

# A Prospective Comparative Study To Evaluate Improvement In Lower Urinary Tract Symptoms With Tamsulosin And Dutasteride Combination Therapy In Patients With Benign Prostatic Hyperplasia And To Evaluate The Impact Of Patient Counselling On Quality Of Life Of Patients

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## ABSTRACT

### AIM AND OBJECTIVES

The Aim of this study is to evaluate improvement in lower urinary tract symptoms using tamsulosin and dutasteride combination therapy in patients with Benign Prostatic Hyperplasia and to evaluate the impact of patient counselling on quality of life and medication adherence among patients.

**MATERIALS AND METHODS:** A Prospective observational study was conducted in a total of 60 BPH patients. The patient satisfaction in improvement in LUTS on treatment with tamsulosin and dutasteride combination therapy was assessed with IPSS Score scale. Data was collected by using a suitably designed proforma, International Prostate Symptom Score (IPSS) for assessing severity of symptoms, IPSS Q8 and BPH impact index for assessing quality of life, Morisky Green Levin scale (MGL) for medication adherence. At the end of the study, all the parameters and scores were compared with baseline.

**RESULTS & DISCUSSION:** A total of 60 patients with BPH along with Lower urinary tract symptoms fulfilled the study criteria were included. Improvement in LUTS by using Tamsulosin + Dutasteride combination therapy were assessed with IPSS scores. Most of them have improvement in their voiding symptoms than storage symptoms by using combination therapy. Medication adherence were also assessed in these patients

**CONCLUSION:** Patient satisfaction on voiding symptoms was more improved than storage

symptoms using Tamsulosin and Dutasteride combination therapy and it is a better drug of choice. Also, it was found that patient counselling can cause a greater impact on improving patients's quality of life and medication adherence.

## I. INTRODUCTION

Lower urinary tract symptoms (LUTS) related to benign prostatic obstruction (BPO) is one of the most common condition in middle age or old men. LUTS is a common disorder in men, affecting up to 52% of men between the age of 40 and 70 years

BPH is a complex disease and is often associated with LUTS which include nocturia, urgency, urinary frequency, UTI and benign prostatic obstruction

BPH with LUTS is a chronic condition which is potentially progressive. This progression include an increase in prostate volume, deterioration in LUTS and maximum increase in urine flow rate (QMAX), increased risk of acute urinary retention (AUR) and BPH related surgery and a deterioration of BPH related quality of life. Prevalence and severity of LUTS in the aging male can be progressive and is an important diagnosis in the health care of patients and society. The recommended test in the diagnosis of BPH are digital rectal examination, IPSS scoring, creatinine measurement/renal ultrasound, uroflowmetry and post voidal residual urine volume.

The aim of the treatment is to evaluate the improvement in lower urinary tract symptoms and impact of patient counselling on quality of life of patients

Alpha blockers and 5 alpha reductase inhibitors alone or in combination are the mostly prescribed drugs to manage patients with LUTS and BPH. Alpha blockers are usually the first line treatment for LUTS because of the rapid onset of action by antagonising alpha adrenergic receptors in prostate and urethra, they causes smooth muscle relaxation in lower urinary tract and hence decreases the functional obstruction

Patient satisfaction is an indicator of safety of the drug, relative incidence of adverse effects and it indirectly help us to measure the patient compliance towards medication regimen. Patient counselling on BPH is fundamental to promote rational drug use and to improve their dietary and life style habits. The purpose of the study is to find out improvement in LUTS using tamsulosin and dutasteride combination and to assess the impact of patient counselling on their perception and practice of disease, quality of life and medication adherence.

## II. METHODOLOGY

A Prospective observational study was conducted in patients who were diagnosed with BPH and shows LUTS. The study period was 6 months after getting clearance from ethical committee. The study was conducted in Urology Department of Cosmopolitan Hospital, PG Institute of Health Science and research, in Thiruvananthapuram kerala

### Inclusion Criteria

- BPH patients who are willing to participate in the study from OP setting.
- Patients who are not a candidate for surgery

### Exclusion Criteria

- Patients not willing for the study and a candidate for surgery.
- Complications of BPH like hematuria, UTI, stone...
- Patients who are contraindicated to tamsulosin and dutasteride
- History of lower urinary tract

malignancy/pelvic surgery.

- Neurological conditions causing bladder dysfunction, hepato-renal insufficiency

### Statistical Analysis

- The collected data on study variables from samples were subjected to analysis using appropriate statistical methods. The mean and standard deviation were used as descriptive statistics to summarise the raw data collected.
- For data entry we had used the software Microsoft excel and all the analysis were carried out with the help of statistical software SPSS v.22 version for WINDOWS.
- For between group comparisons, based on each study parameters, independent sample t test has been applied. For within group comparisons, based on each study variables, paired t test has been used.
- The normality assumption of the data was verified by Kolmogorov – Smirnov test ( $P < 0.05$ ). A calculated P value less than 0.05 is considered to be significant.

## III. OBSERVATIONS AND RESULTS

The proposed study entitled “A Prospective Study to evaluate improvement in lower urinary tract symptoms with tamsulosin and dutasteride combination Therapy in patients with Benign Prostate Hyperplasia and to evaluate the Impact of patient Counseling on quality of life of Patients” was a prospective study carried out in a multispecialty tertiary care hospital. In our study we analyzed the data collected from 60 patients with Benign Prostate Hyperplasia at Urology department. This study aimed to assess the comparative patient satisfaction with Tamsulosin and dutasteride combination therapy and to evaluate the impact of counseling on QoL and Medication adherence among patients with Benign Prostate Hyperplasia.

### DEMOGRAPHIC DETAILS OF THE PATIENTS

In this section, the data relating to demographic details of the patients were collected and the calculated frequencies and percentages are reported.

**DISTRIBUTION OF BPH PATIENTS BASED ON AGE**

**Table 1: Frequency and percentage distribution of total number of patients**

The distribution of total number of patients based on age have been shown on the following table :

Age in years	Frequency	Percent
≤ 60	8	13.3
61 - 70	27	45
71 - 80	16	26.7
>80	9	15
Total	60	100

Average age of the study population was 68.95±8.78 and age ranges from 50 to 85 years

From the table it was observed that out of 60 patients 8(13.3%) were below 60 years of

age,27(45%) patients were in between 61-70 years ,16(26.7%) were in between 71-80 years,9(15%) were above 80 years of age .Thus we found that more than 25 patients attended the urology OPD belong to the age group of 61-70 yrs.

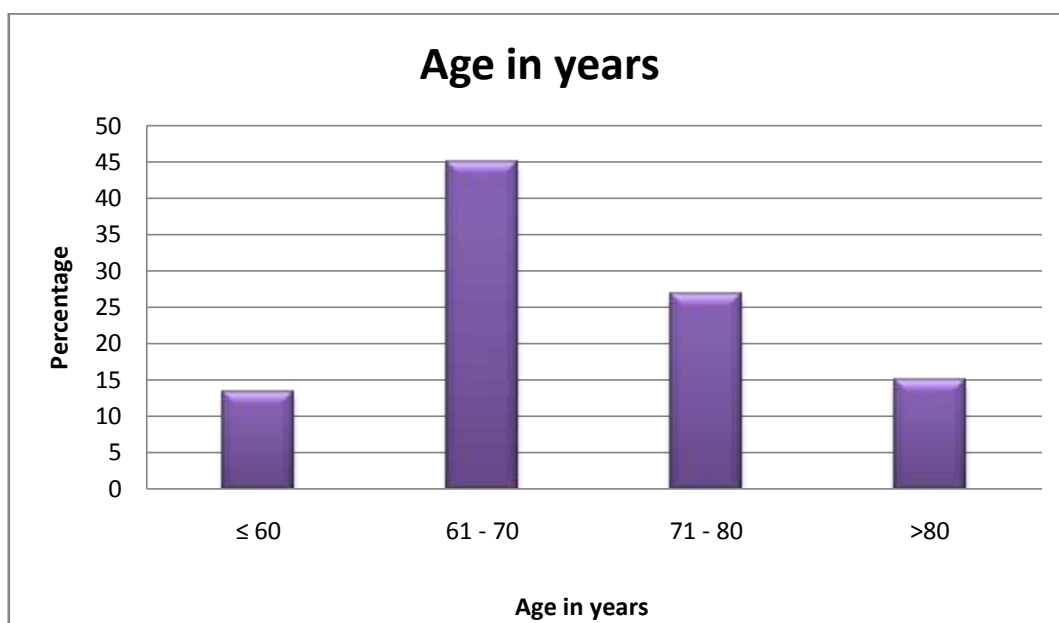


Figure 1: Graphical representation of percentage distribution of total number of patients based on age

**DISTRIBUTION OF BPH PATIENTS BASED ON QUALIFICATION**

**Table 2: Frequency and percentage distribution of patients based on qualification**

The distribution of patients based on qualification have been shown on the following table:

Qualification	Frequency	Percent
High school	23	38.3
Higher secondary	21	35
Graduate	12	20
Post graduate	4	6.7
Total	60	100

From table 2 ,it was observed that out of 60 patients 23(38.3%) have high school qualification,21(35%) have higher secondary as qualification ,12(20%) were graduates ,4(6.7%)

were post graduates.We found that most of the patients attended the urology OP had only high school qualification.

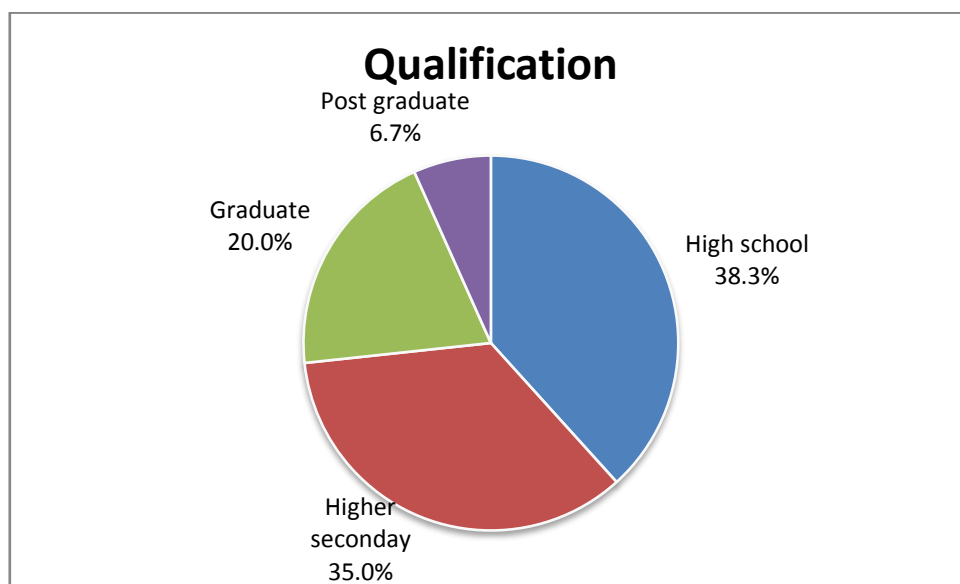


Figure 2: Diagramatic representation of total number of patients based on qualification

### DISTRIBUTION OF BPH PATIENTS BASED ON OCCUPATION

The distribution of total patients based on on occupation have been shown on the following table:

**Table 3:Frequency and percentage distribution of total number of patients based on occupation**

Occupation	Frequency	Percent
Govt. employee	9	15
Manual labour	18	30
Selfemployee	15	25
Business man	10	16.7
Private employee	8	13.3
Total	60	100

From table 3, it was observed that out of 60 patients ,9(15%) were govt employee,18(30%) were manual labour,15(25%) were self

employee,10(16.7%) were buisness man ,8(13.3%) were private employee.We found that mostly manual labours attended the urology OPD.

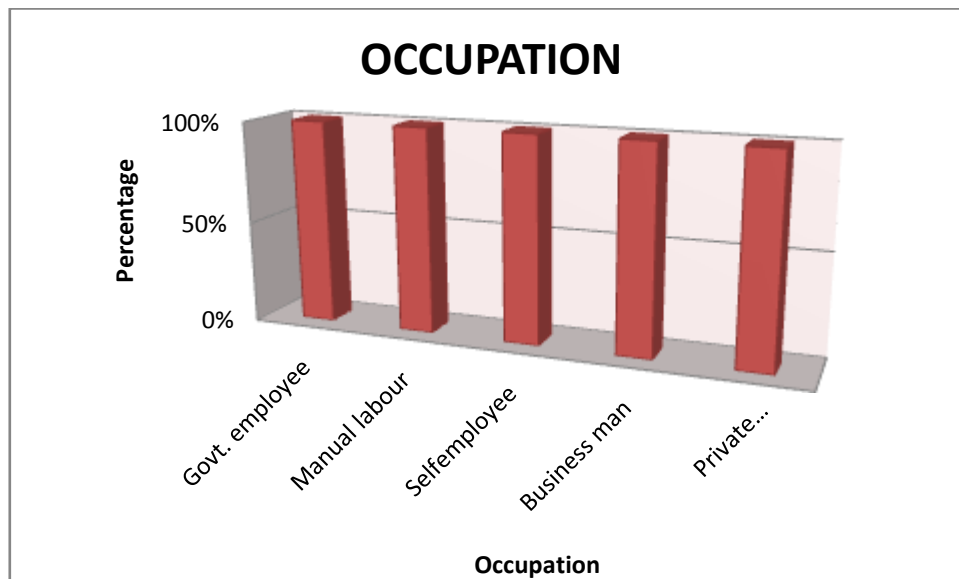


Figure 3 :Graphical representation of percentage distribution of total number o patients based on occupation

### DISTRIBUTION OF PATIENTS BASED ON SYMPTOMS

The distribution of total number of patients based on symptoms have been shown on the folowing table:

**Table 4:Frequency and percentage distribution of total number of patients based on symptoms**

Symptoms	Frequency	Percent
Nocturia	38	63.3

Dysuria	16	26.7
Incomplete urination	26	43.3
Incontinece	16	26.7
Weak urine stream	13	21.7
Dribbling	7	11.7
Urinary urgency	35	58.3
Haematuria	10	16.7
Delayed urinary	7	11.7
Fever	4	6.7
Abdominal pain	10	16.7

From table 4, it was observed that out of 60 patients 38(63.3%) patients had nocturia, 16(26.7%) patient had dysuria, 26(43.3%) patients had incomplete urination, 16(26.7%) patients had incontinence, 13(21.7%) had weak urine stream, 7(11.7%) patients had dribbling, 35(58.3%) had

urinary urgency, 10(16.7%) had haematuria, 7(11.7%) had delay in urine, 4(6.7%) had fever, 10(16.7%) had abdominal pain. We found that most of the patient who were attended the urology OPD must have nocturia as a main symptom.

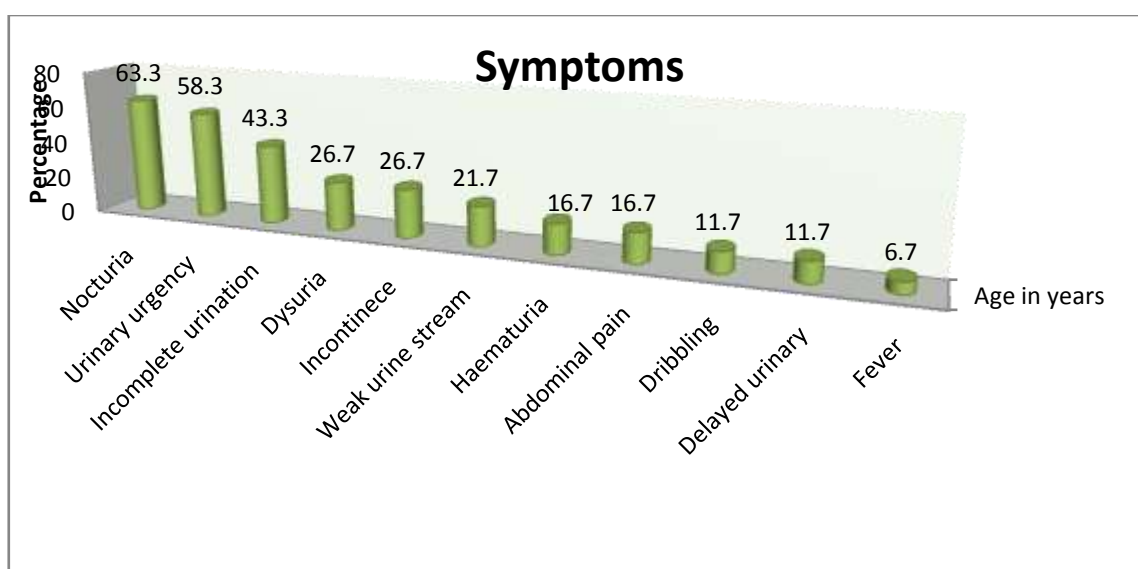


Figure 4: Graphical representation of percentage distribution of total number of patients based on symptoms

#### DISTRIBUTION OF PATIENTS BASED ON CO MORBITIES

**Table 5: Frequency and distribution of total number of patients based on comorbidities**

The distribution of total number of patients based on comorbidities have been shown on the following table:

Comorbidities	Frequency	Percent
HTN	43	71.7
Diabetes	30	50
Dyslipidemia	8	13.3

From table 5, we observed that out of 60 patients 43(71.7%) had history of hypertension, 30(50%) had history of diabetes mellitus

, 8(13.3%) had history of dyslipidaemia. We found that most of the patients attended the urology OPD had a history of hypertension

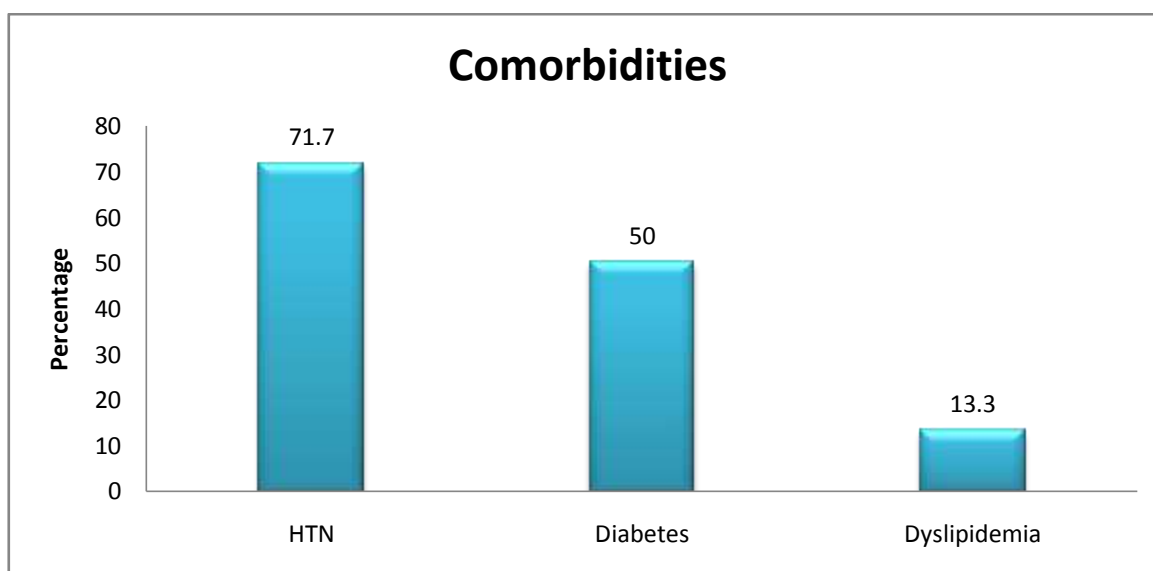


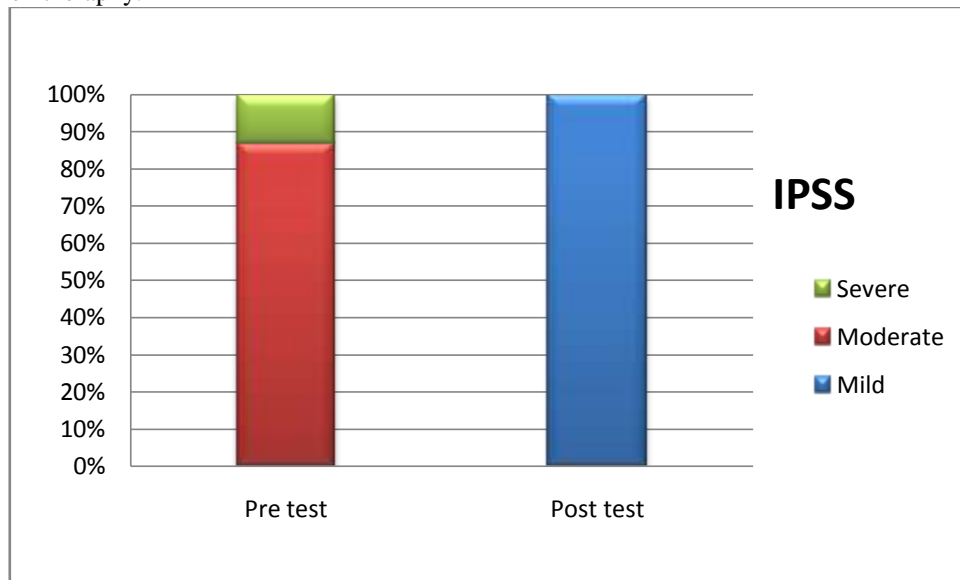
Figure 5: Diagrammatic representation of percentage distribution of total number of patients based on comorbidities

#### ASSESSMENT IN IMPROVEMENT IN LUTS USING IPSS SCALE

Table 6 shows assessment in improvement in LUTS using IPSS scale before and after treatment

IPSS	Pre test		Post test	
	n	%	n	%
Mild	0	0	60	100
Moderate	52	86.7	0	0
Severe	8	13.3	0	0
Total	60	100	60	100

From table 6 it is clear most of the patients has improvement in their LUTS by taking tamsulosin and dutasteride combination therapy.



Graph no 6 showing improvement in their LUTS by taking tamsulosin and dutasteride combination therapy.

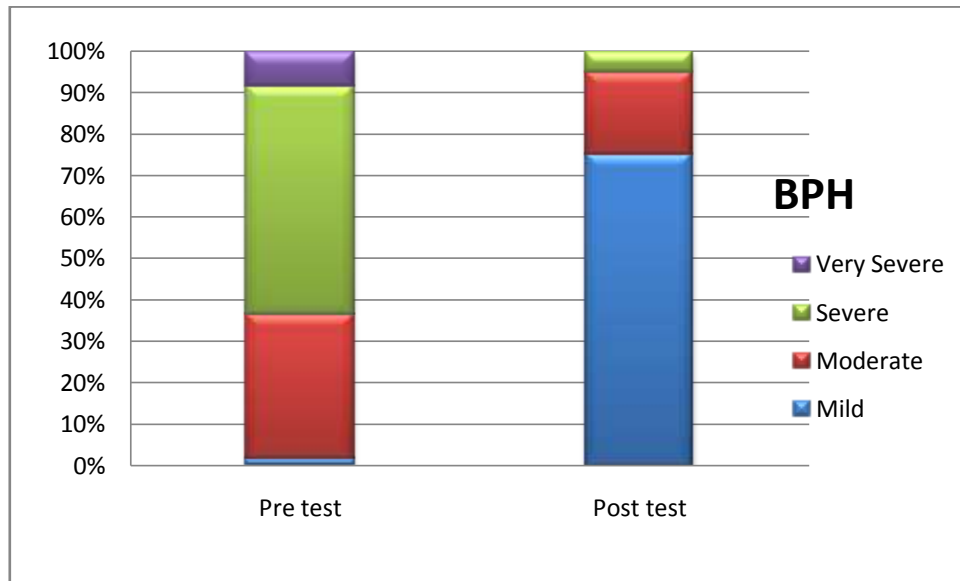
**ASSESSMENT IN BPH IMPACT INDEX AND STAGES**

**Table 7 shows assessment in BPH impact index and stages**

BPH	Pre test		Post test	
	n	%	n	%
Mild	1	1.7	45	75
Moderate	21	35	12	20
Severe	33	55	3	5
Very Severe	5	8.3	0	0
Total	60	100	60	100

Out of 60 patients most of them have changed their stages from moderate to mild (75%) and only 5% of patients comes under severe stages





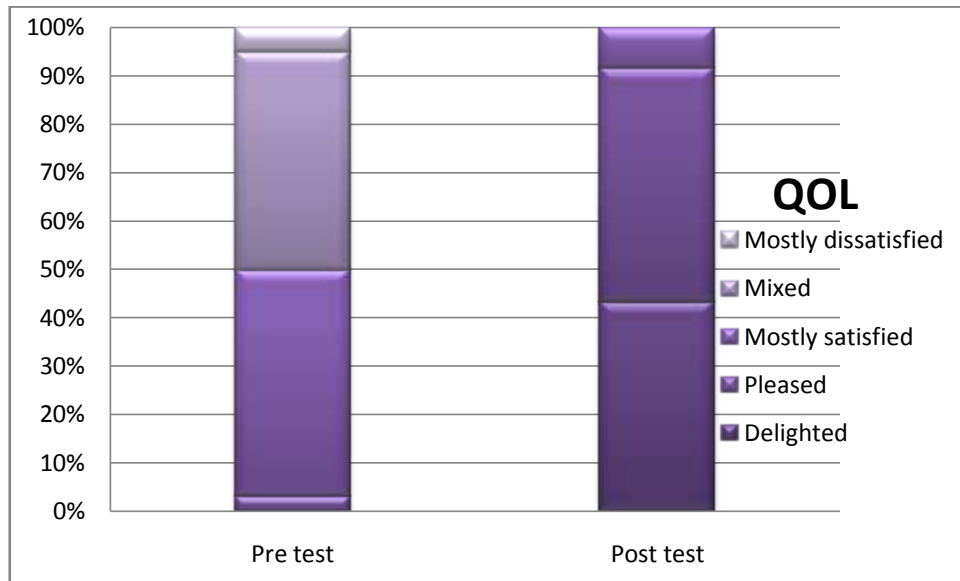
Graph 7 showing assessment in BPH impact index and stages

**ASSESSMENT OF QUALITY OF LIFE AFTER PATIENT COUNSELLING**

**Table 8 showing assessment of quality of life after patient counselling**

QOL	Pre test		Post test	
	n	%	n	%
Delighted	0	0	26	43.3
Pleased	2	3.3	29	48.3
Mostly satisfied	28	46.7	5	8.3
Mixed	27	45	0	0
Mostly dissatisfied	3	5	0	0
Total	60	100	60	100

After the patient counselling of 60 BPH patients most of them were pleased and also 0% of mostly dissatisfied.



Graph 8 showing improvement in Quality of life of patients after counselling.

**ASSESSMENT OF MEDICATION ADHERENCE OF PATIENTS**

The distribution of total number of patients based on adherence have been shown on the following table:

**Table 9 :Frequency and distribution of total number of patients based on adherence**

Adherence	Frequency	Percent
Good	12	20
Fair	24	40
Poor	19	31.7
Very Poor	5	8.3
Total	60	100

From table 9, it was observed that out of 60 patients, 12(20%) adherence was found to be good, 24(40%) adherence was found to be fair, 19(31.7%) adherence was found to be poor, 5(8.3%) adherence was found to be very poor.

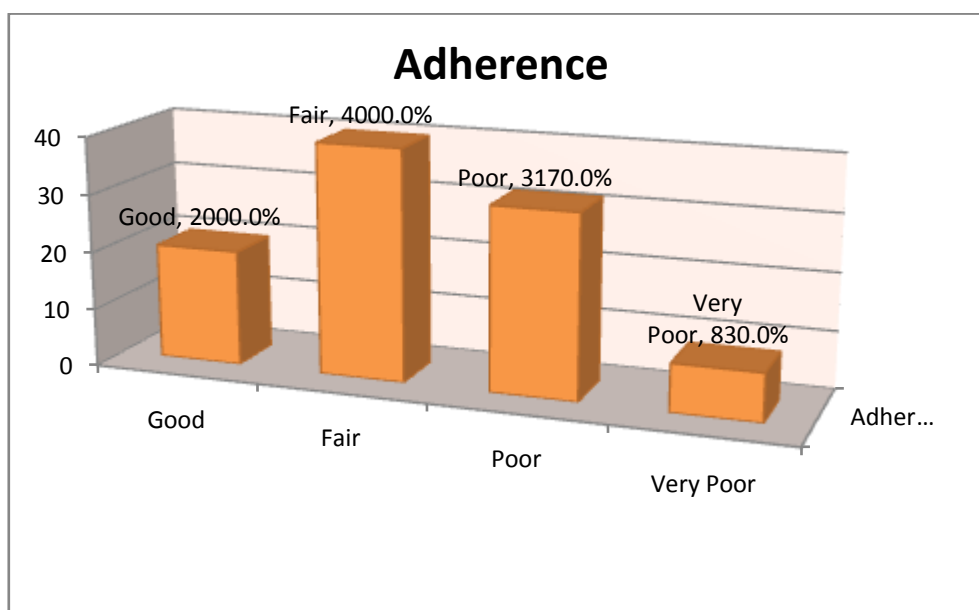


Figure 9 :Diagramatic representation of percentage distribution of total number of patients based on adherence

#### IV. DISCUSSION

Benign Prostatic Hyperplasia(BPH) is the most common benign tumor in men and is responsible for Lower urinary tract symptoms and it is seen in majority of males over the age of 50 years. LUTS increases with age in an overall prevalence of greater than 50% in men 50 years or older and are associated with a significant negative impact on patient’s QOL as postulated by Mahajan P et al.<sup>[35]</sup>. From our study, we found that about 57% of BPH patients attending the Urology OP belonged to an age group of 61-70yrs. It is evident that as age increases the level of dihydrotestosterone and estrogen increases which could lead to stimulatory growth of prostate.

In the current study, we observed that majority of the patients (50 %) are non-diabetic, non-Hypertensive but it is not sure whether they are interlinked or not. Some studies shows that there is a significant and positive relationship of DM with hypertension that was influenced by BPH and as a contradiction to this, there is correlation of DM with hypertension that was not influenced by BPH also exists. A study conducted by Zeng et al. suggested a positive but non-significant correlation between DM and hypertension in BPH patients<sup>[58]</sup>. A study conducted by Michael MC et al. states that there is a common pathophysiological factor for both disease states such as increased sympathetic activity<sup>[57]</sup>. As a contradiction to this, Sarma AV et al. demonstrates that there was no strong evidence for an association between diabetes and BPH across measures more

specific to BPH (i.e., prostate volume, PSA, and peak urinary flow rate).<sup>[48]</sup>

In a placebo-controlled study by Oelke et al., evaluating Tadalafil or Tamsulosin (as an active control) for LUTS/BPH, Tadalafil 5 mg once-daily for 12 weeks resulted in treatment satisfaction that was statistically significantly greater Vs placebo for the overall Treatment Satisfaction Score TSS-BPH score and the ‘Satisfaction with Efficacy’ domain, with no statistically significant differences for the ‘Satisfaction with Dosing’ or ‘Satisfaction with Side-Effects’ domains.<sup>[46]</sup> Our study compared Silodosin instead of Tadalafil and we found that Silodosin was found to have statistically significant patient satisfaction than Tamsulosin.<sup>[46]</sup>

A study conducted by Claus G Roehrborn concludes that FDC therapy with dutasteride and tamsulosin, plus lifestyle advice, resulted in rapid and sustained improvements in men with moderate BPH symptoms at risk of progression with significantly greater symptom and QoL improvements and a significantly reduced risk of BPH progression. Study done by Jack Barkin et al. demonstrated that for the man with an enlarged prostate (>30 mL) and moderate symptom complaints, the combination of dutasteride and tamsulosin compared with monotherapy will provide the most effective and most durable long-term benefits.

Bilal chugtai et al. in a study concludes that Patients with mild symptoms may be excellent for conservative treatment with behavioral therapy (timed voiding, fluid restriction). As symptom

severity increases, patients will be candidates for one, or a combination of currently available treatments

A study conducted by Pontari M.A et.al stated that pain is rarely reported in connection with BPH, where it is a feature of prostatitis, which is common in older men<sup>[41]</sup> and can often be confused with BPH in the older male population<sup>[42]</sup>. In his study, pain was assessed using the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI). A study conducted by Litwin M Set.al, comparing men with Prostatitis and BPH, pain during urination was a feature for 54% and 29% of the groups respectively<sup>[43]</sup>. From our study, we found there don't exist any significant difference in percentage improvement of satisfaction by PPSM Pain due to treatment between Silodosin 8 mg and Tamsulosin 0.4 mg groups i.e., the two groups reported approximately the same level of improvement in PPSM Pain due to the treatment.

On the evaluation of impact of patient counselling on quality of life from our study, it was found that both the tamsulosin and dutasteride combination therapy have improvement on I-PSS Q8 by 48% respectively and improvement on BII by 44.3% respectively. This showed there was an impact on quality of life with counselling. A study conducted by Adepu et al.<sup>[31]</sup> showed the influence of patient education on Lower Urinary Tract Symptoms (LUTS) improvement and health related quality of life in patients with BPH. They concluded that patient counselling has shown significant improvement in knowledge about the disease, symptoms, management of the disease, treatment outcomes and QoL of BPH patients<sup>[31]</sup>. Our study showed a significant improvement in Knowledge by 80.1%, Attitude by 72.7% and Practice by 79.2%. Even though they were literate, they have poor knowledge about disease. On the comparison of medication adherence within the group using MGL scale, we found a significant improvement from first to second review by 31%. This showed significant improvement on medication adherence with the impact of effective counselling.

From our study, the comparative patient satisfaction with Tamsulosin Vs Silodosin showed that Silodosin was the drug which satisfied patient on a higher margin by 40.4% and also proved that effective patient counselling could improve the health related quality of life, KAP and medication adherence.

Several limitations should be considered when interpreting the present results. One limitation of the study is the absence of a placebo arm, which might have resulted in slightly over-estimated responses. The decision not to include a placebo arm was mainly based on ethical considerations since our study duration was of six months

## V. CONCLUSION

BPH is known to be a bothersome disease in elderly men, mostly between 61-70 years of age. Association of BPH with diabetes, hypertension, smoking and alcoholism is still controversial but are not interlinked. On assessing symptomatic distribution of patients, it was inferred that most of the outpatients who consulted the urology OP were moderately symptomatic. Assessment of patient satisfaction is a mode of measuring humanistic outcomes of the treatment in general and particularly must be applied for the currently prescribed combination therapy drugs – dutasteride and Tamsulosin. From the analysis of our observations, we concluded that there was more improvement in LUS by using combination therapy mainly voiding symptoms were more improved. Thus, it is essential that we cover both clinical and humanistic outcomes in the clinical practice.

Patient counseling could significantly increase one's medication adherence, and hence Quality of Life. Though adequate quality counseling practices by clinical pharmacists are available for variety of common diseases, privilege for the same is uncommon for BPH in the current scenario. Despite of the high level of literacy among our study population, the major demerit observed was that, the health literacy was found to be extremely poor. Subsequent improvement in medication adherence, QoL, was observed following an effective counseling session provided during the course of the current research. Hence, the provision of effective counseling is found to have a profound impact on promoting better and positive therapeutic outcomes

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