



Original Research Article

A STUDY ON THE EFFECTIVENESS OF TAMSULOSIN IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA (BPH) HAVING MILD AND MODERATE LOWER URINARY TRACT SYMPTOMS (LUTS)

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ABSTRACT

Background: Effective drugs are available to treat BPH. Even though surgery is gold-standard, given its limitations, people prefer conservative management over surgical-management. **Objective:** To study effectiveness of tamsulosin in patients with benign prostatic hyperplasia (BPH) having mild and moderate lower urinary tract symptoms (LUTS).

Materials and Methods: Hospital-based, prospective study was carried out among 100 cases with BPH having mild to moderate IPSS scores. They were given the treatment and followed at 1, 3 and 6 months for IPSS score and UFR scores.

Results: Mean age was 63.7 years. Mean IPSS was 10.35. Mean UFR was 10.72. Those with almost-always-increased-frequency in first visit were reduced to zero by third visit. Treatment reduced number from 10 with almost-always-urgency to zero in third visit. Regarding nocturia, those who had it almost-always decreased from 18 in first visit to only four in third visit. Those with weak-stream, 10 patients with almost-always-weak stream in first visit and none in third visit. There were four patients with intermittency of >half-the-time in first visit which became zero in third visit. There were 12 cases with incomplete emptying or >half-the-time at first visit and no one in third visit. 51% change was seen from visit I to II in IPSS score of <7. For every category when mean IPSS score was compared there was significant improvement. For every category when mean UFR score was compared there was significant improvement.

Conclusion: Tamsulosin was effective in reducing the symptoms of lower urinary tract as measured by IPSS scoring.

Keywords: effectiveness, tamsulosin, prostate, urinary tract.

INTRODUCTION

In elderly males, the Benign prostatic hyperplasia (BPH) is quite common. It causes the troubling symptoms related to the lower urinary tract. 1 These symptoms of the lower urinary tract bother the affected person. They, thus affect the quality of life. They are also associated with significant out of pocket expenditure putting a lot of burden on the affected individual and their family. 2

Hyperplasia of prostate i.e. benign is common in the fifth and sixth decade of life. With advancing age, the prostate gland may undergo either atrophy or hypertrophy. Its change in the size, produces a variety of symptoms related to the bladder. Clinically the benign hyperplasia of the prostate definition include any one of the following criteria: increase in the volume of the prostate by 20 gm, or when the International Prostate Symptom Score (IPSS) is more

than 11, or when the flow rate of the urine is less than 15 ml per second. 3

It has been estimated that almost 14% males are affected with benign hyperplasia of the prostate in the age group of 40-50 years. The prevalence can increase to 40% in males in the age group of 70-80 years of age. 4 It is being thought that the treatment of benign hyperplasia of the prostate is purely surgical i.e. prostatectomy. But, now a days, even medical treatment is available which is effective and affordable, acceptable by the patients. Benign hyperplasia of the prostate affects both the static and dynamic components of the prostate gland. Static component is related to its anatomy. The dynamic component is related to its physiology. Because of this, the lower urinary tract symptoms appear after the hyperplasia of the prostate gland. This leads to the hope of medical management of the hyperplasia of the prostate gland. The dynamic component is said to be associated with the sympathetic stimulation of alpha receptors. These receptors are seen in the different parts of the prostate gland. These different locations in the prostate gland can be base of the bladder, adenoma of the prostate gland, capsular muscle of the prostate gland. Thus, the drugs with alpha blocking action can be used to overcome the lower urinary tract symptoms, so that they can be used in the treatment. 5 It has been shown that the androgen level influences the growth of the prostate gland. Thus, the suppression of the levels of the androgen can lead to decrease in the volume of the prostate. This can lead to control the static component of the prostate gland. This therapy can reduce the size of the prostate and decrease the symptoms of the lower urinary tract. 5 alpha-reductase inhibitors and various anti-androgens are the drugs thus can be used in the treatment of the benign hyperplasia of the prostate gland. 6

The surgery for the prostate gland or any surgery for that matter is associated with risk. The benign hyperplasia of the prostate is common in elderly people. Older age is associated with more risk when operated compared to younger individuals. Thus, the increased age, presence of comorbidities can affect the choice of surgery. Moreover, some elderly may be afraid of surgery or some may not like it at all. In spite of this, the treatment of choice is surgery and transurethral resection of prostate is that surgery. But, when with the advanced technology, the newer drugs are available, then many are choosing conservative management over the surgery. We have alpha blockers available. We have alpha reductase inhibitors available drugs with us.

In the light of above-mentioned limitations of the surgery of the prostate gland and given the availability of the newer drugs, it is essential to study the effectiveness of newly available drugs. Hence, present study was carried out with the objective to study the effectiveness of tamsulosin in patients with benign prostatic hyperplasia (BPH) having mild and moderate lower urinary tract symptoms (LUTS).

MATERIALS AND METHODS

Hospital based, prospective study was carried out over a period of two years from November 2017 to October 2019 among 100 Patients with mild and moderate lower urinary tract symptoms. The patients coming to the surgery or urology out patient department were included in the present study. Even those admitted to the surgery or urology in patient department were also included if they were found out to be eligible for the study.

Institutional ethics committee permission was obtained as per the standard protocol. This was done after approval from the Scientific committee. The nature of the study was explained to the participants as per the ethical standards. After that, the written informed consent was taken. All the patients were treated/operated as per the standard guidelines.

Patients of age more 40 years, presenting with only mild and moderate symptoms of the lower urinary tract, were included in the present study. Those with carcinoma of Prostate on biopsy, recurrent urinary tract infection, acute retention of urine, haematuria, bladder calculus, neurological disorders, medication interfering with bladder function, renal insufficiency, severe LUTS were excluded from the study.

Detailed history, thorough clinical examination was carried out among those who were selected as eligible as per the present study inclusion and exclusion criteria and those who provided the written informed consent. International Prostatic Symptom Score (IPSS) System was used to assess the symptoms of the lower urinary tract. These symptoms can be increased frequency of the micturition, not able to completely empty the bladder, severe urge to pass the urine, thin stream of the urine, intermittency, passing of more urine at night time i.e. nocturia and staining. Each symptom question has five options ranging from absent to severe. The absent is given a score of zero and the severe option gets a score of five. Thus, the IPSS score ranges from 0-35. Mild condition is the score between 1-7, moderate condition is the score between 8-19 and the severe condition is the score between 20-35.

After history, clinical examination, and scoring for IPSS, the patients were subjected to transabdominal ultrasonography to confirm the prostate volume. Even the size of the prostate can be determined. The radiologist can also see the volume of the postvoid residual urine. The overall condition of the bladder can be known through this along with the status of the upper urinary tract. In addition, routine investigations were carried out as per the standard protocol. Whenever the cancer is suspected, Serum prostate-specific antigen (PSA) was measured for that particular patient.

Those with score of IPSS of up to 19, were given the alpha blocker drugs as per the standard protocol. Patients were asked to come for follow up examination at one, three and six months after the treatment was started. Detailed history of symptoms

related to the lower urinary tract, physical examination and necessary investigations were done at each follow up. All the data was entered in the pre designed, semi structured, pre tested study questionnaire. At follow up, those with unwanted outcome and those with IPSS progression to four or more points were considered for surgery.

The data was entered in the Microsoft Excel worksheet. Proportions, mean and standard deviation were used to describe the data. Independent samples t test was used to study the differences in the mean values of two groups. P value of less than 0.05 was considered as statistically significant.

RESULTS

Table 1: Baseline characteristics

The baseline characteristics	Range	Mean \pm SD
Age	42-86	63.7 \pm 10.21
IPSS	4-18	10.35 \pm 3.31
UFR	8-14	10.72 \pm 1.64
PSA (ng/ml)	1.8-4	2.86 \pm 0.63
Prostate volume (ml)	22-86	34.84 \pm 12.01

Mean age was 63.7 years which ranged from 42-86 years. The mean IPSS was 10.35 because those with mild and moderate IPSS were only included. Mean UFR was 10.72. mean prostate volume was 34.84 ml.

Table 2: International Prostate Symptom Score (IPSS) for frequency

Frequency	I visit		II visit		III visit		% change
	No.	%	No.	%	No.	%	
Not	8	8	10	10	10	10	2%
<1 time	8	8	12	12	13	13	5%
< half the time	18	18	28	28	30	30	12%
About half the time	20	20	32	32	33	33	13%
More than half the time	24	24	18	18	14	14	-10%
Almost always	22	22	--	--	--	--	-22%

After giving the treatment, those with almost always increased frequency in the first visit were reduced to zero, those with >half the time decreased from 24 to 14 in third visit. Those with no increased frequency increased from 8-10.

Table 3: International Prostate Symptom Score (IPSS) for urgency

Urgency	I visit		II visit		III visit		% change
	No.	%	No.	%	No.	%	
Not	12	12	10	10	10	10	-2%
<1 time	8	8	20	20	22	22	14%
< half the time	18	18	20	20	24	24	6%
About half the time	30	30	44	44	38	38	8%
More than half the time	22	22	4	4	6	6	-16%
Almost always	10	10	2	2	--	--	-10%

The treatment reduced the number of cases from 10 with almost always urgency to zero in third visit. The number reduced from 22 in first visit to only six in third visit for more than half the time urgency.

Table 4: International Prostate Symptom Score (IPSS) for nocturia

Nocturia	I visit		II visit		III visit		% change
	No.	%	No.	%	No.	%	
Not	4	4	8	8	10	10	6%
<1 time	4	4	10	10	10	10	6%
< half the time	18	18	30	30	32	32	14%
About half the time	28	28	36	36	38	38	10%
More than half the time	28	28	14	14	6	6	-22%
Almost always	18	18	2	2	4	4	-14%

Regarding nocturia, those who had it almost always decreased from 18 in the first visit to only four in the third visit.

Table 5: International Prostate Symptom Score (IPSS) for weak stream

Weak stream	I visit		II visit		III visit		% change
	No.	%	No.	%	No.	%	
Not	6	6	10	10	12	12	6%
<1 time	10	10	8	8	14	14	4%

< half the time	20	20	32	32	32	32	12%
About half the time	30	30	40	40	36	36	6%
More than half the time	24	24	10	10	6	6	-18%
Almost always	10	10	--	--	--	--	-10%

With regard to weak stream, there were 10 patients with almost always weak stream in the first visit and none in third visit.

Table 6: International Prostate Symptom Score (IPSS) for straining

Straining	I visit		II visit		III visit		% change
	No.	%	No.	%	No.	%	
Not	42	42	44	44	28	28	-14%
<1 time	18	18	22	22	24	24	6%
< half the time	20	20	22	22	26	26	6%
About half the time	20	20	12	12	22	22	2%
More than half the time	--	--	--	--	--	--	--
Almost always	--	--	--	--	--	--	--

Unlike previous symptoms, the straining seemed to be not responding to the treatment. Those with about half the time actually increased from first visit to the third visit.

Table 7: International Prostate Symptom Score (IPSS) for intermittency

Intermittency	I visit		II visit		III visit		% change
	No.	%	No.	%	No.	%	
Not	32	32	34	34	44	44	12%
<1 time	22	22	24	24	18	18	-4%
< half the time	24	24	36	36	32	32	-8%
About half the time	18	18	6	6	6	6	-12%
More than half the time	4	4	--	--	--	--	-4%
Almost always	--	--	--	--	--	--	--

There were four patients with intermittency of >half the time in first visit which became zero in the third visit.

Table 8: International Prostate Symptom Score (IPSS) for incomplete emptying

Incomplete emptying	I visit		II visit		III visit		% change
	No.	%	No.	%	No.	%	
Not	16	16	24	24	40	40	24%
<1 time	8	8	22	22	14	14	6%
< half the time	34	34	34	34	32	32	-2%
About half the time	30	30	20	20	14	14	-16%
More than half the time	10	10	--	--	--	--	-10%
Almost always	2	2	--	--	--	--	-2%

There were 12 cases with incomplete emptying or >half the time at first visit and no one in the third visit.

Table 9: Distribution of International prostate symptom score (IPSS)

IPSS	Baseline	Visit I	Visit II	Visit III	Change from visit I to visit II	Change from baseline to 3 rd visit
< 7	20%	29%	59%	80%	51%	31%
7-12	53%	66%	41%	20%	46%	-33%
13-19	27%	5%	0	0	-5%	-27%

51% change was seen from visit I to II in the IPSS score of <7 and 31% from baseline to third visit. The score decreased by 33% for those with 7-12 at baseline by third visit.

Table 10: Improvement of IPSS

Timeline		Mean ±SD	T value	P value
From baseline to visit I	Baseline	10.35 ±3.31	11.30	< 0.0001
	Visit I	8.68 ±2.64		
From baseline to visit II	Baseline	10.35 ±3.31	17.65	< 0.0001
	Visit II	6.65 ±2.21		
From baseline to visit III	Baseline	10.35 ±3.31	23.43	< 0.0001
	Visit III	5.13 ±2.12		
From visit I to II	Visit I	8.68 ±2.64	15.63	< 0.0001
	Visit II	6.65 ±2.21		
From visit I to III	Visit I	8.68 ±2.64	23.88	< 0.0001
	Visit III	5.13 ±2.12		
From visit II to III	Visit II	6.65 ±2.21	13.86	< 0.0001
	Visit III	5.13 ±2.12		

For every category when mean IPSS score was compared there was significant improvement.

Table 11: Improvement of UFR

Timeline		Mean \pm SD	T value	P value
From baseline to visit I	Baseline	10.72 \pm 1.64	10.97	< 0.0001
	Visit I	11.53 \pm 1.47		
From baseline to visit II	Baseline	10.72 \pm 1.64	20.14	< 0.0001
	Visit II	12.67 \pm 1.37		
From baseline to visit III	Baseline	10.72 \pm 1.64	17.67	< 0.0001
	Visit III	13.86 \pm 1.94		
From visit I to II	Visit I	11.53 \pm 1.47	16.29	< 0.0001
	Visit II	12.67 \pm 1.37		
From visit I to III	Visit I	11.53 \pm 1.47	14.64	< 0.0001
	Visit III	13.86 \pm 1.94		
From visit II to III	Visit II	12.67 \pm 1.37	13.86	< 0.0001
	Visit III	13.86 \pm 1.94		

For every category when mean UFR score was compared there was significant improvement.

DISCUSSION

Benign hyperplasia of the prostate is the most common condition. It mainly affect the males in their later part of life. In India, the proportion of people above the age of 50 years is increasing day by day. Higher incidence of benign hyperplasia of prostate puts high burden on the existing medical health care of the country. The situation remains the same globally. A combination or in isolation use of 5 α -reductase inhibitor, α 1 adrenergic receptor antagonist can help minimize the symptoms of lower urinary tract associated with benign hyperplasia of the prostate.^[7] Previously surgery was the only choice of therapy. But, with good drugs available, conservative management is quite possible. The degree of benign hyperplasia of the prostate is indicated by IPSS and UFR. They can be used for determining how the patient is responding to the treatment also.^[8]

In the present study, we attempted to study the efficacy of tamsulosin in the dose of 0.4 mg. this was done for those who were diagnosed with mild to moderate LUTS. We could include 100 cases. All cases had benign disease. In a study by Subedi N et al,^[9] they found that the age ranged from 50-82 years with a mean of 65 years. Majority were in the age group of 50-59 years followed by 70-79 years i.e. 37.2% and 29% respectively.

In the present study, the mean IPSS score decreased significantly from baseline to third visit of follow up after treatment. The total IPSS decreased from baseline to first visit (10.35 \pm 3.31) to (8.68 \pm 2.64). The total IPSS decreased from baseline to 2nd visit (10.35 \pm 3.31) to (6.65 \pm 2.21). The total IPSS decreased from baseline to 3rd visit (10.35 \pm 3.31) to (5.13 \pm 2.12). The total IPSS decreased from the first visit to 3rd visit (8.68 \pm 2.64) to (5.13 \pm 2.12). Total IPSS score decreased from the first visit to the second visit (8.68 \pm 2.64) to (6.65 \pm 2.21). Total IPSS score decreased from 2nd visit to 3rd visit (6.65 \pm 2.21) to (5.13 \pm 2.12). In another study by one author,^[10] the baseline IPSS was 18.04 \pm 5.06 which decreased to 9.44 \pm 3.98 at the end of four weeks of treatment. Mild adverse effected were noted in 15.1% of the cases.

In the present study, total UFR increased from baseline to first visit (10.72 \pm 1.64) to (11.53 \pm 1.47). The total UFR increased from baseline to 2nd visit (10.72 \pm 1.64) to (12.67 \pm 1.37). The total UFR increased from baseline to 3rd visit (10.72 \pm 1.64) to (13.86 \pm 1.94). The total UFR increased from 1st visit to 2nd visit (11.53 \pm 1.47) to (12.67 \pm 1.37). The total UFR increased from 1st visit to 3rd visit (11.53 \pm 1.47) to (13.86 \pm 1.94). The total UFR increased from 2nd visit to 3rd visit (12.67 \pm 1.37) to (13.86 \pm 1.94). In this study, most patients are having PSA < 7 and Mean \pm SD is 2.86 \pm 0.63. In the present study, the number of patients with prostate volume < 30ml was 53 and percentage was 53%. The number of patient with prostate volume >30ml was 47 and percentage was 47%. Mean \pm SD is 34.84 \pm 12.01. In the study conducted by Sreeja PA et al,^[11] comparing the patients IPSS improvement from baseline and after 48 hrs, there was no significant difference in Score, whereas there was a moderate improvement in the scores after one month. After one month of therapy with tamsulosin, 24% were in between IPSS score of 1-8, 76% were in between IPSS score of 9-19, 0% were in between IPSS score of 20-35. Whereas in the present study, 29% of patients were in between IPSS score of < 7, 66% of patients in between IPSS score of 7-12, 5% were in between 13-19.

The maximum flow rate increased from 1.5-3.5 ml/sec in the study by Sreeja PA et al,^[11] compared to 3-4 ml/sec as per the findings of the present study. Chung BH et al,^[12] found that the mean change in IPSS was 7.5 compared to 5.22 of the present study. We observed that the IPSS improved in 49% of the cases in the present study which was comparable to other study by Roerhborn et al,^[13] who found out it to be 39.2%. Similar finding was reported by Mohanty NK et al,^[14] where they found that the IPSS score decreased from 19 at baseline to 7 in tamsulosin group.

Yokoyama et al,^[15] found that the IPSS scores were reduced significantly in the tamsulosin and tadalafil group compared to the placebo at 12 weeks. The scores were significantly reduced in tamsulosin group when compared to the tadalafil group also.

We did not encounter any major adverse events due to tamsulosin in the present study. There were only mild side effects like headache, fatigue, dizziness etc. Sreeja PA et al,^[11] noted that 40 cases in their study one or the other side effects. Among them 90% had orthostatic hypotension, 42.5% had dizziness, 37.5% had fatigue and headache. Compared to this, in the present study, 10 cases developed orthostatic hypotension. Five reported new episodes of headache. Overall, the incidence of side effects was 17%.

Patients with BPH reported improvement in the quality of life after four weeks of giving the treatment. Even the orthostatic hypotension was mild in nature. However, some studies have reported that the tamsulosin is effective for reduction of IPSS score to a certain extent after which a plateau occurs. A study was carried out in 116 Asian cases.^[16] It was using tamsulosin in the dose of 0.4 mg for 16 weeks. There was a significant improvement in the symptoms of LUTS. But after that a plateau was noticed over next eight weeks of treatment with scores of IPSS remaining constant.

CONCLUSION

Tamsulosin was effective in reducing the symptoms of lower urinary tract as measured by IPSS scoring. It was useful for irritative symptoms and lesser effective for obstructive symptoms. There was a significant improvement in the quality of life. Urine flow rate also increased significantly.

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