

## Original Research Article

# Comparing the effect of Alpha blocker (Silodosin) and Phosphodiesterase type 5 inhibitor (Tadalafil) in benign prostate hyperplasia patients with lower urinary tract symptoms: a single centre study

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## ABSTRACT

**Background:** Benign prostatic hyperplasia (BPH) is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone. The aim of this systematic review is to determine the comparative effectiveness and safety of phosphodiesterase 5 inhibitors (PDE5-Is) and alpha blockers used alone or in combination for the treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH).

**Methods:** We analyzed 54 patients of BPH with LUTS with baseline IPSS, Qmax and PVR over one-year period. They were randomized equally in three groups i.e. group receiving alpha blocker, group receiving phosphodiesterase 5 inhibitors and group receiving combination of the two drugs. These patients were followed up at the end of 1<sup>st</sup> month and 3<sup>rd</sup> month and IPSS, Qmax and PVR was compared.

**Results:** Out of 54, 45 patients completed the study. At the end of the study all the three groups showed significant improvement in IPSS, PVR and Qmax, all  $p < 0.05$ , but the combination group showed much better improvement in terms of percentage. Two patients on alpha blockers had episode of hypotension.

**Conclusions:** Thus, we summarize that phosphodiesterase 5 inhibitors should be preferred over alpha blockers in patients with LUTS/BPH as it has, firstly, outcome similar to alpha blockers. Secondly, have no documented side effect. Third, can be given in any patient, irrespective of the fact that whether the patient is suffering from erectile dysfunction or not.

**Keywords:** Alpha blockers, Benign prostatic hyperplasia, Lower urinary tract symptoms, Phosphodiesterase 5 inhibitors

## INTRODUCTION

Benign prostatic hyperplasia (BPH) is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone.<sup>1,2</sup> The enlarged prostate contributes to voiding symptoms

and irritative symptoms.<sup>3</sup> It was reported that the  $\alpha 1A$ -alpha receptors subtype is predominant in the prostate but recent studies have detected the expression of both  $\alpha 1A$ - and  $\alpha 1D$ -alpha receptors in human prostate tissue.<sup>4,5</sup> It has been reported that  $\alpha 1A$ -alpha receptors blockade relieves bladder outlet obstruction, while the blocking the

1D- alpha receptors is believed to alleviate storage symptoms due to detrusor overactivity.<sup>6,7</sup>

Blockade of the 1A-receptors has been shown to reduce prostatic tone and improve the dynamic aspects of voiding. Blockade of 1B receptors leads to venous and arterial dilation as smooth muscle cells in the vessel walls relax.<sup>8</sup> Stimulation of 1D-receptors can lead to detrusor instability and blockade of these receptors has been shown in animal models to reduce irritative voiding symptoms.<sup>9</sup>

Silodosin is a highly sensitive alpha-1A receptor antagonist with little or no cardiovascular side-effects. It has been shown to have negligible effects on blood pressure and no effect on cardiac repolarization.<sup>8</sup> Silodosin shows an affinity for the  $\alpha$  1A-AR that is 583 and 56-fold higher than its affinity for the  $\alpha$  1B- and  $\alpha$  1D-ARs, respectively.<sup>10</sup>

The selectivity of silodosin for the  $\alpha$  1A- alpha receptors versus the  $\alpha$  1B-AR was reported to be 38-fold greater than that of tamsulosin hydrochloride in studies using Chinese hamster ovary cells expressing three human  $\alpha$  1-alpha receptors subtypes.<sup>11</sup>

Immunohistochemical studies indicate that PDE5 is localized in the endothelial and smooth muscle cells of the lower urinary tract blood vessels.<sup>12</sup> Several in vitro studies have demonstrated that PDE5-Is can relax isolated prostate and bladder neck strips.<sup>13,14</sup>

## METHODS

### Inclusion criteria

All male patient with age >45 years and diagnosed with benign prostate hyperplasia having LUTS.

### Exclusion criteria

- Patient already on alpha blockers,
- Recurrent episodes of LUTS,
- Haematuria,
- Chronic kidney disease,
- Bilateral hydro-ureteronephrosis,
- Bladder calculi,
- Bladder diverticuli,

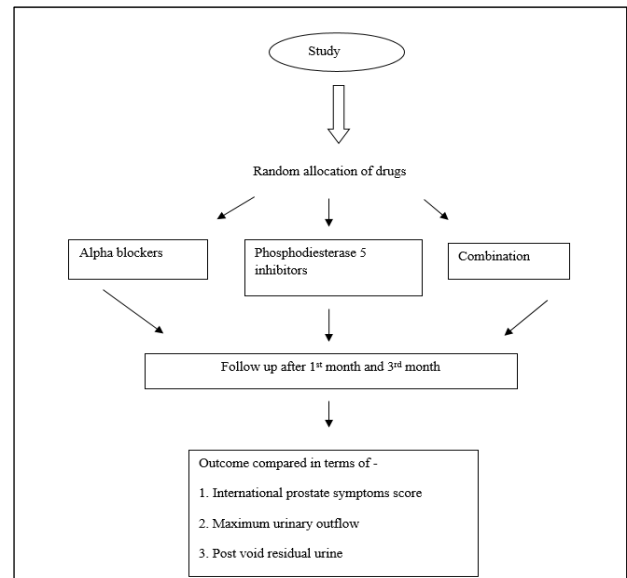
### Study design

The present study was as observational study.

### Study tool

- IPSS based questionnaire.
- Uroflowmetry
- USG KUB with PVR.

The patients presented to OPD were evaluated and diagnosed with LUTS with BPH. IPSS, uroflowmetry and USG was done on 1<sup>st</sup> visit and data were recorded. Patients were prescribed medication randomly and advised to come for follow up after 1 month (4 weeks) and 3 months (12 weeks). On follow up visit same data were recorded and compared.



**Figure 1: Study design.**

### Data management and statistical analysis

A database was constituted using freely available software solutions (SPSS Version 22) and electronic spreadsheets (MS Excel) to store and manage the collected data. Data were analysed using both parametric (ANNOVA) and unpaired 't' tests to ascertain statistical significance.

## RESULTS

Total of 54 patients were enrolled for the study over a period of 1 year. Out of these, 9 (14%) patients dropped out of the study. Five patients belonged to alpha blockers group and two each was from PDE5I and combination group. Patients were randomised in three group's i.e. alpha blockers, PDE5 1 and combination of both.

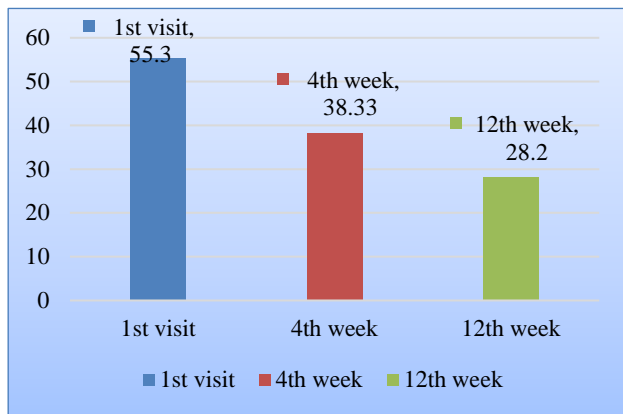
### Age

Mean patient age was 60.33 (SD=8.9) ranging 46-82 years (Figure 2, 3 and 4).

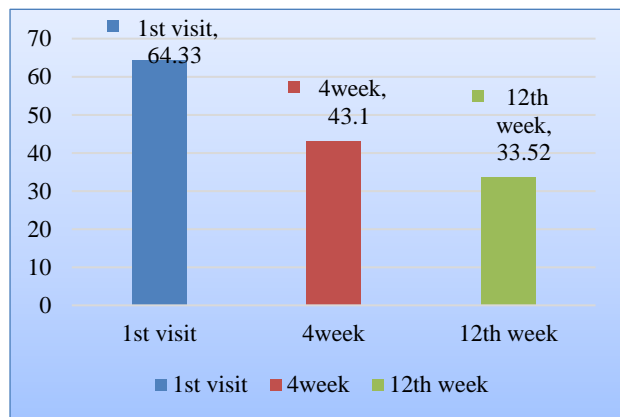
### PVR assessment

In PDE5 I group PVR drops from average 55.33 ml to 28.22 ml (i.e. 49.03% improvement) while in alpha blockers group PVR improve from 64.33 ml (average) to 33.52 ml (47.89% improvement). While in combination

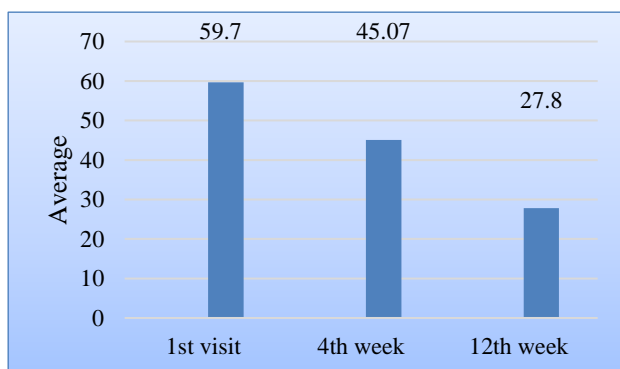
group PVR improves from 59.4 ml to 27.8 ml at 12<sup>th</sup> week (overall 53.40% improvement) (Figure 2, 3 and 4).



**Figure 2: PVR in PDE5 I group.**



**Figure 3: PVR in alpha blockers group.**



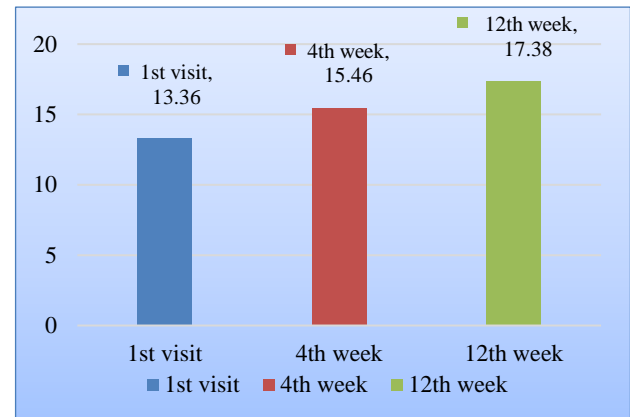
**Figure 4: Combination group.**

In terms of p value there was significant improvement in both the groups individually in all the three parameters,  $p < 0.05$ . But when compared with each other, the improvement was not evidently significant,  $p > 0.05$ .

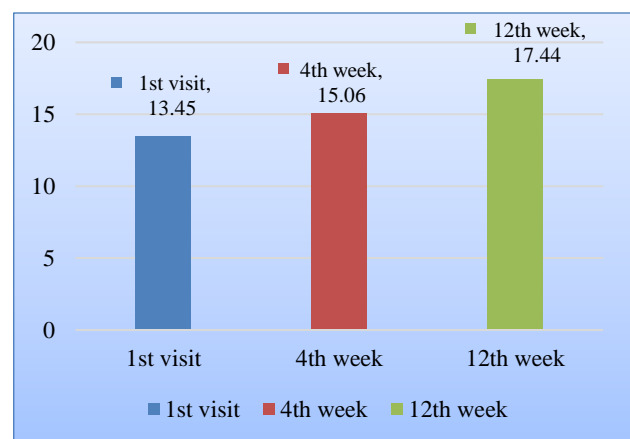
#### **Qmax assessment**

Qmax in PDE5 I group improves from 13.36 to 15.00 at 4<sup>th</sup> week and further to 17.38 at 12<sup>th</sup> week (30.08%

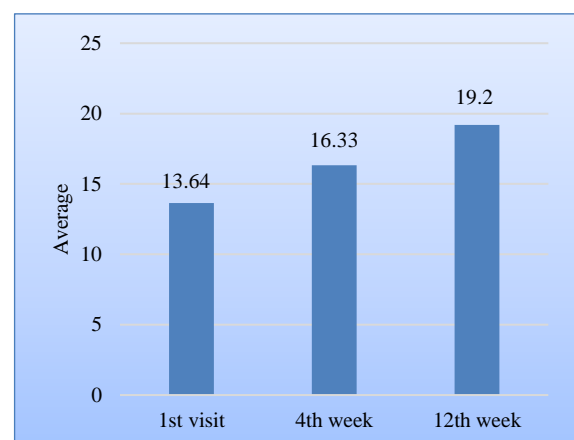
improvement). Among Alpha Blockers group Qmax at the time of presentation was 13.45 and at 4<sup>th</sup> and 12<sup>th</sup> week was 15.06 and 17.44 respectively (29.6% improvement). In combination group Qmax at the time presentation was 13.64 and at 4<sup>th</sup> week was 16.33 (44.06% improvement).



**Figure 5: Qmax in PDE5I group.**



**Figure 6: Qmax in alpha blockers group.**



**Figure 7: Qmax in combination group.**

Again, there was significant improvement in all the three parameters in both the groups individually,  $p < 0.05$ . When

compared with each other, none of the two groups was superior to other,  $p > 0.05$  (Figure 5, 6 and 7).

### IPSS Assessment

In PDE5I Group the IPSS at the time presentation was 16.46 which improves further to 12.4 and 10.66 at 4<sup>th</sup> and 12<sup>th</sup> week respectively. Overall 35.2% improvement seen at PDE5I group. While in Alpha blockers group IPSS was 18.2 at the time of presentation which also improves to 14.2 and 12.4 at 4<sup>th</sup> and 12<sup>th</sup> week respectively. Thus 31.8% improvement seen in alpha blockers group (Figure 8, 9, and 10).

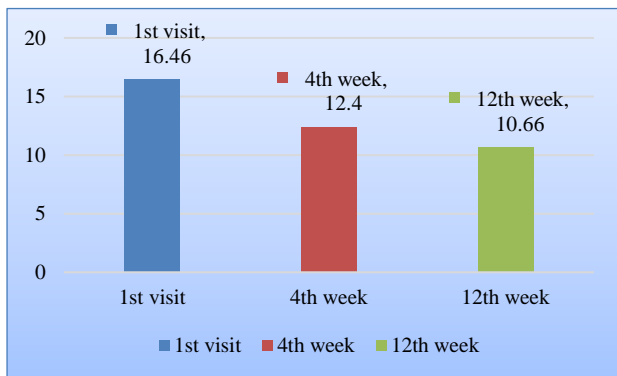


Figure 8: IPSS in PDE5 I group.

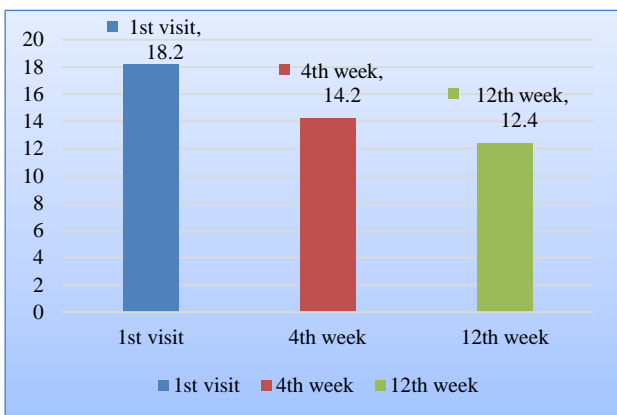


Figure 9: IPSS in Alpha blockers group.

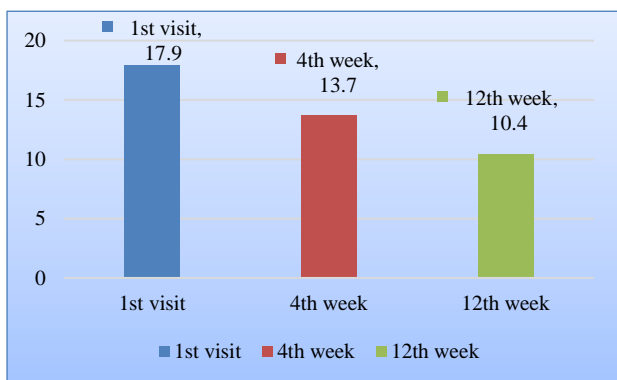


Figure 10: IPSS in combination group.

In this case too, the superiority of one group cannot be established over the other as  $p > 0.05$  in all the three parameters.

Table 1: Comparison of p-value of IPSS between alpha blocker, PDE5I and combination group.

1 - Alpha blocker 2- PDE5I 3- combination	N	Mean	SD	P value
Base IPSS	1.00	15	18.20	0.676
	2.00	15	16.46	
	3.00	15	17.93	
Three IPSS	1.00	15	12.4000	0.236
	2.00	15	10.66	
	3.00	15	10.46	

Table 1 compares the p-value of IPSS, between alpha blockers, PDE5I and combination group at the time of presentation and at the end of 12<sup>th</sup> week. It is concluded that the improvement in IPSS, over the period of 12 weeks, is not significant in any of the group. The p value at the time of presentation was 0.676 while at 3 month it become 0.236 which is not significant.

Table 2: Comparison of P value of Qmax between alpha blocker, PDE5I and combination group.

1-Alpha Blockers 2- PDE5I 3-combination	N	Mean	SD	P value
Base Qmax	1.00	15	13.45	0.758
	2.00	15	13.36	
	3.00	15	13.64	
Three Qmax	1.00	15	17.44	0.553
	2.00	15	17.38	
	3.00	15	19.20	

While Table 2 suggests non-significant improvement in Qmax, when compared between alpha blockers and PDE5I group, over the period of 12 weeks, as shown in terms of p-value ( $p = 0.553$ ). Qmax shows best improvement in combination group but still p value is not significant.

Table 3: Comparison of P value of PVR between alpha blocker, PDE5I and combination group.

1 - Alpha blocker 2 - PDE5I 3 - Combination	N	Mean	SD	P value
Base PVR	1.00	15	64.3333	0.973
	2.00	15	55.33	
	3.00	15	59.66	
Three PVR	1.00	15	33.52	0.339
	2.00	15	28.22	
	3.00	15	27.80	

PVR improvement shows equal in all the groups thus all are comparable. This table 3 compares the p-value of PVR, between alpha blockers and PDE5I, at the time of presentation and at the end of 12<sup>th</sup> week. It is concluded that the improvement in IPSS, over the period of 12 weeks, is not significant ( $p = 0.339$ ).

## DISCUSSION

Treatment of LUTS from BPH has evolved from surgical therapy to medical monotherapy to combination therapy. At present only combination therapy with 5 $\alpha$ -reductase inhibitors with  $\alpha$ -adrenergic antagonists is recommended in clinical practice guidelines. The large long-term studies MTOPS and ComBAT have demonstrated superiority of combination therapy over monotherapy in preventing disease progression.<sup>15,16</sup>

The aim of this study was to compare alpha blocker and phosphodiesterase 5 inhibitor alone or in combination for treatment of LUTS/BPH. Established clinical guidelines recommend combinations of anticholinergics, and a recent randomized trial showed the efficacy of add-on therapy with mirabegron 50 mg once daily for such patients.<sup>17</sup> However, use of these agents must be carefully considered because of their presumed inhibitory effect on detrusor contractility and deterioration of voiding function thereby increasing PVR significantly.<sup>18</sup> Thus, in present study, we have selected tadalafil as an individual drug regimen and as well as an add-on therapy.

In the present study, we found that there is definitive improvement in IPSS (mean  $18.20 \pm 5.65$ ,  $12.4 \pm 3.13$ ) ( $p = 0.000$ ) in alpha blockers group. This is supported by the study conducted by Marks et al where (SD 1.9) and p value was  $<0.0001$ .<sup>14</sup>

In the present study, we conclude that alpha blockers are quite capable of improving the Qmax (mean  $13.45 \pm 2.97$ ,  $17.44 \pm 3.50$ ) ( $p = 0.000$ ). Moon KH et al in their study had shown similar results, where mean (11.2, 14.7)  $p < 0.0001$ .<sup>19</sup>

In the present study, there was significant improvement in PVR (mean  $64.33 \pm 40.95$ ,  $33.52 \pm 18.94$ ) ( $p = 0.001$ ) with alpha blockers alone. But this finding is contraindicated in the study by Moon KH (mean 31.3, 31.7;  $p = 0.9404$ ).<sup>19</sup> In the present study, we found that there is definitive improvement in IPSS (mean  $16.46 \pm 6.34$ ,  $10.66 \pm 3.84$ ) ( $p = 0.000$ ) in PDE5I group alone. This is supported by the study conducted by Lee SW et al where SD was -5.97 and p value was  $<0.05$ .<sup>20</sup>

In the present study, we conclude that PDE5I group are capable of improving the Qmax (mean  $13.36 \pm 5.28$ ,  $17.38 \pm 4.62$ ) ( $p = 0.000$ ). Lee SW et al in their study had shown contradictory results, SD: 2.30,  $p < 0.945$ .<sup>20</sup>

In the present study, there was significant improvement in PVR (mean  $55.33 \pm 32.27$ ,  $28.22 \pm 10.82$ ) ( $p = 0.000$ ) with

PDE5I group alone. This finding is supported by the study by Lee SW et al where SD was -7.2,  $p < 0.009$ .<sup>20</sup>

In the present study, we found that there is definitive improvement in IPSS (mean  $17.93 \pm 5.20$ ,  $10.46 \pm 3.06$ ) ( $p = 0.000$ ) in combination group. This is supported by the study conducted by Lee JY et al (mean  $17.4 \pm 7.7$ ,  $9.2 \pm 4.7$ ) p value was  $<0.001$ .<sup>21</sup>

In the present study, we conclude that combination group are capable of improving the Qmax (mean  $13.6 \pm 4.32$ ,  $19.2 \pm 3.19$ ) ( $p = 0.000$ ). Yoshida T et al in their study had shown similar results, (SD 1.09, 1.04)  $p < 0.026$ .<sup>22</sup>

In the present study, there was significant improvement in PVR (mean  $59.64 \pm 32.35$ ,  $27.80 \pm 15.96$ ) ( $p = 0.000$ ) with combination group. This observation is contraindicated in the study by Yoshida T et al where (mean 15.3, 10.2)  $p = 0.533$ .<sup>22</sup>

Present study shows improvement in IPSS 31.8% ( $p = 0.000$ ) and 35.2% ( $p = 0.000$ ) for alpha blockers and phosphodiesterase 5 inhibitors respectively over the time of 12 weeks.

But the p-value at the end of the study, when compared with each other was 0.187, which is not significant. This suggests that there is no additional beneficial effect of PDE5I over alpha blockers. This is supported by the study conducted by Wang XH et al where  $p = 0.08$ .<sup>23</sup>

In the present study, we found that the change in Qmax for alpha blockers and phosphodiesterase 5 inhibitors are 29.6% and 30.08% respectively. The p-value was 0.895 not significant. This is in accordance with the study as stated earlier where  $p = 0.09$ .<sup>23</sup>

In the present study, we found that the change in PVR for alpha blocker and phosphodiesterase 5 inhibitor, over the period of 12 weeks, are 47.89% and 49.03% respectively and the p-value at the end of the study was 0.349. This outcome is contradicted by the same study where  $p = 0.001$ .<sup>23</sup>

In the present study, we found that the percentage change in IPSS was 31.8% and 41.8% for alpha blockers and combination respectively over the time of 12 weeks. The p-value was 0.099 when compared with each other. The study conducted by Huan X.<sup>23</sup>

In the present study, we found that the change in Qmax for alpha blockers and combination are 29.6% and 44.06% respectively and the p-value at the end of the study was 0.187. The previous study suggested that combination group have superiority ( $p = 0.003$ ) over alpha blockers alone.<sup>23</sup>

In the present study, we found that the change in PVR for alpha blocker and combination, over the period of 12 weeks, are 49.6% and 59.6% respectively with p-value of

0.009. This is contradicted by the study conducted by Huan X where SD was 5.3,  $p = 0.03$ .<sup>23</sup>

In the present study, we found that the percentage change in IPSS was 35.2% and 44.1% for phosphodiesterase 5 inhibitors and combination respectively over the time of 12 weeks with  $p$ -value at the end of the study was 0.876. The change in Qmax for phosphodiesterase 5 inhibitors and combination are 30.08 % and 44.06% respectively ( $p$  value- 0.207). The change in PVR for combination group, over the period of 12 weeks, was 59.6% and mean ( $59.66 \pm 32.35$ ,  $27.80 \pm 15.96$ )  $p$ -value was 0.0001. The pooled analysis in the study by Huan X et al suggested that combination group have better outcome in terms of IPSS ( $p = 0.0001$ ).<sup>23</sup>

In the present study there is definitive improvement in the total IPSS, Qmax, and PVR from baseline to 12<sup>th</sup> weeks in all the 3 groups individually which is demonstrated in Figure 4. But this improvement is not significant, or we can say that the outcome of the results when compared to each other failed to establish definitive beneficial effect of one group over the other.

Since PDE5I are proven to have beneficial effect in patients of erectile dysfunction, we conclude that use of PDE5I, with or without alpha blockers, in patients of LUTS/BPH is rational and very well justified.<sup>24</sup>

As far as side effects of the prescribed medication is concerned, there were episodes of postural hypotension in two patient taking silodosin out of which one patient dropped out of the study because of this reason. There is documented evidence of orthostatic hypotension. No any other side effect was seen in remaining two groups.<sup>25</sup>

## CONCLUSION

We observed that most of the patients who presented with LUTS/BPH were from 5<sup>th</sup> decade of life. We also conclude that when the outcome of the individual drugs was compared with each other, no clear-cut advantage was seen of a particular group in terms of outcome.

Alpha blockers have the disadvantage of orthostatic hypotension which is a well know side effect of this group. We draw an inference that PDE5I should be preferred over commonly used alpha blockers for treatment of LUTS/BPH because of the fact that patient's response to this medication is similar to alpha blockers. In addition to that, PDE5I have proven role in erectile dysfunction. Moreover, no any incidence of adverse drug reaction was noticed in this group.

Still the present study is needed to be backed by further studies with larger sample size and long duration of follow up.

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