



ORIGINAL ARTICLE

## Efficacy of tamsulosin in patients with lower urinary tract symptoms due to benign prostate enlargement and having intravesical prostate protrusion.

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**ABSTRACT... Objective:** To study the efficacy of Tamsulosin in patients with IPP due to BPE. **Study Design:** Descriptive study. **Setting:** Department of Urology, Madinah Teaching Hospital Faisalabad. **Period:** Oct 2020 to April 2021. **Methods:** After approval from ethical review committee and informed consent a total of 96 male patients between the ages 50-90 years who had LUTS due to benign prostate enlargement of  $\geq 30g$  were included in the study. Patients with no IPP or having uncontrolled hypertension / diabetes were excluded from the study as well as those having LUTS due to any other etiology e.g. neurogenic bladder or bladder stone. IPSS was calculated for all the patients and entry was made in the research performa. All patients received Cap. Tamsulosin 0.4 mg at bedtime for 2 weeks. On follow up in outpatient department, IPSS was calculated again and any improvement of 3 points of the IPSS score was taken as significant and as an evidence of efficacy of Tamsulosin. All the data including any complication was collected and secured on the performa. **Results:** Pretreatment and post treatment mean IPSS was calculated to be  $19.54 \pm 5.87$  and  $17.27 \pm 4.29$  respectively. Frequency of efficacy of Tamsulosin in patients with Intravesical prostatic protrusion due to benign prostatic enlargement was recorded in 42.71% (n=41) whereas 57.29% (n=55) had no efficacy. Stratification with regards to grade of IPP shows that 12 of 25 cases of grade I, 19 of 40 cases in grade II and 10 of 31 cases in grade III had efficacy, p value was 0.23. **Conclusion:** We concluded that tamsulosin is effective in patients with intravesical prostatic protrusion due to benign prostatic enlargement, however, further trials are required to validate our results.

**Key words:** Benign Prostate Enlargement (BPE), Intravesicle Prostate Protrusion (IPP), International Prostate Symptom Score (IPSS), Tamsulosin.

### INTRODUCTION

Lower urinary tract symptoms (LUTS) encompass a spectrum of clinical presentations associated with various phases of the micturition process.<sup>1</sup> LUTS afflict 57.1% of males and 48% of females, indicating a significant prevalence across both genders.<sup>2</sup> The prevalence of LUTS in elderly males spans from 10.3% to 25.1%, indicating a notable occurrence within this demographic cohort.<sup>3</sup> LUTS are categorized into voiding, storage, and post-micturition urinary symptoms. Storage symptoms encompass frequency, urgency, nocturia, and urge incontinence, while voiding symptoms consist of straining to void, poor stream, intermittency, and hesitancy. Sensation of incomplete emptying characterizes the post-

micturition symptomatology.<sup>4,5</sup>

Benign prostatic enlargement (BPE) stands as the primary etiology of LUTS in the elderly, impacting approximately 23% of males aged 50 and above.<sup>6</sup> Bladder outlet obstruction (BOO) in aging males is typically attributed to benign prostatic enlargement (BPE) unless alternative causes are established. Its prevalence rises substantially, affecting nearly 50% of men over 65 years old and virtually every man over 80 years old.<sup>7,8</sup> BOO can manifest as both mechanical and functional in nature. Mechanical BOO arises from prostatic enlargement, while functional BOO results from heightened prostatic smooth muscle tone.<sup>9</sup>

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Of all the validated questionnaires utilized for evaluating the severity of LUTS, the International Prostate Symptom Score (IPSS) is recognized as the most widely accepted. Within the IPSS framework, scores ranging from 0 to 7 are indicative of mild symptoms, 8 to 19 signify moderate symptoms, and 20 to 35 denote severe symptomatology.<sup>3,5,10</sup>

Intravesical prostate protrusion (IPP) denotes the measurement between the bladder neck and the tip of the prostate's protrusion into the bladder lumen. It is classified into three grades according to this measurement: Grade I corresponds to IPP less than 5mm, Grade II ranges from 5 to 10 mm, and Grade III denotes IPP exceeding 10mm.<sup>2,11</sup> The median lobe of the prostate originates from the periurethral zone, its excessive growth results in its protrusion into the bladder.<sup>12</sup> It is typically assessed in the mid-sagittal view utilizing transabdominal ultrasound scanning. Recent research has highlighted IPP as a potential predictive factor in the management of benign prostatic enlargement (BPE). Its clinical significance stems from the observation that the projected median lobe of the prostate contributes to a "ball valve" type of obstruction, characterized by incomplete opening, and impedes the funneling effect of the bladder neck.

LUTS resulting from BPE are typically addressed initially through pharmacological interventions. Among these, alpha blockers are commonly considered the first-line therapy due to their ability to prompt swift amelioration of voiding, storage, and post-micturition symptoms.<sup>6,9</sup> Tamsulosin stands out as one of the most frequently prescribed alpha blockers, renowned for its efficacy in delivering substantial enhancements in International Prostate Symptom Score (IPSS) and Quality of Life (QoL) measures, thus offering satisfactory symptom relief.<sup>6,7</sup> As of now, only a limited number of researchers have explored the correlation between IPP and outcomes of alpha-blocker therapy. Studies by Topazio L et al<sup>8</sup>, Matsukawa Y et al<sup>9</sup>, and Liu Q et al<sup>13</sup> have all concurred that IPP exhibits a positive correlation with bladder outlet obstruction (BOO) and serves as a reliable predictor for

the effectiveness of  $\alpha$ -blocker therapy among patients with benign prostatic enlargement (BPE). Contrarily, Krivoborodov GG et al's research indicates that IPP measurements below 10mm do not demonstrate a correlation with bladder outlet obstruction (BOO).<sup>14</sup> Similarly, findings from Kadihasanoglu M et al's study reveal no statistically significant variance in International Prostate Symptom Score (IPSS) or flow rates between patients with and without intravesical prostate protrusion (IPP).<sup>15</sup> In one particular study, 48.46% of the total patient cohort with intravesical prostate protrusion (IPP) exhibited positive responses to Tamsulosin therapy.<sup>8</sup> The aim of this investigation is to evaluate the effectiveness of Tamsulosin in individuals diagnosed with benign prostatic enlargement (BPE) and concurrent IPP. By accurately predicting the response to alpha-blocker therapy in patients presenting with IPP, clinicians can judiciously consider timely surgical interventions, thereby optimizing resource allocation and patient care.

## METHODS

After taking approval from the local ethical review committee (Tuf/Dean/2020/68) and informed consent a total of 96 male patients between the ages 50-90 years who had LUTS due to benign prostate enlargement  $\geq 30$ g were included in the study conducted from Oct. 2020 to April 2021, with an objective to study the efficacy of Tamsulosin in patients with IPP due to BPE. Patients with no IPP or having uncontrolled hypertension / diabetes were excluded from the study as well as those having LUTS due to any other etiology e.g. neurogenic bladder or bladder stone. IPSS was calculated for all the patients and entry was made in the research performa. After this all patients received Cap. Tamsulosin 0.4 mg at bedtime for 2 weeks. On follow up in outpatient department, IPSS was calculated again and any improvement of 3 points of the IPSS score was taken as significant and as an evidence of efficacy of Tamsulosin. All the data including any complication was collected and secured on the pro forma. Data was analyzed using SPSS v-25. Mean and standard deviation was calculated for all quantitative variables like age, pre-treatment IPSS and post-treatment IPSS. Frequency and

percentage was calculated for all the qualitative variables like the efficacy of Tamsulosin and grade of IPP. Effect modifiers like gender and age were controlled by stratification. Post stratification chi-square test was applied. P-value < 0.05 was taken as significant.

## RESULTS

Out of the total 96 patients frequency of grade of IPP was recorded 26.04 % (n=25) as grade I, 41.67% (n=40) had grade II and 32.29% (n=31) had grade III. (Table-I). Frequency of efficacy of Tamsulosin in patients with Intravesical prostatic protrusion due to benign prostatic enlargement was recorded in 42.71% (n=41) whereas 57.29% (n=55) had no efficacy. (Table-II). Pretreatment and post treatment mean IPSS was calculated to be  $19.54 \pm 5.87$  and  $17.27 \pm 4.29$  respectively. There was no serious complication noted in any of the patients included in study.

IPP Grade	Number of Patients (%)
I	25 (26.04 %)
II	40 (41.67 %)
III	31 (32.29 %)
Total	96 (100 %)

Table-I. Frequency of IPP Grade

Efficacy	Number of Patients (%)
Yes	41 (42.71 %)
No	55 (57.29 %)
Total	96 (100 %)

Table-II. Frequency of efficacy of tamsulosin

Age distribution shows that 56.25% (n=54) cases were between 50-70 years of age whereas 43.75% (n=42) were between 71-90 years of age, mean age was calculated as  $68.57 \pm 7.51$  years. Stratification for frequency of efficacy with regards to age and grade of IPP is shown in Table-III and Table-IV respectively.

Age (in years)	Efficacy		P-Value
	Yes	No	
50-70	26 (48.1%)	28 (51.85%)	0.22
71-90	15 (35.71%)	27 (64.29%)	

Table-III. Efficacy after age stratification

IPP Grade	Efficacy		P-Value
	Yes	No	
I	12 (48%)	13 (52%)	0.3
II	19 (47.5%)	21 (52.5%)	
III	10 (32.26%)	21 (67.74%)	

Table-IV. Efficacy after IPP grade stratification

## DISCUSSION

Benign prostatic enlargement (BPE) stands as the foremost cause of lower urinary tract symptoms (LUTS) in the elderly, affecting 23% of men aged over 50, predominantly by inducing bladder outlet obstruction (BOO). Initial management typically involves pharmacological therapy, with Tamsulosin, an alpha blocker noted for its up to 38-fold selectivity for  $\alpha$ -1A receptors in prostate, bladder neck, and urethra. Nonetheless, few studies have scrutinized the efficacy of Tamsulosin, prompting our investigation into predicting the response to  $\alpha$ -blocker therapy in patients with intravesical prostatic protrusion (IPP), with the aim of potentially guiding surgical decisions to optimize resource allocation.

Our study, conducted at Madinah Teaching Hospital, Faisalabad, a tertiary-level facility with a robust Urology department, involved 96 cases. Among these, 56.25% (n=54) fell within the 50-70 age group, while 43.75% (n=42) were aged between 71-90, with a mean age of  $68.57 \pm 7.51$  years. We observed a frequency of Tamsulosin efficacy in patients with IPP due to BPE to be 42.71% (n=41).

Our findings align with those of Topazio L et al<sup>8</sup>, who enrolled 142 patients, excluding 12 due to incomplete data. They categorized patients into IPP grade groups: 50 in grade 1 (group A), 52 in grade 2 (group B), and 28 in grade 3 (group C). Treatment success rates were 82%, 38.5%, and 7.1%, respectively, with significant differences noted between groups A vs B-C and B vs C. The odds ratio for treatment success was 59 and 8.1 in groups A and B, respectively, compared to group C. Even after multivariate regression, the correlation between IPP grade and treatment success persisted, highlighting the significance of intravesical prostatic protrusion in predicting  $\alpha$ -blocker therapy outcomes.

However, it's noteworthy that Krivoborodov GG et al<sup>14</sup> reported that IPP less than 10mm lacks correlation with BOO, while Kadihasanoglu M et al<sup>15</sup> found no significant differences in IPSS and flow rates between patients with and without IPP. These contrasting findings underscore the

complexity of the relationship between IPP, BOO, and treatment outcomes, necessitating further investigation and clinical judgment.

## CONCLUSION

We concluded that tamsulosin is effective in patients with intravesical prostatic protrusion due to benign prostatic enlargement, however, further trials are required to validate our results.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## SOURCE OF FUNDING






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