Safety and Efficacy of Silodosin versus Tadalafil in Benign Prostatic Hyperplasia Patients with Lower Urinary Tract Symptoms; A prospective comparative study

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Abstract

Introduction: A histological term for the proliferation of smooth muscle and epithelial cells in the prostatic transition zone is benign prostatic hyperplasia. There are many options for therapy for the management of BPH.

Aim of the study: To evaluate the safety and effectiveness of silodosin versus tadalafil in the treatment of BPH-related lower urinary tract symptoms (LUTS/BPH).

Subjects and Methods: This prospective randomized study was carried out on 97 male patients with LUTS. It was performed at Fayoum University Hospital (urology outpatient clinic) from April 2020 to June 2021.

Results: At the end of the study, we noticed a statistically highly significant improvement in IIEF scores in cohort II to be 22.9±2.3 vs. 20.8±3.7 in cohort I with (*P<0.001*) and a highly significant improvement in Qmax in cohort I to be 13.6±2.4 ml/sec vs. 10.4±2.6 ml/sec in cohort II with (*P<0.001*). On the other hand, there were no statistically significant variations in IPSS scores between the study cohorts with (*P=0.5*)

Conclusion: Both Silodosin and Tadalafil are safe and effective as medical treatments for LUTS/BPH. Silodosin achieved significantly greater improvement regarding LUTS/BPH than Tadalafil.

Key words: Silodosin; Tadalafil; Urinary tract; Benign Prostatic Hyperplasia; BPH.

1. Introduction

Benign prostatic hyperplasia (BPH) is a histology term describing the proliferation of smooth muscle and epithelial cells in the prostatic transition zone. Lower urinary tract symptoms (LUTS) are frequently caused by bladder outlet obstruction (BOO) and/or BPH-related changes in smooth muscle tone and resistance [1].

BPE, commonly known as BOO, is an enlargement of the prostate gland that affects around 50% of men with BPH. LUTS are voiding and/or storage disorders that can induce nocturia at night and during the day, as well as urine hesitancy, a weak stream, straining, and prolonged voiding. The most common LUTS symptoms are nocturia, weak stream, and urine hesitancy. LUTS/BPH have a detrimental impact on quality of life [2].

Trends in the medical treatment of LUTS/BPH have improved during the last 25 years. As the condition advanced from one that required surgical intervention to one

that could be successfully managed medically, the Food and Drug Administration (FDA) began to approve medications for LUTS/BPH in the early 1990s. The first two commonly used therapies are 5-alpha reductase inhibitors (5-ARIs) and alpha-blockers (AB) [3].

The American Urological Association (AUA) statement on the management of BPH in males with LUTS/BPH includes alfuzosin, terazosin, tamsulosin, and doxazosin as viable treatment options. Monotherapy with 5-ARI medications such as finasteride and dutasteride is another treatment option for LUTS/BPH. Systematic studies reveal that 5-ARIs are safe and effective, and they may be more effective than AB in slowing disease progression. The AUA recommends AB/5-ARI combinations as appropriate and efficient therapeutic options for males with LUTS/BPH and enlarged prostates. Newer drugs and several pharmacological classes have showed promise in treating LUTS/BPH. Silodosin, a new selective AB, was approved by the FDA for the treatment of BPH in 2008 [4].

Inhibiting PDE-5 isoenzymes in lower urinary tract tissues relaxes smooth muscle in the bladder, urethra, and prostate, as well as supporting vasculature, lowering tension in the smooth muscle of the prostatic stroma and capsule. This is assumed to be the mechanism of action of PDE-5 inhibitors like Tadalafil in treating LUTS caused by BPH. This muscle relaxation reduces detrusor muscle overactivity in the bladder walls and neck, causing the bladder neck to open [5].

The purpose of this study was to compare the safety and efficacy of Silodosin versus Tadalafil in the treatment of BPH-related lower urinary tract symptoms (LUTS/BPH).

2. Subjects and methods

2.1. Subjects

This prospective randomized study was carried out on 97 male patients with LUTS. It was performed at Fayoum University Hospital (urology outpatient clinic) from April 2020 to June 2021.

After approval of the local institutional ethics committee, detailed informed consent was obtained from the patients (properly explaining the aims, methods, anticipated benefits, and potential drawbacks relevant to the decision to participate in the study). The randomization sequence was given in a list that was created using Random Allocation Software version 1.0.0 (Developed by M. Saghaie, MD., Department of Anesthesia, Isfahan University of Medical Sciences, Isfahan, Iran.) with a 1:1 allocation using random block sizes of 2, 4, and 6 to receive either Silodosin (Cohort I, n= 65) or Tadalafil (Cohort II, n=63).

Inclusion criteria

That included male patients aged ≥45 years, with IPSS score ≥13, Qmax ≤15 ml/s of a voided volume of more than 150 ml, a prostate volume ≥ 20 ml, the physical and mental capacity to fill out and understand the study questionnaires (IPSS and IIEF).

Exclusion criteria

That included patients with post-voiding residual urine volume >300 ml, high PSA with suspected prostate cancer, clinically significant

cardiovascular, hepatic, or renal disorders. Also, patients suffered from neurogenic bladder, previous prostatic or urethral surgery, used 5α-reductase inhibitor within six months before enrollment, had contraindications to Tadalafil or Silodosin as nitrate consumption or allergy to any of the medication, or active UTI were excluded.

2.2. Methods

Clinical assessment

a) History taking with special emphasis on the following:
- Detailed medical history of any previous medication for the LUTS or any chronic illness.
- The surgical history of any previous operations regarding the prostate, urethra, and bladder.
- Assessment of LUTS and the severity through the IPSS questionnaire.
- Sexual history: evaluation of the sexual activity was done through the IIEF-5 questionnaire to evaluate the different aspects of erection and to assess the severity of ED if present.

b) Physical examination
- General and abdominal examination including:
- Vital signs including blood pressure as both study medications may lower the blood pressure as a side effect.
- Abdominal examination especially for the supra pubic for palpable bladder in case of chronic retention.

c) Local examination
- Meatal stenosis or any urethral discharge or any scars of previous operations.
- DRE: after obtaining the patient verbal consent and explaining the aim of the procedure to him, the patient was placed in the lateral position, resting on their left side with their hips and knees flexed to 90 degrees or greater. The anal region was checked for

any anomalies, such as fistulae and fissures, by generously applying lubricating gel to the gloved finger and pushing the taut buttock upward with the other hand to expose the anus. The rectum was then reached for with the index finger after being slowly and delicately placed into the anal canal. We palpate anteriorly with the fin-ger pulp to palpate the surface of the prostate.

Laboratory Investigations

- Urine culture, urine analysis, and sensitivity: to exclude active infection of the urinary tract. If present, it should be treated first.
- PSA to exclude any probability of prostate cancer. Any patient with PSA> 4ng/ml was excluded from the study.
- KFTs are routinely requested in the assessment, especially when upper urinary tract affection is suspected.

The anal region examination

It was checked for any anomalies, such as fistulae and fissures, by generously applying lubricating gel to the gloved finger and pushing the taut buttock upward with the other hand to expose the anus. The rectum was then reached for with the index finger after being slowly and delicately placed into the anal canal. We palpate anteriorly with the finger pulp to palpate the surface of the prostate.

Radiological Investigations

Pelvis-abdominal Ultrasound: to assess the prostatic size, PVR, and concomitant urinary bladder pathology as bladder stones or masses and to evaluate the upper urinary tract for hydronephrosis.

Urodynamic Studies

Uroflowmetry to measure the maximum flow Qmax and voided volume using standard calibrated devices and a voided volume of at least 150 ml needed to be obtained for a valid

assessment. Patients with Qmax of more than 15ml/sec were excluded. In our present study, we used the Urinary flow meter (FLOW STAR MMS Medical Measurement Systems) ®, which is PC based wireless flow meter.

Post-Treatment Evaluation

All patients were assessed at regular follow-up visits after 4, 8, and 12 weeks from the start of treatment or in case of any serious side effects such as marked hypotension, or dizziness. If so, the patient has managed accordingly to the hospital emergency and visited the outpatient clinic later.

Follow up assessment included the following:

a) History taking
- Any recent side effects related to the study medication as headache, back pain, nasal congestion, ejaculatory problems, and hypotension.
- Reassessment of the severity of LUTS by IPSS questionnaire.
- Sexual evaluation of the sexually active patients through the IIEF-5 questionnaire.
b) General examination
- Vital signs mainly blood pressure to detect in drop blood pressure.
- Abdominal examination: for the supra pubic for palpable bladder in case of chronic retention.
- Local examination of the genitalia for any recent urethral discharge.
- Uroflowmetry: was carried out in every follow-up visit to follow up Qmax.
- Pelvis-abdominal Ultrasound: to assess PVR and to evaluate the upper urinary tract for hydronephrosis.

All the data from follow-up visits were collected and recorded in each patient's file to be statistically analyzed and compared to the pretreatment data.

c) Efficacy Endpoints

The primary efficacy endpoint was the mean change in IPSS and Qmax after 12 weeks of once treatment with Tadalafil 5mg or Silodosin 8mg. The secondary endpoint was the change in the IIEF-5 questionnaire scores in sexually active patients. Safety endpoints assessment included patient-reported treatment-emergent adverse effects (TEAEs) throughout the trial.

2.3. Statistical Analysis

Data was gathered, coded to make data manipulation easier, double-entered into Microsoft Access, and analyzed using SPSS software version 22 running on Windows 7. (SPSS Inc., Chicago, IL, USA). Simple descriptive analysis using percentages and numbers for qualitative data, arithmetic means for measuring central tendency, and standard deviations for quantifying dispersion for parametric quantitative data. The one-sample Kolmogorov-Smirnov test was used to check the normality of the quantitative data in each research cohort before inferential statistical tests were chosen. For quantitative parametric data, an Independent samples test was used to compare quantitative measures between two independent cohorts. The Mann-Whitney test was used to compare two independent cohorts. Paired t-test was used to compare two dependent quantitative data. For qualitative data, the Chi-square test was used to compare two of more than two qualitative cohorts, the mac-Nemar test was used to compare two cohorts of dependent data, and the general linear model to was used compare repeated measures. The *P-value<0.05* was considered statistically significant.

3. Results

This study included 101 patients who were complaining of LUTS/BPH. During follow-up, five patients dropped out for personal causes and 97 patients completed the study. They were randomly divided into two cohorts according to the received treatment cohort I (50 patients) was treated with Silodosin and cohort II (47 patients) was treated with Tadalafil.

The age of the patients in cohort I ranged from 48 to 67 years with a mean age of 58.2 ± 5.1 years. Cohort II ranged from 49 to 68 years with a mean age of 59.3 ± 5.2 years. The mean PSA level in cohort I was 2.1 ± 0.71 ng/ml and in cohort II was 1.9 ± 0.54 ng/ml. The mean PVRU was 11.6 ± 16.1 ml in cohort I and 11 ± 14.9 ml in cohort II. There were no significant variations with $P>0.05$ as regards age, PSA, and PVRU. There were variations between study cohorts as regards prostate size, it was 43.3 ± 8.8 gm in cohort I vs 39.3 ± 10.1 gm in cohort II. Comparing the baseline characteristics of all patients in the two cohorts; Qmax was 10.07 ± 2.7 ml/sec in cohort I vs 9.8 ± 2.8 ml/sec in cohort II with ($P=0.6$). As Regards the IPSS score, it was 19.3 ± 4.8 in cohort I vs 19.9 ± 4.5 in cohort II with ($P=0.5$). Also, the IIEF score was 20.6 ± 3.9 in cohort I vs 21.5 ± 2.9 in cohort II with ($P=0.3$). There were no significant variations with $P>0.05$ between both cohorts as regards baseline assessment of Qmax, IPSS, and IIEF scores (Table 1).

Table 1: Demographics and baseline characteristics of all patients.

Variables	Cohort I (Silodosin, N=50)	Cohort II (Tadalafil, N=47)	*P-value*
Age (years)	58.2±5.1	59.3±5.2	0.2
PSA ng/ml	2.1± 0.71	1.9±0.54	0.06
Prostate size (gm)	43.3±8.8	39.3±10.1	0.01*
Qmax(ml/sec)	10.07±2.7	٩,٨±٢.٨	0.6
PVRU (ml)	11.6±16.1	11±١٤.٩	0.8
IPSS	19.3±4.8	19.٩±4.٥	0.5
IIEF	20.6±3.9	2١,٥±٢.9	0.3

* Significant

After four weeks of treatment, Qmax was 10.1 ± 2.72 ml/sec in cohort I vs 9.8 ± 2.8 ml/sec in cohort II ($P=0.5$), IPSS score was 16.3 ± 4.8 in cohort I vs 17.6 ± 5.1 in cohort II with ($P=0.4$), IIEF score was 20.8 ± 2.8 in cohort I vs 21.6 ± 2.8 in cohort II with ($P=0.2$). There were no significant variations ($P>0.05$) between the two cohorts after four weeks of treatment (Table 2).

After eight weeks of treatment, we noticed a significantly higher mean of IIEF scores with $P<0.05$ among cohort II to 22.5 ± 2.9 vs 20.9 ± 3.6 in cohort I with ($P=0.01$) and highly significant improvement in Qmax with $P<0.05$ among cohort I to be 12.2 ± 2.6 ml/sec vs 9.8 ± 2.3 ml/sec with ($P<0.001$). On the other hand, there were no significant variations in IPSS scores between the study cohorts with ($P=0.4$) (Table 2).

At the end of the study, we noticed a highly significant improvement in IIEF scores in cohort II to be 22.9 ± 2.3 vs 20.8 ± 3.7 in cohort I with ($P<0.001$) and a highly significant improvement in Qmax in cohort I to be 13.6 ± 2.4 ml/sec vs 10.4 ± 2.6 ml/sec in cohort II with ($P<0.001$). On the other hand, there were no significant

variations in IPSS scores between the study cohorts with (*P=0.5*) Table (2).

Regarding study cohort I, there was a significant increase in Qmax. It was reported in the follow-up assessment after eight weeks of treatment (*P<0.001*). In addition, there was a significant improvement in IPSS scores that started from the beginning of the treatment regimen to the end of the study (*P=0.001*). On

the other hand, there was no significant change in the IIEF level with *P>0.05*.

Regarding study cohort II, there was a significant increase in Qmax started after the eighth week of treatment (*P<0.05*). In addition, there was a significant improvement in IPSS scores that started from the beginning of the treatment regimen (*P<0.001*). There was a significant increase in IIEF scores that started after the fourth week of treatment (*P<0.05*).

Table 2: Comparison of Qmax, IPSS and IIEF after 4, 8, and 12 weeks.

Period	Variables	Cohort I (Silodosin, N=50)	Cohort II (Tadalafil, N=47)	*P-value*
4 weeks	Qmax (ml/sec)	10.1±2.72	9.8±2.8	0.5
	IPSS	16.9±4.8	17.6±5.1	0.4
	IIEF	20.8±3.8	21.6±2.8	0.2
8 weeks	Qmax (ml/sec)	12.2±2.6	٩,٨±2.3	*<0.001**
	IPSS	16.01±4.9	16.7±5.2	0.4
	IIEF	20.9±3.6	22.5±2.9	0.01*
12 weeks	Qmax (ml/sec)	13.6±2.4	10.4±٢.6	0.001*
	IPSS	15.4±5.1	16.1±5.5	0.5
	IIEF	20.8±3.7	22.9±2.3	0.001*

*   Significant

As regards the side effects in both study cohorts, retrograde ejaculation was significantly higher in cohort I (6.3 %) than in cohort II in which no patients suffer from retrograde ejaculation (0%, *P=0.003*) with the high statistical variations between both cohorts. Back pain was significantly higher in cohort II (6.3 %) than in cohort I in which no patients suffer from

back pain (0%, *P=0.03*). Dizziness was reported by two patients (3%) in cohort I and reported by one patient (1.5%) in cohort II (*P = 0.6*) with no statistical variations. Headache also was reported in three patients (3%) in cohort II vs no patient in cohort I who had a headache with no statistical variations (*P=0.6*) (Table 3).

Table 3: Comparisons of side effects in the study cohorts.

Variables	Cohort I (Silodosin, N=50)	Cohort II (Tadalafil, N=47)	*P-value*
Retrograde ejaculation	9 (13.8%)	0 (0%)	0.003*
Hypotension	1 (1.5%)	0 (0%)	0.4
Dizziness	2 (3%)	1 (1.6%)	0.6
Back pain	0 (0%)	4 (6.3%)	0.03*
Headache	0 (0%)	3 (37.5%)	0.4

4. Discussion

Beyond the obvious permissive action of androgens, the pathophysiology of benign prostatic enlargement is still unknown. Lower urinary tract symptoms previously only seen in male BPE patients are now known to be caused by a variety of additional underlying illnesses involving the central and peripheral nerve systems, the urinary bladder, the prostate, and the pelvic floor. Although terminology for LUTS and prostate disorders has been established, it is not always used consistently. A practicing urologist still finds it challenging to detect and treat LUTS and benign prostatic enlargement [6].

The European Association of Urology's 2020 guidelines recommend PDE-5 inhibitors and 1 adrenoceptor blockers as first-line medical treatment for LUTS and BPH [7]. Because both ED and LUTS usually have a severe influence on quality of life, our research focused on Tadalafil as a treatment for LUTS and BPH with the goal of overcoming the sexually unpleasant side effects of alpha blockers, represented in our trial by silodosin. In this study, the IIEF-5 questionnaire, the IPSS questionnaire, and the mean change in Qmax are used to monitor and evaluate therapy effectiveness.

In the current study, there were no statistically significant differences in terms of age, PSA, PVRU, and sexual activity between both cohorts, but there were statistically significant differences in terms of prostate size, with a higher mean noted among cohort I treated with silodosin (43.3±8.8 gm) vs. 39.9±10.1 gm in the Tadalafil cohort. Despite differences in prostate size between our study cohorts, there were no significant differences in baseline Qmax, IPSS, or IIEF levels between the two cohorts.

In the silodosin cohort, there were extremely significant differences in Qmax between the first assessment of 10.07±2.7 ml/sec and the follow-up evaluation of 13.6 2.4 ml/sec at the end of the study. Yamanishi *et al.* (2010) found a statistically significant improvement in Qmax with silodosin (6.3± 3 ml/sec to 8.3± 3 ml/sec at the conclusion of the research) in a study on 36 individuals with LUTS or BPH taking silodosin 8 mg daily for 12 weeks [8]. Yoshida *et al.* (2012) found a statistically significant improvement in Qmax with silodosin (8.4±3.8 ml/sec to 11.5±4.7 ml/sec) in 57 patients with LUTS or BPH receiving silodosin 8 mg for 12 weeks) [9].

Only at the end of the research did we observe statistical differences in Qmax in the Tadalafil cohort, reaching 10.4±2.6 ml/sec vs. 9.8±2.9 ml/sec in the initial evaluation. Dong *et al.* (2013) published a study comparing Tadalafil vs. placebo in patients with LUTS or BPH and found that 5 mg of Tadalafil significantly improved Qmax (mean variations 0.63 ml/s) [10]. Furthermore, our findings were consistent with those of Oelke *et al.* (2012) on 511 patients with LUTS/BPH who showed that Qmax rose considerably with Tadalafil versus placebo, with a mean difference of 2.4± 5.5 ml/sec vs. 1.2 ±4.8 ml/sec) [11]. This is also supported by the study conducted by Singh *et al.* (2018) on patients with LUTS or BPH, who reported that Qmax increased significantly with Tadalafil from 13.36 to 15.00 ml/sec after four weeks and further to 17.38 ml/sec after 12 weeks [12].

In contrast to the bulk of Tadalafil research for LUTS and BPH, which generally indicated only a quantitative, non-significant improvement in Qmax, this study found a significant improvement in Qmax with Tadalafil. The variations were most likely explained by the probability that the silodosin group's mean baseline Qmax in our trial was lower than in the other studies. A lower Qmax allows more room

for improvement and increases the possibility of a Qmax improvement. In multiple in vitro studies, human bladder neck and prostate smooth muscles were reported to relax when exposed to PDE-5 inhibitors, which may have improved Qmax.

When we examine both cohorts at the end of our series, there was a statistically significant improvement in Qmax in the Silodosin cohort over the Tadalafil cohort (13.6± 2.4 vs. 10.4±2.6, *P=0.001*). Similar to our findings, a previous study compared Tadalafil vs. Silodosin vs. their combination in patients with LUTS or BPH and found a statistically highly significant improvement in Qmax in the Silodosin cohort over the Tadalafil cohort with (13.6±2.4 vs. 10.4±2.6, *P=0.001*) [13].

In our study, the silodosin cohort demonstrated a substantial drop in IPSS scores between the first evaluation of 19.3±4.8 and the four-week follow-up score of 16.9±4.8. With continual progress throughout the investigation to reach 15.4±5.4. Yokoyama *et al.* (2011) reported similar results in a 12-week study comparing tamsulosin vs. silodosin in patients with LUTS or BPH, reporting that the mean IPSS score in the silodosin cohort improved from 18.7±0.7 to 14.7±0.9 (*P=0.001*) at 4 weeks to 13.8±1.2 at 12 weeks [14].

In our series, IPSS scores in the Tadalafil group improved significantly between baseline assessment and continuing improvement to reach 10.1±5.5 at post-treatment evaluation. According to Roehrborn *et al.* (2008) study on LUTS/BPH patients on Tadalafil, IPSS improvements at 4, 8, and 12 weeks were significant. In this study, the IPSS mean change from baseline to endpoint was significant for Tadalafil 5 mg [1]. McVary *et al.* (2007) published a double-blind, placebo-controlled trial of Tadalafil in males with both ED and LUTS [15]. He exhibited a significant improvement in the IPSS after 12 weeks

(Tadalafil 3.8 versus placebo 1.7). Porst *et al.* (2011) reported a study on the effectiveness of Tadalafil 5 mg against placebo in a randomized, double-blind, placebo-controlled, 12-week study enrolling 325 males with LUTS/BPH in 2011 [16]. Tadalafil 5 mg significantly elevated IPSS (5.6 versus 3.6) when compared to placebo.

The Silodosin group in the current investigation had no significant differences in IIEF scores between baseline and follow-up assessments until the end of the study. These findings were comparable to the Gul *et al.* (2020) study, which found no significant differences in IIEF scores in patients taking Silodosin on a daily basis for LUTS/BPH between baseline (20.59±3.28) and follow-up (20.59±3.28) at the end of the study [17]. Yokoyama *et al.* (2011) published a 12-week study comparing tamsulosin vs. silodosin in patients with LUTS or BPH and found no significant improvement in the mean IIEF-5 score in the silodosin cohort (6.2 0.8 at the start of the study vs. 6.2±0.8 at 12 weeks) [14]. There was a statistically significant improvement in IIEF-5 scores with the Tadalafil cohort (21.5± 2.9 at baseline vs. 22.9± 2.3). Karabakan *et al.* (2017) showed that a three-month Tadalafil treatment induced a highly significant variation in IIEF-5 scores (9.5± 3.7 at the baseline vs. 16.1± 4.7 at the end of the study) [18].

In our study, the incidence rate of side effects for silodosin was 18.5% (n=12), which was higher than for tadalafil, which was 12.6% (n=8). Dong *et al.* (2013) found a 12.6% incidence rate of side effects in men treated with Tadalafil against 4.8% in men treated with placebo in a trial comparing the safety of Tadalafil versus placebo in men with LUTS or BPH [10]. Yoshida *et al.* (2012) published a study comparing Silodosin vs. Tadalafil on 191 individuals with LUTS or BPH and found Silodosin to have a higher rate of adverse effects (23.4%) than our results and Tadalafil to have a

lower incidence (8.4%) [9]. These findings were close to those of Gul *et al.* (2020), who studied 234 patients using silodosin for LUTS or BPH and found a higher rate of adverse effects (22.2%) than our data [17].

In our study, the Silodosin cohort had retrograde ejaculation, dizziness, and hypotension. The most prevalent side effect was retrograde ejaculation, which occurred in nine patients (13.8%) in the Silodosin cohort but not in the Tadalafil cohort. Our findings were comparable to those of Chapple *et al.* (2011), who published a clinical trial investigating the effects of silodosin therapy for LUTS in men with LUTS or BPH and found that the percentage of subjects reporting retrograde ejaculation' was 14.2% in the silodosin cohort vs. 1.1% in the placebo treatment cohorts [19]. According to a systematic review and meta-analysis of three trials comparing tamsulosin to silodosin and two studies comparing placebo to silodosin, the percentage of males who suffered ejaculatory dysfunction after taking 8 mg of silodosin ranged from 9.7% to 28.1% [20]. Silodosin-related ejaculatory problems could be explained by relaxation of the bladder neck, insufficient contraction of the seminal vesicles, and insufficient rhythmic contraction of the pelvic floor muscles, resulting in retrograde ejaculation [17].

Conclusion

Silodosin and Tadalafil are both safe and effective therapies for LUTS/BPH. Silodosin significantly outperformed Tadalafil in terms of LUTS/BPH improvement. Tadalafil helps with

In contrast to our findings, a previous study compared silodosin to tadalafil as a medication for males with LUTS or BPH and found that silodosin had a lower incidence of retrograde ejaculation of 5.3% [11]. In addition, in a study of silodosin as a medicinal treatment for LUTS/BPH, they identified a 2.1% incidence of dizziness and hypotension [9]. In our study, the most prevalent adverse effect in the Tadalafil cohort was back pain (6.3%), followed by headache (4.7%) and dizziness (1.6%). A prior study found that the most often reported side effects of Tadalafil as a medical treatment for LUTS/BPH were headache (3.6%), dyspepsia (3.3%), and back pain (2.9%) [10]. Another study found that Tadalafil 5mg caused 3.8% of headaches and 2.5% of back discomfort in patients with LUTS/BPH [17].

The clinical improvement of LUTS/BPH patients after therapy with Tadalafil or Silodosin was noted in our study. Some limitations of the current study included the lesser number of patients in each arm despite having adequate patients based on power analysis and the shorter follow-up compared to other studies. We need to completely grasp the precise effect of both medications, thus we urge for ensuring diversity in the severity of LUTS/BPH and how it may affect treatment efficacy. Furthermore, we propose additional comparison research on solely sexually active ED patients.

both LUTS and ED. Furthermore, it is not linked to the sexual side effects seen with LUTS/BPH drugs.

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