

A PILOT 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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Article Received on
12 July 2020,

Revised on 02 August 2020,
Accepted on 23 August 2020,

DOI: 10.20959/wjpr202010-18514

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ABSTRACT

Objective: 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. **Patients and methods:** 15 patients were included in the study and were given tamsulosin and dutasteride combination therapy (0.4+0.5)mg OD. Patients were interviewed during first visit in the department appropriate patient counselling was provided and were followed up in the next two weeks. The patients improvement in lower urinary tract symptoms and satisfaction on treatment was assessed by using IPSS Score(International prostate symptom score) questionnaire and the impact of patient counselling on quality of life was assessed by using

IPSS Q8 and BPH impact index(BII)at each visit. **Results:** A total of 15

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:** From this study it is concluded that most of samples showed improvement in LUTS using Tamsulosin + Dutasteride combination therapy. Pharmacist intervention in the form of counselling is hence an integral factor in improving the quality of life in patients and also medication adherence of patients.

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.

METHODOLOGY

A Prospective observational study was conducted in patients who were diagnosed with BPH and shows LUTS. The study period was 3 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 and IP setting either on treatment or new patient.
- ✓ Patients who are not a candidate for surgery.

EXCLUSION CRITERIA

- ✓ Patients who are not willing for the study and a candidate for a surgery.
- ✓ Complications of BPH like hematuria, UTI, stone if present.
- ✓ Patients who are contraindicated for the use of tamsulosin and dutasteride.
- ✓ History of lower urinary tract surgery/pelvic surgery.
- ✓ Neurological conditions causing bladder dysfunction, hepatorenal insufficiency.

A Sample size of 15 was calculated using appropriate statistical analysis. All the 15 patients were received tamsulosin and dutasteride combination therapy(0.4+0.5)mg OD were interviewed during the first visit in the department and appropriate patient counselling was provided and were followed up in the next two weeks. All the information relevant to the study will be collected from case records and direct interview with patients. Data will be collected by using a suitably designed proforma.

The patient improvement in LUTS and Satisfaction on treatment was assessed by using IPSS(International prostate symptom score) questionnaires and the impact of patient counselling on quality of life was assessed using IPSS Q8 and BPH impact index(BII)at each visit.

The patients were reviewed after 1 st month and 2 nd month of taking the medication. At the end of the study all parameters and scores were compared from baseline to end of study. IPSS is a symptom severity assessing tool which comprises of 6 questions concerning the symptom

severity and one question concerning the quality of life and total scores then divided as 0-7:mild, 8-19:moderate and 20-35: severe.

BII is a tool used to assess impact of presenting lower urinary tract symptoms on patients with 4 questions base on 0-4 point scale and the fourth question on 0-5 point scale.Total score of 0-13 range is divided as 0-3 ;mild, 4-8;moderate and 9-13; severe.

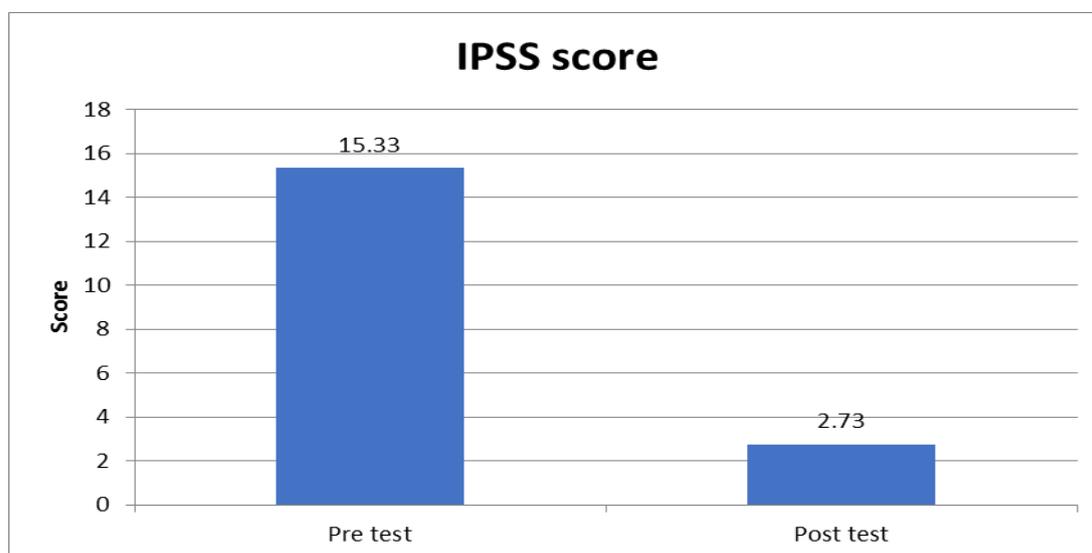
RESULT

ASSESSMENT IN IMPROOVEMENT OF SYMPTOMS USING IPSS SCALE

On analysing the graph it shows that there is a wide improvement in IPSS in these 15 subjects.The lower urinary tract symptoms are reduced from 15.33 to 2.73% in the IPSS by taking TamsulosinDutasteride combination therapy.

Table 1.

	N	IPSS score		Wilcoxon signed rank test	
		Median	IQR	z	p
Pre test	15	14	12-20	3.412	0.001
Post test	15	3	2-4		

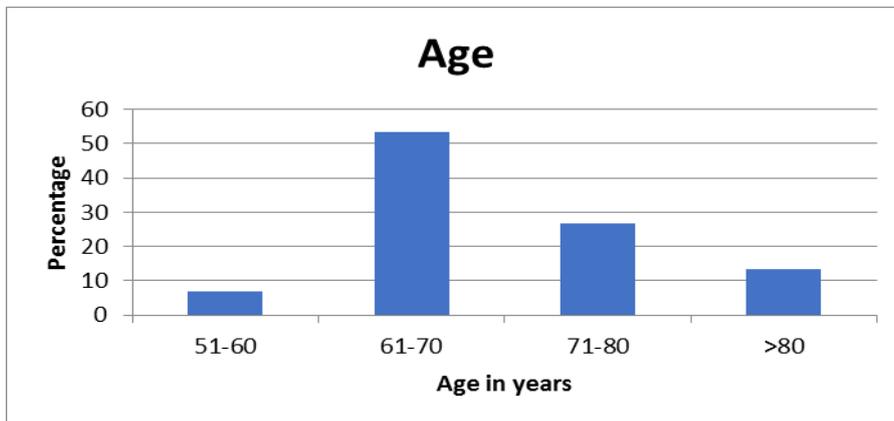


AGE DISTRIBUTION OF BPH

Out of 15 samples, most of the patiens comes under the age group of 61-70 and this age group showed more lower urinary tract symptoms of BPH.

Table 2.

Age in years	Frequency	Percent
51-60	1	6.7
61-70	8	53.3
71-80	4	26.7
>80	2	13.3
Total	15	100.0

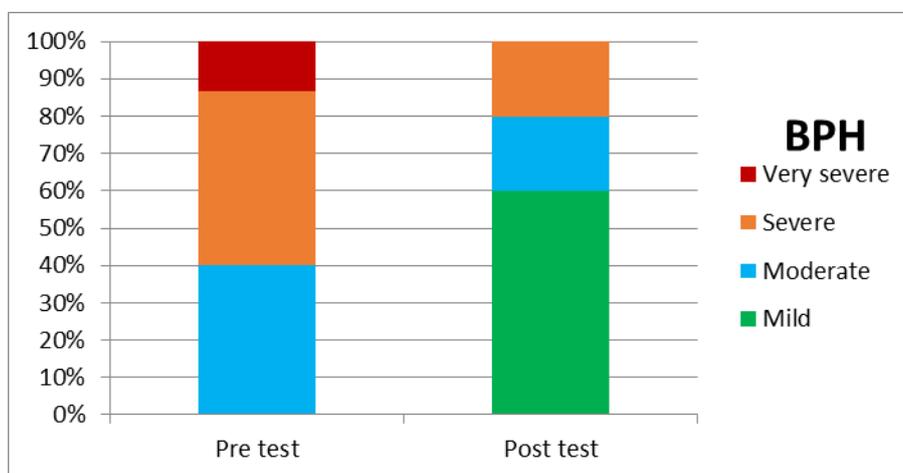


ASSESSMENT IN BPH IMPACT INDEX AND STAGES

Out of these 15 samples most of them have changed their stages from severe to mild after taking the combination therapy of Tamsulosin and Dutaseride.

Table 3.

BPH	Pre test		Post test	
	n	%	n	%
Mild	0	0	9	60.0
Moderate	6	40.0	3	20.0
Severe	7	46.7	3	20.0
Very severe	2	13.3	0	0
Total	15	100.0	15	100.0



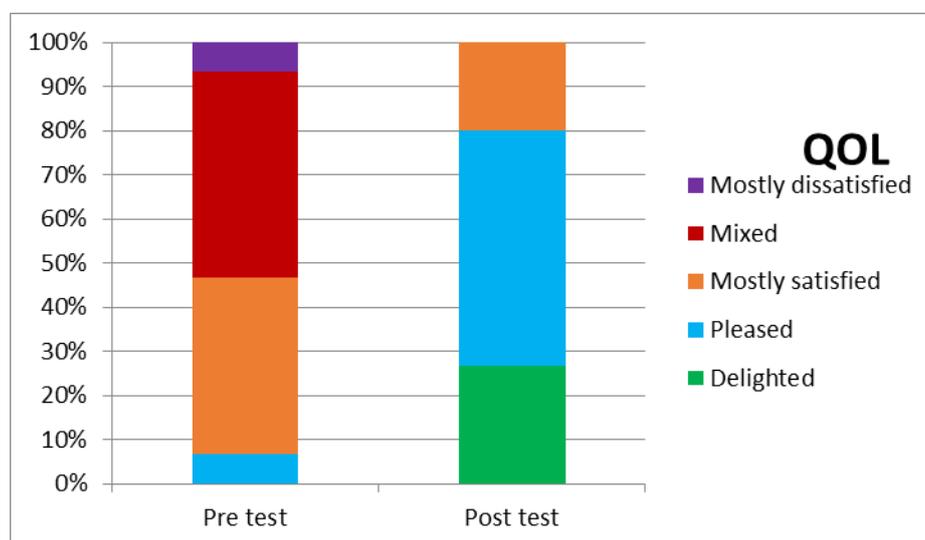
ASSESSMENT OF QUALITY OF LIFE AFTER PATIENT COUNSELLING

After the patient counselling among the 15 patients most of them were pleased and were satisfied as there is improvement in LUTS.

Table 4.

QOL	Pre test		Post test	
	n	%	n	%
Delighted	0	0	4	26.7
Pleased	1	6.7	8	53.3
Mostly satisfied	6	40.0	3	20.0
Mixed	7	46.7	0	0
Mostly dissatisfied	1	6.7	0	0
Total	15	100.0	15	100.0

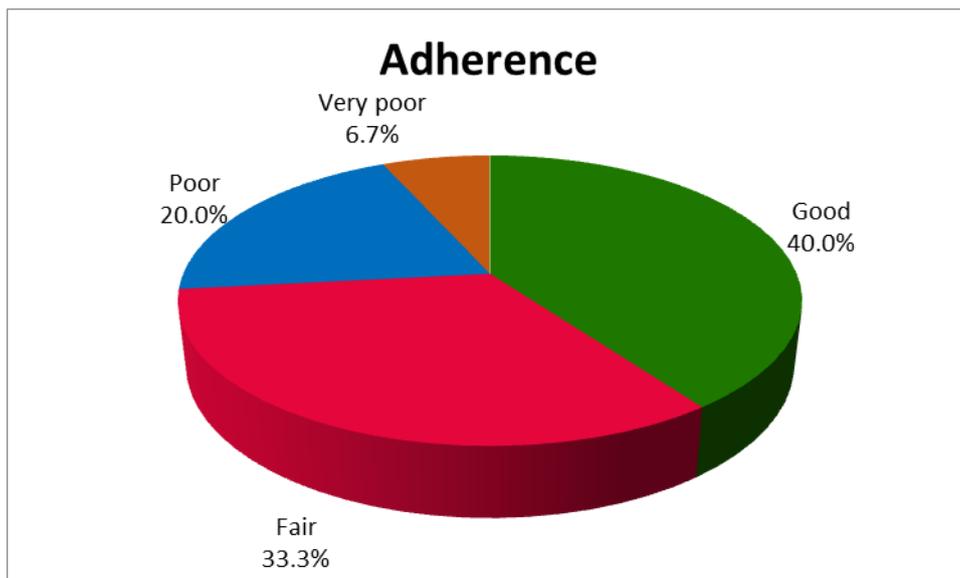
Wilcoxon signed rank test $z = 3.493$ $p < 0.001$

**ASSESSMENT IN IMPROVEMENT IN MEDICATION ADHERENCE AFTER COUNSELLING**

From these 15 samples it shows a wide range of improvement in medication adherence. Around 40% showed good adherence, only less showed very poor adherence.

Table 5.

Adherence	Frequency	Percent
Good	6	40.0
Fair	5	33.3
Poor	3	20.0
Very poor	1	6.7
Total	15	100.0

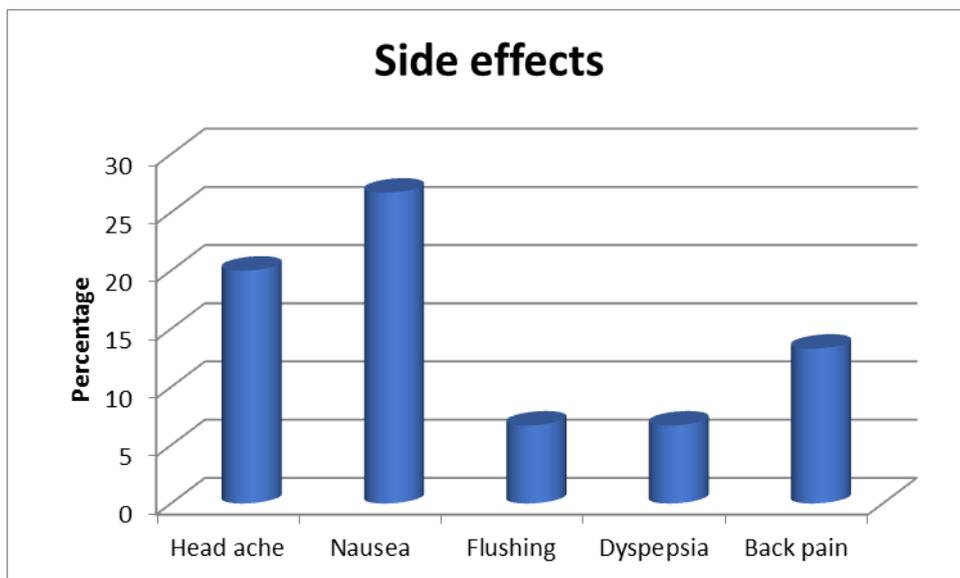


ASSESSMENT OF SIDE EFFECTS ON TAKING TAMSULOSIN DUTASTERIDE COMBINATION

Out of these 15 subjects most of them showed nausea as side effect and head ache to some extent.

Table 6.

Side effects	Frequency	Percent
Head ache	3	20.0
Nausea	4	26.7
Flushing	1	6.7
Dyspepsia	1	6.7
Muscle pain	0	0
Back pain	2	13.3



DISCUSSION

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 chughtai 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.

Our study is similar to a study of *Maria geitonaetal et al.* which concludes Budget impact analysis (BIA) results indicated that the gradual introduction of DUT + TAM FDC, would increase the overall budget of the disease, however providing better clinical outcomes. DUT + TAM FDC drug acquisition cost is partly offset by the reduction in the costs associated with the treatment of the disease.

In another study of *Claus G Roehrborn et al.* concludes that provide support for the long-term use of dutasteride and tamsulosin combination therapy in men with moderate-to-severe LUTS due to BPH and prostatic enlargement.

CONCLUSION

There are lot of studies conducted regarding the efficacy and safety of fixed dose combination of tamsulosin and Dutasteride in the treatment of Benign prostatic hyperplasia. But in our study we evaluates the improvement of Lower urinary tract symptoms by using tamsulosin plus Dutasteride combination therapy. Hence we concludes that most of the patients has improvements in their voiding symptoms.

However a large sample size and a longer duration of study are necessary for a better and reliable results.

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