

ORIGINAL ARTICLE**Comparison of Tamsulosin and tadalafil in relieving benign prostatic hyperplasia related symptoms**

Hompriya Issar

Assistant Professor, Department of General Surgery, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh, India

ABSTRACT:

Background: Benign prostatic hyperplasia (BPH) is the most common neoplastic condition afflicting men and constitutes a major factor impacting the health of the male. The present study compared tamsulosin and tadalafil in relieving benign prostatic hyperplasia related symptoms in males. **Materials & Methods:** 90 males of >45 years of age with LUTS were divided into 2 groups. In group I, Tadalafil 10 mg once daily with an intervening 4-week period of placebo (P4) wash out followed by Tamsulosin 0.4 mg once daily were administered for a period of 6 weeks and in group II, reverse of it was administered. Parameters such as IPSS scores, uroflowmetry parameters and International Index of Erectile Function-5 scores were recorded. **Results:** Age group 45- 55 years had 8, 55-65 years had 20 and >65 years had 52 patients. The difference was significant ($P < 0.05$). Comorbidities such as diabetes mellitus was present in 2 in group I and 4 in group II, bronchial asthma 4 in group I and 2 in group II, hypertension was present in 6 in group I and 7 in group II and both hypertension and diabetes mellitus was present in 3 in group I and 5 in group II. The mean IPSS total score at baseline in group I was 17.4 and 16.7 in group II, at 2 weeks was 16.2 in group I and 16.3 in group II and at 8 weeks was 9.0 in group I and 9.3 in group II. IPSS voiding score at baseline in group I was 11.2 and 10.4 in group II, at 2 weeks was 10.0 in group I and 9.9 in group II and at 8 weeks was 5.1 in group I and 6.2 in group II. IPSS storage score at baseline in group I was 5.0 and 4.9 in group II, at 2 weeks was 4.5 in group I and 4.3 in group II and at 8 weeks was 2.9 in group I and 2.8 in group II. IPSS QOL score at baseline in group I was 2.8 and 4.4 in group II, at 2 weeks was 2.6 in group I and 3.9 in group II and at 8 weeks was 2.4 in group I and 2.1 in group II. The difference was non-significant ($P > 0.05$). **Conclusion:** Benign prostatic hyperplasia is frequent complaint in men above 45 years of age. Both Tadalafil and Tamsulosin improved LUTS and benign prostatic hyperplasia symptoms.

Key words: Benign prostatic hyperplasia, Symptoms, IPSS

Corresponding author: Hompriya Issar, Assistant Professor, Department of General Surgery, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh, India

This article may be cited as: Issar H. Comparison of Tamsulosin and tadalafil in relieving benign prostatic hyperplasia related symptoms. *J Adv Med Dent Sci Res* 2016;4(1):196-199.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is the most common neoplastic condition afflicting men and constitutes a major factor impacting the health of the male. BPH and sexual dysfunction is often co-existent in ageing males.¹ This pathologic change is important because of the intimate anatomic relationship between the prostate and the bladder neck. The association of BPH with aging has been demonstrated repeatedly in autopsy studies using calculated or actual weight, prostate volume, or histologic criteria.²

Benign prostatic hyperplasia (BPH) is a histological diagnosis associated with unregulated proliferation of connective tissue, smooth muscle and glandular epithelium within the prostatic transition zone.³ Prostate tissue is composed of two basic elements: A glandular element composed of secretory ducts and acini; and a stromal element composed primarily of collagen and smooth muscle.⁴ In BPH, cellular proliferation leads to increased prostate volume and increased stromal smooth muscle tone. McNeal describes two phases of BPH progression.⁵ Environmental and hereditary factors also influence the development of clinical BPH. The incidence of

BPH is reported to be much lower in Chinese and Japanese men living in Asia than in white populations.⁶ The present study compared tamsulosin and tadalafil in relieving benign prostatic hyperplasia related symptoms in males.

MATERIALS & METHODS

The present study comprised of 90 males of >45 years of age with LUTS secondary to benign prostatic hyperplasia (BPH). All were informed regarding the study and written consent was obtained.

Data such as name, age etc. was recorded. A thorough clinical examination was performed. All patients were divided into 2 groups. In group I, Tadalafil 10 mg once daily with an intervening 4-week period of placebo (P4) wash out followed by Tamsulosin 0.4 mg once daily were administered for a period of 6 weeks and in group II, reverse of it was administered. Parameters such as IPSS scores, uroflowmetry parameters and International Index of Erectile Function-5 scores were recorded. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Age wise distribution of patients

Age group (Years)	Number	P value
45-55	8	0.02
55-65	20	
>65	52	

Table I shows that age group 45- 55 years had 8, 55-65 years had 20 and >65 years had 52 patients. The difference was significant (P< 0.05).

Table II Presence of co- morbidities

Comorbidities	Group I	Group II	P value
Diabetes mellitus	2	4	0.08
Bronchial asthma	4	2	
Hypertension	6	7	
Both hypertension and diabetes mellitus	3	5	

Table II shows that comorbidities such as diabetes mellitus was present in 2 in group I and 4 in group II, bronchial asthma 4 in group I and 2 in group II, hypertension was present in 6 in group I and 7 in group II and both hypertension and diabetes mellitus was present in 3 in group I and 5 in group II. The difference was significant (P< 0.05).

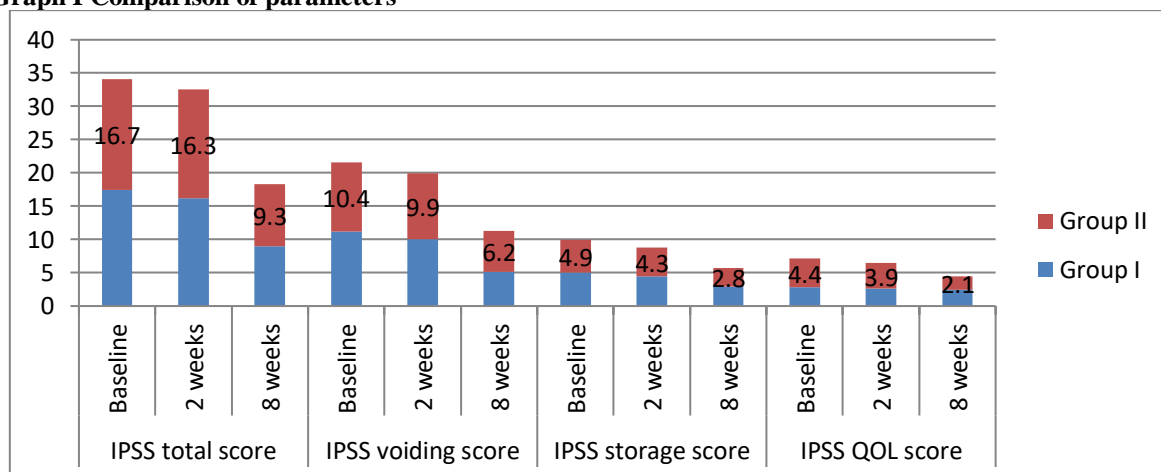
Table III Comparison of parameters

Variables	Duration	Group I	Group II	P value
IPSS total score	Baseline	17.4	16.7	0.27
	2 weeks	16.2	16.3	
	8 weeks	9.0	9.3	
IPSS voiding score	Baseline	11.2	10.4	0.03
	2 weeks	10.0	9.9	
	8 weeks	5.1	6.2	
IPSS storage score	Baseline	5.0	4.9	0.05
	2 weeks	4.5	4.3	
	8 weeks	2.9	2.8	
IPSS QOL score	Baseline	2.8	4.4	0.81
	2 weeks	2.6	3.9	
	8 weeks	2.4	2.1	

Table III, graph I shows that mean IPSS total score at baseline in group I was 17.4 and 16.7 in group II, at 2 weeks was 16.2 in group I and 16.3 in group II and at 8 weeks was 9.0 in group I and 9.3 in group II. IPSS voiding score at baseline in group I was 11.2 and 10.4 in group II, at 2 weeks was 10.0 in group I and 9.9 in group II and at 8 weeks was 5.1 in group I and 6.2 in group II. IPSS storage score at baseline in group I was

5.0 and 4.9 in group II, at 2 weeks was 4.5 in group I and 4.3 in group II and at 8 weeks was 2.9 in group I and 2.8 in group II. IPSS QOL score at baseline in group I was 2.8 and 4.4 in group II, at 2 weeks was 2.6 in group I and 3.9 in group II and at 8 weeks was 2.4 in group I and 2.1 in group II. The difference was non- significant (P> 0.05).

Graph I Comparison of parameters



DISCUSSION

A strong correlation between erectile dysfunction (ED) and lower urinary tract symptoms (LUTS) secondary to BPH has been observed.⁷ Sexual disorders and their related bother has been found to correlate strongly with age and the severity of LUTS, independent of the other co-morbidities.^{8,9} Although a causal link between LUTS and ED is not well established, four main pathophysiological mechanisms, with varying degrees of overlap currently support this relationship.¹ These and other studies support a genetic factor in the development of these lesions.¹⁰ Clinical evaluation to assess the presence and degree of voiding dysfunction and/or the role of BPH in its presence has an increasingly broad spectrum of treatment goals. These include providing information on a range of epidemiologic studies, selecting patients for drug or interventional studies, and providing information and advice to individual patients.¹¹ The present study compared tamsulosin and tadalafil in relieving benign prostatic hyperplasia related symptoms in patients.

We found that age group 45- 55 years had 8, 55-65 years had 20 and >65 years had 52 patients. Karadag et al¹² compared the efficacy and safety of alfuzosin (Alf) and tamsulosin (Tam) in patients with lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH). One hundred men with benign prostatic hyperplasia (BPH) with lower urinary tract symptoms (LUTS) were enrolled. BPH patients with IPSS greater than 8 and maximum urinary flow rate (Q(max)) lower than 15 ml/s were randomly divided into a Alf-Tam group (Alf for 8 weeks, followed by Tam for 8 weeks) or a Tam-Alf group (Tam for 8 weeks, followed by Alf for 8 weeks). In the first treatment period, each drug significantly improved IPSS and Q (max). In both the Alf-Tam and Tam-Alf groups, cross-over was effective in improving IPSS and Q (max). Alf and Tam significantly lowered IPSS and significantly increased Q (max) from baseline ($P < 0.001$). Neither drug affected serum PSA levels. They found that comorbidities such as diabetes mellitus was present in 2 in group I and 4 in group II, bronchial asthma 4 in group I and 2 in group II, hypertension was present in 6 in group I and 7 in group II and both hypertension and diabetes mellitus was present in 3 in group I and 5 in group II.

We found that mean IPSS total score at baseline in group I was 17.4 and 16.7 in group II, at 2 weeks was 16.2 in group I and 16.3 in group II and at 8 weeks was 9.0 in group I and 9.3 in group II. IPSS voiding score at baseline in group I was 11.2 and 10.4 in group II, at 2 weeks was 10.0 in group I and 9.9 in group II and at 8 weeks was 5.1 in group I and 6.2 in group II. IPSS storage score at baseline in group I was 5.0 and 4.9 in group II, at 2 weeks was 4.5 in group I and 4.3 in group II and at 8 weeks was 2.9 in group I and 2.8 in group II. IPSS QOL score at baseline in group I was 2.8 and 4.4 in group II, at 2 weeks was

2.6 in group I and 3.9 in group II and at 8 weeks was 2.4 in group I and 2.1 in group II. Bechara et al¹³ assessed the efficacy and safety of tamsulosin 0.4 mg/day vs. tamsulosin 0.4 mg/day plus tadalafil 20 mg/day in patients with LUTS in a crossover design study. 30 men with a history of LUTS/BPH of at least 6 months, were randomized into two groups to receive tamsulosin 0.4 mg/day vs. tamsulosin 0.4 mg/day plus tadalafil 20 mg/day for 45 days, and then switched to the other treatment mode for other 45 days. Twenty-seven patients completed the study. Improvements of IPSS score and IPSS-QOL were significant with both treatments but greater with the drug combination. Both regimens similarly improved the Qmax and decreased the PVR volume from baseline ($P < 0.001$) with no significant differences between tamsulosin alone vs. tamsulosin and tadalafil ($P > 0.05$). The IIEF improved with tamsulosin plus tadalafil ($P < 0.001$) but not with tamsulosin alone ($P > 0.05$). The GAQ showed that all patients preferred the combination scheme. Both treatments were well tolerated. The limitation of the study is small sample size.

CONCLUSION

Authors found that benign prostrate hyperplasia is frequent complaint in men above 45 years of age. Both Tadalafil and Tamsulosin improved LUTS and benign prostrate hyperplasia symptoms.

REFERENCES

1. McNeal J. Pathology of benign prostatic hyperplasia. Insight into etiology. *Urol Clin North Am.* 1990;17:477–86.
2. Jung JH, Jae SU, Kam SC, Hyun JS. Correlation between lower urinary tract symptoms (LUTS) and sexual function in benign prostatic hyperplasia: Impact of treatment of LUTS on sexual function. *J Sex Med.* 2009;6:2299–304.
3. McVary KT, Roehrborn CG, Avins AL, Barry MJ, Bruskewitz RC, Donnell RF, et al. Update on AUA guideline on the management of benign prostatic hyperplasia. *J Urol.* 2011;185:1793–803.
4. Stroup SP, Palazzi-Churas K, Kopp RP, Parsons JK. Trends in adverse events of benign prostatic hyperplasia (BPH) in the USA, 1998 to 2008. *BJU Int.* 2012;109:84–7.
5. Taylor BC, Wilt TJ, Fink HA, Lambert LC, Marshall LM, Hoffman AR, et al. Prevalence, severity, and health correlates of lower urinary tract symptoms among older men: The MrOS study. *Urology.* 2006;68:804–9.
6. Parsons JK, Mougey J, Lambert L, Wilt TJ, Fink HA, Garzotto M, et al. Lower urinary tract symptoms increase the risk of falls in older men. *BJU Int.* 2009;104:63–8.
7. McVary KT, McKenna KE. The relationship between erectile dysfunction and lower urinary tract symptoms: Epidemiological, clinical, and basic science evidence. *Curr Urol Rep.* 2004;5:251–7.
8. McVary KT, Monnig W, Camps JL, Young JM, Tseng LJ, Van den Ende G. Sildenafil citrate improves erectile function and urinary symptoms in men with erectile dysfunction and lower urinary tract symptoms associated with benign prostatic hyperplasia: A

- randomized, double-blind trial. *J Urol.* 2007;177:1071–7.
9. Roehrborn CG, McVary KT, Elion-Mboussa A, Viktrup L. Tadalafil administered once daily for lower urinary tract symptoms secondary to benign prostatic hyperplasia: A dose finding study. *J Urol.* 2008;180:1228–34.
 10. Stief CG, Porst H, Neuser D, Beneke M, Ulbrich E. A randomised, placebo-controlled study to assess the efficacy of twice-daily vardenafil in the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Eur Urol.* 2008;53:1236–44.
 11. Madani AH, Afsharimoghaddam A, Roushani A, Farzan A, Asadollahzade A, Shakiba M, et al. Evaluation of tadalafil effect on lower urinary tract symptoms of benign prostatic hyperplasia in patients treated with standard medication. *Int Braz J Urol.* 2012;38:33–9.
 12. Karadağ E, Öner S, Budak YU, Atahan O. Randomized crossover comparison of tamsulosin and alfuzosin in patients with urinary disturbances caused by benign prostatic hyperplasia. *Int Urol Nephrol.* 2011;43:949–54.
 13. Bechara A, Romano S, Casabé A, Haime S, Dedola P, Hernández C, et al. Comparative efficacy assessment of tamsulosin vs. Tamsulosin plus tadalafil in the treatment of LUTS/BPH. Pilot study. *J Sex Med.* 2008;5:2170–8.