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Research Article:

# Comparative Study of Tamsulosin and Alfuzosin on Irritative Symptoms in Benign Prostatic Hyperplasia: Efficacy and Tolerability

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## Abstract

**Background:** : Benign prostatic hyperplasia (BPH) is a common condition in aging men, often presenting with lower urinary tract symptoms, such as frequency, urgency, and nocturia. Tamsulosin and Alfuzosin, α1-adrenergic receptor antagonists, are among the primary pharmacological treatments. The current prospective study aimed to assess the safety and effectiveness of tamsulosin and alfuzosin in patients with BPH without dosage titration over a period of 4 weeks. **Methods:** A total of 52 patients were involved in this study, presenting with irritative symptoms of BPH and aged 45 years and above. Participants were then divided into two groups: the Tamsulosin group (26 participants), who received tamsulosin 0.4 mg, and the alfuzosin group (26 participants), who received alfuzosin 10 mg. The irritative score of the International Prostate Symptom Score (IPSS) questionnaire was used to assess the participants, in addition to the post-void residual volume (PVRV) by ultrasonography. **Results:** Baseline characteristics, including PVRV, were similar between groups. Tamsulosin and alfuzosin reduce BPH irritative symptoms similarly. Both significantly reduce frequency, urgency, and nocturia ($p < 0.0001$). However, the study compared change scores between groups; tamsulosin showed a greater mean reduction in PVRV than alfuzosin on between-group testing. Side effects were minimal; 4% of patients in the alfuzosin group experienced hypotension, and 4% reported sexual dysfunction, while no side effects were observed in the tamsulosin group. **Conclusion**: Treatment with tamsulosin or alfuzosin demonstrates significant improvement in the irritative symptoms of BPH, with both drugs showing comparable efficacy, while a numerically greater reduction in PVRV is observed with tamsulosin. No significant side effects were reported that affected the tolerability of either medication.



## 1. Introduction

Benign prostatic hyperplasia (BPH) is a common histopathological condition in the elderly male, which may result in progressively enlarged prostates and the emergence of lower urinary tract symptoms (LUTS) (1). Activation of alpha-1 (α-1) receptors in the lower urinary tract contributes to the development of LUTS through both static (irreversible) components, such as increased structural mass of the prostate gland, and dynamic (reversible) components, which involve increased tension of the smooth muscle in the prostate, prostate capsule, and bladder neck (2).

The International Prostate Symptom Score (IPSS) questionnaire is a tool endorsed by the American Urological Association (AUA) and European Association of Urology

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(EAU) to evaluate BPH severity (3). It helps determine the severity of LUTS, monitor the progression of symptoms, direct treatment options, and evaluate the success of treatment. While the IPSS itself includes 7 questions without dividing them in the form, researchers and clinicians routinely classify the questions into obstructive (Voiding) symptoms (incomplete emptying, intermittency, weak stream, and straining) and irritative (Storage) symptoms (frequency, urgency, and nocturia). However, the American Urological Association Symptoms Index (AUASI) is another tool to evaluate the BPH severity, but the IPSS differs by including an additional question to assess the quality of life (4,5).

α-1 receptor antagonists are the first-line treatment for patients with BPH despite their side effects on blood pressure. α-1A receptors are predominantly located in the bladder base, prostate, and ureterotrigonal region, including the distal 5 cm of the ureter (6). Consequently, the higher the selectivity of α-1 receptor antagonists toward α-1A receptors, the lower the incidence of side effects. α-1 receptor antagonists can cause dizziness and lightheadedness, particularly when standing up (orthostatic hypotension). Other adverse effects include headache, nasal congestion, retrograde ejaculation (semen flows into the bladder instead of out), and fainting (7,8).

Five α-1 receptor antagonists (terazosin, doxazosin, tamsulosin, alfuzosin, and silodosin) have been approved by the United States Food and Drug Administration (US FDA). Tamsulosin was the third α-1 antagonist approved in 1997 for the management of BPH. Tamsulosin was introduced as the premier subtype-selective α-1 antagonist (9). Tamsulosin exhibits about 12-fold more affinity for α-1 adrenoceptors in the human prostate compared to blood vessels. The primary reason for recommending tamsulosin over terazosin and doxazosin was not due to higher efficacy, but rather the lack of dosage titration needs and negligible impact on blood pressure with related side effects (e.g. dizziness). However, the convenience of eliminating the dose titration was accompanied by ejaculatory dysfunction (10,11).

Alfuzosin is the fourth α-1 selective antagonist approved by the FDA in 2003. Radioligand binding experiments did not demonstrate any receptor selectivity of alfuzosin for the α-1 subtypes. The remarkable tolerance is attributed to its slow-release design (12). In addition to that, the chemical structure of alfuzosin differs from other α-1 antagonists by the lack of a piperidine moiety and the presence of a diamino propyl spacer, which increases water solubility and decreases lipophilicity, resulting in a lower ability to penetrate the blood-brain barrier. The AUA Guidelines Committee determined that alfuzosin has equivalent clinical effectiveness to tamsulosin and other authorized alpha blockers, while not inducing ejaculatory dysfunction (13).

Alfuzosin and tamsulosin have been compared in the literature before, but Iraqi patients have not been included in these studies. There is a lack of knowledge on the impact of the medicines on individuals who come from different geographical regions and have distinct dietary and lifestyle variables, in addition to genetic polymorphism. Different genetics could contribute to different responses to α blockers; therefore, characterizing outcomes in this setting is of clinical interest (14). The current prospective study aimed to assess the safety and effectiveness of tamsulosin and alfuzosin without dosage titration in patients with BPH over a 4-week period.

## 2. MATERIALS AND METHODS

### 2.1. Study design, period, and ethical approval

This prospective, multi center, nonrandomized, parallel group comparative study is carried out at a private urology clinic in Mosul, Nineveh province. This study aimed to compare the efficacy and tolerability of tamsulosin and alfuzosin. The research adheres to the ethical standards established in the Declaration of Helsinki by the World Medical Association, which regulates the ethical practices in studies involving human participants and/or animal specimens.

### 2.2. Study participants

All individuals who participated in the study were enrolled based on strict selection criteria using a convenience sampling technique. The inclusion criteria were: outpatients, males aged 45 years and above, and the presence of irritative symptoms of BPH for at least 1 month. Exclusion criteria included urethral stricture disease, pelvic irradiation, bladder neck disease, acute bacterial prostatitis, acute urinary tract infection, urolithiasis, severe visceral disease, postural hypotension, neurogenic bladder dysfunction, suspected prostate cancer, known hypersensitivity to either medications, and medications that cause prostatic enlargement or urine retention.

Every selected patient was assessed by clinical history and presentation of irritative LUTS, general physical examination, and digital rectal examination. The clinical presentation is assessed by using the IPSS score regarding the irritative symptoms with a series of numbers indicating the condition ( 0 = the symptom never occurs, 1= the symptom occurs less than 20% of the time (rarely), 2= the symptom occurs less than 50% of the time (occasionally), 3= the symptom occurs about 50% of the time (sometimes), 4= the symptom occurs more than 50% of the time (frequently), 5= the symptom occurs almost always (very frequently) (15).

A total of 52 participants were enrolled in this 4-week follow-up study. After providing written informed consent, participants were assessed at baseline to collect demographic and clinical data, including age, other diseases, other medications, increase in daytime frequency, urgency, and nocturia. Ultrasonographic assessment for

the prostate was done to detect the post-void residual volume (PVRV). Participants were then divided into two groups: Tamsulosin group (26 participants) who were taking tamsulosin (Omnic Ocas ®) 0.4 mg once daily before bedtime without titration for a 4-weeks duration, and the alfuzosin group (26 participants) who taking alfuzosin (Xatral XL ®) 10 mg once daily before bedtime without titration for a 4-weeks duration. The primary outcome measure of the study was the change in irritative symptoms score (frequency, urgency, and nocturia) and changes in the PVRV, while the secondary outcome was the incidence of adverse effects, including dizziness, fatigue, hypotension, sexual dysfunction, and other adverse effects. Both primary and secondary outcomes, clinical examinations, the presence of irritative LUTS, ultrasonography, and digital rectal examination were carried out at both basal and after 4 weeks of taking the medications.

### 2.3. Statistical analysis

The data are presented as the mean values with the standard deviations (mean±SD). Between-group comparisons were performed on change scores (baseline to 4 weeks) using unpaired t tests, with an ANCOVA sensitivity analysis adjusting for baseline values. Adverse event frequencies were compared using Fisher's exact test. No formal a priori power calculation was performed; this exploratory study was pragmatically sized and is hypothesis-generating. A paired t-test was implemented to facilitate individual comparisons of the tested data. The statistical variations of the various examined groups were analyzed using one-way analysis of variance (ANOVA) and Tukey's post hoc test to identify any significant variability in the groups' means. Prior to conducting any statistical analysis, the normality tests (Kolmogorov-Smirnov, Shapiro-Wilk) were used to verify the normal distribution of the enrolled groups. The statistical significance was determined using GraphPad Prism 8.0.1, with a p-value of less than 0.05 considered significant.

## 3. Results

The mean age of the tamsulosin group is 65.57 ± 11.57, while that of the alfuzosin group is 65.8 ± 7.1, which is insignificant when comparing the age of both groups that participated in the study. Baseline characteristics, including PVRV, did not differ significantly between groups. In a group of 26 patients treated with alfuzosin, there were notable improvements across several irritative urinary symptoms. The total irritative score is enhanced from 7.92 ± 3.77 to 3.04 ± 3.05 with a highly significant p value (<0.0001). Before starting treatment, the average irritative score for frequency of urination was 3.08 ±1.35, which significantly decreased to 1.04 (±0.98) after treatment, with a p value of less than 0.0001, indicating strong statistical significance. Similarly, the urgency score dropped from an average of 2 ±1.56 to 0.84 ±1.43, and nocturia episodes were reduced from 2.84 ±1.65 to 1.16 ±1.07, both with highly significant p values (<0.0001). Regarding post-void residual volume (PVRV), the volume was reduced from 94.75 ± 67.47 to 44.62 ± 38.59 with a significant p value (0.0166). These results suggest that alfuzosin was effective in alleviating irritative urinary symptoms in this patient group (**Table 1**).

**Table 1.** Description of irritative symptoms score for patients using alfuzosin

| Alfuzosin group (n=26) | | | |
|---|---|---|---|
| **Parameter** | **Before** | **After (4 weeks)** | ***p* value** |
| **IPSS/ Irritative symptoms** | 7.92 ± 3.77 | 3.04 ± 3.05 | <0.0001 |
| **Frequency** | 3.08 ± 1.352 | 1.04 ± 0.9781 | <0.0001 |
| **Urgency** | 2 ± 1.555 | 0.84 ± 1.434 | <0.0001 |
| **Nocturia** | 2.84 ± 1.65 | 1.16 ± 1.068 | <0.0001 |
| **PVRV (ml)** | 94.75 ± 67.47 | 44.62 ± 38.59 | 0.0166 |

Data are presented as mean ± SD and are significantly different where indicated using a paired t-test followed by Tukey's post hoc multiple comparison test. n; number, PVRV; post-void residual volume, IPSS; International Prostate Symptom Score

Among the 26 patients who received tamsulosin, there was a clear reduction in the irritative urinary symptoms score. The total irritative score is enhanced from 8.11 ± 2.5 to 2.88 ± 2.06 with a highly significant p value (<0.0001). Before treatment, patients experienced an average score for urinary frequency of about 2.8 ±1.39, which dropped to just 0.8 ±0.85 after treatment. The sense of urgency also improved, with scores decreasing from 1.85 ±1.59 before treatment to 0.38 ±0.85 afterwards. Nighttime urination, or nocturia, was another area of improvement, falling from an average score of 3.46 ±1.45 to 1.31 ±1.05 following tamsulosin use. Regarding post-void residual volume (PVRV), the volume was reduced from 88.47 ± 80.63 to 16.08 ± 26.55 with a highly significant p value (<0.0001). All of these changes were highly statistically significant, with p values less than 0.0001, highlighting the effectiveness of tamsulosin in managing irritative urinary symptoms and enhancing patients' daily lives (**Table 2**).

**Table 2.** Description of irritative symptoms score for patients using tamsulosin

| Tamsulosin group (n=26) | | | |
|---|---|---|---|
| **Parameter** | **Before** | **After (4 weeks)** | ***p* value** |
| **IPSS/ Irritative symptoms** | 8.11 ± 2.5 | 2.88 ± 2.06 | <0.0001 |
| **Frequency** | 2.808 ± 1.386 | 0.8077 ± 0.8494 | <0.0001 |
| **Urgency** | 1.846 ± 1.592 | 0.3846 ± 0.8521 | <0.0001 |
| **Nocturia** | 3.462 ± 1.449 | 1.308 ± 1.05 | <0.0001 |
| **PVRV (ml)** | 88.47 ± 80.63 | 16.08 ± 26.55 | <0.0001 |

Data are presented as mean ± SD and are significantly different where indicated using a paired t-test followed by Tukey's post hoc multiple comparison test. n; number, PVRV; post-void residual volume, IPSS; International Prostate Symptom Score

The results show very comparable effects between the two medications in alleviating irritative symptoms of BPH, despite tamsulosin having higher efficacy in reducing PVRV compared to alfuzosin. In terms of tolerability and side effects, 4% of patients in the alfuzosin group developed hypotension, and another 4% experienced sexual dysfunction. In each case, this corresponded to 1/26 patients. On the other hand, no adverse events were reported in the tamsulosin group. Between-group differences in adverse events were not statistically significant (Fisher's exact test, $p > 0.05$). However, the study did not report on dizziness, fatigue, or other potential side effects. No cases of retrograde ejaculation were reported in the tamsulosin group during the 4 week follow up.

## 4. Discussion

BPH is one of the most common conditions affecting aging men, with up to 90% of men over the age of 85 experiencing this disease. α-1 receptor antagonists are considered the gold standard for managing BPH, despite their potential side effects (16). There are five medications in this class, all approved for the treatment of BPH, each with its own efficacy and tolerability profile. Among them, tamsulosin and alfuzosin are the most frequently prescribed (17). This study set out to determine the effects of alfuzosin and tamsulosin on the irritative symptoms of BPH, as well as to evaluate their side effect profiles.

The current study shows that both tamsulosin and alfuzosin show comparable effects in reducing the severity of irritative symptoms of BPH. Both of them show significance in reducing the frequency of urination, urgency, and nocturia with a highly significant p value (<0.0001). Notably, while both drugs were effective, tamsulosin demonstrated a greater capacity to reduce PVRV compared to alfuzosin, with p-values of <0.0001 for tamsulosin and 0.0166 for alfuzosin, suggesting a potential advantage of tamsulosin in this particular aspect of BPH management. A possible explanation for the tamsulosin effect is pharmacologic one, tamsulosin exhibits greater functional selectivity for α1A receptors concentrated in the prostate and bladder neck, which can produce a larger short-term decrease in dynamic outlet resistance and thereby a greater reduction in PVRV, whereas alfuzosin's uroselectivity is primarily pharmacokinetic (extended release formulation and tissue distribution related to the chemical structure) rather than α1 subtype–selective (18). The 4-week time frame of our study may preferentially capture these dynamic effects on emptying rather than longer-term symptom convergence.

In the field of efficacy, the results of the current study align with those of BUZELIN (1997), Agrawal (2009), and Griwan (2010), who stated that both tamsulosin and alfuzosin showed comparable effects in improving the irritative symptoms of BPH (11,19,20). On the other hand, Dash (2010) showed that tamsulosin was significantly more effective than alfuzosin in improving irritative symptoms of BPH after 12 weeks of treatment, although the group differences in outcome measures were small. However, the longer duration of treatment may be attributed to the different results compared to the current study (21). Taken together, these data suggest similar overall symptom relief, with short-term differences in parameters related to emptying (e.g., PVRV) mainly attributed to receptor selectivity and pharmacokinetics.

No side effects were reported in the tamsulosin group, while 4% of patients in the alfuzosin group developed hypotension and another 4% developed sexual dysfunction. These results are statistically non-significant and in accordance with most previous studies (11,19,21). However, Agrawal (2009) reported that significant development of retrograde ejaculation was reported in the tamsulosin group after 3 months of treatment. However, the longer duration of treatment may be attributed to the different results compared to the current study (20).

Mechanistically, the greater selectivity of tamsulosin on α1A receptors at the ejaculatory ducts and vas deferens is associated with higher rates of ejaculatory dysfunction in longer studies, whereas alfuzosin, lacking α1 subtype selectivity and relying on extended release pharmacokinetics, tends to show a lower occurrence of retrograde ejaculation despite comparable symptom improvement. While less common than ejaculatory issues, some α blockers, including alfuzosin, can occasionally be associated with erectile dysfunction due to their broader vascular effects, though this was a minor finding in this study. Conversely, vascular α1 blockade contributes to

blood pressure–related adverse events and the minimal hemodynamic impact observed with both medications in this study likely reflects the bedtime administration, with tamsulosin generally producing fewer orthostatic symptoms in larger comparative studies.

The strengths of this study include its prospective design and the use of validated symptoms. However, several limitations should be acknowledged. The sample size was relatively small, and the study duration may not capture long-term efficacy or potential adverse effects. Additionally, the lack of a placebo or control group limits the ability to attribute improvements solely to the pharmacological intervention

## 5. Conclusion

Treatment with tamsulosin or alfuzosin demonstrates significant improvement in the irritative symptoms of BPH, with both drugs showing comparable efficacy, while a numerically greater reduction in PVRV is observed with tamsulosin. No significant side effects were reported that affected the tolerability of either medication; however, hypotension and sexual dysfunction occurred in the alfuzosin group at rates of 4% each.

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## Conflict of interest

The authors have no relevant financial or non-financial interests to disclose.

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## Author's contributions

Khalil A. Hadid: Writing – review & editing; writing—original draft preparation; and conceptualization. Muthanna K. Zaki: Writing – review & editing; writing—original draft preparation; and conceptualization. Fawaz A. Alassaf: Supervision, project administration, formal analysis, and conceptualization. Mohammed N. Abed: Supervision, project administration, formal analysis, and Conceptualization. Bashar M. Al-Hammodi: Clinical investigation and data collection. Zaid Saad Khudhur: Clinical investigation and data collection. Nooman Hadi Saeed: : Clinical investigation and data collection

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**دراسة مقارنة بين التامسولوسين والألفوزوسين على الأعراض التهيجية في تضخم البروستاتا الحميد (BPH): الفعالية والتحمل**

**الخلاصة**

**الخلفية:** يُعدّ تضخّم البروستاتا الحميد حالة شائعة لدى الرجال المتقدّمين في العمر، وغالبًا ما يتظاهر بأعراض السبيل البولي السفلي مثل تكرار التبوّل، والإلحاح، والتبوّل الليلي. يُعدّ تامسولوسين وألفوزوسين، وهما من مضادات مستقبلات الأدرينالين ألفا-1، من العلاجات الدوائية الأساسية. هدفت هذه الدراسة المستقبلية إلى تقييم سلامة وفعالية تامسولوسين وألفوزوسين لدى مرضى تضخّم البروستاتا الحميد دون معايرة الجرعة، ولمدة 4 أسابيع. **الطرق:** شملت الدراسة 52 مريضًا بعمر 45 سنة فأكثر يعانون من أعراض مُهيِّجة لتضخّم البروستاتا الحميد. قُسّم المشاركون إلى مجموعتين: مجموعة التامسولوسين (26 مشاركًا) تلقّت تامسولوسين 0.4 ملغ، ومجموعة الألفوزوسين (26 مشاركًا) تلقّت ألفوزوسين 10 ملغ. استُخدم المكوّن المُهيِّج من استبيان الدرجة الدولية لأعراض البروستاتا (IPSS) لتقييم المشاركين، إضافة إلى قياس حجم البول المتبقي بعد التبوّل (PVRV) بالموجات فوق الصوتية. **النتائج:** كانت الخصائص الأساسية، بما في ذلكPVRV ، متشابهة بين المجموعتين. خفّض كلٌّ من تامسولوسين وألفوزوسين الأعراض المُهيِّجة لتضخّم البروستاتا الحميد بدرجة متقاربة. وقد خفّضا بشكل ملحوظ تكرار التبوّل، والإلحاح، والتبوّل الليلي .($p < 0.0001$) ومع ذلك، وعند مقارنة تغيّر الدرجات بين المجموعتين، أظهر تامسولوسين انخفاضًا متوسطًا أكبر في PVRV مقارنةً بألفوزوسين في الاختبار بين المجموعات. كانت الآثار الجانبية طفيفة؛ إذ شهد 4% من مرضى مجموعة الألفوزوسين انخفاضًا في ضغط الدم، وأبلغ 4% عن خلل وظيفي جنسي، بينما لم تُسجَّل آثار جانبية في مجموعة التامسولوسين. **الخلاصة:** يُظهر العلاج بتامسولوسين أو ألفوزوسين تحسّنًا ملحوظًا في الأعراض المُهيِّجة لتضخّم البروستاتا الحميد، مع تقارب فعالية كلا الدوائين، فيما لوحِظ انخفاض عددي أكبر في PVRV مع تامسولوسين. لم تُسجَّل آثار جانبية مهمّة أثّرت على تحمّل أيٍّ من الدواءين.

**الكلمات المفتاحية :** ألفوزوسين، تضخم البروستاتا الحميد، متلازمة الاحتقان الانتصابي، أعراض تهيجية، تامسولوسين