



Research Article

A STUDY ON EFFICACY OF TAMSULOSIN IN THE MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA: A PROSPECTIVE

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ABSTRACT

Background: Tamsulosin hydrochloride can significantly improve benign prostatic hyperplasia (BPH) symptoms after the first dose and achieve long-term efficacy in European and American populations; however, the corresponding studies from India are rarely seen. The purpose of this study was to evaluate the long-term efficacy and safety of Tamsulosin hydrochloride 0.4 mg once daily in patients with BPH in Kerala, India. **Objective:** To evaluate the efficacy of Tamsulosin in the management of benign prostatic hyperplasia, who was treated for 1 month. **Materials and method:** Of the 96 patients from the urology department who participated in this investigation, 83 patients were evaluable. Tamsulosin 0.4 mg/day was administered orally for a 1-month period. The primary efficacy parameters were improvement in the total, obstructive and irritative International Prostate Symptom Score (IPSS), measured at baseline and at 1 month, and in the maximal urinary flow rate (Q_{max}) measured at baseline and at 1 month. The secondary efficacy parameters were a decrease of $\geq 30\%$ in IPSS and an increase in Q_{max} of $\geq 30\%$ from baseline. Changes in parameters between baseline and at 1 month were assessed using Student's paired t-test. **Results:** Statistically significant, gradual improvements in all efficacy parameters were observed over the 1-month period. Tamsulosin 0.4 mg/day resulted in a mean reduction in total IPSS ($p < 0.001$) and a mean increase of 4.56 mL/sec in Q_{max}, Q_{avg} and Voided volume at 1 month ($p < 0.001$). **Conclusion:** Our study suggests that Tamsulosin 0.4mg is effective for the treatment of Benign Prostatic Hyperplasia in elderly patients. The severity of symptoms was assessed by using IPSS and we concluded that, after 1 month of therapy, symptoms are reduced. Statistically significant gradual improvement in efficacy parameters was observed over 1 month period.

Keywords: Benign Prostatic Hyperplasia, Tamsulosin, α_1 -Adrenoceptor Antagonists, Receptor Subtype, Alpha-Adrenergic Receptor, Lower Urinary Tract Symptoms.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a common and progressive disease affecting elderly males, often

associated with lower urinary tract symptoms (LUTS) characterized by voiding symptoms (hesitancy, weak/slow stream, intermittency, straining, and incomplete voiding), storage symptoms (frequency, urgency, nocturia, urge incontinence), and post-maturation symptoms (postvoid dribbling), which may adversely affect the quality of life (QOL).[1] In addition, BPH can also lead to more serious complications, such as acute urinary retention, recurrent urinary tract infections, hematuria, bladder calculi, and renal dysfunction.[2] BPH typically develops after the age of 40 years, ranging in prevalence from $> 50\%$ at 60 years, to as high as $\sim 90\%$ by 85 years of age.[3] The

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management of BPH involves non-pharmacological, pharmacological, or surgical intervention and the choice of therapy typically depends on the pattern and severity of symptoms. Though surgery is the definitive treatment for BPH, the risk, complications, and the cost of surgical intervention, have prompted the need for effective and safe non-invasive modalities of treatment like drug therapy. Two major classes of drugs used in the management of BPH are α 1-blockers and 5 α - reductase inhibitors, the former addressing the dynamic component by relaxing the smooth muscles of the prostate and prostatic urethra, providing quicker symptomatic relief, and the latter affecting the static component by inducing gradual regression in gland size. The clinical benefit of α 1-blockers has shown to be independent of baseline prostate volume. [4, 5] The α 1 receptors are postsynaptic and present in vascular and nonvascular smooth muscles. There are several subtypes of α 1 receptors which include α 1A, α 1B, and α 1D. [6] The α 1A receptors, predominantly located in the smooth muscles of the genitourinary tract, are the primary regulators of smooth muscle tone in the bladder neck, and prostate; α 1B receptors are present in the vascular smooth muscle and regulate the vascular tone, and α 1D subtype mediates contraction of the bladder muscle. [7] The α 1 antagonists generally preferred in the management of BPH are Alfuzosin, Tamsulosin, and Silodosin because of their minimal hemodynamic adverse effects, Unlike the other common alpha-blockers that are not selected for this subtype, such as Doxazosin, Alfuzosin, and terazosin, Tamsulosin has high alpha-1a- adrenergic receptor affinity [7,8]. Because of this prostate selectivity, Tamsulosin may improve urinary symptoms and flow with fewer adverse effects. Many studies have shown the efficacy and tolerability of Tamsulosin at doses of 0.2 to 0.8 mg once daily in patients with symptomatic BPH.[9] Therefore, we are conducting this study to assess the safety, efficacy, and quality of life of Tamsulosin in the treatment of benign prostatic hyperplasia in our clinical setup

MATERIALS AND METHOD

A prospective observational study was conducted in the Department of Urology in Karuna Medical college hospital Vilayodi, Chittur, Palakkad for a period of 6 months from Oct 2021 to April 2022. Ethical committee approval was obtained (KMC/IHEC/04/2022) from the Institution Ethical Committee of Karuna Medical College and Hospital, Chittur. Signed informed consent was obtained from all participants prior to the study. Out of 96 patients, based on the inclusion and exclusion criteria 83 patients were enrolled in the study. Men Above 50 years of age and Newly assessed BPH patients or patients already having BPH and treated with Tamsulosin

0.4 mg were included in the study. Patients with prostate cancer, prostatitis, other cases of bladder outlet obstruction such as stricture or urethral stone, neurogenic bladder, Patients who are not willing to participate in the study, and mentally unsound patients were excluded from the study. A specially designed data entry form was used to collect patient demographics, medical and medication history, signs and symptoms, investigation, and treatment. The severity of symptoms of benign prostatic hyperplasia was assessed by using the international prostate symptom score (IPSS) before therapy and 1 one month. The primary efficacy evaluations included the change from baseline in total IPSS score and change in peak urine flow rate (Qmax), whereas the secondary efficacy evaluations included changes from baseline in IPSS scores, the actual values, and change from baseline values for free flow parameters. Data will be entered in MS EXCEL and statistical analysis using Graph pad prism software version 8 and the student t-test is used to compare the baseline and follow up.

RESULT AND DISCUSSION

A total of 83 male patients who have been treated with Tamsulosin 0.4 mg at the Department of Urology of Medical College Hospital, Palakkad was included in the study. The age-wise distribution of the patient included 9 patients (10.84%) between 40-50 years, 21 patients between 51-60 years (25.30%), and 28 patients between 61-70 years (33.73%), 25 patients between 71-80 years (30.12%). In our study, majority of patients are under the age of 60- 70(33.73). The age-wise distribution of the patients is summarized in table 1.

Many literatures are revealed that a four grades ultrasound classification of BPH where Grade I BPH is <30 g, Grade II 30-50 g, Grade III 50-85 g and Grade IV is >85 g. in our study population (n=83), 53.01% under Grade I, 36.14% under Grade II and 1.08% under Grade III. In our study, majority of the patients came under Grade I BPH.

EFFICACY

There is a gradual increase in Post void residual from baseline of the mean and standard deviation of 112.71 ± 43.76 to after one month about 113 ± 50.83 , it is non-significant in our study (p-value 0.8166). There is a significant improvement in maximum urinary flow rate variation, from baseline 6.28 ± 3.07 to 113.58 ± 50.83 after 1 month (p-value < 0.0001) A significant improvement is seen in the Qmax, Qavg and voided volume. The maximum flow rate of urine from baseline is 6.28 ± 3.07 and after 1 month is 9.21 ± 4.64 (p value < 0.0001), average urine flow rate at baseline of the mean and standard deviation is 4.6 ± 2.72 and after 1 month is 6.9 ± 3.75 (p value < 0.0001)

Table1. Patient demographics-Age wise distribution of patient's with BPH

Age groups(Age in years)	Number of patients (n=83)	Percentage (%)
40-50	9	10.84
51-60	21	25.30
61-70	28	33.73
71-80	25	30.12

Table 2. Mean changes in free flow parameters from baseline to endpoint during the treatment with 0.4mg Tamsulosin

Parameters	Baseline	Endpoint	p-Value
PVR(ml)	112.71±43.76	113.58±50.83	0.8166Ns
Qmax(ml/sec)	6.28±3.07	9.21±4.64	<0.0001
Qavg(ml/sec)	4.6±2.72	6.9±3.75	<0.0001
Voided volume	190.54±41.98	232.84±61.21	<0.0001

Table 3. Changes observed in objective parameters (IPSS) at baseline and after 1 month of Tamsulosin treatment

Parameters	Mean ± SD		p- Value
	Baseline	After 1 month	
Incomplete emptying	2.14±1.15	1.67±1.01	<0.0001
Frequency	1.76±1.09	1.46±0.88	<0.0001
Intermittency	1.59±1.18	1.30±1.05	<0.0001
Urgency	1.75±1.19	1.28±0.95	<0.0001
Weak stream	1.54±1.33	1.12±1.04	<0.0001
Straining	1.31±1.41	0.96±1.17	<0.0001
Nocturia	2.48±1.11	1.90±0.94	<0.0001

Manohar et al., demonstrated that Tamsulosin had a better effective in alleviating BPH symptoms and frequently produced a variety of adverse effect such as dizziness, decreased blood pressure, increased heart rate, occasional abdominal pain, nausea and allergic reaction.[10] The efficacy and severity of symptoms was assessed by using IPSS at baseline and after 1 month of therapy. The first question includes incomplete emptying from baseline 2.14±1.15 and after 1 month of therapy 1.67±1.01 (p<0.0001). The second question is based on frequency at baseline 1.76±1.09 and after 1 month 1.46±0.88(p<0.0001), third question on intermittency at baseline 1.59±1.18 and after 1 month 1.30±1.05(p<0.0001), fourth question on urgency at base line 1.75±1.19 and after 1 month 1.28±0.95(p<0.0001), fifth question on weak stream at baseline 1.54±1.33 and after 1 month 1.12±1.04(p<0.0001), sixth question on straining at baseline 1.31±1.41 and after 1 month 0.96±1.17(p<0.0001), and seventh question based on nocturia at baseline 2.48±1.11 and after 1 month 1.90±0.94(p<0.0001). There is a significant increase in total IPSS from baseline to after 1 month of tamsulosin 0.4mg treatment in patients. Previous reports on the efficacy of Tamsulosin were based on a dosage regimen of 0.4 mg/day. Clinical studies showed that Tamsulosin 0.4 mg/day administrated for 12 weeks results in a 35-

43% decrease in the prostatic score and a 13–18% increase in Qmax compared with baseline [11] Gacci *et al.* reported that AIBs show a 30%–40% reduction in IPSS and a 20%–25% increase in Qmax, but does not affect the increase in BPO and decreases the effect after 2years [12]

CONCLUSION

Our study suggests that Tamsulosin 0.4mg is effective for the treatment of Benign Prostatic Hyperplasia in elderly patients. The severity of symptoms was assessed by using IPSS and we concluded that, after 1 month of therapy, symptoms are reduced. Statistically significant gradual improvement in efficacy parameters was observed over 1 month period.

LIMITATION

Due to small number of participants, it is difficult to perform the sample size calculation; therefore, careful interpretation for the results might be required. This study has a short-term follow-up period of 1month. Therefore, we believe that well-designed long term and multicenter trials of clinical efficacy of these therapies are needed for further evaluation and a better understanding of the key prognostic determinants of the disease and treatment options. And it also resulted in missing of follow-ups and could not complete the follow-up.

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