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ORIGINAL ARTICLE

Benign prostatic hyperplasia related symptoms in males – A Comparative study between Tamsulosin and tadalafil

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ABSTRACT:
Background: Male health is significantly impacted by benign prostatic hyperplasia (BPH), the most prevalent neoplastic disorder affecting males. In older men, BPH and sexual dysfunction frequently coexist. The present study compared tamsulosin and tadalafil in relieving benign prostatic hyperplasia related symptoms in males. **Materials & Methods:** 110 males of >45 years of age with LUTS were divided into 2 groups of 55. Tadalafil 10 mg once daily was given to group I for six weeks, followed by a four-week placebo (P4) washout and 0.4 mg of Tamsulosin once daily. Group II received the opposite treatment. The International Index of Erectile Function-5 scores, uroflowmetry parameters, and IPSS scores were among the parameters that were noted. **Results:** Age group 45- 55 years had 12, 55-65 years had 40 and >65 years had 58 patients. The difference was significant (P< 0.05). Comorbidities such as diabetes mellitus was present in 3 in group I and 5 in group II, bronchial asthma 4 in group I and 3 in group II, hypertension was present in 5 in group I and 6 in group II and both hypertension and diabetes mellitus was present in 4 in group I and 7 in group II. The difference was significant (P< 0.05). The mean IPSS total score at baseline in group I was 18.4 and 17.7 in group II, at 3 weeks was 17.2 in group I and 17.3 in group II and at 9 weeks was 10.6 in group I and 10.1 in group II. IPSS voiding score at baseline in group I was 12.2 and 11.4 in group II, at 3 weeks was 11.4 in group I and 10.9 in group II and at 9 weeks was 6.1 in group I and 7.2 in group II. IPSS storage score at baseline in group I was 6.0 and 5.9 in group II, at 3 weeks was 5.5 in group I and 5.3 in group II and at 9 weeks was 3.9 in group I and 3.8 in group II. IPSS QOL score at baseline in group I was 3.8 and 5.4 in group II, at 3 weeks was 3.6 in group I and 4.9 in group II and at 9 weeks was 3.4 in group I and 3.1 in group II. The difference was non-significant (P> 0.05). **Conclusion:** In males over 45, benign prostrate hyperplasia is a common complaint. Tamsulosin and tadalafil both reduced the symptoms of benign prostate hyperplasia and LUTS.
Key words: Benign prostatic hyperplasia, lower urinary tract symptoms, Tamsulosin

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INTRODUCTION

Male health is significantly impacted by benign prostatic hyperplasia (BPH), the most prevalent neoplastic disorder affecting males. In older men, BPH and sexual dysfunction frequently coexist.[1] The close anatomical link between the prostate and the neck of the bladder makes this pathologic alteration significant. Autopsy investigations that use real or computed weight, prostate volume, or histologic criteria have frequently shown that BPH is associated with aging.[2]

The histological diagnosis of benign prostatic hyperplasia (BPH) is linked to the prostatic transition zone's unchecked growth of glandular epithelium, smooth muscle, and connective tissue.[3,4] Two fundamental components make up prostate tissue: a stromal component made mostly of collagen and smooth muscle, and a glandular component made up of secretory ducts and acini. Prostate volume and stromal smooth muscle tone rise as a result of cellular proliferation in BPH. McNeal outlines two stages in the development of BPH. Clinical BPH development is also influenced by genetic and environmental factors.[5] Compared to Caucasian populations, Chinese and Japanese men in Asia are said to have a significantly reduced incidence of BPH.Several studies have been conducted in men presenting with LUTS consistent with benign prostatic hyperplasia (BPH-LUTS) with and without concomitant ED to determine whether phosphodiesterase type 5 inhibitors (PDEIs) are effective for the treatment of symptomatic BPH.[6]The present study was conducted to compare tamsulosin and tadalafil in relieving benign prostatic hyperplasia related symptoms in males.

MATERIALS & METHODS

The present study comprised of 110 males of age more than 45 years of age with lower urinary tract symptoms (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 through clinical examination was performed. All patients were divided into 2 groups. Tadalafil 10 mg once daily was given to group I for six weeks, followed by a four-

week placebo (P4) washout and 0.4 mg of Tamsulosin once daily. Group II received the opposite treatment. The International Index of Erectile Function-5 scores, uroflowmetry parameters, and IPSS scores were among the parameters that were noted. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

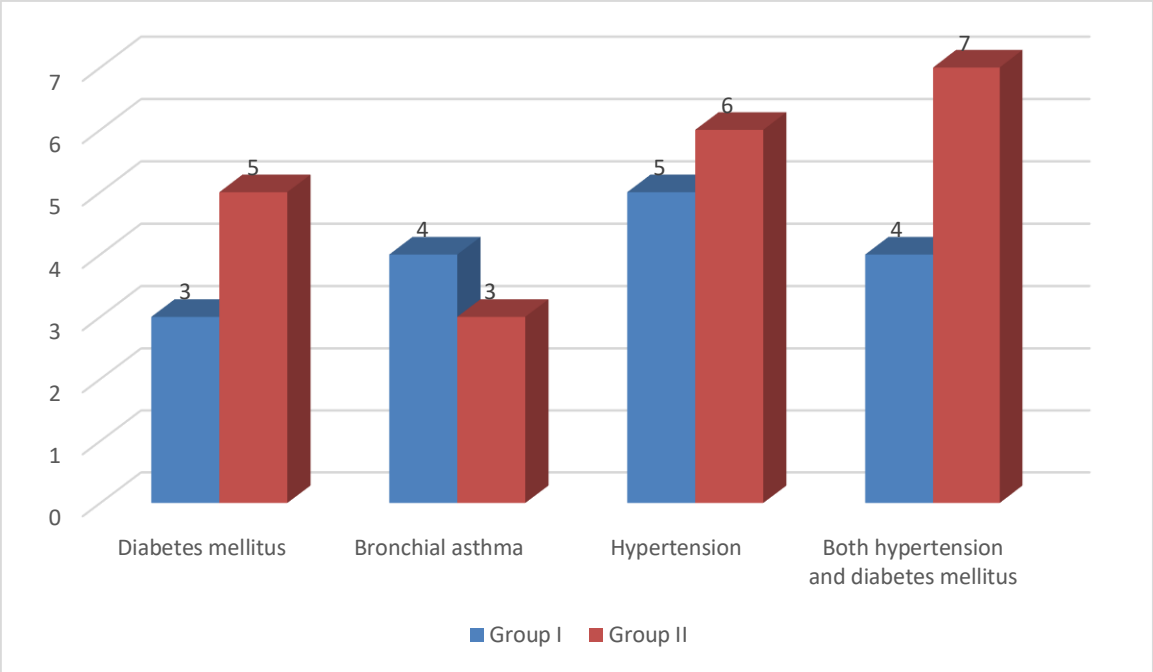
RESULTS

Table I Distribution of patients

Age group (Years)	Number	P value
45-55	12	0.05
55-65	40	
>65	58	

Table I shows that age group 45- 55 years had 12, 55-65 years had 40 and >65 years had 58 patients. The difference was significant (P< 0.05).

Graph I Presence of co- morbidities



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

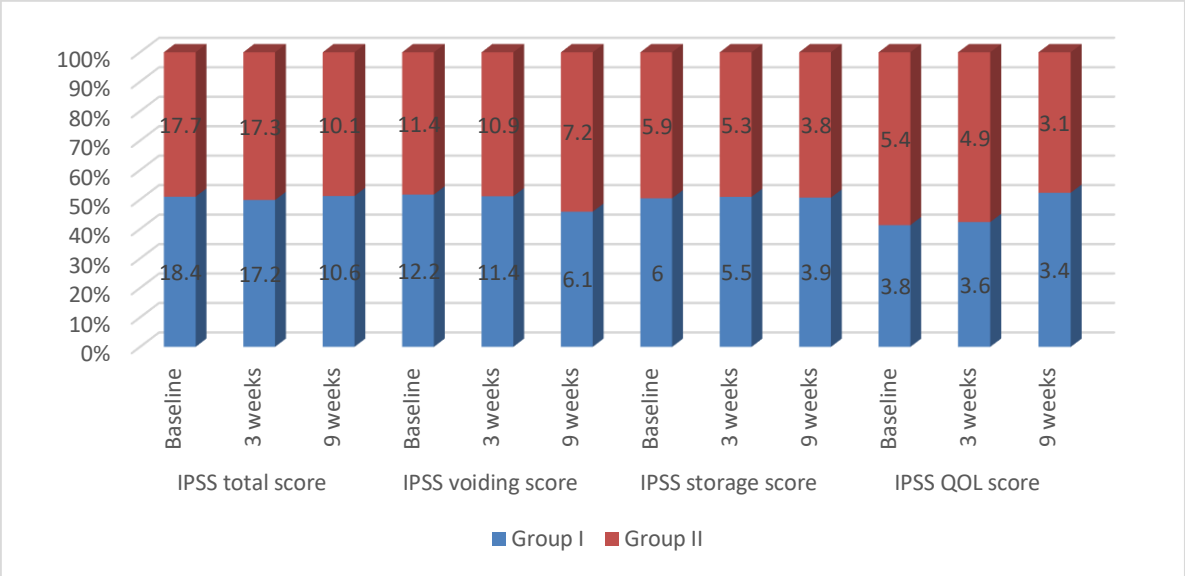
Table II Comparison of parameters in both groups

Parameters	Duration	Group I	Group II	P value
IPSS total score	Baseline	18.4	17.7	0.67
	3 weeks	17.2	17.3	
	9 weeks	10.6	10.1	
IPSS voiding score	Baseline	12.2	11.4	0.25
	3 weeks	11.4	10.9	
	9 weeks	6.1	7.2	
IPSS storage score	Baseline	6.0	5.9	0.08
	3 weeks	5.5	5.3	
	9 weeks	3.9	3.8	
IPSS QOL score	Baseline	3.8	5.4	0.71
	3 weeks	3.6	4.9	
	9 weeks	3.4	3.1	

Table III, graph I shows that mean IPSS total score at baseline in group I was 18.4 and 17.7 in group II, at 3 weeks was 17.2 in group I and 17.3 in group II and at 9 weeks was 10.6 in group I and 10.1 in group II. IPSS voiding score at baseline in group I was 12.2 and 11.4 in group II, at 3 weeks was 11.4 in group I and 10.9 in

group II and at 9 weeks was 6.1 in group I and 7.2 in group II. IPSS storage score at baseline in group I was 6.0 and 5.9 in group II, at 3 weeks was 5.5 in group I and 5.3 in group II and at 9 weeks was 3.9 in group I and 3.8 in group II. IPSS QOL score at baseline in group I was 3.8 and 5.4 in group II, at 3 weeks was 3.6 in group I and 4.9 in group II and at 9 weeks was 3.4 in group I and 3.1 in group II. The difference was non- significant (P> 0.05).

Graph I Comparison of parameters



DISCUSSION

Regardless of the various co-morbidities, there is a substantial correlation between age and the severity of LUTS and sexual abnormalities and the problems they cause.[7] It has been noted that erectile dysfunction (ED) and lower urinary tract symptoms (LUTS) brought on by BPH are strongly correlated.[8] Four primary pathophysiological pathways, with differing degrees of overlap, now support the association between LUTS and ED, despite the lack of a clear causal link between the two conditions. A genetic component to the development of these lesions is supported by these and other research.[9] A wider range of treatment objectives are being addressed by clinical evaluation to determine the existence and severity of voiding dysfunction and/or the part that BPH plays in it. These involve choosing patients for medication or interventional trials, informing and counseling specific patients, and disseminating information on various epidemiology research.[10]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 12, 55-65 years had 40 and >65 years had 58 patients. In a crossover design research, Bechara et al[11] evaluated the safety and effectiveness of tamsulosin 0.4 mg/day against tamsulosin 0.4 mg/day + tadalafil 20 mg/day in patients with LUTS. For 45 days, 30 males with a history of LUTS/BPH spanning at least 6 months were randomly assigned to one of two groups to receive 0.4 mg of tamsulosin per day or 0.4 mg of tamsulosin with 20 mg of tadalafil per day. After 45 days, they switched to the other treatment mode. The trial was finished by 27 patients. Both treatments significantly improved IPSS score and IPSS-QOL, however the medication combination had a larger effect. There were no significant differences between tamsulosin alone and tamsulosin with tadalafil (P > 0.05), and both regimens improved the Qmax and decreased the PVR volume from baseline (P < 0.001). When tamsulosin and tadalafil were combined, the IIEF increased (P < 0.001), but not when tamsulosin was taken alone (P > 0.05). According to the GAQ, every patient favored the combined plan. The two therapies were both well received.

We found that comorbidities such as diabetes mellitus was present in 3 in group I and 5 in group II, bronchial asthma 4 in group I and 3 in group II, hypertension was present in 5 in group I and 6 in group II and both hypertension and diabetes mellitus was present in 4 in group I and 7 in group II. The effectiveness and safety of tamsulosin (Tam) and alfuzosin (Alf) in treating individuals with lower urinary tract symptoms (LUTS) linked to benign prostatic hyperplasia (BPH) were compared by Karadag et al.[12]They recruited one hundred males with lower urinary tract symptoms (LUTS) and benign prostatic hyperplasia (BPH). Two groups were randomly assigned: the Alf-Tam group (Alf for 8 weeks, followed by Tam for 8 weeks) and the Tam-Alf group (Tam for 8 weeks, followed by Alf for 8 weeks) for BPH patients with IPSS greater than 8 and a maximum urine flow rate (Q(max)) less than 15 ml/s. During the initial phase of treatment, every medication markedly enhanced IPSS and Q (max). IPSS and Q (max) were improved by cross-over in

both the Tam-Alf and Alf-Tam groups. Compared to baseline, Alf and Tam significantly raised Q (max) and decreased IPSS ($P < 0.001$). Serum PSA levels were unaffected by either medication. Comorbid conditions included diabetes mellitus in two of the groups I and II, bronchial asthma in four of the groups I and II, hypertension in six of the groups I and VII, and both diabetes mellitus and hypertension in three of the groups I and five of the groups II, they discovered.

We found that mean IPSS total score at baseline in group I was 18.4 and 17.7 in group II, at 3 weeks was 17.2 in group I and 17.3 in group II and at 9 weeks was 10.6 in group I and 10.1 in group II. IPSS voiding score at baseline in group I was 12.2 and 11.4 in group II, at 3 weeks was 11.4 in group I and 10.9 in group II and at 9 weeks was 6.1 in group I and 7.2 in group II. IPSS storage score at baseline in group I was 6.0 and 5.9 in group II, at 3 weeks was 5.5 in group I and 5.3 in group II and at 9 weeks was 3.9 in group I and 3.8 in group II. IPSS QOL score at baseline in group I was 3.8 and 5.4 in group II, at 3 weeks was 3.6 in group I and 4.9 in group II and at 9 weeks was 3.4 in group I and 3.1 in group II. Stief CG et al[13]investigated the effects of vardenafil on LUTS and QoL in men with BPH/LUTS, with or without concomitant ED.Men aged 45-64 yr with BPH/LUTS and an International Prostate Symptom Score (IPSS) > or =12 were randomised to receive either 10mg vardenafil or placebo twice daily. LUTS were assessed with the use of two primary efficacy parameters, IPSS score and maximum urinary flow rate (Qmax), as well as postvoid residual (PVR) urine volume; ED was measured with the use of the erectile function (EF) domain score of the International Index of Erectile Function (IIEF-EF); and QoL was assessed with the Urolifetrade mark QoL-9 questionnaire.After 8 weeks of treatment, there was a significant improvement in the IPSS total score in the vardenafil group compared with placebo (-5.9 and -3.6, respectively; $p=0.0013$). Nominally significant improvements in irritative and obstructive IPSS subscores ($p=0.0017$ and $p=0.0081$, respectively), EF ($p=0.0001$), and Urolife QoL-9 ($p<0.0001$) were also associated with vardenafil treatment. Qmax and PVR urine volume did not change significantly with treatment, although baseline values were already considered close to normal. Vardenafil was generally well tolerated, with most adverse events considered mild or moderate in severity.

The limitation of the study is small sample size.

CONCLUSION

Authors found that in males over 45, benign prostrate hyperplasia is a common complaint. Tamsulosin and tadalafil both reduced the symptoms of benign prostate hyperplasia and LUTS.

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