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Outcome of Tadalafil in Comparison to Tamsulosin in Management of Symptomatic Benign Prostatic Hyperplasia

Abul Bashar Shahriar Ahmed[1]*, Md Mahfuzur Rahman[2], Rajiv Mazumder[3], Firoj Mondal[4]

[1]Assistant Professor, Department of Urology, Enam Medical College & Hospital, Savar, Dhaka, Bangladesh,
E-mail: drfuadshahriar@yahoo.com,
Orcid Id: 0000-0001-7238-1998.
[2]Assistant Registrar, Department of Urology, NIKDU, Dhaka, Bangladesh, E-mail: mahfuzdrj8@gmail.com,
Orcid Id: 0000-0003-1879-8287.
[3]Resident Phase B, Department of Urology, Dhaka Medical College & Hospital, Dhaka, Bangladesh, E-mail: rajivurology@gmail.com,
Orcid Id: 0000-0002-9829-6983.
[4]Department of Urology, Enam Medical College & Hospital, Bangladesh,
E-mail: frijmondal97@gmail.com,
Orcid Id: 0000-0001-7806-801X.

*Corresponding author

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Abstract

Background: The high incidence of lower urinary tract symptoms due to benign prostatic hyperplasia is common in older men. Numerous authors evaluated the actions of PDE5i in improving the symptoms of BPH related LUTS. Tadalafil is being investigated for the treatment of lower urinary tract symptoms suggestive of benign prostatic hyperplasia. **Aim**: To assess the outcome of tadalafil 5mg/day vs tamsulosin 0.4mg/day in patients with symptoms of LUTS due to BPH. **Methods**: A randomized control trial was conducted from March 2019 to February 2021 in the department of urology, Enam Medical College and Hospital. Sixty men, older than 45 years with history of symptomatic BPH for six months or more were randomized into two groups. One group received tadalafil 5 mg/day and the other were given tamsulosin 0.4mg/day for twelve weeks. International Prostatic Symptoms Score (IPSS), IPSS quality of life (IPSS-QOL), maximum flow rate (Q max), post voidal residual volume (PVR) were assessed before & after administration of drugs. **Results:** Out of sixty patients, fifty-six patients completed the study. Two patients from each groups dropped out because of drug related adverse effects. Improvements of IPSS total score and IPSS-QOL were significant in both groups. Improvement was noted following first week of therapy and continued upto 12 weeks. Both regimens similarly improved Q max and decreased the PVR volume from the baseline ($p<0.001$) with no significant difference between tadalafil 5mg/day and tamsulosin 0.4mg/day. **Conclusions:** Monotherapy with low dose daily tadalafil 5mg resulted in significant improvement of LUTS in symptomatic BPH.

Keywords:- Tadalafil, Tamsulosin, Symptomatic, Prostatic & Hyperplasia.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a histological diagnosis characterized by smooth muscle and epithelial cell proliferation in the transition zone of prostate leading to nonmalignant enlargement. It is the most common benign tumor in men, and the incidence is age related. The prevalence of histologic BPH in autopsy studies rises from approximately 20% in men aged41–50, to 50% in men aged 51–60, and to >90% in men older

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Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

than 80 years. No doubt, when living long enough, most men will develop some histologic features consistent with BPH. Although clinical evidence of disease occurs less commonly, symptoms of prostatic obstruction are also age related. At age 55, approximately 25% of men report obstructive voiding symptoms. At age 75, 50% of men complain of a decrease in the force and caliber of their urinary stream. LUTS secondary to BPH (LUTS/BPH) increases with age and negatively impacts patients' quality of life. The current standard medical treatments for LUTS/BPH consist of α1-adrenergic blockers, 5α-reductase inhibitors and phytotherapies (used alone or in combination). Tadalafil is a phosphodiesterase type 5 (PDE5) inhibitor (PDE5-I) widely approved for the treatment of ED. Several placebo-controlled studies in men with LUTS/BPH have demonstrated improvements in International Prostate Symptom Scores (IPSS) with tadalafil. This drug was recently approved in the United States for treatment of symptoms of BPH (LUTS/BPH) and for the treatment of coexisting ED. Compared with the other PDE5-I, tadalafil is unique in its longest half-life amounting to 17.5 hours, where drug efficacy potentially lasts up to 36 h. No untoward concern of increased morbidity has been reported with its long half-life. The special characteristics of tadalafil are its significantly different chemical structure. Although the mechanisms for improvement in LUTS with PDE5 inhibition have yet to be fully clarified, proposed contributors include inhibition of PDE5 isoenzymes present in the bladder, prostate, urethra, and supporting vasculature that cause increase in intracellular nitric oxide–cyclic guanosine monophosphate concentration, relaxation of the smooth muscle cells in these structures, improve blood perfusion, and reduce afferent signaling from the urogenital tract. Regarding the use of tadalafil alone, significant improvements in LUTS/BPH have been recently reported by increasing numbers of studies. Therefore, conducting an analysis of the current evidence was necessary to determine the relative outcome and safety of monotherapy with tadalafil for LUTS/BPH. Oger et al., (2008) demonstrated that combination of alfuzosin and tadalafil is more efficient than each compound alone to relax adrenergic tone or to enhance relaxation of the human corpus cavernosum.[1] Kaplan et al., (2007) studied the safety and efficacy of the combination of alfuzosin and sildenafil vs monotherapy with alpha blockers in patients with sexual dysfunction and LUTS.[2] They also observed a statistically significant increase in Q max that is similar for both active treatments. Although these studies cannot give an answer comparing the two active treatments directly, tadalafil seems to be at least as efficient as tamsulosin while having an extra benefit in improving all aspects of sexual life. These studies showing that tadalafil improves LUTS to a similar extent as tamsulosin, an α-adrenergic antagonist that is widely prescribed for this condition. In Bangladesh, α-blocker tamsulosin 0.4 mg once daily is given as a first-line treatment for LUTH/BPH. So tamsulosin 0.4 mg once daily was included as an active control. In this study, we shall try to compare the outcome of Tadalafil (5mg) versus Tamsulosin (0.4mg) in the management of symptomatic BPH. The actual relationship between BPH, lower urinary tract symptoms (LUTS), and bladder outlet obstruction is complex and requires a solid understanding of the definitional issues involved. The etiology of BPH and LUTS is still

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Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

poorly understood, but the hormonal hypothesis has many arguments in its favor. The degree of LUTS does not necessarily correspond to the size of the prostate. Patients with mild symptoms (IPSS/AUA-SI score <7) or moderate-to-severe symptoms (IPSS/AUA-SI score ≥8) of benign prostatic hyperplasia (BPH) who are not bothered by their symptoms and are not experiencing complications of BPH should be managed with a strategy of watchful waiting. In these situations, medical therapy is likely to improve their symptoms or quality of life (QOL). Patients managed expectantly with watchful waiting are usually re-examined annually. The two main medications for management of BPH are alpha blockers and 5α-reductase inhibitors. Selective α1-blockers are the most common choice for initial therapy. They include doxazosin, terazosin, alfuzosin, tamsulosin, and silodosin. All are equally effective but have slightly different side effect profiles. Less-selective α1 receptor antagonist such as terazosin and doxazosin may lower blood pressure. Most commonly used drug tamsulosin cause postural hypotension and retrograde ejaculation. The 5-alpha-reductase inhibitor finasteride and dutasteride are another treatment option. Antimuscarinics such as tolterodine may also be used, especially in combination with alpha blockers. They act by decreasing acetylcholine effects on the smooth muscle of the bladder, thus helping control symptoms of an overactive bladder. Tadalafil was recently approved by the European Association of Urology for treatment of BPH (LUTS/BPH). In Bangladesh, there is no statistically proven data regarding effects on patients with symptomatic BPH but we find a lot of patients from this group in our day to day urological practice. Brock et al., 2013 reported similar findings without any significant difference in adverse events between patients with or without ED.[3] In the open-label extension study, no new or unexpected adverse event was recorded while treatment discontinuation due to adverse events was 5.2% without significant differences between placebo and all tadalafil doses used. For several years, well before data became available, concerns were raised in terms of combining an α-adrenergic antagonist with a PDE5i. Giuliano et al., 2006 in a randomized, double-blind, placebo-controlled, crossover study in 18 healthy middle-aged men who received alfuzosin 10 mg daily for 7 days and either a single 20 mg dose of tadalafil or placebo on day 7 reported that tadalafil 20 mg showed no clinically relevant hemodynamic interactions with alfuzosin 10 mg daily.[4] Goldfischer et al., 2012 reported on the safety of daily co-administration of alpha-blockers with tadalafil 5 mg in men with BPH-associated LUTS.[5] All patients were stable on α-adrenergic antagonists for 4 weeks as recommended by US Food and Drug Administration (FDA) and European Medicines Agency (EMA) precautions. The proportion of patients who reported treatment-emergent dizziness (due to orthostatic hypotension) was not significantly different between the two treatment groups (tadalafil 7%; placebo 5.7%; p = 0.403). No difference between treatment groups was observed with respect to patients meeting the criteria for a positive orthostatic test (30 per treatment group, p = 1.00). However, consistent with the results of previous clinical pharmacology studies of healthy subjects, a trend was seen for increased hemodynamic signs and symptoms in men taking non-uroselective alpha-blockers, most notably those taking doxazosin. BPH

Annals of International Medical and Dental Research
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Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

involves hyperplasia of prostatic stromal and epithelial cells, resulting in the formation of large, fairly discrete nodules in the transition zone of the prostate. Stroma is composed of varying amounts of collagen and smooth muscle. When sufficiently large, the nodules impinge on the urethra and increase resistance to flow of urine from the bladder. Symptoms of BPH either related to obstructive component of the prostate or the secondary response of the bladder to the outlet resistance. The obstructive component was divided into mechanical and dynamic obstruction. As prostatic enlargement occurs, mechanical obstruction may result from intrusion into the urethral lumen or bladder neck leading to higher bladder outlet resistance. The dynamic component of prostatic obstruction explains the variable nature of symptoms experienced by patients. The prostatic stroma is composed of smooth muscle and collagen fibers & rich in adrenergic nerve supply. The level of autonomic stimulation thus set the tone to the prostatic urethra. There are several hypotheses for LUTS due to BPH. The irritative voiding of BPH results from the secondary response of the bladder to increased outlet resistance. The urothelium expresses NOS and releases NO in response to various stimuli. Because the eNOS isoform has been described in endothelial cells of the prostate, it has been hypothesised that eNOS regulates local vascular perfusion, whereas nNOS regulates smooth muscle tone and glandular activity. NOS activity has been identified in the urothelium, smooth muscle, blood vessels, and nerves of the bladder, with a higher concentration in the outlet region. The anti-proliferative and pro-apoptotic effects of NO donors on cultured bladder, prostate, and urethra smooth muscle cells suggests a role for the nitrogenic pathway in BPH-related LUTS. The second hypothesis is based on enhancement of RhoA-Kinase signaling. Smooth muscle tone is regulated not only through a calcium-dependent mechanism but also through the activity of the RhoA–Kinase calcium-sensitizing pathway. An up-regulated RhoA–Kinase pathway can impair smooth muscle relaxation, finally resulting in BPH-LUTS. Involuntary bladder contractions were associated with increased signalling of the muscarinic receptor-activated RhoA–ROCK pathway. Up-regulated RhoA–ROCK signaling was demonstrated in urinary bladder and prone to develop BPH and overactive bladder (OAB). The third hypothesis is based on the autonomic nervous system hyperactivity and metabolic syndrome effects on LUTS, prostate growth. Autonomic hyperactivity is subject to dysregulation of parasympathetic and sympathetic tone. It has been established that the alpha-adrenoceptor system with increased sympathetic activity plays an important role in the pathophysiology LUTS secondary to BPH. Finally, the fourth hypothesis illustrates atherosclerosis as a common mechanism for LUTS and BPH. These theories are compatible and may overlap substantially. Atherosclerosis of prostate, penis, and bladder is regarded as the mechanism that connects all of the previously described theories because pelvic atherosclerosis reduces. Phosphodiesterase messenger RNA and protein have been localised across the whole human urogenital tract with different patterns of expression and concentrations demonstrated by Montorsi et al., 2004.[6] The hypothesis that impaired NO–cGMP signalling contributes to the pathophysiology of BPH provided further background for a potential role of NO donor drugs and PDE5-Is in the management of BPH-associated LUTS by Kedia et al,. 2008.[7] In this

Annals of International Medical and Dental Research
E-ISSN: 2395-2822 | P-ISSN: 2395-2814
Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

respect, PDE5-Is increased the levels of cyclic adenosine monophosphate and cGMP in the human prostate and plasma, and the distribution of PDE5- Is was found to be higher in the prostate than in the plasma of treated men (Zhao et al., 2011).[8] Filippi et al., 2007 reported the antiproliferative effects in the prostatic stroma by PDE5-Is. PDE5 regulates bladder smooth muscle tone via a strong inhibition of NO–cGMP signalling, supporting a therapeutic role for PDE5-Is in bladder dysfunction.[9] In particular, the effect of PDE5-Is on storage LUTS seems to be partially determined by a cGMP-dependent RhoA–Kinasesignalling inhibition (Morelli et al., 2009).[10] Preclinical study by Kedia et al., 2009 reported tadalafil resulted partial reversal of reduced tissue concentration of norepinephrine and endothelin-1 in prostate.[11] Filippi et al., 2007, concluded it also had an anti-proliferative effect on cultured prostate and bladder smooth muscle cells.[9] These mechanisms may decrease smooth muscle tension in the prostatic stroma and capsule and attenuate cellular proliferation associated with prostate and bladder hypertrophy, respectively. An assessment of the activity of PDE5i on endothelin-1-induced contraction of human prostatic tissue done by Kedia et al.,2009 showed that tadalafil had greater activity when compared with sildenafil or vardenafil and among PDE5i, only tadalafil achieved >50% relaxation of the pre-contracted strips.[11]

Figure 1: Mechanisms by which tadalafil may reduce benign prostatic hyperplasia (BPH)-associated lower urinary tract symptoms.

Annals of International Medical and Dental Research
E-ISSN: 2395-2822 | P-ISSN: 2395-2814
Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

Yoshimura et al., 2001 concluded PDE5i cause an inhibitory effect of NO on ion channels in afferent neurons and on afferent nerve activity in the bladder.[12] Calcium channels in bladder afferent neurons are inhibited by NO. Morelliet al., 2011 showed tadalafil inhibits in vitro PDE5 activity, prominently expressed in the human vesicular-deferential arteries and increases prostate tissue oxygenation in spontaneously hypertensive rats.[13] Bertolotto et al., (2009) concluded tadalafil increased prostatic blood perfusion in a preliminary evaluation of men using contrast-enhanced ultrasound.[14] Roumeguere et al., 2010 showed tadalafil attenuates the expression of various inflammatory markers (tumor necrosis factor [TNF]-α, interleukin [IL]-1β and IL-8) and therefore may reduce atherosclerotic damage and overall inflammation by reducing leukocyte recruitment.[15] Based on current data Andersson et al., 2011 proposed a mechanism of action of tadalafil which is presented in [Figure 1].[16]

MATERIAL AND METHODS

This was a randomized controlled trial conducted in the Department of Urology, Enam Medical College and Hospital from March 2019 to February 2021. Study Population was patients with BPH who attended in outpatient department of urology, Enam Medical College and Hospital. Total sixty (60) patients were selected by random sampling. Men more than 45 years of age who had symptoms of LUTS for >6 months, IPSS score > 13, maximum urinary flow rate (Qmax) below 15 ml/s & no H/O taking taking alpha blocker or 5 alpha reductase inhibitors were included in this study. All noncompliant patients, Prostate-specific antigen (PSA) > 10.0 ng/ml, Post void residue (PVR) > 100 ml at screening were excluded from this study. Urinary retention or lower urinary tract stones within 6 months Patient with urethral stricture Patient with neurogenic bladder, men who have used finasteride or dutasteride within 3-6 months were excluded.

Symptoms divide into obstructive and irritative symptoms. Obstructive symptoms include hesitancy, decrease force and caliber of stream, sensation of incomplete bladder emptying, double voiding, straining to urinate, and post void dribbling. Irritative symptoms include urgency, frequency, and nocturia. Physical examination, DRE, and focused neurological examination are performed on all patients. Abdominal examination was usually normal unless retention of urine (distended bladder). The external meatus was examined to exclude meatal stenosis, and the epididymes are palpated for signs of inflammation. DRE of BPH usually results in smooth, firm, elastic enlargement of the prostate. Prostate size estimated by DRE does not correlate with severity of symptoms or degree of obstruction. DRE can roughly estimate the true size of prostate and cannot assess the middle lobe.

IPSS score (International Prostate symptom score) was used to assess extent of LUTS.

Importance of IPSS:

a) Standard baseline assessment of severity of symptoms in patient with LUTS.
b) To assess the response of therapy.
c) Recommended for all patient before the initiation of therapy.

Annals of International Medical and Dental Research
E-ISSN: 2395-2822 | P-ISSN: 2395-2814
Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

d) To detect the progression of symptoms in patient under watchful waiting.
International Prostate Symptom Score (I-PSS)

In the past month:	**Not at All**	**Less than 1 in 5 Times**	**Less than Half the Time**	**About Half the Time**	**More than Half the Time**	**Almost Always Total score**
1. Incomplete Emptying How often have you had the sensation of not emptying your bladder?	0	1	2	3	4	5
2. Frequency How often have you had to urinate less than every two hours?	0	1	2	3	4	5
3. Intermittency How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
4. Urgency How often have you found it difficult to postpone urination?	0	1	2	3	4	5
5. Weak Stream How often have you had a weak urinary stream?	0	1	2	3	4	5
6. Straining How often have you had to strain to start urination?	0	1	2	3	4	5
	None	1 Time	2 Times	3 Times	4 Times	5 Times
7. Nocturia How many times did you typically get up at night to urinate?	0	1	2	3	4	5
Quality of Life Due to Urinary Symptoms	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy Terrible
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5 6

Annals of International Medical and Dental Research
E-ISSN: 2395-2822 | P-ISSN: 2395-2814
Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

Symptoms may be classified according to IPSS scoring system:

1. Mild symptoms : Score 0-7.
2. Moderate symptoms : Score 8-19.
3. Severe symptoms : Score 20-35.

Quality of life score was assessed before & after administration of drugs. Pre & post treatment Post voidal residual urine were measured by ultrasound of kidney, ureter & bladder. Urinary flow was measured by Qmax in uroflowmetry.The patients in control group were given Tamsulosin (0.4mg) once daily; patients in other group were given tadalafil (5mg) once daily. Then they were asked to come for follow-up at 4th, 8th & 12th week. In these follow ups, relevant histories were taken & investigations to assess PVR and urinary flow rate were done.The data were collected in a data collection form. These were analyzed with standard statistical method. The data presented on continuous scale was expressed as mean and standard deviation (SD) from the mean. It was compared between groups of interest with the help of student's t-Test. Both paired & unpaired t-Test was done. P-value <0.05 was considered as significant.No patient was included whose ability to give voluntary consent was questionable. No potential risks existed in designing this study. Ethical clearance was taken from the ethical review committee of Enam Medical College.

RESULTS

Of 60 patients randomized, 93% of subjects completed the study. Two patients in tadalafil group discontinued the treatment at different stages for severe headache where as another two patients withdrawal their treatment for postural hypotension in tamsulosin group.Data were expressed as mean±SD, Unpaired t-test was performed to compare two drugs, ns = Not significant

Table 1: Comparison of PVR between Tadalafil and Tamsulosin group (n=60). Showed results of assessment of all patients according to PVR in the form of mean+SD for each category. There was no significant difference of P value between two groups.

PVR	Tadalafil 5mg (n=30) Mean±SD	Tamulosin 0.4 mg (n=30) Mean±SD	P value
4 weeks	31.64±9.51	32.37±10.78	0.788^{ns}
8 weeks	32.2±7.39	32.30±8.28	0.967 ^{ns}
12 weeks	18.29±8.12	18.57±9.01	0.901 ^{ns}

Table 2: Comparison of Qmax between Tadalafil and Tamsulosin group (n=60). Showed results of assessment of all patients according to Qmax in the form of mean+SD for each categories. There was no significant difference of P value between two groups.

Qmax	Tadalafil 5mg (n=30) Mean±SD	Tamulosin 0.4 mg (n=30) Mean±SD	P value
4 weeks	16.79±2.75	16.97±2.62	0.799 ns
8 weeks	17.36±2.83	18.0±3.35	0.435 ns
12 weeks	20.50±3.45	20.25±3.25	0.781 ns

Annals of International Medical and Dental Research
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Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

Table 3: Comparison of IPSS Total Score between Tadalafil and Tamsulosin group (n=60). Showed results of assessment of all patients according to IPSS in the form of mean + SD for each categories. There was no significant difference of P value between two groups.

IPSS Total Score	Tadalafil 5mg (n=30) Mean±SD	Tamulosin 0.4 mg (n=30) Mean±SD	P value
4 weeks	18.12±3.45	17.26±3.56	0.346ns
8 weeks	14.74±3.41	15.90±2.78	0.154ns
12 weeks	14.39±3.32	14.21±1.24	0.782ns
Data were expressed as mean±SD, Unpaired t-test was performed to compare two drugs, ns = Not significant			

Table 4: Comparison of QOL between Tadalafil and Tamsulosin group (n=60). Showed results of assessment of all patients according to QOL in the form of mean+SD for each category. There was no significant difference of P value between two groups.

QOL Score	Tadalafil 5mg (n=30) Mean±SD	Tamulosin 0.4 mg (n=30) Mean±SD	P value
4 weeks	2.18±0.48	2.33± 0.48	0.223ns
8 weeks	2.04±0.55	2.29±0.52	0.075ns
12 weeks	1.96±0.72	2.25±0.44	0.065ns

Table 5: Comparison of variables before & after Tamsulosin administration:

Variables	Before Tamsulosin	12 weeks after Tamsulosin	p-value
IPSS score	24.88±4.12	14.39±3.32	<0.001
QOL score	4.56±0.55	2.25±0.44	<0.001
PVR	146.72±36.05	18.57±9.01	<0.001
Q-max	11.27±4.33	20.25±3.25	<0.001

Paired t-test was done to compare variables before & after Tamsulosin administration. P-value <0.05 was considered significant.

Table 6: Comparison of variables before & after Tadalafil administration.

Variables	Before Tadalafil	12 weeks after Tadalafil	p-value
IPSS score	23.55±4.45	14.39±3.32	<0.001
QOL score	4.32±0.78	1.96±0.72	<0.001
PVR	140.21±29.53	18.29±8.12	<0.001
Q-max	12.43±4.84	20.50±3.45	<0.001

Paired t-test was done to compare variables before & after Tadalafil administration. P-value <0.05 was considered significant.

DISCUSSION

Several studies evaluating tadalafil or tamsulosin (as an active control) for LUTS/BPH showed, tadalafil 5 mg once daily for 12 week resulted in significant improvements in LUTS/BPH similar to tamsulosin 0.4 mg once daily. Based on

Annals of International Medical and Dental Research
E-ISSN: 2395-2822 | P-ISSN: 2395-2814
Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

analyses the first tadalafil shows significant improvement in LUTS/ BPH after 1 week and a significant increase in Qmax at 12 week. In addition, tadalafil but not tamsulosin significantly improved measures of LUTS/BPH QOL, global impressions of BPH symptom impact, and BPH treatment satisfaction. Mac Vary et al., 2007 stated that total IPSS improvement with tadalafil and tamsulosin was clinically meaningful (improvement of three or more points from baseline) and continued throughout the 12 weeks.[17] Porst et al., 2011 noted that tadalafil significantly improved IPSS results from baseline to end point compared to placebo.[18] Reduction in IPSS result was apparent after one week and significant after 4 week. Roehborn et al., 2008 reported similar improvement of IPSS that are consistent with patients using tadalafil in > 1000 men with BPH-LUTS.[19] Furthermore AUA guideline 2011 states the magnitude of IPSS improvement for tadalafil is similar to that reported after 3-9 months of alpha blocker treatment. In my study, total IPSS reduction was apparent even at one week and was statistically significant with both tadalafil and tamsulosin. Patients of both of these two groups showed significant improvement for IPSS total score starting from week one and maintained up to week 12. However, for nocturia question patients of tamsulosin group had better outcome than tadalafil group. These findings are consistent with those from a tadalafil dose finding study in men with BPH/LUTS by Mc Vary et al., 2007.[20] In addition, both tadalafil and tamsulosin significantly improved measures of LUTS/BPH QOL; but patient in tadalafil group did better. This finding also matched with other studies. Similar improvement of total IPSS were also reported for tadalafil 5mg or tamsulosin 0.4 mg once daily in a small pilot study of Korean men with LUTS-BPH by Chul et al., 2011.[21] The magnitude of improvement in total IPSS at end point with tadalafil 5 mg in this study was consistent with several previous reports like Roehrborn et al.,2008; Broderick et al.,2010 and the improvement was also comparable to that seen in previous studies with alpha blockers like tamsulosin 0.4 mg like Oleke et al., 2012.[22,23,24] Stief et al., 2008 reported an improvement of Qmax of 1.6 with vardenafil compared with one with placebo after 8 weeks.[25] Both tadalafil and tamsulosin were significant on improving Qmax. Oleke et al., 2012 reported the significant improvement of Q max against placebo with both tadalafil and tamsulosin.[24] Porst et al., 2011 observed small Q max changes by tadalafil (5mg).[18] Bechara et al., 2008 concluded that changes in Q max and PVR was greater in the combination of tamsulosin and tadalafil whereas monotherapy in which tamsulosin group behaved marginally better than tadalafil group.[26] Sing et al., 2014 concluded that combination of tamsulosin and tadalafil did not produce significant changes in Q max and PVR when compared with alpaha blocker monotherapy and with tadalafil group.[27] Clearly an improvement in Q max was equally observed with all three schemes of drugs by Bechara et al., 2008.[26] In this study nearly similar improvement in Q max was noted from baseline to week 4 and week 12 for both tadalafil 5 mg group and tamsulosin 0.4 mg group. My result is consistent with some study. Several studies like Porst et al., 2011; Gacci et al., 2012 concluded that tadalafil 5 mg once daily dose significantly improved the IPSS QoL.[18,28] Mc Vary et al (2007) reported the significant improvement of patient QOL

Annals of International Medical and Dental Research
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Vol-7, Issue-5 | September-October 2021
Page no- 110-122 | Section- Research Article (Urology)

related to LUTS/BPH after 12 weeks of treatment with 5/20 mg tadalafil.[20] AUA guideline proved the relative 2 fold improvement of at 12 weeks in IPSS QOL than in a meta-analysis of alpha blocker therapy for LUTS. This study shows significant improvement in QOL form baseline to week 12 for both tadalafil 5 mg group and tamsulosin 0.4 mg group. In this study, tadalafil shows better outcome than tamsulosin that is similar to other studies. This 3 months study focused on the short-term impact of tadalafil 5 mg once daily. However, results of an open-label extension study enrolling 427 men with LUTS/BPH showed that efficacy improvements with tadalafil were maintained for an additional one year of treatment, with a safety profile consistent with that previously reported for long term studies of tadalafil once daily in men with BPH related LUTS.

CONCLUSIONS

Tadalafil 5 mg or tamsulosin 0.4 mg once daily resulted in significant and similar improvements in IPSS as well as QOL in LUTS/BPH symptoms as early as one week and throughout the 12 weeks treatment period. In addition, tadalafil and tamsulosin similarly improved Qmax through 12 wk. Treatment satisfaction was more with tadalafil than tamsulosin. Thus, the results of these studies correctly prove my hypothesis "Tadalafil is similarly equivalent to tamsulosin to relief symptoms of benign prostatic hyperplasia. From the result of this study and review of literature, it can be recommended that, tadalafil 5 mg daily can be used safely in patients with symptomatic BPH related LUTS.

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