ORIGINAL RESEARCH

Assessment of efficacy of tadalafil with tamsulosin in the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia

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ABSTRACT
Background: Benign prostatic hyperplasia (BPH) is highly prevalent in elderly men and often results in lower urinary tract symptoms (LUTS). The present study was conducted to compare the efficacy of tadalafil with tamsulosin in the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).
Materials & Methods: 78 patients of diagnosed with LUTS secondary toBPHwere divided into 2 groups. Group I were given tadalafil 5 mg and group II tamsulosin 0.4 mg. Maximum flow rate (Qmax), Postvoid residual urine (PVR), International Prostate Symptom Score (IPSS), International Prostate Symptom Score Quality of life (IPSS QoL) and Sexual Health Inventory for Men (SHIM) scoring were compared.
Results: mean prostate size in group I was 32.5 gram and in group II was 30.1 gram. Qmax was 13.6 ml/sec in group I and 12.8 ml/sec in group II. PVR was 51.4 ml in group I and 83.2 ml in group II. IPSS was 12.7 in group I and 14.9 in group II, IPSS QoL was 2.3 in group I and 3.0 in group II. The difference was significant (P< 0.05).
Conclusion: Once daily tadalafil 5 mg is well tolerated and can be considered for the treatment of LUTS secondary to BPH when associated with ED.
Key words: Benign prostatic hyperplasia, lower urinary tract symptoms, Men

INTRODUCTION

Benign prostatic hyperplasia (BPH) is highly prevalent in elderly men and often results in lower urinary tract symptoms (LUTS). LUTS secondary to BPH increases with age and negatively impacts patients' quality of life.[1] The current standard of care in men with moderate to severe LUTS secondary to BPH is treatment with alpha-blockers or in men with enlarged prostates with5-alpha-reductase inhibitors either alone or in combination and transurethral surgery in those who have failed medical therapy.[2,3]
The prevalence of bothersome LUTS/BPH increases with age, and epidemiologic and pathophysiologic links between LUTS/BPH and erectile dysfunction (ED) have been demonstrated.[4] Medical therapy for LUTS/BPH currently consists of a-blockers, 5a-reductase inhibitors, or combination therapy. Although efficacious, these therapies have the potential for side-effects relating to sexual dysfunction.[5] 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. The a-blocker tamsulosin is often a first-line treatment for LUTS/BPH.[6]The present study was conducted to compare the efficacy of tadalafil with tamsulosin in the treatment of lowerurinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

MATERIALS & METHODS

The present study comprised of 78 patients of diagnosed with LUTS secondary toBPH. All gave their written consent for the participation in the study.

Data such as name, ageetc. was recorded. Patients were divided into 2 groups. Group I were given tadalafil 5 mg and group II tamsulosin 0.4 mg. Patients were assessed at baseline 1, 4 and 12 weeks with efficacy measures being Maximum flow rate (Qmax), Postvoid residual urine (PVR), International Prostate Symptom Score (IPSS), International Prostate Symptom Score Quality of life (IPSS QoL) and Sexual Health Inventory for Men (SHIM) scoring.Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Distribution of patients

| Groups	Group I	Group II
Methods	tadalafil 5 mg	tamsulosin 0.4 mg

Table I shows that group I were given tadalafil 5 mg and group II tamsulosin 0.4 mg.

Table II Assessment of parameters

Parameters	Group I	Group II	P value
Prostate size (g)	32.5	30.1	0.81
Qmax (ml/sec)	13.6	12.8	0.92
PVR (ml)	51.4	83.2	0.05
IPSS	12.7	14.9	0.17
IPSS QoL	2.3	3.0	0.21

Table II, graph I shows that mean prostate size in group I was 32.5 gram and in group II was 30.1 gram. Qmax was 13.6 ml/sec in group I and 12.8 ml/sec in group II. PVR was 51.4 ml in group I and 83.2 ml in group II. IPSS was 12.7 in group I and 14.9 in group II, IPSS QoL was 2.3 in group I and 3.0 in group II. The difference was significant (P< 0.05).

Graph I Assessment of parameters
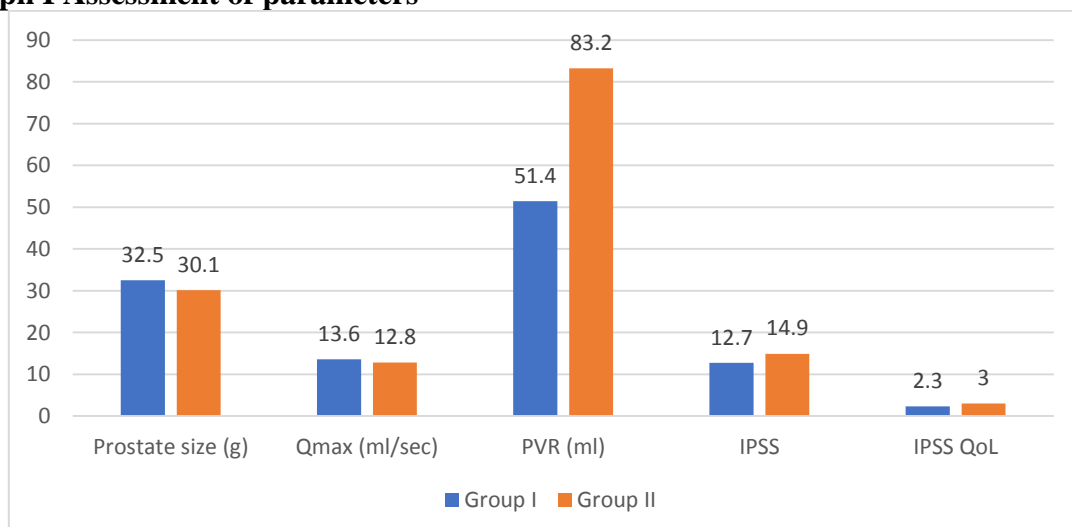
DISCUSSION

In the presence of moderate or severe LUTS due to BPH, medical management has become the standard of care in patients.[7] Alpha1-adrenoreceptor antagonists were the most widely prescribed drugs, while use of PDE5-Is has been recently gaining popularity for LUTS secondary to BPH. The 2016 Guidelines on the Management of Male LUTS published by the European Association of Urology (EAU) and guidelines compiled by the American Urological Association (AUA) recommend the use of several different pharmacotherapies for the treatment of LUTS, depending on the clinical situation.[8,9] Alpha-blockers and 5-ARIs are considered the first-line medical treatment in men with moderate to severe LUTS. The newest drug class, PDE5-Is, are mentioned in the 2013 EAU guidelines.[10,11]The present study was conducted to compare the efficacy of tadalafil with tamsulosin in the treatment of lowerurinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

We found that mean prostate size in group I was 32.5 gram and in group II was 30.1 gram. Qmax was 13.6 ml/sec in group I and 12.8 ml/sec in group II. PVR was 51.4 ml in group I and 83.2 ml in group II. IPSS was 12.7 in group I and 14.9 in group II, IPSS QoL was 2.3 in group I and 3.0 in group II. Pogula et al[12]compared the efficacy of tadalafil 5 mg with tamsulosin 0.4 mg in the treatment of Lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). Patients were assessed at baseline 1, 4 and 12 weeks with efficacy measures being Maximum flow rate (Qmax), Postvoid residual urine (PVR), International Prostate Symptom Score (IPSS), International Prostate Symptom Score Quality of life (IPSS QoL) and Sexual Health Inventory for Men (SHIM) scoring. In tadalafil group, 12 (24%) patients were having mild LUTS and 38 (76%) were having moderate LUTS. In tamsulosin group, 9 (18%) patients were having mild LUTS and 41 (82%) patients were having moderate LUTS. Seventeen patients in tadalafil group had associated ED (erectile dysfunction) and 13 patients had associated ED in tamsulosin group.

OelkeM et al[13] found that IPSS significantly improved versus placebo through 12 weeks with tadalafil and tamsulosin and as early as 1 week. BPH Impact Index significantly improved versus placebo at first assessment (week 4) with tadalafil and tamsulosin and through 12 weeks. The IPSS Quality-of-Life Index and the Treatment Satisfaction Scale–BPH improved significantly versus placebo with tadalafil (both $p < 0.05$) but not with tamsulosin (both $p > 0.1$). The International Index of Erectile Function–Erectile Function domain improved versus placebo with tadalafil but not tamsulosin. Qmax increased significantly versus placebo with both tadalafil (2.4 ml/s; $p = 0.009$) and tamsulosin (2.2 ml/s; $p = 0.014$). Adverse event profiles were consistent with previous reports. This study was limited in not being powered to directly compare tadalafil versus tamsulosin.

Gacci et al[14] reported that the degree of improvement in IPSS after PDE5-I treatment depended on the baseline characteristics of the patients, such as age, body mass index (BMI) and the baseline IPSS, indicating that young men with a low BMI and severe urinary symptoms (as measured by IPSS) are the best candidates for PDE5-I therapy. Aging and obesity appear to be associated with a testosterone decline, which can decrease the main target of PDE5-I in the bladder.

The limitation the study is small sample size.

CONCLUSION

Authors found that once daily tadalafil 5 mg is well tolerated and can be considered for the treatment of LUTS secondary to BPH when associated with ED.

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