



The survey of effect of combination therapy with tamsulosin – finasteride compared with tamsulosin alone on symptom improvement of benign prostatic hypostatic

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Abstract

Introduction: Benign prostatic hyperplasia (BPH) is a histologic change in the prostate and one of the common diseases in middle-aged and old men. BPH, as a life-altering urinary condition requires prompt medical interventions, both medical and surgical. Alpha-1 blockers (α 1-blockers) are first-line treatment for BPH. 5 α -reductase inhibitors (5-ARIs), like finasteride are very effective in patients with BPH who do not respond to α 1-blockers.

Objectives: This study was designed to compare the effect of tamsulosin (a selective α 1-blockers) on BPH with the effect of combination therapy with tamsulosin and finasteride.

Patients and Methods: This randomized controlled clinical trial study was done in Isfahan. Around 120 men with BPH divided into 2 groups with 60 patients in each group. Both groups were evaluated with the American Urological Association (AUA) symptom score. Scoring form of AUA symptoms to determine the severity of symptoms resulting from BPH was developed by America Urological Association. Total of its scores was between 0 and 35. Then, one group received tamsulosin and the other group received combination therapy with finasteride and tamsulosin. After 4 weeks, the AUA symptom score was done for both of groups. Results were analyzed by the paired *t* test, *t* test and chi-square through SPSS version 16.

Results: No significant differences in mean of age and the AUA symptom score distribution were seen between two groups ($P > 0.05$). After 4 weeks of therapy, the AUA symptom score was significantly decreased in the patients who received tamsulosin and finasteride compared with the patients who received tamsulosin alone ($P < 0.05$).

Conclusion: The results of our study showed that tamsulosin and finasteride are effective drugs for BPH treatment. Combination therapy with finasteride and tamsulosin was significantly more effective, in our study, compared to tamsulosin alone.

Introduction

Benign prostatic hyperplasia (BPH) is the most common problems in older men. Despite efforts that have been made in the past 3 decades on its underlying etiology in older men, the factors affecting its development have not been proven. Fifty percent of 51-60 years old men and 90% of 80 years old men show histopathological BPH changes (1). Due to the many problems that this disease can cause in people (2), various pharmacological and non-pharmacological treatments have been proposed. One of these treatments is surgical treatment that is the second most common cause of surgery in men after cataract. However, since these patients are at high risk for invasive procedures due to anesthetic and simultaneous problems (cardiovascular,

Key Point

In a study on 120 men with benign prostatic hyperplasia, we found, the combination of tamsulosin and finasteride has been more effective in improving BPH compared with tamsulosin alone.

respiratory, gastrointestinal and brain problems), and in case of incidence of complications, treatment will be difficult and response to treatment will be later. Moreover, efforts to find less invasive or non-invasive treatment have been made in recent years followed by considerable success. Several attempts have made to administer safer drugs having lower complications (1). In recent studies, alpha 1-blockers have been administered as first-line treatment of BPH.

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For this reason, using a drug such as tamsulosin which is a specific inhibitor of alpha 1 (type A) in the prostate and bladder neck seems to be necessary and valuable. On the other hand, finasteride can be used in patients who have used less amount of alpha 1-blockers or showed no response for them (1,3). The administration of drugs in combination with each other has been considered recently.

Objectives

The aim of this study was to accurately investigation of the effect of tamsulosin and finasteride on this disease; hence we can examine this drug combination compared with alpha-blockers alone (tamsulosin) in society.

Patients and Methods

Study population

This study was a clinical trial. The study population consisted of all men with BPH referred to the urology clinic of Doctor Ali Shariati hospital. Men with BPH whose BPH has been diagnosed through a physical examination and clinical investigations and other differential diagnoses and men who had no absolute surgery indications or there was no surgery possibility for them as well as people who were willing to participate in the research were included in the study. Additionally, men with BPH who had no clinical symptoms of blockage or had absolute surgery indication, patients who had to withdraw the drug, patients who did not take the drug regularly, according to prescription, and those who were not willing to participate in the study were excluded from the study. Firstly, the procedure was explained for patients and in the case of their consent, they were included to study. Then, they were divided into two equal groups and they were evaluated and scored based on scoring form of America Urological Association (AUA) symptom. Scoring form of AUA symptoms to determine the severity of symptoms resulting from BPH was developed by the America Urological Association. Total of its scores was between 0 and 35.

For one group, 0.4 mg of tamsulosin was given daily, and 0.4 mg of tamsulosin along with 5 mg of finasteride were given daily for another group. In addition, every patient underwent PSA and sonography test before the treatment, and a separate questionnaire was developed and completed for each patient. After 1 month, patients were visited once

more and their clinical symptoms were checked.

Ethical issues

1) The research followed the tenets of the Declaration of Helsinki and its later amendments. 2) Informed consent was obtained; and 3) Permission of the ethical review committee of Najafabad Azad University, School of Medicine, Isfahan, Iran was obtained prior to execution of the study. This study was conducted as the medical doctorate of Ali Jabbari Sabbagh at this university (thesis# 84/517).

Statistical analysis

Continuous variables in each group of subjects were presented as mean values ± standard deviation (SD). To analyze the findings of this study, SPSS 16 software was used. A $P < 0.05$ was considered as the significance level. For comparison before and after treatment or comparison between groups, paired t-test was applied.

Results

The results of this study showed that the mean age of the subjects was 69 years and statistical tests showed that frequency distribution of mean age is equal in both groups ($P > 0.05$). Paired *t* test showed that the frequency of symptoms in patients treated with tamsulosin had a significant difference before and after treatment and those treated with tamsulosin experienced significant improvement in symptoms ($P < 0.05$). Paired *t* test also showed that the severity of symptoms in patients treated with tamsulosin and finasteride was significantly different before and after treatment ($P < 0.05$) (Table 1). Based on paired *t* test analysis, the severity of symptoms in patients treated with tamsulosin and finasteride has been significantly reduced compared to that in patients who used only tamsulosin ($P < 0.05$) (Figure 1). Accordingly, paired *t* test showed that reduction of mean AUA symptoms in patients treated with tamsulosin and finasteride was significantly higher than that in the group used only tamsulosin ($P < 0.05$) (Table 2).

Discussion

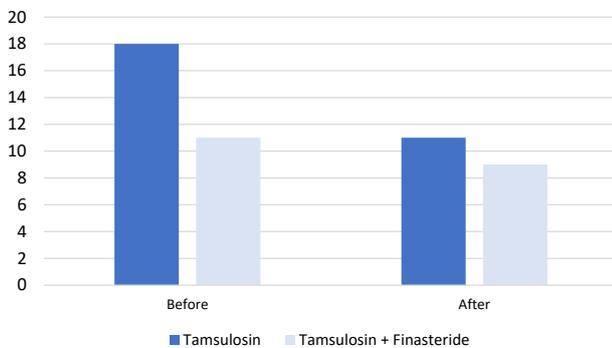
Results showed that the severity of symptoms after treatment with tamsulosin drug has been reduced in the

Table 1. Comparing the frequency of symptoms severity in patients treated with tamsulosin and finasteride before and after treatment

Urinary symptoms	Frequency after and before treatment											
	Never		Less than 1 in 5 times of urinations		Less than half of times		Almost half of times		More than half of times		Almost always	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
Incomplete bladder emptying	0	4	8	21	16	27	14	6	19	2	3	0
Frequent urination	0	9	11	18	17	24	26	9	6	0	0	0
Frequently interrupted urine	6	15	3	25	31	18	13	0	8	2	0	0
Urgency to urinate	25	30	23	20	9	10	3	0	0	0	0	0
Weak stream of urine	0	6	0	27	0	18	14	9	21	0	25	0
Straining	4	16	6	23	14	15	17	6	19	0	0	0
Nocturia	0	6	0	16	11	23	18	13	25	2	6	0

Table 2. Comparing the mean of AUA symptoms in 2 groups of study before and after treatment

Urinary symptoms	Mean of AUA score before and after taking drug	Mean of AUA score after taking drug	Rate of symptoms improving based on mean of AUA score before and after taking drug
Patients treated with tamsulosin	18.51±1.27	11.75±1.30	6.76
Patients treated with tamsulosin and finasteride	18.73±1.22	9.55±1.47	9.18

**Figure 1.** Comparing the mean scores of urinary symptoms before and after treatment.

studied patients. Lopatkin et al (4) and Hasan et al (5) stated that tamsulosin has been effective in the treatment of BPH. Additionally, Kirbiy et al (6) also indicated that tamsulosin has been effective in improving the symptoms in patients affected with BPH. Suzuki et al (7) showed that BPH treatment with tamsulosin led to improvement in lower urinary symptoms, improved quality of life, and reduced size of the prostate. In addition, Ratisa et al (8) highlighted that treatment with tamsulosin improved symptoms and the quality of patients' lives. The results of study also showed that the severity of symptoms has been effective in the case of combined treatments. Hence, combination of tamsulosin and finasteride has been more effective in improving BPH compared with tamsulosin alone. The study conducted by Kaviani et al (9) showed that in patients with irritative symptoms of BPH, the combination of an alpha-blocker and anticholinergic has been a safe and rational treatment without increasing the rate of urinary retention. The study conducted by Ismaila et al (10) suggested that combined treatment of dutasteride and tamsulosin had important clinical benefits in improving BPH and it is cost-effective in the health care systems. The relative risk of clinical progression of BPH has been effective. Roehrborn et al and (11) Siami et al (12) showed that combined treatment of dutasteride and tamsulosin had a significant impact on improving BPH symptoms. Elkelany et al (13) also showed that the combined treatment of finasteride and tadalafil has been effective in reducing symptoms of BPH. Therefore, it can be noted that treatment with tamsulosin alone or in combination with finasteride can be effective step in improving the symptoms of BPH in patients. Finally, researchers recommend that another study to be conducted to compare other drugs used in the treatment of BPH.

Limitations of the study

Our study has some limitations; first, this is small retrospective study which includes a relatively small proportion of patients. Secondly, drug levels and sensitivity tests were not conducted for patients to correlate with the fungal peritonitis.

Authors' contribution

AJS and MK conceived the study and collected the data from study participants. AJS analyzed the data and drafted the final manuscript. All authors read, revised, and approved the final manuscript.

Conflicts of interest

There were no points of conflicts.

Ethical considerations

Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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