality of life<sup>41-43</sup>, side effects of drug(s)<sup>43</sup>, erectile dysfunction and urinary incontinence are known to affect the quality of life<sup>44,45</sup>. Furthermore, several demographic factors<sup>46</sup> including duration of therapy<sup>47,48</sup>, age<sup>49</sup>, comorbidities<sup>50</sup> and complications are reported determinants of patients quality of life<sup>51,52</sup>. The relative impact of these factors on quality of life vary widely between individuals and population groups so it is

important to assess the impact of residual symptoms of the disease, drug(s) and demographic factors on patients quality of life.

The major goal of pharmacotherapy is not only to reduce prostate size but also to relieve clinical symptoms and normalize PSA level all of which are expected to improve patient's quality of life. The major aim of this study is therefore to assess the prevalence of clinical symptoms and their effect on patient's quality of life on long term drug therapy.

## Methods

**Settings:** The study was done at the Urology Department of Ibrahim Badamosi Babangida Specialist Hospital in Minna, capital of Niger State, Nigeria. The hospital is a tertiary health facility with a 105 bed capacity owned by the State government and one of two health facilities where cases of BPH are managed in the State.

**Study design:** This was a cross-sectional retrospective survey of patients treatment outcomes documented in medical records for a three year period (2021 – 2023).

**Sample size/sampling:** The sample size was determined using the formula

$$N = \frac{Z^2 P(1-P)}{e^2}$$

Where: N = sample size, Z score at 95% confidence interval = 1.96, P = estimated prevalence of BPH (50%), e = (5%).

The estimated sample size was calculated to be 443 which include 15% attrition rate to give the final sample size of 443 patients. The patients were sampled using convenience sampling method from information obtained from the hospitals database.

Patients were eligibility if they:

- § have been on drug therapy for at least six months
- § have had no previous surgery as part of BPH treatment
- § have attended  $\geq 80\%$  of clinic appointments

**EPIC-CP questionnaire:** The expanded BPH index composite for clinical practice (EPIC-CP) is a 10 item disease specific questionnaire that is used to measure severity of urinary incontinence, urinary irritation/obstruction, bowel, sexual and vitality/hormonal symptoms. The items rate severity of symptoms from “no problems to big problems” and scored on a 0 – 4 Likert scale. The score of zero indicate no reported clinical symptoms while increasing scores represent increasing

severity of symptoms. The questionnaire consist of five subscales which include 'urinary incontinence' (item 1-4), "urinary irritation/obstruction" (item 5), "bowel symptoms" (item 6), "sexual symptoms" (item 7-9) and vitality/hormonal symptoms (item 10). Each subscale has a maximum score of 12 ( $\leq 4 = \text{no or mild symptoms}$ ,  $5 - 8 = \text{moderate symptoms}$  and  $9 - 12 = \text{severe symptoms}$ ) and higher scores represent increasing severity of clinical symptoms.

SF-12 questionnaire: This is a 12 item tool used for assessing general quality of life and it consist of six sub scales including "general health, physical functioning, limitation due to physical health, limitation due to emotional health, emotional wellbeing, energy/fatigue and pain". The summary is calculated as physical and mental component scores and an average score of 50 and standard deviation of 10 is used to determine quality of life. Physical and mental component scores less than 50 represent poor quality of life and vice versa.

Questionnaire administration: The selected patients identified from the hospitals electronic database were followed during routine physician consultations and questionnaires self-administered on them after verification of their medical information extracted prior to clinic days. A total of 443 questionnaires (EPIC-CP, SF-12) were self-administered out of which 412 were used for final analysis giving a return rate of 93%. The questionnaires were completed by ticking the option that best reflect patient's opinion or experience with symptoms and wellbeing.

Data analysis: The data was entered into Microsoft excel, coded and then loaded into SPSS version 21 for descriptive and inferential statistics. The EPIC-CP item scores for each subscale summed up and a score of  $> 4$  (maximum score - 12) and global score of  $> 20$  (maximum score- 60) indicate the presence of clinically significant symptoms<sup>53</sup>. The SF-12 was summarized into physical component score and mental component scores using standard procedure. The quality of life was determined to be good if the average score was above 50 and poor if less than this 50. One way ANOVA and Students t test were used to assess differences in quality of life based on demographic variables. Chi square test was used to determine association between patient factors and severity of clinical symptoms. P values  $< 0.05$  was considered statistically significant.

Ethical issues: The approval for this study was obtained from the health research ethics committee of the hospital (Reference no. M2020-05).

## Results

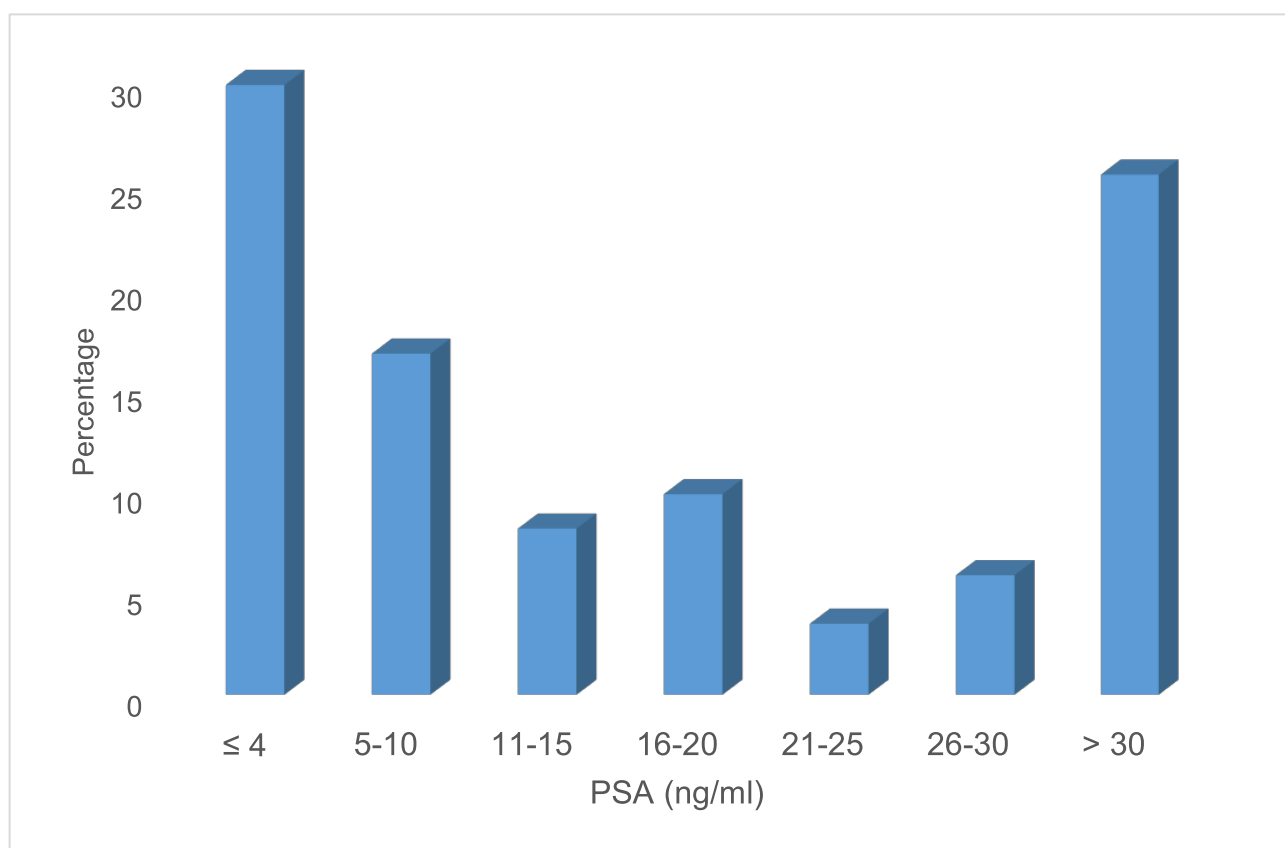
Demographic data showed that most patients were retired (68.2%) and had tertiary level education (88.1%). The mean age was  $65.1 \pm 8.6$  years and most had no comorbidities (78.2%). The mean duration of therapy was  $4.9 \pm 2.4$  years (Table 1).

**Table 1: Demographic data**

Variable	Number (%)
<b>Age (yrs.)</b>	
$\leq 50$	23 (5.5)
51 – 60	72 (17.5)
61 – 70	317 (77)
<b>Mean (SD)</b>	<b>66.7 <math>\pm</math> 4.9</b>
<b>Educational status</b>	
Primary	35 (8.5)
Secondary	14 (3.4)
Tertiary	363 (88.1)
<b>Occupation</b>	
Civil servant	35 (8.5)
Self employed	77 (18.7)
Private sector employed	12 (2.9)
Unemployed	7 (1.7)
Retired	281 (68.2)

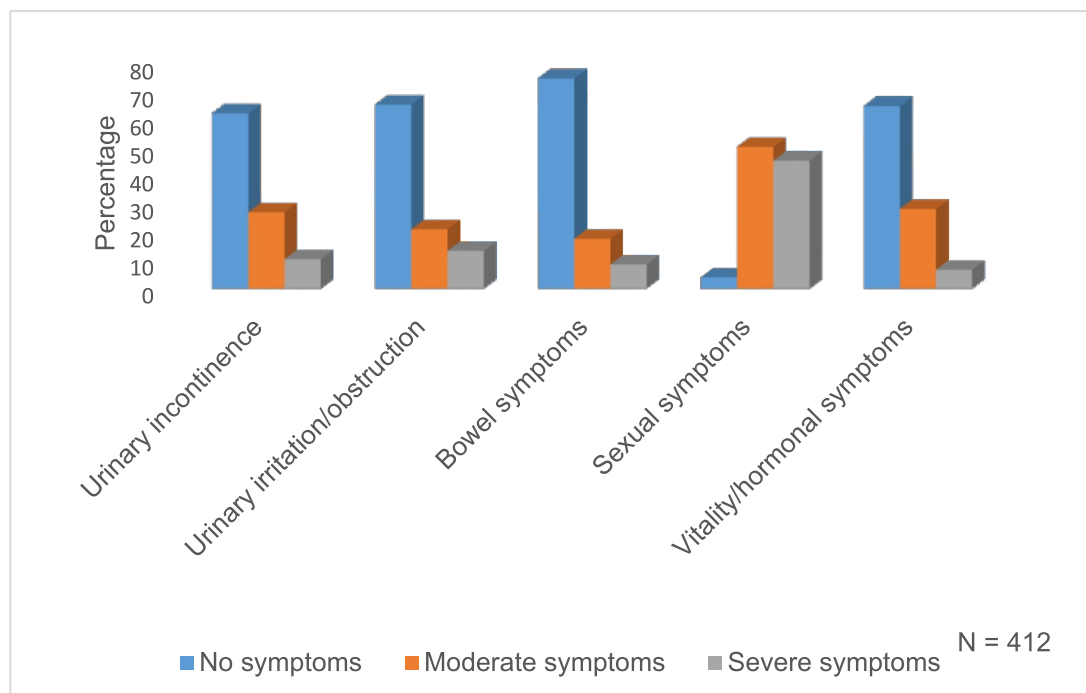
<b>Comorbidities</b>	
Diabetes mellitus	24 (5.8)
Hypertension	30 (7.3)
Asthma	7 (1.7)
Cardiovascular diseases	29 (3.1)
<b>Income (N)</b>	
≤60	35 (8.5)
61 – 90	115 (27.9)
91 – 120	161 (39.1)
121 – 150	101 (24.5)
<b>Mean (SD)</b>	<b>109.3 ± 23.8</b>
<b>Therapy (yrs.)</b>	
< 2	46 (11.1)
2 – 5	197 (47.8)
> 5	169 (41)
<b>Mean (SD)</b>	<b>4.9 ± 2.4</b>

The PSA results showed that only a third of patients achieved the normal level of  $\leq 4$  ng/ml (30%), while those with 5 – 10 ng/ml and 11 – 20 ng/ml constituted 25% and 18.1% respectively. A quarter of patients on therapy still had PSA levels above 30 ng/ml (25.6%) (**Figure 1**).



**Figure 1: Distribution of PSA values**

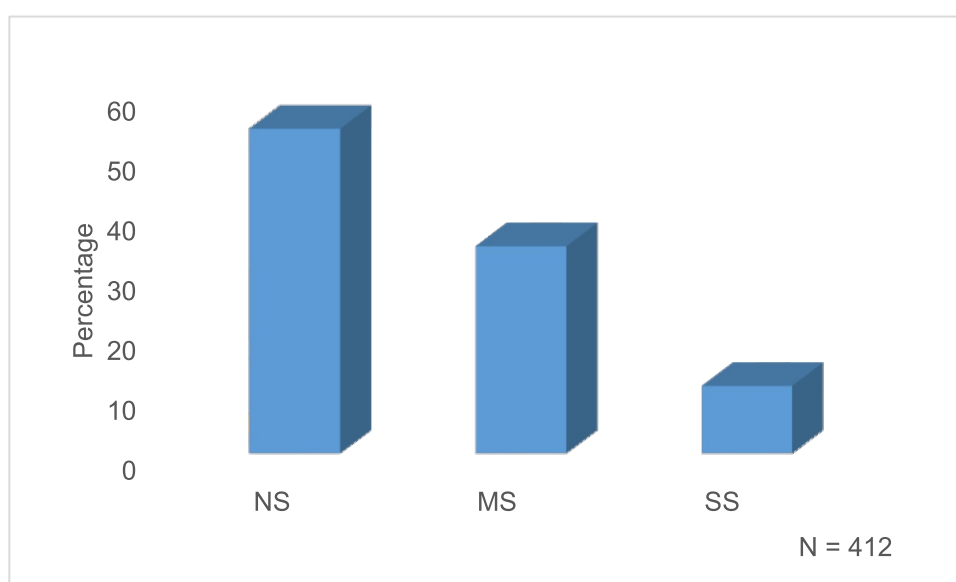
The most frequently encountered symptoms were sexual/erectile dysfunction (96.1%) and vitality/hormonal problems (35%). Other common problems included urinary incontinence (37.6%), urinary obstruction/irritation (34.5%) and bowel symptoms (26.2%) (**Figure 2**).



Key: No symptoms -  $\leq 4$ , moderate symptoms - (5 – 8), severe symptoms - (9 – 12)

Figure 2: Subscale prevalence of symptoms

The results showed that more than half of patients have no clinical symptoms (54.1%), while those with moderate and severe symptoms accounted for 34.6% and 11.3% respectively<sup>53</sup>(Figure 3).

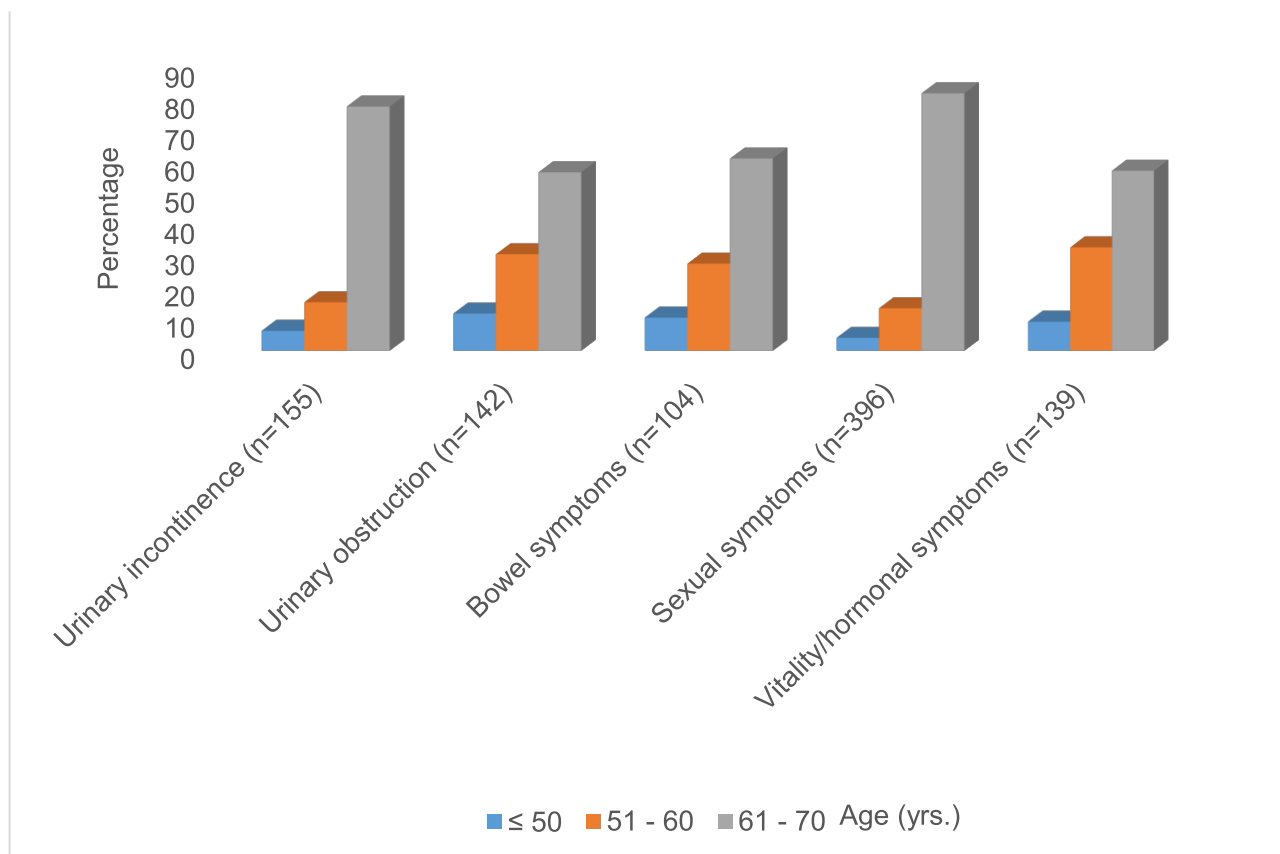


Key: NS – no symptoms, MS – moderate symptoms, SS – severe symptoms

Global score  $\leq 20$  – no symptoms, 21 – 40 – moderate symptoms, 41 – 60 – severe symptoms

**Figure 3:** Severity of clinical symptoms

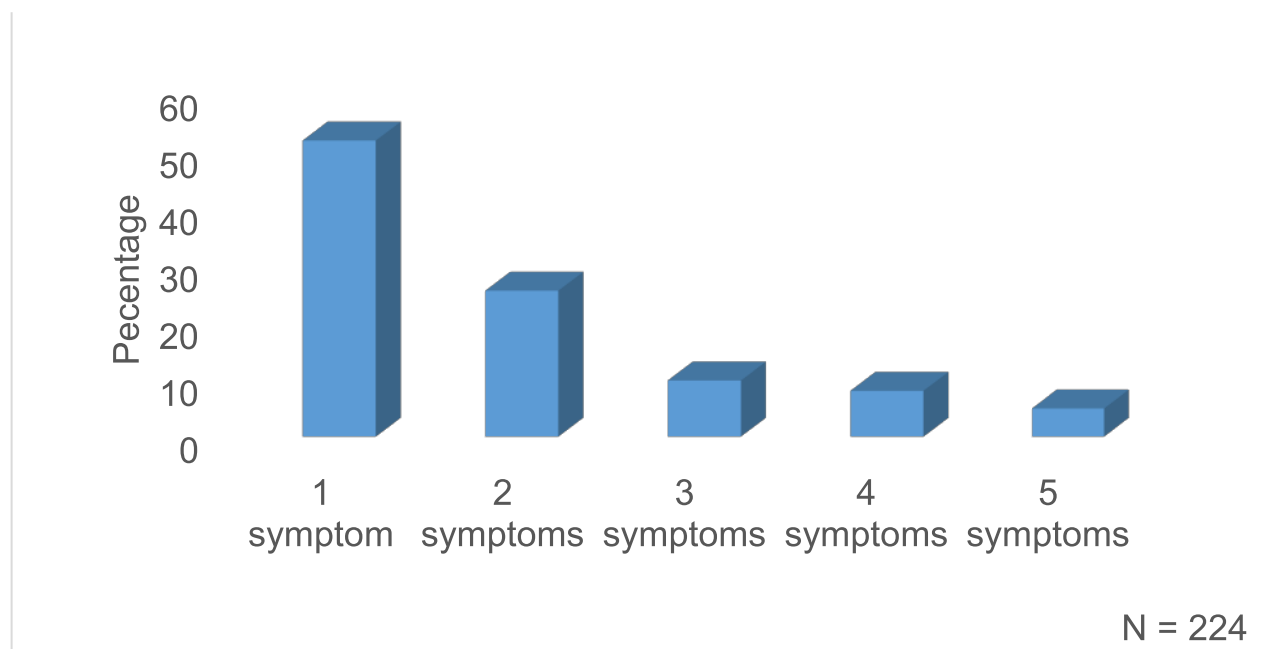
There was increased prevalence of clinically significant symptoms with advancing age. Patients who were  $\leq 50$  years had symptoms prevalence of 4.1 – 11.9% compared to 13.6 – 33.1% (51 – 60-year-olds) and 57.1 – 82.3% among patients over 60 years of age. Sexual symptoms were the most reported (82.3%) compared to urinary incontinence (78.1%), bowel symptoms (61.5%), vitality/hormonal symptoms (57.6%) and urinary obstruction (57.1%). Among 61 – 70 year olds symptoms were more than twice the rates reported among other age groups (**Figure 4**).



Key: Subscale score  $>4$  is clinically significant

**Figure 4:** Distribution of age related clinically significant symptoms

Majority of patients experienced one symptom (51.8%), followed by two symptoms (25.5%) and 4.9% who have symptoms from the five subscales (**Figure 5**).



**Figure 6:** Prevalence symptoms per patient

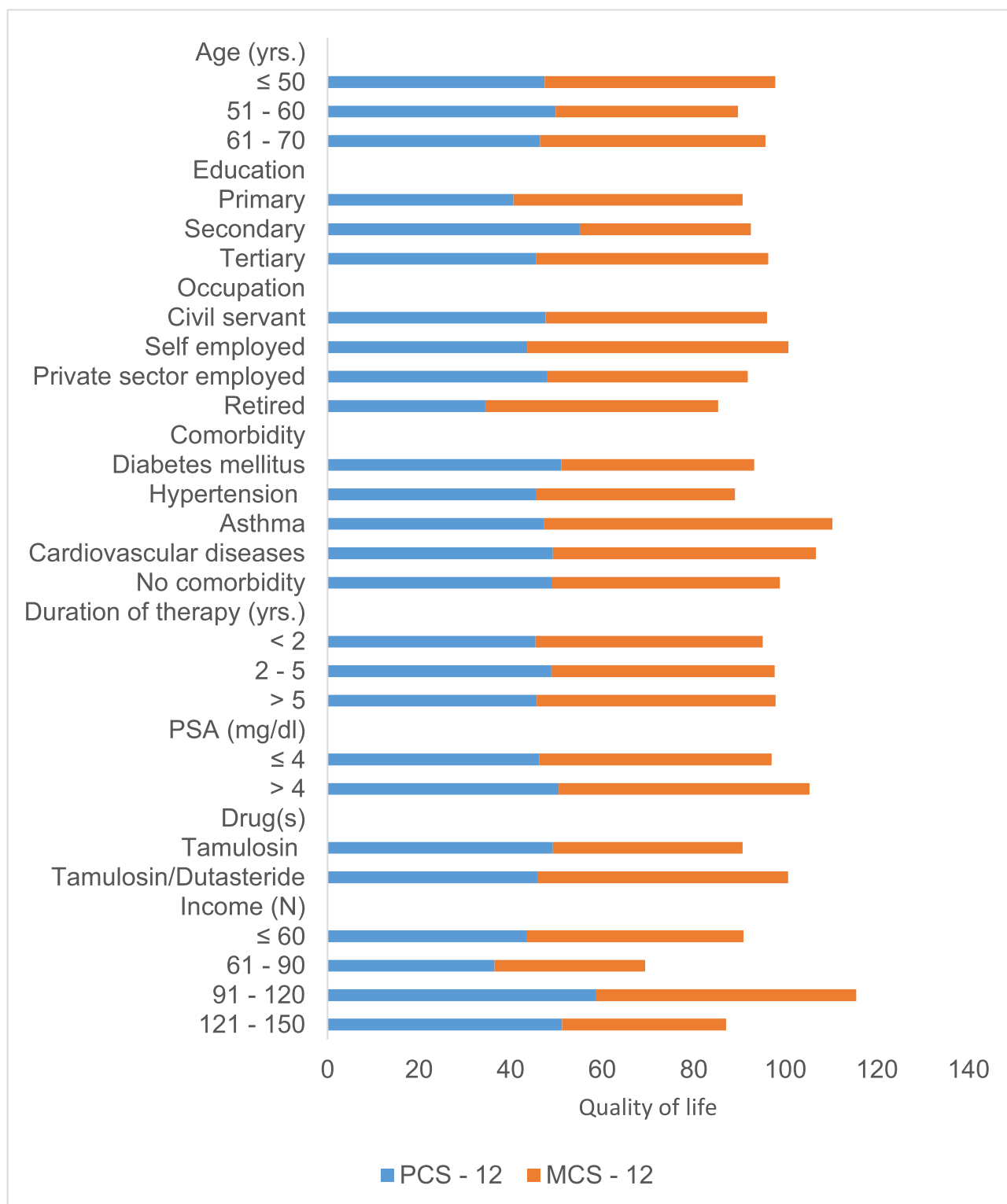
There was significant association between severity of clinical symptoms and advancing age ( $P = 0.042$ ) and PSA level ( $P < 0.001$ ) using subscale score of  $\leq 4$  on EPIC-CP scale to determine the absence of clinically significant symptoms (**Table 2**).

**Table 2:** Association between demographic factors and clinical symptoms

Variable	CSS	CIS	P value
<b>Age (yrs.)</b>			
$\leq 50$	8 (1.9)	15 (3.6)	<b>0.042</b>
51 – 60	24 (5.8)	48 (11.7)	
61 – 70	67 (16.3)	250 (60.7)	
<b>Comorbidity (<math>n = 88</math>)</b>			
Diabetes mellitus	10 (11.4)	12 (13.6)	0.543
Hypertension	16 (18.2)	14 (15.9)	
Asthma	4 (4.5)	3 (3.4)	
Cardiovascular diseases	19 (21.6)	10 (11.4)	
<b>Duration of therapy (yrs.)</b>			
$< 2$	21 (5.1)	25 (6.1)	0.077
2 – 5	68 (16.5)	129 (31.3)	
$> 5$	48 (11.6)	121 (29.4)	
<b>PSA (mg/dl)</b>			
$\leq 4$	69 (16.8)	59 (14.3)	<b>&lt;0.001</b>
$> 4$	87 (21.1)	197 (47.8)	

Key: CIS – clinically insignificant symptoms, CSS – clinically significant symptoms

The physical quality of life was good for patients who earned ninety thousand naira and above (58.2), secondary education (55.1) and those living with diabetes (51.1), while mental quality of life was good for patients living with asthma (63.1), CVD (57.5), self-employed (57.1), Tamulosin/Dutasteride regimen (54.7) and retired (54.5). Overall patients had better mental quality of health compared to physical component (**Figure 6**).



**Figure 6:** Quality of life based on patients variables



There were significant differences in physical and mental components of quality of life related to PSA level ( $p<0.001$ ) and income ( $p<0.001$ ). Physical quality of life significantly differed with level of education ( $p=0.014$ ), comorbidity ( $p<0.001$ ) and duration of therapy ( $p<0.001$ ), while mental quality of life differed with age ( $p=0.014$ ) and drug regimen ( $p<0.001$ ) (Table 3).

**Table 3:** Demographic variables and quality of life

Variable	Number (%)	PCS-12*			P value	MCS**			P value
		Mean (SD)	Min	Max		Mean (SD)	Min	Max	
<b>Age (yrs.)</b>									
≤ 50	23 (5.6)	47.2 (7.2)	29.8	52.4	0.687	50.4 (10.7)	23.3	59.1	0.014**
51 – 60	72 (17.5)	49.7 (4.6)	33.7	61.4		54.1 (8.2)	23.5	62.5	
61 – 70	317 (76.9)	49.2 (5.4)	24.0	63.6		48.9 (11.5)	23.8	67.2	
<b>Education</b>									
Primary	35 (8.5)	54.5 (7.7)	45.7	59.7	0.014**	46.3 (10.2)	28.9	59.1	0.060
Secondary	14 (3.4)	49.2 (5.2)	24.0	63.6		50.1 (10.9)	23.3	67.2	
Tertiary	363 (88.1)	55.1 (5.9)	48.8	61.4		49.7 (11.1)	28.3	67.2	
<b>Occupation</b>									
Civil servant	35 (8.5)	48.4 (8.4)	29.8	61.8	0.734	46.2 (12.7)	23.3	68.9	0.080
Self employed	77 (18.7)	48.3 (4.3)	26.4	52.5		49.2 (10.7)	27.3	60.6	
Private sector employed	12 (2.9)	47.9 (3.6)	44.1	55.3		57.1 (2.1)	53.5	60.7	
Unemployed	7 (1.7)	49.5 (6.2)	24.0	63.6		50.2 (11.0)	23.8	67.2	
Retired	281 (68.2)	49.3 (3.2)	32.3	60.6		49.7 (11.1)	28.3	55.5	
<b>Comorbidity</b>									
Diabetes mellitus	22 (5.3)	51.1 (4.1)	46.4	55.3	<0.001**	57.1 (10.1)	42.0	63.9	0.141
Hypertension	30 (7.3)	44.5 (7.2)	34.9	49.7		42.9 (12.5)	28.3	67.3	
Asthma	7 (1.7)	37.1 (5.3)	28.7	45.6		42.8 (5.2)	39.1	50.1	
Cardiovascular diseases	29 (7.0)	44.5 (7.3)	41.1	47.9		46.5 (11.7)	28.3	67.2	
No comorbidity	324 (78.6)	49.4 (5.2)	24.0	63.6		49.7 (11.1)	25.3	67.2	
<b>Duration of therapy (yrs.)</b>									
< 2	46 (11.2)	47.9 (5.1)	24.0	62.0	<0.001	49.7 (10.2)	23.9	67.2	0.710
2 – 5	197 (47.8)	51.2 (5.3)	36.2	63.2		49.6 (12.1)	23.4	63.9	
> 5	169 (41.0)	45.7 (5.9)	34.9	55.3		52.2 (13.4)	28.3	67.2	
<b>PSA (mg/dl)</b>									
≤ 4	127 (30.8)	46.3 (6.9)	24.0	61.6	<0.001*	39.8 (10.5)	23.8	67.2	<0.001*
> 4	285 (69.2)	50.5 (3.9)	36.2	63.6		54.3 (8.1)	23.3	63.9	
<b>Drug(s)</b>									
Tamulosin	152 (36.9)	43.9 (7.7)	24.6	63.6	0.618*	41.7 (12.3)	24.3	67.2	<0.001*
Tamulosin/Dutasteride	260 (63.9)	49.1 (3.4)	29.8	53.4		54.4 (6.9)	26.6	62.5	
<b>Income (₦)</b>									
≤ 60	35 (8.5)	43.4 (8.7)	22.0	55.3	<0.001**	47.5 (10.6)	28.3	67.2	<0.001**
61 – 90	115 (27.9)	49.9 (7.5)	30.8	63.6		35.4 (8.9)	23.3	56.3	
91 – 120	161 (39.1)	49.3 (2.9)	36.2	60.2		56.4 (4.0)	39.9	63.9	
121 – 150	101 (24.5)	50.2 (2.0)	46.1	52.3		56.3 (1.3)	52.7	58.8	

**Key:** PCS – physical component summary, MCS – mental component summary, \* – students *t* test, \*\* – one way ANOVA

## Discussion

The management of BPH involving drug therapy for patients diagnosed in the early stages of the disease is able to lead to relief of symptoms and reduction in prostate size. However, patients on drug therapies have frequently reported continuing experience with residual symptoms of varying severity<sup>54</sup> and reduction in prostate size<sup>55-57</sup>. The nature and severity of these symptoms and their impact on the quality of life of patients vary widely between studies<sup>36,44,48</sup>. The results of this study showed that clinical symptoms persist in about half of all patients and disproportionately affect older patients above 60 years of age. The most reported symptoms include sexual dysfunction, urinary incontinence/obstruction and hormonal symptoms comparable to previous studies<sup>58-60</sup>.

The prevalence of comorbidities like diabetes mellitus, hypertension and cardiovascular diseases is consistent with previous studies, although wide variations have been reported<sup>61-63</sup>. The widespread prescription of Tamulosin and Tamulosin / Dutasteride combination therapy is comparable to previous studies<sup>64,65</sup> because these drugs have demonstrated remarkable reduction in prostate size<sup>66,67</sup>, reduce clinical symptoms<sup>68,69</sup> and lessen the severity of symptoms<sup>70,71</sup>. While Tamulosin monotherapy is effective in reducing symptoms in the early stages of the disease<sup>69,72</sup>, Tamulosin/Dutasteride combination therapy have shown superiority in the relief of urinary and other clinical symptoms<sup>71,72</sup>.

In spite of concerns about specificity and sensitivity of PSA test as laboratory indicator<sup>74</sup>, it remains widely used in diagnosis and monitoring of therapy either alone or in combination with other methods<sup>75,76</sup>. Drug therapy is expected to reduce plasma PSA level to within normal range, however only a small percentage of patients achieved this target in this study similar to other studies<sup>77</sup>.

While symptoms of urinary incontinence/obstruction were considerably lower than in a similar study<sup>78</sup>, sexual symptoms were widespread among respondents particularly among older patients<sup>79</sup>. The prevalence of symptoms observed in this study are comparable to several studies in Nigeria<sup>80-82</sup>, however contrasting results have been reported<sup>83</sup>. The high variability of residual symptoms may be attributed to differences in study settings, patient characteristics and assessment tool as well as prostate size reduction achieved with therapy<sup>64</sup>.

The high prevalence of clinical symptoms observed in this study among older patients have also been consistently reported<sup>82,83</sup> for which sexual dysfunction is the most prominent complaint of patients<sup>35,79</sup>. While urinary

incontinence/obstruction, bowel and hormonal symptoms were reported by a third of patients in this study, the proportion vary widely between studies<sup>31,63</sup>.

The quality of life among patients was generally poor and within the range reported in other studies<sup>83-85</sup>, although contrasting results have been reported in similar studies<sup>86,87</sup>. The high prevalence of clinically significant symptoms is a major contributor to decline in patient's quality of life<sup>46</sup>. It has been suggested that in the course of therapy patients develop psychological adjustment<sup>35,37,38</sup> to distress from the disease and its associated symptoms, however some impact on emotional wellbeing remain in spite of clinical improvement that may be achieved with drug therapy.

There are several studies that highlighted the psychological impact of "masculine identity threat"<sup>36</sup> caused by sexual dysfunction<sup>30</sup> which adds another layer of distress from interruptions to sexual intimacy and spousal relationships<sup>35,58,79</sup>. In addition, medication side effects<sup>64,66,69</sup>, financial difficulties and unmet emotional needs particularly among the retired may further contribute to stress<sup>39</sup> and poor quality of life<sup>32-34</sup>. The presence of undiagnosed depression<sup>40</sup> is a common occurrence among patients with BPH. The distress from routine laboratory tests, medical procedures and meeting up with physician appointments further compound psychological distress and reduction in quality of life<sup>39</sup>.

Recent studies reported direct association between severity of urinary symptoms<sup>7</sup> and reduced quality of life<sup>83</sup>. Among older patients comorbidities<sup>50,62</sup>, age related frailty<sup>75</sup> negatively affects emotional wellbeing and quality of life<sup>84</sup>. The association between age<sup>7</sup> and PSA level<sup>75</sup> on severity of clinical symptoms observed in this study contrasts with findings from literature<sup>65,84</sup>. While psychological coping mechanism for distress from sexual dysfunction and other clinical symptoms is complex, the impact on quality of life is not in doubt<sup>34-36</sup>.

The relationship between demographic factors and quality of life is not linear<sup>83,88-90</sup>, as educational status<sup>91</sup>, comorbidities<sup>62,91,92</sup>, severity of symptoms and income have unpredictable impact on quality of life<sup>93,94</sup>. There are significant differences in physical and mental quality of life related to age, level of education, comorbidities, duration of therapy, PSA level and income similar to results from similar studies<sup>47-50</sup>. While the interplay between demographic factors and quality of life is highly variable, there is need for patient specific interventions designed to address factors affecting improvement in quality of life in the course of therapy.

**Conclusion:** The high prevalence of clinical symptoms such as erectile dysfunction and urinary incontinence / obstruction remains an ongoing clinical challenge. While the quality of life was generally poor, mental component was comparatively better. There were significant differences in quality of life based on demographic variables; however suboptimal control of symptoms is a major issue that needs to be addressed if better quality of life is to be achieved for patients.

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**Conflict of interest:** The authors declare no conflict of interest

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