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Lower Urinary Tract Symptoms Associated with Benign Prostatic Hyperplasia in Patients: A Comparison between Silodosin and Tadalafil

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Authors' contributions

This work was carried out in collaboration among all the authors. Author MDR designed the study, wrote the protocol and first draft of the manuscript. Authors MS and MDR managed the literature searches and statistical analysis. Author MKV manages the analysis of the study. All authors read and approved the final manuscript.

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ABSTRACT

Background: Benign prostatic hyperplasia (BPH) is a highly prevalent and a very common disease in elderly men. LUTS secondary to BPH increases with age and has a negative impact on patient's quality of life. LUTS associated with BPH has variety of interventional treatment options like medical management and surgical management, where α1 blockers are tried as first line either alone or in combination with 5-α reductase inhibitors. The aim of our study is to compare the therapeutic efficacy of silodosin with tadalafil over a period of 4 weeks.
Methods: A prospective, observational, hospital based study. A total of 136 patients were involved in this study. 68 patients received silodosin 8 mg once daily and 68 patients received tadalafil 5 mg once daily as decided by the Urologist **.** At the end of 4th week the therapeutic efficacy of both the drugs were assessed by IPSS, IPSS QoL index score and OABSS. Adverse drug reaction in each group were also noted.

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Results: Both silodosin and tadalafil were statistically significant in decreasing total IPSS, IPSS QoL index score and total OABSS at end of 4th week. But silodosin produced statistically significant reduction in total IPSS and IPSS QoL index score when compared to tadalafil. Silodosin produced numerically greater but statistically not significant reduction in total OABSS when compared to tadalafil. Incidence of adverse effects were more in silodosin group.
Conclusion: In our study we noted that both silodosin and tadalafil were efficacious in treating LUTS associated with BPH but silodosin was superior to tadalafil. Tadalafil is efficacious in patients with concomitant ED.

Keywords: Silodosin; tadalafil; lower urinary tract symptoms; benign prostatic hyperplasia; erectile dysfunction; alpha blockers; phosphodiesterase-5 inhibitors.

ABBREVIATIONS

AUA :American Urological Association
AUC : Area under the curve
AUR : Acute urinary retention
BOO : Bladder outlet obstruction
BP : Blood pressure
BPH : Benign prostatic hyperplasia
EAU : European Association of Urology
hs : highly significant
IPSS : International prostate symptom score
IPSS QoL : International prostate symptom score Quality of life
LUTS : Lower urinary tract symptoms Ns: not significant
OABSS : Overactive bladder symptom score
TUIP : Transurethral incision of prostate
TURP : Transurethral resection of prostate
Vhs : Very highly significant

1. BACKGROUND

Benign prostatic hyperplasia (BPH) is a highly prevalent and a very common disease in elderly men with incidence increasing to involve about 90% of men aged more than 80 years [1].

BPH is a common and frequent cause of LUTS in middle aged and elderly men that has a negative impact on patient's quality of life [2,3,4]. Irritative or storage symptoms consists of frequency, urgency, nocturia and urge incontinence. Obstructive or voiding symptoms consists of intermittency, poor stream, incomplete voiding, straining to void, terminal dribbling and hesitancy [5,6].

Various treatment modalities are available for optimal management of LUTS. The first line treatment for BPH is α1 blockers. Phosphodiesterase – 5 (PDE-5) inhibitors like tadalafil has also shown promising results of late [7]. To reduce the stroma of the prostate, 5-α reductase inhibitors like finasteride or dutasteride can be given [8]. Anticholinergics drugs can be added to control frequency, urgency or urge incontinence [7].

Various surgical options are transurethral resection of prostate (TURP), transurethral incision of prostate (TUIP), laser enucleation of prostate and laser evaporation of prostate [9].

Silodosin is a third generation α1 blocker and its effect on LUTS has been found to be superior than all other α1 blockers. But still some men with BPH experience inadequate and not completely satisfactory improvement in LUTS even after treatment with silodosin [7,10]. Tadalafil is one of the newer agents and many studies have shown it can be used as monotherapy in patients with or without concomitant erectile dysfunction(ED). Tadalafil is approved in many countries for the treatment of LUTS associated with BPH, and previous randomized controlled clinical studies have demonstrated that its efficacy is similar to that of another α1 blocker tamsulosin [7,11].

Although several studies compared the effects of the α1 blocker tamsulosin with tadalafil, only few studies have been done comparing silodosin and tadalafil. So we did an observational hospital based study to compare the efficacy and adverse effect profile of silodosin and tadalafil in patients with LUTS associated with BPH.

2. METHODS

This was a prospective, observational, analytical study at a tertiary care hospital in the state of karnataka, India. Instututional ethical committee clearance was taken .After taking written consents 136 patients attending the Urology

OPD and diagnosed with BPH from January 2019 to March 2020 were taken. The source article from which the parameters for sample size calculation was derived is the study by Singh PD et al. [12].

A thorough clinical examination by a qualified urologist which included proper history consisting of International prostate symptom score(IPSS),IPSS quality of life index(IPSS QoL index) and Overactive bladder symptom score(OABSS), physical examination including digital rectal examination and investigations like uroflowmetry and ultrasonogram of Kidney, Ureter and Bladder(KUB) and prostate along with post void residual volume were done to diagnose patients with BPH.

Patients who were Suspected or diagnosed with prostate cancer ,Acute urinary tract infections , Neurogenic Bladder , Severe cardiovascular , hepatic and/or renal disorders were excluded from the study. Also patients who had a post voidal residual urine of more than 100 ml and a history of use of silodosin ,tadalafil, anti-androgens or 5-α reductase inhibitor within 24 weeks prior to enrolment were also excluded.

Patients were randomly divided into 2 groups (Group S and T). Group S patients received silodosin 8 mg per day orally at night for 4 weeks while Group T Patients received tadalafil 5 mg per day orally at night for 4 weeks.

After 4 weeks the patients were reassessed with IPSS (both voiding and storage sub scores), IPSS QoL index score and OABSS to evaluate the efficacy of silodosin and tadalafil.

Analysis was done by descriptive statistics. Comparison was done by students unpaired t test and chi square test. Pre to post comparison of quantitative data was done by students paired t test and qualitative data by Cramers test. A statistical package SPSS version. 23.0 was used to do the analysis. $p < 0.05$ was considered as significant.

3. RESULTS

This study was conducted in 136 patients who were randomnly assigned into two groups of 68 each . The demographics of the patient are depicted in Table 1. At presentation the baseline IPSS voiding score was calculated in all patients which was repeated at week 4 after starting the treatment (Table 2). The IPSS voiding score was then compared and showed significant improvement after treatment (Table 3). Similarly IPSS storage sub score was calculated and compared that showed significant improvement, (Table 4,5). Similarly OABSS score was also calculated and compared (Table 6,7). All the scoring systems showed significant improvement after treatment onset (Table 8).

Erectile dysfunction was compared in both the groups at baseline and at 4 weeks which showed a significant improvement in the tadalafil group (Fig. 1).

Other adverse effects such as nausea, retrograde ejaculation, dizziness, nasal congestion and postural hypotension were also compared, the difference being statistically insignificant (Fig. 2).

4. DISCUSSION

Medical management has become the standard of care in almost all patients with BPH. α_1 blockers were the most widely prescribed drugs, whereas the use of PDE-5 inhibitors has recently gained popularity and has shown promising results .α_1 blockers and 5-α reductase inhibitors are considered the first-line medical treatment in men with moderate to severe LUTS related to BPH. The newest class of drugs that is the PDE-5 inhibitors are mentioned in the 2013 EAU guidelines [2,9]. Treatment has progressed from surgical treatment to medical monotherapy to combination therapy of 5α-reductase inhibitors with α_1 adrenergic antagonists [13].

Both α_1 blockers and PDE-5 inhibitors act mainly to relieve the dynamic obstruction of the prostate with a direct relaxation of the bladder whereas PDE-5 inhibitors relaxes smooth muscle in the human bladder neck, prostatic capsule and prostatic urethra and decreases detrusor muscle over activity [2,8].

This study compared the efficacy of silodosin versus tadalafil in treating the LUTS associated with BPH. Adverse effects of both the drugs were also noted.

A total of 136 patients were evaluated of which 68 received silodosin and 68 received tadalafil and they were evaluated at the end of 4 weeks using IPSS, IPSS QoL Index score and OABSS. Similar studies have been done by Yoshida et al [3] and Singh et al. [12]. The sample size is comparable with our study.

Table 1. Demographics of the patient included in the study

Demographic	Group S (Silodosin)	Group T (Tadalafil)
Mean Age (years)	62.3 ± 7.03	59.3 ± 6.06
BMI (Kg/m^2)	26.3 ± 2.8	25.4 ± 2.8
Prostatomegaly		
GRADE I	16 (23.5%)	22 (32.4%)
GRADE II	40 (58.8%)	40 (58.8%)
GRADE III	12 (17.6%)	6 (8.8%)
DM –II (No of patients)	33 (48.5%)	25 (36.8%)
HTN (No of patients)	36 (52.9%)	23 (33.8%)

Table 2. Comparing the individual symptoms and total IPSS voiding sub score at baseline and 4th week in each group

Symptom	Group	IPSS at Baseline			IPSS at 4th week		
		Mean	Std deviation	t	Mean	Std deviation	t
Incomplete	S	3.000	0.712	1.758	1.868	0.667	1.093
emptying	T	2.779	0.750	p=0.081 ns	1.985	0.586	p=0.276 ns
Intermittency	S	2.294	0.947	1.020	1.309	0.718	0.127
	T	2.147	0.718	p=0.309 ns	1.324	0.633	p=8.89 ns
Weak stream	S	2.662	0.765	595	1.515	0.658	1.301
	T	2.588	0.674	p=0.553 ns	1.662	0.660	p=0.195 ns
Straining to void	S	2.912	0.842	108	1.809	0.778	1.023
	T	2.897	0.736	p=0.914 ns	1.941	0.731	p=0.308 ns
Total voiding sub	S	10.868	2.497	1.150	6.500	2.175	1.162
score	T	10.412	2.111	p=0.252 ns	6.912	1.953	p=0.247 ns

ns – not significant

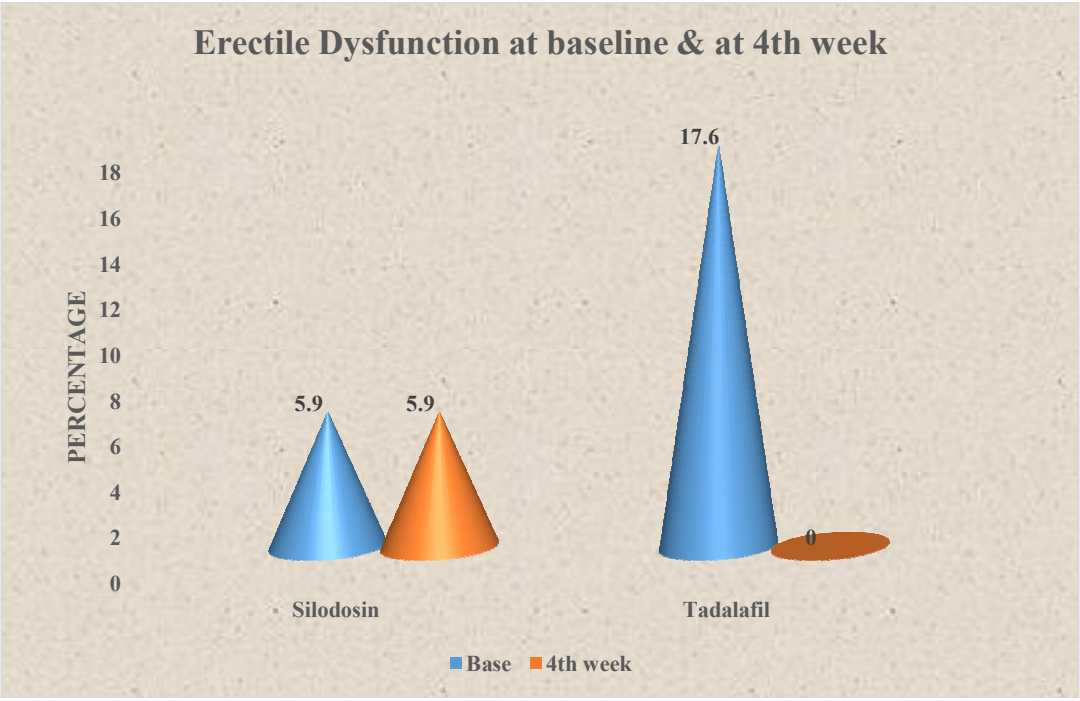

Fig. 1. Depicting erectile dysfunction at baseline and 4th week

Table 3. Comparing the difference in individual symptoms and total IPSS voiding sub score from baseline to 4th week within each group

Group		Paired differences		t	p
		Mean	Std. deviation		
Silodosin	In complete emptying - Baseline to 4th week	1.132	.571	16.367	<0.001 vhs
	Intermittency - Baseline to 4th week	.985	.635	12.802	<0.001 vhs
	Weak stream - Baseline to 4th week	1.147	.554	17.088	<0.001 vhs
	Straining to void – Baseline to 4th week	1.103	.550	16.532	<0.001 vhs
	Total voiding sub score - Baseline to 4th week	4.368	1.564	23.034	<0.001 vhs
Tadalafil	Incomplete emptying - Baseline to 4th week	.794	.442	14.800	<0.001 vhs
	Intermittency – Baseline to 4th week	.824	.571	11.883	<0.001 vhs
	Weak stream - Baseline to 4th week	.926	.498	15.334	<0.001 vhs
	Straining to void – Baseline to 4th week	.956	.438	17.987	<0.001 vhs
	Total voiding sub score – Baseline to 4th week	3.500	1.100	26.249	<0.001 vhs

vhs – very highly significant

Table 4. Comparing the individual symptoms and total IPSS storage sub score at baseline and 4th week in each group

Synptoms	Group	IPSS at baseline			IPSS at 4th week		
		Mean	Std deviataion	t	Mean	Std deviation	t
Frequency	S	2.632	644	.000	1.809	0.605	2.079
	T	2.632	621	p=1 ns	2.000	0.457	p=0.039sig
Urgency	S	2.397	694	1.158	1.618	0.713	0.245
	T	2.265	638	p=0.249 ns	1.647	0.686	p=0.807ns
Nocturia	S	2.279	928	.775	1.294	0.774	0.116
	T	2.162	840	p=0.44 ns	1.279	0.709	p=0.908ns
Total storage sub score	S	7.309	1.831	.841	4.721	1.647	0.816
	T	7.059	1.629	p=0.402 ns	4.926	1.273	p=0.416

ns – not significant

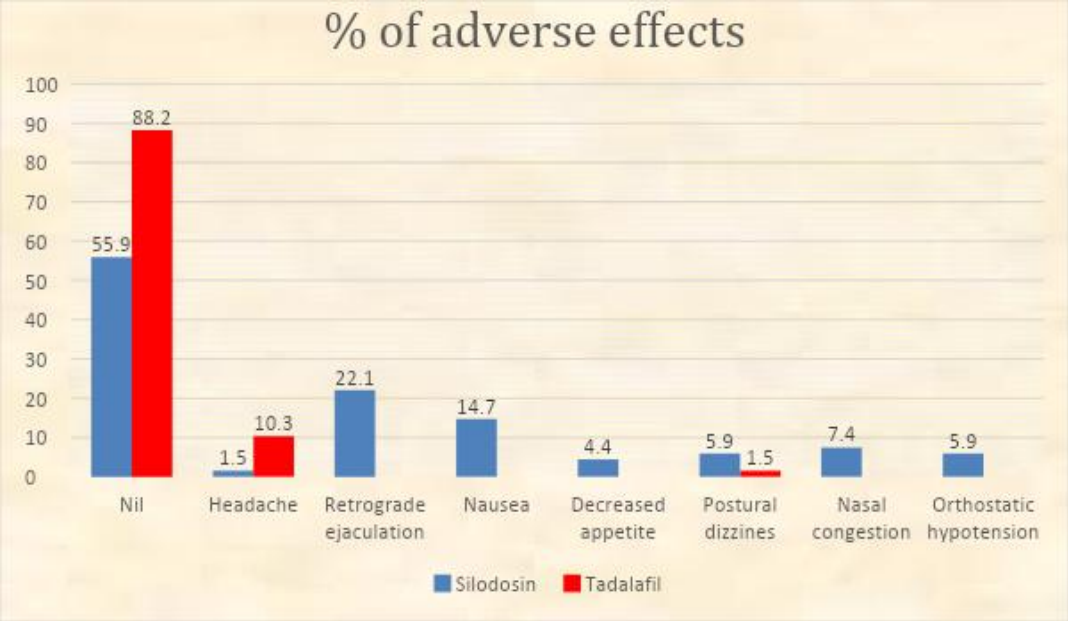

Fig. 2. Percentage of side effects in both groups

Table 5. Comparing the difference in individual symptoms and total IPSS storage sub score from baseline to 4th week within each group

Group		Paired Differences		t	p
		Mean	Std. Deviation		
Silodosin	Frequency – Baseline to 4th week	.824	.487	13.948	<0.001 vhs
	Urgency - Baseline to 4th week	.779	.542	11.856	<0.001 vhs
	Nocturia – Baseline to 4th week	.985	.611	13.305	<0.001 vhs
	Total storage sub score – Baseline to 4th week	2.588	1.082	19.722	<0.001 vhs
Tadalafil	Frequency – Baseline to 4th week	.632	.544	9.590	<0.001 vhs
	Urgency - Baseline to 4th week	.618	.547	9.308	<0.001 vhs
	Nocturia – Baseline to 4th week	.882	.533	13.642	<0.001 vhs
	Total storage sub score – Baseline to 4th week	2.132	1.035	16.985	<0.001 vhs

vhs – very highly significant

Table 6. Comparing the individual symptoms of OABSS at baseline and 4th week after treatment in each group

Symptom	Group	OABSS at baseline			OABSS at 4th week		
		Mean	Std deviation	t	Mean	Std deviation	t
Frequency	S	1.471	0.503	0.171	1.044	0.207	0.725
	T	1.456	0.502	p=0.865 ns	1.074	0.263	p=0.47 ns
Nocturia	S	2.265	0.891	0.497	1.309	0.758	0.228
	T	2.191	0.833	p=0.62 ns	1.338	0.745	p=0.82 ns
Urgency	S	2.250	0.720	0.617	1.500	0.763	0.114
	T	2.176	0.668	p=0.538 ns	1.515	0.743	p=0.91 ns
Urinary incontinence	S	0.265	0.614	2.714	0.088	0.334	1.707
	T	0.044	0.270	p=0.008 hs	0.015	0.121	p=0.09 ns

ns – not significant, hs- highly significant

Table 7. Comparing the difference in individual symptoms of OABSS from baseline to 4th week within each group

Group		Paired Differences		t	p
		Mean	Std. Deviation		
Silodosin	Frequency - Baseline to 4th week	.426	.498	7.058	<0.001 vhs
	Nocturia – Baseline to 4th week	.956	.633	12.447	<0.001 vhs
	Urgency - Baseline to 4th week	.750	.500	12.369	<0.001 vhs
	Urinary incontinence - Baseline to 4th week	.176	.421	3.456	<0.001 vhs
Tadalafil	Frequency - Baseline to 4th week	.382	.519	6.073	<0.001 vhs
	Nocturia – Baseline to 4th week	.853	.554	12.706	<0.001 vhs
	Urgency - Baseline to 4th week	.662	.536	10.189	<0.001 vhs
	Urinary incontinence - Baseline to 4th week	.029	.170	1.425	.159 ns

vhs – very highly significant
ns – not significant

Table 8. Comparing the difference in various scores from baseline to 4th week within each group

Score	Group (baseline to 4th week)	Paired differences		T	P
		Mean	Sd		
Total Ipss	S	6.941	2.198	26.038	<0.001 vhs
	T	5.632	1.656	28.041	<0.001 vhs
Total ipss qol index	S	1.662	0.704	19.461	<0.001vhs
	T	1.309	0.697	15.493	<0.001vhs
Total oabss	S	2.309	1.200	15.863	<0.001vhs
	T	1.926	1.069	14.854	<0.001vhs

In our study the baseline characteristics of the patients with regard to age and BMI corresponded very well with a study by Singh et al. [12] but in the study by Yoshida et al. [3] the mean age was higher compared to our study [3].

Baseline assessment of prostatomegaly by DRE in both the groups was statistically non-significant.

The total IPSS at baseline was not statistically significant (p = 0.229) similar to the studies by Yoshida et al. [3] and Singh et al. [12] In the study by Singh et al. [12] they only compared the total IPSS but we compared all the symptoms of IPSS.

Total IPSS voiding and storage sub scores at baseline were comparable in both the groups and the difference was statistically insignificant. However, the change in total IPSS from baseline to 4th week in Group S was statistically very highly significant ($p < 0.001$) and the percentage difference between baseline and at end of 4th week was 38.474 +/- 10.736. Change in total IPSS at end of 4th week in tadalafil group was statistically very highly significant ($p < 0.001$) and the percentage difference was 32.322 +/- 7.996. When we compared percentage difference, silodosin was very highly significant in improving total IPSS from baseline ($p < 0.001$). This matches with the result of the study by Yoshida et al. [3] where both silodosin and tadalafil significantly reduced the IPSS but reduction by silodosin was more statistically significant than that by tadalafil [3].

Both the drugs achieved a statistically very highly significant reduction in each symptom of IPSS voiding sub score (incomplete voiding, intermittency, weak steam and straining to void) and IPSS storage sub score (frequency, urgency and nocturia). All the p values were less than 0.001. But silodosin was very highly significant ($p < 0.001$) in reducing the IPSS voiding sub score than tadalafil and silodosin was highly significant ($p = 0.008$) in reducing the IPSS storage sub score also.

In IPSS voiding sub score silodosin demonstrated very highly significant reduction in incomplete emptying ($p < 0.001$) and significant reduction in weak stream (p=0.024) than tadalafil where as silodosin demonstrated a numerically greater but not statistically significant reduction in intermittency (p=0.389) and straining to void (p=0.189) which matched with the study by Yoshida et al. [3].

In IPSS storage sub score silodosin achieved a highly significant decrease in frequency than tadalafil (p= 0.005) whereas the reduction in urgency (p=0.205) and nocturia (p =0.740) was numerically greater but statistically not significant for silodosin when compared to tadalafil. But in study by Yoshida et al. [3] silodosin achieved a significant decrease in nocturia than tadalafil (p=0.0387) [3].

IPSS QoL index score also showed a significant improvement for both the groups at the end of 4 weeks corresponding to Yoshida et al. [3]

Both silodosin and tadalafil demonstrated a very highly significant decrease in IPSS QoL index score from baseline as compared to the end of 4th week but Silodosin achieved very highly significant improvement than tadalafil ($p < 0.001$). This matched with the results of study by Yoshida et al. [3].

Both silodosin and tadalafil demonstrated a very highly significant decrease in total OABSS from baseline as compared to the end of 4th week with a percentage difference for silodosin and tadalafil being 35.835 +/- 13.875 and 32.467 +/- 14.693 respectively. Silodosin achieved numerically greater but not statistically significant improvement than tadalafil ($p = 0.172$).

Both silodosin and tadalafil demonstrated very highly significant decrease in frequency, nocturia and urgency, but in case of urinary incontinence silodosin achieved a very highly significant reduction than tadalafil.

Silodosin exhibited a numerically greater, but not statistically significant difference in frequency, nocturia, urgency and urinary incontinence sub scores of OABSS than tadalafil. However study by Yoshida et al. [3] showed significantly greater decrease in nocturia and urgency sub scores in silodosin group .Silodosin exhibited numerically greater, but not statistically significant changes in other OABSS sub scores as compared to tadalafil [3].

In our study we additionally looked for the effect of both the drugs on patients with concomitant erectile which was not done in the study by Yoshida et al. [3] and Singh et al. [12]. At end of 4th week all the patients in tadalafil group did not complain of erectile dysfunction (highly significant; p=0.001) whereas patients in

silodosin group still had complaints of erectile dysfunction.

Both silodosin and tadalafil were generally well tolerated with no serious drug reactions. But incidence of adverse drug reactions were more in silodosin group .The most commonly reported adverse reaction was retrograde ejaculation which occurs as a result of smooth muscle relaxation in the prostate, urethra, bladder neck, and vas deferens [14]. In study by Yoshida et al. [3] also more adverse drug reactions were noted in silodosin group.[3]Retrograde ejaculation was followed by nausea seen in 10 patients (14.7%), nasal congestion (7.4%), orthostatic hypotension and postural dizziness (both 5.9%), decreased appetite (4.4%) and headache (1.5%). The most common adverse effects noted in the silodosin group in the study by Yoshida et al. [3] was ejaculation disorder (6.4%) followed by retrograde ejaculation and soft faeces (both 5.3%) [3].

The most frequently encountered adverse effect in tadalafil group was headache seen in 7 (10.3%) patients and dizziness was seen in 1 (1.5%) patient which are comparable to Yoshida et al. [3].

With advancing age, the incidence and prevalence of both ED and ejaculatory dysfunction increase and are associated with severity of LUTS [12,15].

PDE-5 inhibitors are used as first line management in treatment of erectile dysfunction. FDA has approved tadalafil at a dose of 5 mg for treatment of LUTS with the objective to treat both the diseases simultaneously and without worsening either of the diseases [12].

ED and LUTS associated with BPH are epidemiologically linked and almost share common pathophysiological pathways. Tadalafil is the only approved drug available today which can be used to treat both symptoms. The treatment of subclinical ED is however debatable. However in young and middle aged patients, sexual function is the biggest priority and in those patients if they have sexual dysfunction like ED along with LUTS related to BPH, tadalafil can be the drug of choice [12].

5. CONCLUSION

The results of this study have shown that both silodosin and tadalafil were efficacious in treating lower urinary tract symptoms associated with benign prostatic hyperplasia and demonstrated statistically significant decrease in total IPSS, IPSS QoL index score and total OABSS. However silodosin exhibited statistically significant decrease in total IPSS and IPSS QoL index score when compared to tadalafil. Silodosin showed only a numerically greater but not statistically significant decrease in total OABSS when compared to tadalafil. However we found in our study that when tadalafil is given to patients with LUTS associated with BPH and having concomitant erectile dysfunction, it reduced symptoms of both the diseases. Both the drugs were well tolerated and no serious adverse events were noted. Both silodosin and tadalafil can be used as monotherapy for treatment of LUTS associated with BPH. However further studies with larger number of cases and with a longer duration of follow up including more parameters like uroflowmetry and USG are necessary to validate these promising results.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT AND ETHICAL APPROVAL

This study was approved by the ethics committee of Father mullers medical college with approval number ECR/540/Inst/KA/2014/RR-17. The patient provided written consent for participating in the study. Availability of data and materials -All data generated or analysed during this study are included as supplementary material. Any additional information can be obtained from corresponding author.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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