

An Analysis of Cases of Benign Prostatic Hyperplasia in a Tertiary Hospital in Eastern Nigeria: Incidence, Treatment, and Cost of Management

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

Background: Benign prostatic hyperplasia (BPH) is one of the most common conditions in aging men. Although BPH is not life threatening, the clinical manifestations such as lower urinary tract symptoms (LUTS) reduce patients' quality of life. BPH is associated with high healthcare costs and is a burden on the patients' families and society.

Objective: To assess the incidence, treatment pattern, and direct cost of management of BPH in a tertiary hospital, in Eastern Nigeria.

Methods: A retrospective descriptive assessment of case notes of patients diagnosed with BPH between September 2017 and August 2019. The treatment pattern was assessed for 12 months. Costs were calculated for BPH-related clinical procedures and medications.

Results: The incidence rate of BPH in this population is 6.7%. One-hundred and two case notes were retrieved and evaluated. About 50.4% of the patients visited the hospital between 2 to 4 times, with a mean visit of 4.4 times a year. Ninety-

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nine percent of the patients received pharmacological interventions, while the combination of alpha blockers and 5-alpha reductase inhibitors was the most frequently prescribed drug therapy for BPH. The total annual direct cost of managing BPH in this healthcare facility is about ₦4,966,080 (Nigerian Naira), an equivalent of \$12,810 USD.

Conclusion: The combination of alpha blockers and 5-alpha reductase inhibitors was the most frequently prescribed drugs for BPH in this facility. Most patients made out-of-pocket payments hence, appropriate treatment options must be selected for each patient in order to prevent complications and reduce costs.

Keywords: Benign prostatic hyperplasia; incidence; direct cost; treatment pattern.

1. INTRODUCTION

Benign Prostatic Hyperplasia (BPH) is characterized by the non-malignant growth of the prostate gland. It commonly occurs in men above 40 years of age. Although almost all men will develop histologic or microscopic evidence of BPH by their eighth decade of life, the condition does not require treatment until it becomes symptomatic [1,2].

The most common presentation of BPH is lower urinary tract symptoms (LUTS) and the condition becomes clinically relevant when it is associated with bothersome LUTS. The enlarged gland is reported to cause lower urinary tract symptoms by direct bladder outlet obstruction from enlarged tissue (static component) and increased smooth muscle tone and resistance within the enlarged gland (dynamic component) [1,2,3]. As the population of ageing men increases, BPH becomes an important public health concern. This disease is associated with high annual healthcare costs and places a considerable financial burden on the patients' families and society [3]. BPH is associated with an increased risk of falls, depression and diminished health-related quality of life based on qualities such as sleep, psychological condition, activities in daily life, and sexual activities [4,5].

The prevalence of BPH as reported in epidemiological studies vary considerably among different populations. In a multinational, community-based study using the IPSS questionnaire, the incidence rates of BPH among men between the ages of 40 years and 79 years were 14%, 18%, 24%, 38%, and 56% in France, Scotland, Sweden, the US and Japan, respectively [6,7].

Another population-based study showed that the incidence rate of BPH detected using the IPSS

questionnaire and abdominal ultrasonography; among Iranian men aged 40 to above 70 years, was 23.8% [8]. Wang *et al.* in 2015 reported a pooled overall prevalence of 36.6% from a meta-analysis on the prevalence of clinical BPH in China [3]. In Nsukka, Eastern Nigeria, a prevalence of 25.3% has been reported, which can be compared to the 23.7% prevalence rate in Ekiti, Western Nigeria [9,10]. Some hospital-based studies however, showed higher prevalence rates of 60-72.2% in Port-Harcourt, Nigeria; 88.8% in Ghana and 23.3% in Saudi Arabia [11-13]. Cross-cultural differences in the perception, poor health seeking behaviour, and/or unwillingness to report urinary symptoms may play an important role in the observed differences in the prevalence of BPH [6].

There are various options available for the management of BPH, these include; "watchful waiting" and/or lifestyle modification, to see if the symptoms would resolve or progressively deteriorate; pharmacologic therapies, complementary and alternative medicines (CAM), or surgical procedures [2]. Medications are generally first line for treatment of LUTS due to BPH [14]. The aim of management is to relieve the symptoms, and importantly the alteration of disease progression and prevention of complications that can be associated with BPH [2].

The cost of management of BPH is on the increase with the high prevalence reported. Various studies have revealed the prevalence of BPH and different treatment modalities in different parts of the world, especially in the developed countries. The true cost of intervention and treatment of BPH is comprised of three components. First, direct costs (drugs, procedures, imaging, office visits), second, indirect costs (lost earnings) and thirdly,

intangible costs (pain and suffering). It has been estimated that BPH treatment costs approximately \$4 billion annually in the United States [15].

In Nigeria not much study has been carried out on the incidence, pattern of treatment, and cost of management of patients with BPH. Data on the treatment pattern and the cost of management of BPH would be a useful tool for health administrators and policy makers. This study was thus aimed at assessing the incidence, treatment pattern as well as the direct costs of management of BPH in Nigeria.

2. METHODS

2.1 Study Design

This was a cross-sectional retrospective and descriptive study using the case notes of patients diagnosed with BPH and receiving clinical care at Federal Medical Centre, Owerri, between September 2017 and August 2019.

2.2 Study Setting

The study was carried out at Federal Medical Centre (FMC) in Owerri, the capital city of Imo state, Eastern Nigeria. The hospital is a 530-bed tertiary health care facility. It is a major referral healthcare facility with various medical specialties, including urology. The hospital primarily provides tertiary healthcare services to residents within and outside the state.

2.3 Eligibility Criteria and Sample Size Determination

The case notes of adult male patients aged forty years and above diagnosed with benign prostatic hyperplasia at the urology department of the hospital during the period of the study (September 2017 to August 2019) were selected and used for the study. The case notes of patients who were diagnosed of prostate cancer, as well as those who did not attend clinic appointments for the management of BPH for at least one year were not included in the study.

Sample size was determined using the formula:

$$n = \frac{Z^2 pq}{d^2} [16]$$

Where: n = minimum sample size; Z = normal standard deviation set at 1.96 corresponding to

95% confidence level; p = expected prevalence rate (68%) [11]; q = 1-p (1-0.68 = 0.32); d = margin of error (0.05).

2.4 Data Collection

The record of patients diagnosed and treated for BPH in the hospital within the period under review, September 2017 to August 2019, was obtained from the clinic attendance register at the medical records unit of the urology department of the hospital. Patient case notes were retrieved from the medical records department of the hospital. Data extracted from the case notes of eligible patients included demographic characteristics, social habits, patients' co-morbidities, screening and diagnostic investigations and procedures, drug utilization and treatment pattern, documented adverse drug effects, and disease complications.

To determine treatment pattern for BPH in the hospital, the frequency of hospital visits within 12 months was calculated for each patient, the drugs prescribed, and the duration of therapy was obtained. Data on patients who underwent surgical interventions, as well as patients who presented at the accident and emergency (A&E) unit of the hospital on account of BPH related complications were also collected.

The frequency of BPH-related medical services and costs were determined. The current costs of laboratory investigations, surgical procedures, clinical consultations, and other services rendered in the hospital were obtained. The total medication cost per patient was also estimated. The duration of drug therapy was calculated based on the total number of days the medication was prescribed for each patient. The actual cost of drugs dispensed to each patient within the study period was calculated as a product of average number of days dispensed (number of visit) and the cost of medication. These costs were estimated on the assumption that the patients purchased their medications only from the hospital pharmacy after each hospital visit.

2.5 Data Analysis

Data was analysed using Statistical Package and Service Solutions (SPSS) Version 20.0. Frequencies and mean were used to summarize descriptive statistics. The analysis conducted was descriptive in nature only, no modelling or adjustments were made in our estimates.

2.6 Ethical Clearance

Ethical approval was obtained from the Health Research Ethics Committee of the Federal Medical Centre, Owerri, after a thorough review of the study protocol.

3. RESULTS

3.1 Demographics Characteristics

There was a total of 8,497 patient visits to the urology out-patient clinic within the period under review, out of which 3951 of them were BPH related. This comprised of both old and new patients. Based on clinical examination, five hundred and seventy-three (573) new BPH patients were recorded with an incidence rate of BPH of 6.7% (67 per 1000 persons).

A total of 103 case notes of patients retrieved were eligible and form the basis of this report. The mean age of the study population was 68.0 ± 9.5 (median, 69 years); with an age range of 42-96 years. Persons aged 61-70 years accounted for about 40.8% of the sample. Majority of the patients were retirees (45.7%) while 24% were self-employed.

3.2 Hospital Visits and Presentation

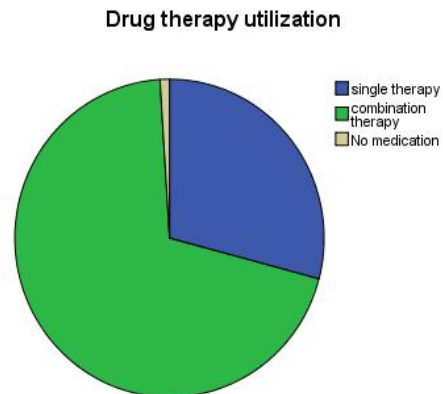
The mean frequency of clinic visits by the patients was 4.4± 1.8. Fourteen patients (13.6%) visited the urology clinic twice in a 12-month period, while 24 patients (23.3%) visited 3 times and another 24 (23.3%) visited 4 times with a mean of 4.4 visits over 12 months per patient. About 25.2% of the patients visited the clinics between 5 - 6 times, while about 14.5% of the patients visited the clinic more than 6 times. Seventy-four patients (71.4%) presented at the urology out-patient department of the hospital. The most common symptoms were lower urinary tract symptoms suggestive of BPH. The symptoms included but not limited to dysuria, urinary frequency, urgency with or without incontinence, nocturia, urinary hesitancy and poor stream. A summary of the hospital presentation, medical co-morbidity and clinical intervention given, and payment plan is presented in Table 1 below.

Frequently reported symptoms resulting in emergency department visitations were acute urinary retention AUR, recurrent urinary tract infection, chronic urinary retention, haematuria, and other BPH related complications. Seven patients (6.8%) had to undergo surgical

procedures during treatment, out of which five of them were TURP and two had open prostatectomy.

3.3 Pattern of Drug Utilization

The management of benign prostatic hyperplasia was either pharmacological or non-pharmacological. Patients were switched from either a monotherapy of alpha blocker or a combination of an alpha blocker and a 5-alpha reductase inhibitor depending on the clinical presentation and the response to medical treatment. The combination of alpha blocker (tamsulosin) and 5-alpha reductase inhibitor (finasteride, dutasteride) were the most frequently prescribed drug therapy. A total of 72 (69.9%) patients had at one point received both medications. However, 30 patients (29.1%) received only an alpha blocker (tamsulosin) during the study period.



The average number of therapy days was 84.5 days (of 365 possible days during follow-up) for patients on tamsulosin, while 75.7 days and 83.6 days for patients taking tamsulosin/finasteride and tamsulosin/dutasteride combination respectively. Other alpha blockers prescribed were alfuzosin (2, 1.9%) and terazocin (1,1%). The muscarinic receptor antagonist (or anticholinergics) tolterodine was prescribed for 21 (20.4%) patients while oxybutynin was prescribed for one patient. Antibiotics such as quinolones (59, 57.2%) and nitrofurantoin (37, 35.9%) was also prescribed frequently for catheterized patients and those diagnosed with urinary tract infections. The total cost of alpha blocker (tamsulosin alone) prescribed was ₦523,400 (\$1342), while the total cost of alpha blockers and 5alpha reductase inhibitors prescribed was ₦1,614,140 (\$4140).

Table 1. Hospital and clinical presentation

Characteristics	Frequency (%)	Mean \pm Std Dev
Number of hospital visits per year		
2-4	52 (50.4)	4.4 \pm 1.8
5-7	36 (35.0)	
8-10	15(14.6)	
Hospital presentation		
Out-patient department	74 (71.8)	
Accident and emergency	29 (28.2)	
Interventions		
Non-pharmacological (watchful waiting)	1 (1.0)	
Pharmacological	102 (99.0)	
Surgery (TURP, Prostatectomy)	7(6.8)	
Medical co-morbidities		
Hypertension	48(46.6)	
Diabetes mellitus	10(9.7)	
UTI	33(32.0)	
Erectile dysfunction	8 (7.8)	
Peptic ulcer disease	3 (2.9)	
COPD	2 (1.9)	
Other urethral/urinary tract disorders	6 (5.8)	
HIV	2(1.9)	
Haemorrhoids	3(2.9)	
Payment plan		
NHIS	5(4.9)	
Out-of-pocket	98(95.1)	

(TURP, Transurethral resection of the prostate; UTI, Urinary tract infection; COPD, Chronic obstructive pulmonary disease; HIV Human immunodeficiency virus; NHIS, National Health Insurance Scheme)

Table 2. Pattern of drug utilization

Drugs	No of Patients (%)	Total Duration (days)	Mean	Std Deviation	Total costs ₦
Alpha blocker					
Tamsulosin alone	30 (29.1)	2536	84.51	44.362	523,400
Alpha blocker +5alphaRI					
Tamsulosin+Finasteride	55 (53.4)	4165	75.73	58.148	749,700
Tamsulosin+Dutasteride	17 (16.5)	1421	83.59	38.058	341,040
Alfluxocin	2 (1.90)	84	42.00	19.79899	30,240
Terazocin	1 (0.97)	28	28.00	-	6,700
Tolteridine	21 (20.4)	514	24.48	21.53513	308,400
Oxybutinin	1 (0.97)	28	28.00	-	2,800
Levofloxacin	28 (27.2)	334	11.93	3.05418	80,160
Ofloxacin	12(11.6)	150	12.50	4.90825	13,500
Ciprofloxacin	19(18.4)	201	10.58	5.54092	20,100
Nitrofurantoin	37(35.9)	617	16.68	15.27171	27,770
Metronidazole	15 (14.6)	52	0.40	6.06630	1,900
Tinidazole	5 (4.9)	62	12.40	5.41295	11,160
Cefixime	3 (2.9)	25	8.33	2.88675	9,000
Doxycycline	1(0.97)	21	21.00	-	1,260

Table 3. Patients' expenditure on diagnostic screening and monitoring tests/ procedures

Laboratory Investigations/ Procedures	Number of patients	Percentage (%)	Number of procedures	Total Cost (₦)
PSA	102	99.0	125	437,500
S/E/U/Cr	101	98.1	110	275,000
FBC/differentials	95	92.2	105	210,000
Urine analysis	94	91.3	96	48,000
Urine m/c/s	93	90.3	100	100,000
HbsAg/HCV	20	19.4	20	24,000
ECG	22	21.4	22	22,000
Chest xray	22	21.4	22	44,000
Fasting blood sugar	26	25.2	27	13,500
Retroviral screening	45	43.7	47	23,850
Abdomino-pelvic scan	84	81.6	86	172,000
TRUS	53	51.5	54	216,000
Prostate biopsy	27	26.2	27	1,026,000
Total				2,611,850

(PSA, prostate specific antigen; FBC, full blood count; SEUCr, serum electrolyte urea and creatinine; HbsAg/HCV Hepatitis B surface antigen and Hepatitis C virus tests; ECG, electrocardiogram, TRUS, transrectal ultrasonography)

Table 4. Total annual cost of bph management

Intervention	Cost per month -₦	Days dispensed	Annual cost per patient	Total cost ₦
Medication Cost				
Tamsulosin	3,600	4399	43,200	523,400
Tamsulosin+finasteride	5,400	4165	64,800	749,700
Tamsulosin+Dutasteride	7,140	1421	85,680	341,040
Other alpha blockers				37,440
Antimicrobials				164,850
Anticholinergics				311,200
Total medication costs				2,127,630
Consultation cost			2,200	226,600
Diagnostic test/procedures				2,611,850
Grand total				4,966,080

3.4 Diagnostic Screening and Monitoring Tests/Procedures

The most common diagnostic screening and monitoring test was the Prostate-Specific Antigen (PSA) test. Overall, 102(99%) patients received one or more PSA test over 12 months of follow-up. Another common laboratory investigation among patients was the serum, electrolyte, urea and creatinine (S/E/U/Cr) test. This was carried out in 101(98.1%) patients. Table 3 presents the various diagnostic screening and monitoring tests/procedures carried out by the patients within the period of the study and the estimated cost of the procedures.

4. DISCUSSION

We sought to assess the incidence of BPH in Federal Medical Centre, Owerri. We found 573

cases of LUTS/BPH, with an estimated incidence of 6.7%. The overall incidence of BPH was found to be 15 cases per 1000-man years in the Triumph project carried out in Netherlands with a sample population of 80,774 male patients [17]. Another survey in Korea reported an incidence of 21.05 per 1000 patients [18]. The reported incidence rate of BPH in different populations can vary due to the difference in the criteria used in determining the condition and a difference in size of the population studied.

The prevalence of BPH was highest among males aged 61-70 years, accounting for nearly 41% of the sample size. A similar observation was reported in a systematic review on the prevalence of BPH in China which found 44% of BPH in males aged 60-69 years [3]. Also, Wang and his colleagues also reported the highest prevalence of BPH to be about 69% in the 80

years and above age group and 2.9% in 40-49 years age group. However, there was a decrease in number of patients aged above 70 years in this study. This may be due to the socio-economic status of this patient population, as most of them are retirees, lacking sufficient funds to seek proper medical attention.

The average number of hospital visits was 4.4 visits per patient in 12 months. About half of the patients visited the hospital 2 to 4 times annually. This is in contrast with a report in the US where 66.2% of the patients visited their primary care physician at least once and 36.2 % had at least 1 visit to a urologist in a 12-month follow-up period (average 1.9 visits per patient over 12 months) [19]. Twenty-eight patients (27.2%) presented once, while 3 patients (2.9%) presented twice at the emergency department of hospital. On the contrary, 10.5% of patients in a study carried out in the U.S had at least one emergency visit while on treatment [19]. The relatively high number of visits to FMC Owerri, a tertiary healthcare facility as observed in this study may be as a result of the poor state of the primary health care system in Nigeria. Research reports suggest that men with bothersome symptoms and moderate to severe LUTS are more likely to visit the hospital and seek medical attention than those with mild symptoms [20, 21].

In our study, 99% of the patients were on various medications for BPH, while alpha blockers (tamsulosin) were the most prescribed medication. Our finding is in line with previous reports [18, 22]. About 71% of patients had received a combination of alpha blockers and 5 alpha reductase inhibitors. Roehrborn *et al.* observed that patients who received combination therapy showed improvement in LUTS and quality of life as well as BPH progression at two years [23].

However, some of the patients on combination therapy were at some point switched to a monotherapy of alpha blocker depending on the clinical presentation. This could be explained by the dynamic nature of the symptoms [18]. A combined therapy in the management of BPH has been shown to be beneficial to the patient, however it comes with the disadvantages of increased adverse effect and cost which could be a burden for this class of elderly patients [24]. Nearly 46% of them are retirees who have irregular income and were dependent on their children and/or relatives to meet their healthcare needs.

The cost of alpha blocker was ₦3600 (\$10) per month while that of a combination was ₦5400 (\$15) and ₦7140(\$19.8) per month for either the tamsulosin/finasteride and tamsulosin/dutasteride combination therapy, respectively. The higher cost of the combination therapy could have contributed to the reduced mean days the patients were on medication. The mean number of days on medication was calculated to be 84.5 days for patients on tamsulosin monotherapy (alpha blocker) while 75.7 and 83.6 days for patients on tamsulosin/finasteride and tamsulosin/dutasteride (AB and 5-ARI) combination respectively. This cannot be compared with other studies with mean days on medication of 230 for alpha blockers and 260 for 5-ARIs. This could be related to the fact that 98% of the patients who visited the hospital in this study made out-of-pocket payments as they were not under any health insurance cover. This is unlike other studies done in developed countries where majority of the patients were under different healthcare plans [18, 19].

The frequency of reported side effects by patients in our study was low (8.9%). Some of the side effects reported include dizziness, headache and erectile dysfunction. This is similar to findings in other studies [19, 24, 25]. The low incidence of side effect may be due to the lack of awareness of reporting and documentation of adverse drug effects among healthcare professionals. The patients on the other hand may not be able to associate the symptoms they experience to the drugs they were receiving at that time hence the poor reports. Erectile dysfunction was one of the major adverse effects found among BPH patients, with a prevalence of 3.9% in this study. Similarly, in a previous study carried out in Southwestern Nigeria, patients had to withdraw from the study as a result of erectile dysfunction [25]. However, other researchers have argued that sexual dysfunction is related to BPH and is independent of drugs, age, and other co-morbidities like hypertension and diabetes [19, 26].

As expected, the prostate-specific antigen (PSA) test was the most common screening test carried out by the patients. Ninety-nine percent of the patients carried out the PSA test. The PSA test is usually carried out to monitor and predict the disease progression as well as to rule out prostate cancer. A raised PSA value amongst other presentations was as an indication for prostate biopsy for patients in this study.

The use of surgical interventions in this study was relatively limited (6.8%). Other studies carried out in the U.S and Brazil also reported same, with associated high cost for these procedures [18, 19]. The rate of complications after surgical treatment was high in this study with reports of acute urinary retention, haematuria, and urinary tract infection (UTI). This was in line with reports by Black *et al.*, in 2006, who observed high rate of UTI, AUR and surgical re-treatment with an added mean cost of \$1888 among patients with surgical procedure [19].

Majority of BPH patients are retirees or approaching the retirement age, the finances to cater for their healthcare needs may not be sufficient. Policy makers and all stakeholders must ensure that more persons are enrolled under the available health insurance schemes in the country in other to cater for the cost associated with BPH management.

5. CONCLUSION

The incidence rate of BPH in FMC Owerri was 6.7%. Almost all the patients received pharmacological interventions with the combination of alpha blockers and 5-alpha reductase inhibitors being the most frequently prescribed drug therapy for BPH. The total annual direct cost of managing BPH in this healthcare facility is about ₦4,966,080 (Nigerian Naira), an equivalent of \$12,810 USD. Majority of the patients made out-of-pocket payments for the healthcare services they received, hence there is a need for extension of health insurance for more BPH patients considering the rising healthcare costs.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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