

# Evaluation of Medication Adherence and Quality of Life in Patients with Benign Prostatic Hyperplasia

**Dr. Swetha Narayan<sup>1</sup>, Dr. Divya Jyothi S<sup>2</sup>, Dr. MI Rahman<sup>3\*</sup>,  
Dr. Chetak Raghavan<sup>4</sup>, Dr. Shivakumar Babu<sup>5</sup>**

<sup>1,2,3,4</sup>Pharm.D, Department of Pharmacy Practice, Acharya & BM Reddy College of Pharmacy, Bengaluru, Karnataka

<sup>5</sup>Professor & Head, Department of Urology, ESIC MC-PGIMSR Model Hospital, Bengaluru, Karnataka

\*Corresponding Author: Dr. MI Rahman

## ABSTRACT

Benign Prostatic Hyperplasia (BPH) is a non-malignant enlargement of the prostate gland that surrounds the urethra, leading to lower urinary tract symptoms (LUTS) such as nocturia, urgency, frequency, and incomplete bladder emptying. These symptoms result from urethral compression and bladder outlet obstruction, which, if left untreated, can lead to complications including acute urinary retention, bladder stones, urinary tract infections, and renal impairment. This study aimed to evaluate the relationship between medication adherence and quality of life among patients diagnosed with BPH. An observational study was conducted among 101 outpatients from the Department of Urology, ESI PGIMSR and Model Hospital, Rajajinagar, Bengaluru. Data were collected using validated questionnaires: the SF-36 for assessing quality of life and the Medication Adherence Rating Scale (MARS) for evaluating adherence levels. Demographic data were analyzed using descriptive statistics, and the association between medication adherence and quality of life was examined using Spearman's rho correlation analysis in SPSS version 24. The majority of patients were within the age group of 60–69 years. The correlation analysis revealed a statistically significant positive relationship ( $P = 0.040$ ) between medication adherence and quality of life, suggesting that patients with higher adherence to their prescribed therapy experienced better quality of life outcomes. The study concludes that improving medication adherence plays a crucial role in enhancing the overall well-being and clinical outcomes of patients with BPH, emphasizing the importance of patient education and continuous follow-up to optimize treatment benefits.

**KEYWORDS:** Benign Prostatic Hyperplasia, Quality of life, Medication adherence, Silodosin, Dutasteride.

## INTRODUCTION:

Benign Prostatic Hyperplasia (BPH) is a non-malignant enlargement of the prostate gland that commonly affects aging men. It results from hyperplasia of stromal and epithelial cells within the prostate transition zone, leading to urethral constriction and subsequent Lower Urinary Tract Symptoms (LUTS) such as

nocturia, urgency, frequency, and weak urine stream. Although benign, untreated BPH may lead to acute urinary retention, urinary tract infections, bladder stones, or renal insufficiency. The prevalence of BPH increases with age, affecting about one-quarter of men in their 50s, one-third in their 60s, and nearly half of those aged 80 and above. <sup>(1,2,3)</sup>

BPH, also known as Benign Prostatic Enlargement (BPE), is characterized by a non-cancerous overgrowth of prostatic tissue surrounding the urethra, causing bladder outlet obstruction and LUTS. BPE refers to the enlarged size of the gland, LUTS to the urinary abnormalities, and bladder outlet obstruction to the blockage of urine flow. BPH primarily occurs due to the proliferation of stromal and epithelial cells in the prostate transition zone. If left untreated, it can result in serious complications such as Acute Urinary Retention (AUR), bladder stones, urinary tract infections, and renal failure. <sup>(1,2,3)</sup>

Age plays a major role in the development of BPH and LUTS (1). Studies indicate that the prevalence of BPH reaches 70% among men aged 60–69 years and over 80% in men older than 70 years in the United States. A meta-analysis in mainland China (1989–2014) reported prevalence rates among men aged  $\geq 40$  years as follows: 2.9% (40–49 years), 29.0% (50–59 years), 44.7% (60–69 years), 58.1% (70–79 years), and 69.2% ( $\geq 80$  years). Western men tend to have larger prostate volumes than those in Southeast Asia; however, Indian men exhibit higher mean International Prostate Symptom Scores (IPSS) despite smaller prostate sizes. <sup>(2)</sup>

The exact cause of BPH remains unclear. It primarily affects men above 40 years of age. Hormonal imbalance—specifically, decreased serum testosterone and increased intraprostatic estrogen—stimulates prostate cell proliferation. Elevated dihydrotestosterone (DHT) levels also promote stromal and epithelial cell growth within the prostate. Furthermore, an imbalance between apoptosis and cellular proliferation contributes to prostatic enlargement <sup>(2,5)</sup>.

The development of BPH is influenced by modifiable and non-modifiable factors. Non-modifiable factors include age, genetics, and geography, whereas modifiable factors include hormonal changes (testosterone, DHT, estrogen), metabolic syndrome, obesity, diabetes mellitus, diet, inflammation, and physical inactivity. Key contributors include diabetes, diet, obesity, metabolic syndrome, and chronic inflammation. Dietary factors such as high alcohol or caffeine intake and excessive vitamin C may worsen symptoms, whereas vitamin A and carotenoids may have protective effects. Twin studies have demonstrated higher concordance rates for LUTS among monozygotic twins, indicating a genetic component. Chronic inflammation contributes to BPH pathogenesis, and daily NSAID use has been associated with reduced LUTS and prostate volume. Obesity and metabolic syndrome are associated with increased prostate size and LUTS severity, likely through hormonal and inflammatory pathways. <sup>(2,6,7)</sup>

Prostate growth and function are regulated by testosterone and its active metabolite dihydrotestosterone (DHT) under the control of the hypothalamic–pituitary–testicular axis. Testosterone acts as a pro-hormone and is converted to DHT via the enzyme  $5\alpha$ -reductase. DHT binds to androgen receptors, promoting expression of growth-related genes in coordination with insulin-like growth factors (IGF). The effects of DHT can be inhibited by  $5\alpha$ -reductase inhibitors such as finasteride and dutasteride, while metformin may antagonize IGF effects. Prostate enlargement compresses the urethra and obstructs bladder outflow, causing increased detrusor pressure and incomplete bladder emptying. Although BPH may elevate PSA levels, it is not a precursor to prostate cancer, as BPH occurs in the transitional zone while malignancies arise in the peripheral zone. <sup>(2,6,7)</sup>

Common symptoms include frequent or urgent urination, nocturia, weak or intermittent urine stream, dribbling, and incomplete bladder emptying. Less common symptoms include urinary tract infections,

hematuria, and urinary retention. Severity of symptoms does not always correlate with prostate size. Untreated BPH can rarely lead to renal impairment or complete urinary obstruction. <sup>(4,8)</sup>

Early diagnosis prevents complications such as urinary infections and renal damage and helps distinguish BPH from prostate cancer. Diagnostic methods include symptom questionnaires, urine flow tests, Digital Rectal Examination (DRE), PSA testing, cystoscopy, transrectal or transabdominal ultrasound, MRI, and urodynamic studies. These tests help evaluate prostate size, obstruction, and bladder function. <sup>(2,9,10)</sup>

The management of BPH aims to relieve symptoms and prevent disease progression. Pharmacological therapy includes alpha-blockers such as Tamsulosin (0.4–0.8 mg) and Silodosin (4–8 mg), which improve urine flow by relaxing smooth muscles but may cause dizziness or hypotension; 5 $\alpha$ -reductase inhibitors such as Finasteride (5 mg) and Dutasteride (10 mg), which reduce prostate size by inhibiting DHT formation but may cause erectile dysfunction and fatigue; and phosphodiesterase-5 inhibitors such as Tadalafil (5 mg), which help alleviate LUTS and improve erectile function. <sup>(11,12)</sup>

Surgical interventions are indicated for patients unresponsive to medication or with complications such as recurrent urinary retention, infections, or renal impairment. Common procedures include Transurethral Resection of the Prostate (TURP), Holmium Laser Enucleation, Prostatic Urethral Lift, and Water Vapor Therapy. <sup>(12)</sup>

BPH is a highly prevalent condition among aging men, influenced by hormonal, genetic, and metabolic factors. Early detection and timely management are crucial to prevent complications and maintain urinary function. Understanding the hormonal and inflammatory mechanisms underlying BPH may aid in the development of more targeted and effective treatment strategies. <sup>(1,12)</sup>

## **MATERIALS & METHODOLOGY:**

The study was conducted in the Department of Urology, ESI PGIMS, Rajajinagar, Bangalore. This was an Observational study carried out for a period of 6 months, in out-patients visiting urology department of the hospital.

**SAMPLE SIZE:** A total of 101 subjects fulfilling the inclusion and exclusion criteria were included in the study.

The sample size was determined using the formulae-

$$N = Z^2 * P * (1-P) / m^2$$

where, Z = Z value=1.96 ; P = prevalence ; M = margin of error=5% (0.05) ; confidence interval =95%

Therefore, the Sample size (N) was found to be 101.

## **STUDY CRITERIA:**

### **1. INCLUSION CRITERIA:**

- a. Patients of male gender above 40 years old diagnosed with BPH.
- b. Outpatients visiting the department of Urology
- c. Patients willing to participate and provide informed consent.

### **2. EXCLUSION CRITERIA:**

- a. Patients with chronic co-morbidities.
- b. Excluded patients with Surgical Co-morbidities

## **SOURCE OF DATA:**

- Patient case sheet (Medical profile form).
- One to one interview with the patients.

### STUDY TOOLS:

- a. MEDICATION ADHERENCE RATING SCALE (MARS) for assessing Medication Adherence in the patients.
- b. 36 ITEM SHORT FORM SURVEY (SF-36) is used to assess the patient's Quality of Life.

### STUDY PROCEDURE

- The study was conducted after obtaining approval from the IEC.
- Subjects for the study were identified by the investigator by conducting a hospital visit based on the inclusion and exclusion criteria.
- The purpose of the study was explained to the participants and their consent was obtained.
- Relevant data was recorded on the data collection form.
- All the data obtained were entered into a Microsoft excel sheet and the appropriate analysis was performed.

### STATISTICAL ANALYSIS:

All recorded data were entered and analyzed using MS Excel for determining for the statistically significant. Descriptive statistics were computed for quantitative variables and frequencies and percentages were calculated for categorical values. Column charts, pie-charts, bar graphs were made to find the nature of data distribution. Spearman's correlation analysis was applied to the data to find the association between the Medication Adherence and Quality of Life of the patient.

### RESULTS

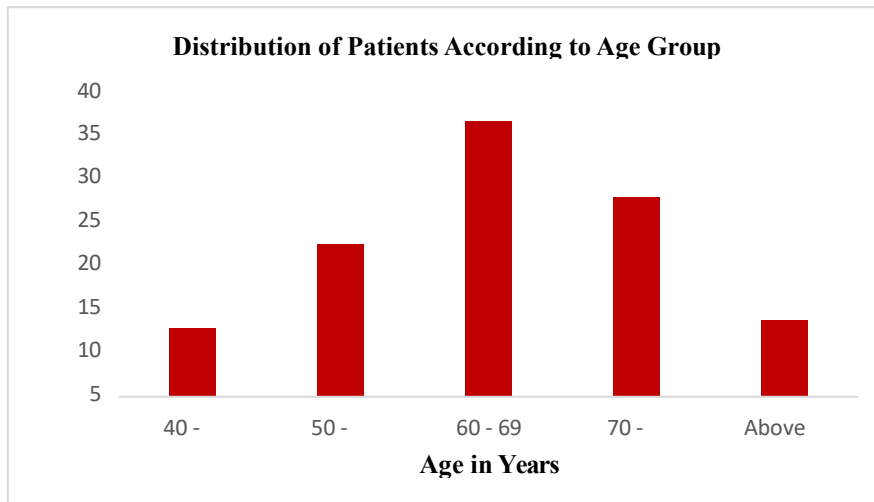
The study was conducted in the department of Urology, ESI hospital, Rajajinagar, Bengaluru, during the year 2024 for a period of 3 months. A total of 101 patients who satisfied the inclusion and exclusion criteria were included in the study.

### DISTRIBUTION OF PATIENTS BY AGE

Out of 101 patients, the majority of patients were from the age group of 60 – 69 (35.6%).

Distribution of Patients based on Age Group		
Age Group	Number of Patients	Percentage
40 - 49	9	8.9
50 - 59	20	19.8
60 – 69	36	35.6
70 – 79	26	25.7
Above 80	10	9.9

**Table 1: Distribution of Patients according to Age group**



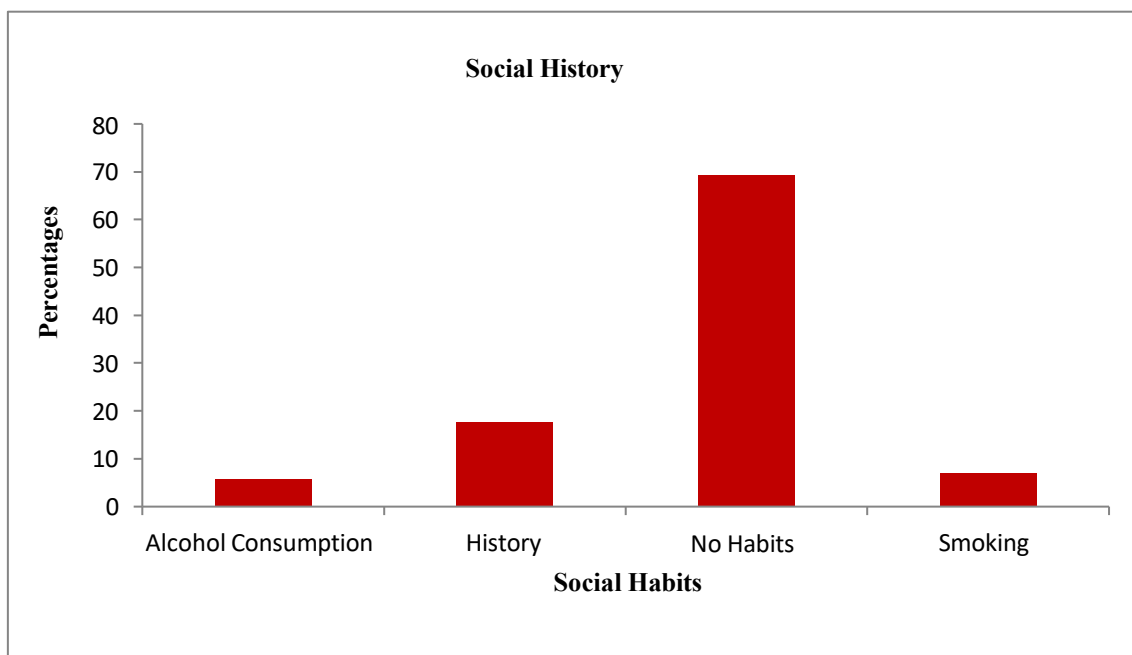
**Figure 1: Distribution of Patients according to Age group**

**DISTRIBUTION OF PATIENTS ON BASIS OF SOCIAL HISTORY**

Out of 101 patients, the majority of 70(69.3%) patients did not have any Social habits.

Distribution of Patients based on Social History		
Habits	Number of patients	Percentage
Alcohol Consumption	6	5.9 %
History of smoking and drinking	18	17.8 %
No Habits	70	69.3 %
Smoking	7	6.9 %

**Table 2: Distribution of patients on social history**



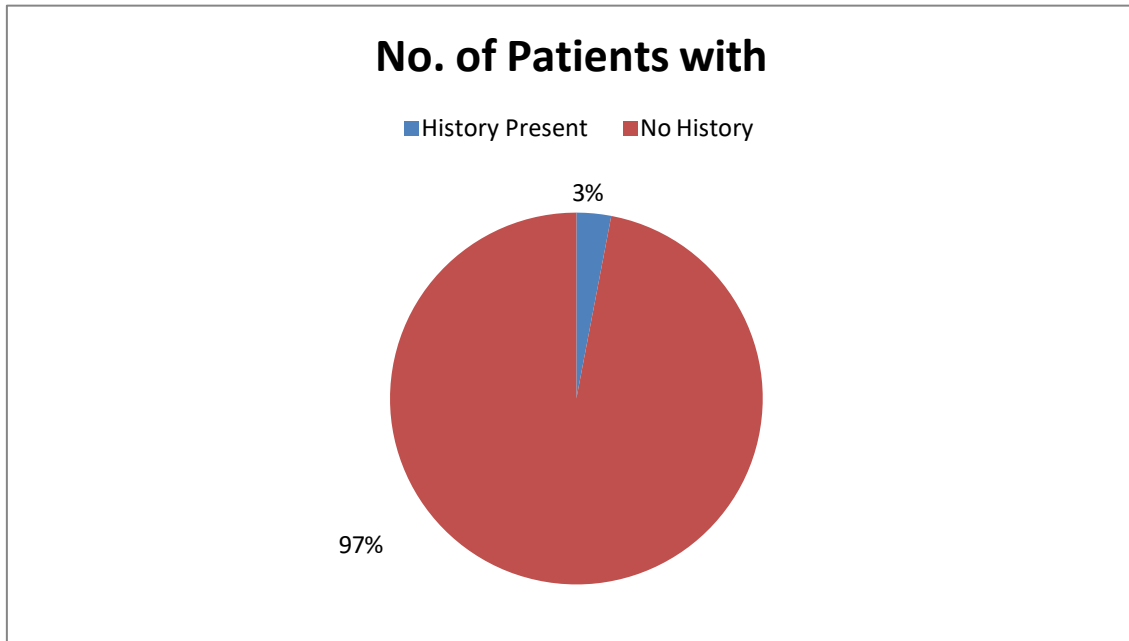
**Figure 2: Distribution of Patients according to Social History**

**DISTRIBUTION OF PATIENTS ACCORDING TO FAMILY HISTORY**

Out of 101 patients, the majority of 98 patients (97%) patients had no family history of BPH.

Distribution of Patients According to Family History		
Family History	Number of Patients	Percentage
History Present	3	3 %
No History	98	97 %

**Table 3: Distribution of patients on basis of Family history**



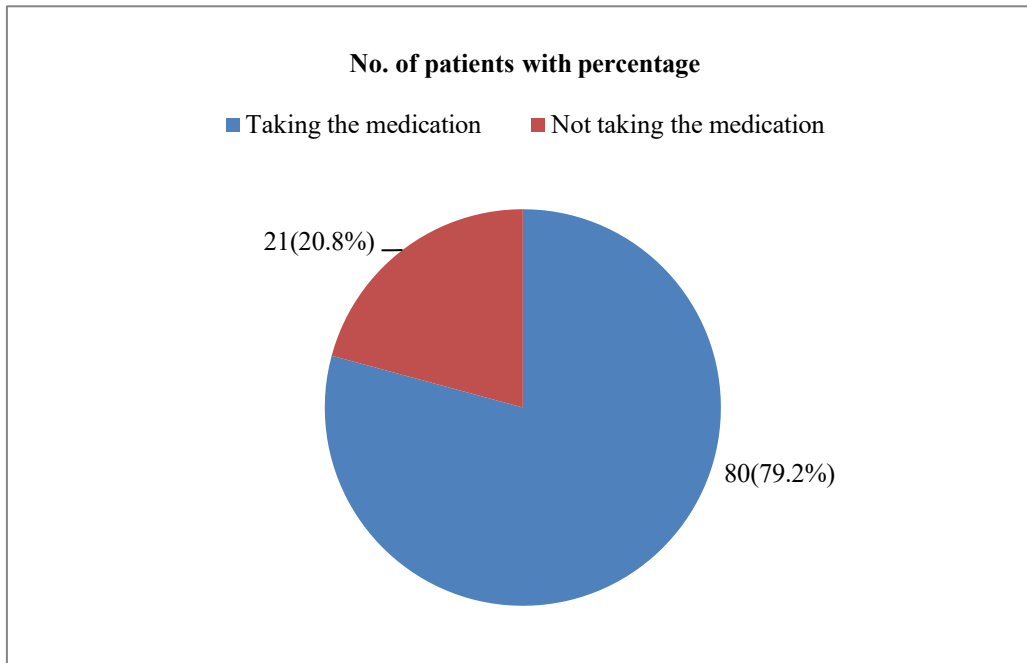
**Figure 3: Distribution of Patients According to Family History**

**DISTRIBUTION OF PATIENTS ACCORDING TO COMORBIDITIES**

Out of 101 patients the majority of 50 (49.5 %) had no co morbidities, 23 patients (22.8 %) had hypertension and 11 patients (10.9%) had diabetes.

Distribution of Patients According to Co – morbidities		
Disease	Number of Patients	Percentage
CVS	4	4%
DM	19	18.8
Fatty Liver	1	1%
HTN	23	22.8%
HYS	1	1%
No diseases	50	49.5%
Phi	1	1%
Renal Calculi	1	1%
UTI	1	1%

**Table 4: Distribution of patients with Co-morbidities**



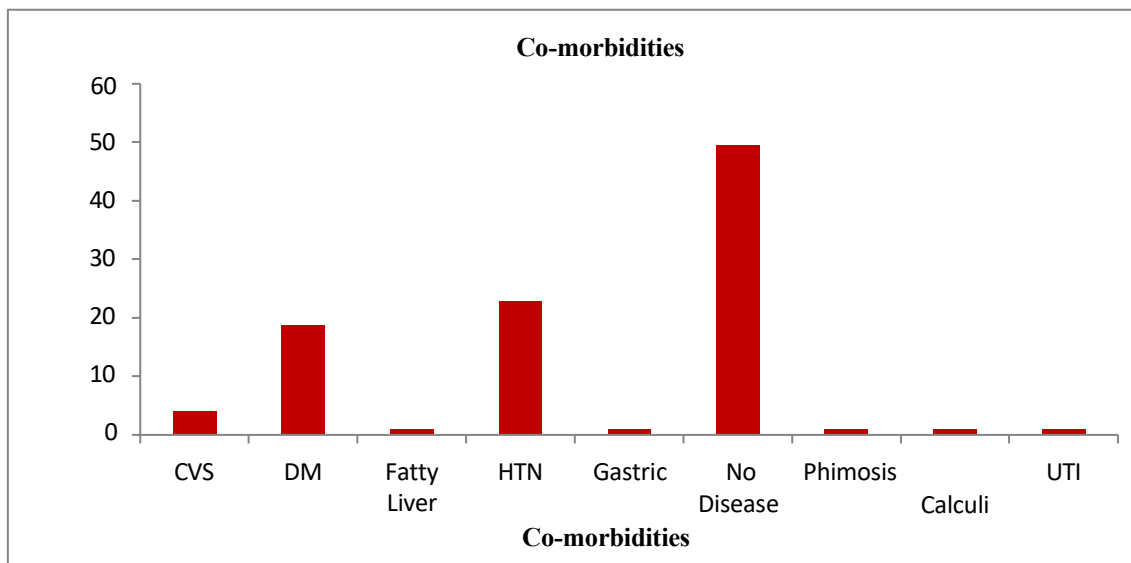
**Figure 4: Distribution of Patients According to Co-morbidities**

**DISTRIBUTION OF PATIENTS BASED ON INTAKE OF TABLET SILODOSIN AND DUTASTERIDE COMBINATION**

Out of 101 Patients 21 (20.8%) were not taking this medication and 80 (79.2%) were taking this medication.

Distribution of patients based on taking the tablet Silodosin and Dutasteride		
Medication History	No. of Patients	Percentage
Taking the medication	80	79.2
Not taking the medication	21	20.8

**Table 5: Distribution of patients based on intake of tablet Silodosin and Dutasteride**



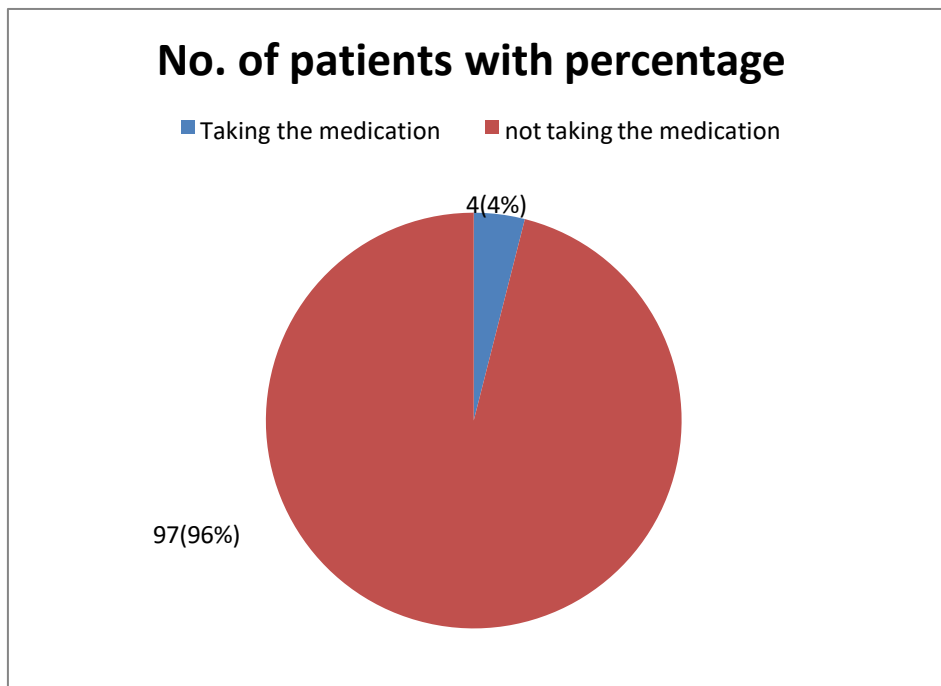
**Figure 5: Distribution of patients based on taking the tablet Silodosin and Dutasteride**

**DISTRIBUTION OF PATIENTS BASED ON INTAKE OF TABLET ALFUZOSIN AND DUTASTERIDE COMBINATION**

Out of 101 Patients 97(96.0%) were not taking this medication and 4 (4.0%) were taking this medication.

Distribution of patients based on taking the tablet Alfuzosin and Dutasteride		
Medication History	No. of Patients	Percentage
Taking the medication	4	4.0
Not taking the medication	97	96.0

**Table 6: Distribution of patients based on intake of tablet Alfuzosin and Dutasteride**



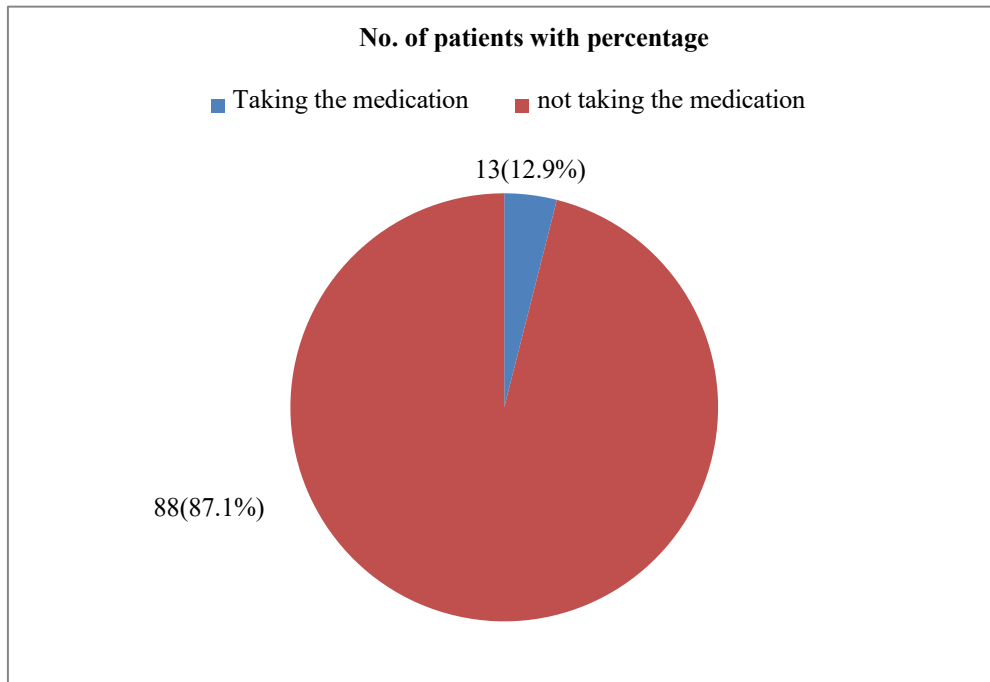
**Figure 6: Distribution of patients based on taking the tablet Alfuzosin and Dutasteride**

**DISTRIBUTION OF PATIENTS BASED ON INTAKE OF TABLET TAMSULOSIN AND DUTASTERIDE COMBINATION**

Out of 101 Patients 88 (87.1%) were not taking this medication and 13(12.9%) were taking this medication.

Distribution of patients based on taking the tablet Tamsulosin and Dutasteride		
Medication History	No. of Patients	Percentage
Taking the medication	13	12.9
Not taking the medication	88	87.1

**Table 7: Distribution of patients based on intake of tablet Tamsulosin and Dutasteride**



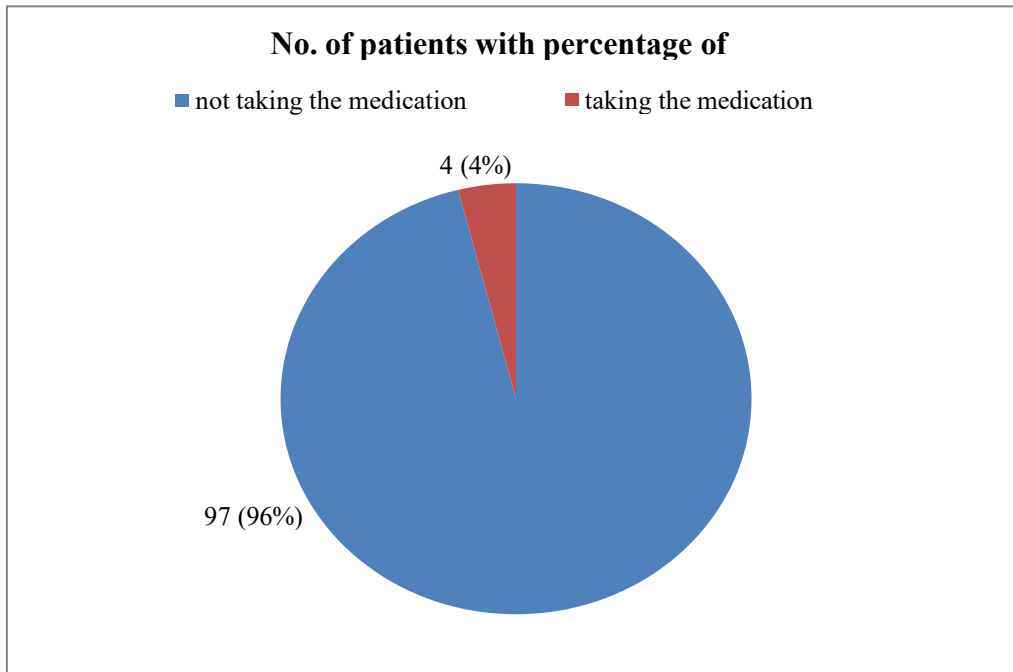
**Figure 7: Distribution of patients based on taking the tablet Tamsulosin and Dutasteride**

**DISTRIBUTION OF PATIENTS BASED ON INTAKE OF TABLET TAMSULOSIN**

Out of 101 patients 97 (96.0%) were not taking this medication and 4 (4.0%) takes the medication.

Distribution of patients based on taking the tablet Tamsulosin		
Medication History	No. of patients	Percentage
Not Taking the medication	97	96.0%
Taking the medication	4	4.0%

**Table 8: Distribution of patients based on intake of tablet Tamsulosin**



**Figure 8: Distribution of patients based on taking the tablet Tamsulosin**

**DISTRIBUTION OF PATIENTS BASED ON INTAKE OF TABLET MIRABEGRON & SILODOSIN COMBINATION**

Out of 101 patients 89 (88.1%) were not taking this medication and 12 (11.9%) takes the medication.

Distribution of patients based on taking the tablet Mirabegron & Silodosin		
Medication History	No. of patients	Percentage
Not Taking the medication	89	88.1%
Taking the medication	12	11.9%

**Table 9: Distribution of patients based on intake of tablet Mirabegron & Silodosin**

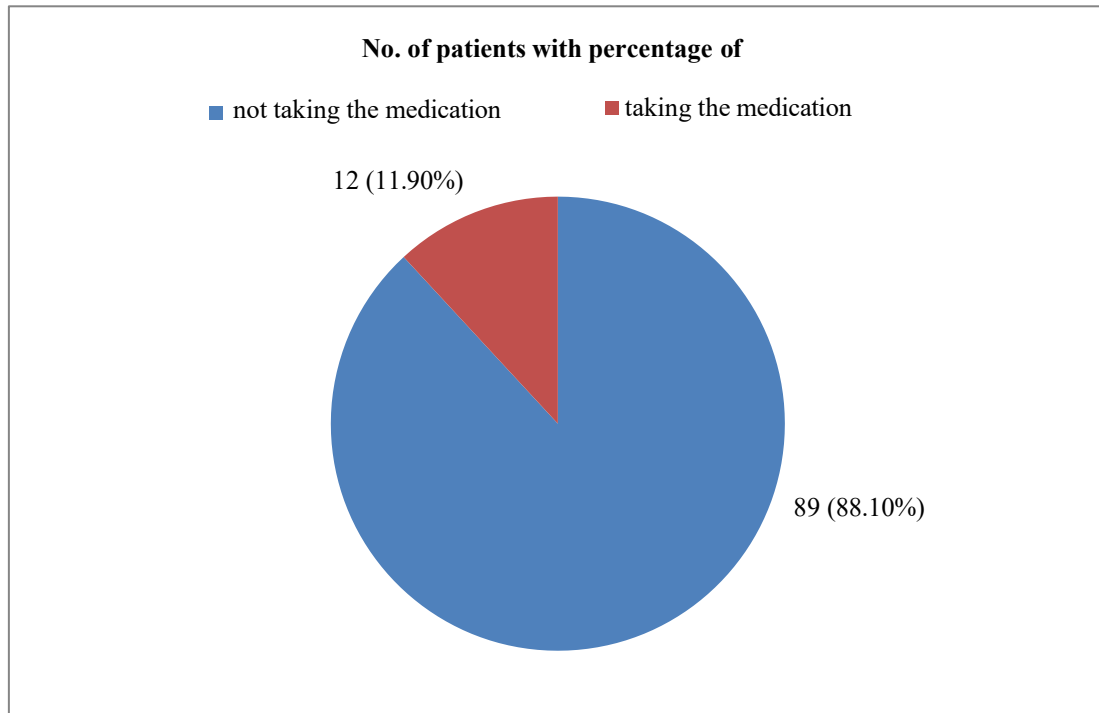


Figure 9: Distribution of patients based on taking the tablet Mirabegron & Silodosin

**MEDICATION ADHERENCE AND QUALITY OF LIFE**

Correlations			
		MARS Scoring	SF 36
Spearman's rho	MARS Scoring	1.000	0.204
		0.0	0.040
		101	101

Table 10: Correlation between Medication adherence and Quality of life

The data was studied using the Spearman’s rho (correlation coefficient) between MARS Scoring and SF 36 and it is 0.204. This indicates a weak positive correlation between the variables. As mars scores increase SF scores increase since r value is 0.204 which is positively correlated and it is significant (p value=0.040) The p-value associated with this correlation is 0.040, which suggests the result is statistically significant at the 5% significance level (since p<0.05).

**DISCUSSION**

This Study was a 6 month long observational study that was conducted in the department of Urology at ESIC- MC&PGIMSR, Rajaji Nagar, Bengaluru. The study was conducted to evaluate medication adherence and quality of life in patients diagnosed with BPH visiting the outpatient department of Urology. Based on inclusion and exclusion criteria, a total of 101 patients were included in this study.

Our study categorized patients based on the age starting from 40 years, which was comparable with the study conducted by Wang et al., (August 2015). Maximum number of patients diagnosed with BPH came under the age range of 60-69 (35.6%) whereas it was above 80 years (69.2%) of age in case of the study compared. <sup>(13)</sup>

In our study, combination of Silodosin and Dutasteride were the primary choice to treat BPH, which was in line with the study conducted by Manjula.S et al., (2024).<sup>(14)</sup>

Majority of the studies including ours and the one conducted by Erkoc Mbet al., (2018) used SF-36 as a tool to find the quality of life of patients with BPH.<sup>(15)</sup>

Our study showed a positive correlation which was evident between Medication Adherence and Quality of Life, which was comparable with many studies conducted Worldwide including the one conducted by Hu Zhang et al (August 2020).<sup>(16)</sup>

## CONCLUSION

Our study aimed to evaluate medication adherence and quality of life in patients diagnosed with BPH visiting the outpatient department of urology at a teaching hospital in Bengaluru, and the study subjects consisted of patients who met inclusion and exclusion criteria. Majority of the patients were prescribed with Silodosin and Dutasteride combination for treating BPH. The study showed a positive correlation between Medication Adherence and Quality Of life which was found out using Spearman's rho correlation analysis.

In nutshell, the more the Adherence towards Medicines betters the Quality of Life.

## ACKNOWLEDGEMENT

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