https://doi.org/10.31925/farmacia.2026.1.1 **REVIEW**

META-ANALYSIS OF EFFICACY AND SAFETY OF ALFUZOSIN IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

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Abstract

Benign prostatic hyperplasia (BPH) frequently leads to voiding dysfunction and reduced quality of life in men, with pharmacological therapy representing the primary treatment option. This meta-analysis evaluated the efficacy and safety of Alfuzosin, an α1-adrenergic receptor antagonist, as monotherapy for BPH. A systematic search of major databases identified randomized controlled trials published up to December 31, 2023. Eligible studies were screened using predefined criteria, followed by data extraction and quality assessment. Statistical analyses were performed with RevMan 5.3. Fifteen studies involving 4,264 patients were included. Results showed that Alfuzosin significantly improved International Prostate Symptom Score values and increased peak urinary flow rate compared with placebo. Additionally, Alfuzosin was associated with fewer adverse events than Silodosin, suggesting a favorable safety profile. However, no significant differences were observed in post-void residual urine volume or overall quality of life when compared with placebo, Tamsulosin, or Silodosin. Overall, Alfuzosin appears to be an effective and well-tolerated therapeutic option for BPH, demonstrating efficacy comparable to other α1-blockers while offering potential safety advantages.

Rezumat

Hiperplazia benignă de prostată (HBP) determină frecvent disfuncții de micțiune și scăderea calității vieții la bărbați, terapia farmacologică reprezentând opțiunea principală de tratament. Această meta-analiză a evaluat eficacitatea și siguranța alfuzosinului, un antagonist al receptorilor α1-adrenergici, utilizat ca monoterapie în HBP. O căutare sistematică în bazele de date a identificat studii randomizate controlate publicate până la 31 decembrie 2023. Studiile eligibile au fost selectate conform unor criterii prestabilite, urmate de extragerea datelor și evaluarea calității metodologice. Analizele statistice au fost realizate cu RevMan 5.3. Au fost incluse cincisprezece studii, însumând 4.264 de pacienți. Rezultatele au arătat că alfuzosinul a îmbunătățit semnificativ scorul simptomatic prostatic și a crescut debitul urinar maxim comparativ cu placebo. De asemenea, alfuzosinul a fost asociat cu mai puține reacții adverse decât silodosinul, sugerând un profil de siguranță favorabil. Nu au fost observate diferențe semnificative privind volumul rezidual postmicțional sau calitatea vieții comparativ cu placebo, tamsulosin sau silodosin. În concluzie, alfuzosinul reprezintă o opțiune terapeutică eficientă și bine tolerată pentru HBP.

Keywords: benign prostatic hyperplasia, alfuzosin, placebo, tamsulosin, silodosin, meta-analysis

Introduction

Benign prostatic hyperplasia (BPH) is clinically characterized by hyperplasia of prostatic stroma and glands (1). Lower urinary tract symptoms of BPH mainly include hesitancy, weak stream, difficulty initiating urination, and incomplete emptying, significantly impacting patients' quality of life (QoL) (2). Current research identifies age, obesity, alcohol consumption, lack of physical activity, and diabetes as potential risk factors for the development of BPH (3).

In clinical practice, α1-adrenergic receptor blockers (such as Alfuzosin, Tamsulosin, and Silodosin) and 5α-reductase inhibitors (such as Finasteride and Dutasteride) are commonly applied for treating BPH. Treatment guidelines recommend the combination of α1-adrenergic receptor blockers with 5α-reductase inhibitors as a therapeutic approach for BPH (4, 5). However, combined therapy has shown slight superiority in efficacy and increases the economic burden on patients. Therefore, most studies analyze the effectiveness of monotherapy for BPH. Alfuzosin is a selective α1-adrenergic receptor antagonist belonging to the quinazoline derivative class. It acts by blocking α1-adrenergic receptors in the smooth muscle of the urethra and prostate, inducing relaxation and reducing resistance to urine flow. This mechanism helps alleviate symptoms associated with prostate enlargement, such as urethral tension, resistance and increased pressure, and bladder outlet obstruction (6). Furthermore, Alfuzosin drastically increases urine flow rate by 30% in patients with urinary flow rates ≤ 15 mL/second (7). Additionally, Alfuzosin reduces detrusor pressure, increases bladder capacity, decreases residual urine volume, and improves irritative and

obstructive lower urinary tract symptoms (8). Alfuzosin undergoes hepatic metabolism and exhibits good oral absorption, with peak plasma concentrations achieved 0.5-3.0 hours post-administration and a bioavailability of 64% (9). The meta-analysis (MA) by Liu *et al*. (2015) confirmed that alfuzosin has a comparable adverse event rate to tamsulosin in treating ureteral stones, further supporting its safety (10). However, Alfuzosin should not be co-administered with calcium channel blockers due to potential severe drug interactions leading to hypotension. In summary, Alfuzosin operates through a unique pharmacological mechanism and plays a crucial role in alleviating symptoms associated with BPH. Nevertheless, the efficacy of Alfuzosin as monotherapy for BPH requires further comprehensive analysis and synthesis. Based on this, this MA included clinical randomized controlled trials of Alfuzosin in treating BPH, aiming to compare its efficacy and safety with placebo, Tamsulosin, and Silodosin, reflecting real-world clinical usage. This study was to provide reliable and scientifically grounded evidence for the use of Alfuzosin in treating BPH, offering an evidence-based reference for clinical decision-making.

Materials and Methods

Data source

Computer searches were conducted in PubMed, EMBASE, The Cochrane Library, Web of Science, Springer, and ResearchGate from inception to December 31, 2023. The search strategy employed both subject headings and free-text terms, including "BPH," "Benign prostatic enlargement," "Benign prostate hyperplasia," and "Alfuzosin." Search strategy example was (BPH OR "benign prostatic hyperplasia" OR "benign prostatic enlargement") AND (alfuzosin). To mitigate publication bias, additional searches were conducted in ClinicalTrials.gov and conference abstract repositories (*e.g.,* AUA, EAU proceedings). However, potential bias may remain due to limited access to unpublished study data.

Criteria

Inclusion criteria: i) clinical randomized controlled trials investigating Alfuzosin for treating BPH; ii) the included subjects were required to have a confirmed diagnosis of BPH based on PSA testing (< 4 ng/mL), transrectal ultrasonography (prostate volume > 30 mL), or International Prostate Symptom Score (IPSS > 7), and were confirmed to have concurrent urinary tract infections, urolithiasis, or prostate malignancies were excluded; iii) intervention involving Alfuzosin monotherapy in the treatment group, while the control group received either placebo, tamsulosin, or silodosin; iv) outcome measures including residual urine volume, International prostate symptom score (IPSS), peak urine flow rate, QoL score, or adverse events, with at least one of these endpoints assessed.

Exclusion criteria: i) duplicate publications; ii) the study investigated combination therapies involving α1-blockers with 5α-reductase inhibitors (*e.g.*, finasteride, dutasteride) or other medications; iii) studies involving combination therapy with other medications; iv) basic experimental studies, literature reviews, meta-analyses, conference abstracts, case reports, or retrospective studies; v) incomplete literature or unavailable data.

Literature quality evaluation

Two reviewers independently conducted methodological quality assessment of papers utilizing the Cochrane Handbook for Systematic Reviews of Interventions, version 5.1.0. Discrepancies in their assessments were resolved through consensus reached via discussion or by involving a third reviewer to achieve agreement. The assessment criteria covered seven aspects: random sequence generation, allocation concealment, participants and personnel blinding, outcome evaluation blinding, incomplete outcome data, selective reporting, and other bias. Each item was evaluated as low risk, high risk, or unclear risk regarding predefined standards.

Literature data extraction

Independently, two researchers extracted relevant data from papers using a pre-designed Excel spreadsheet. The extracted results were then cross-checked for consistency. In cases where discrepancies or disagreements arose during data extraction, consensus was reached via collective discussion or by involving a third researcher to independently extract the data. The extracted basic literature data included the first author, publication year, grouping methods, intervention measures, and sample size. Outcome data extracted included residual urine volume, IPSS, peak urine flow rate, QoL score, and adverse events rate.

Statistical processing

Statistical analysis was conducted using *RevMan5.3*. Heterogeneity among studies was initially assessed with the I^2 test. Studies were considered homogeneous if $I^2 \leq 50\%$ and $p \geq 0.10$, warranting a fixed-effects model (FEM). In cases where $I^2 > 50\%$ and $p < 0.10$ meant significant heterogeneity, efforts were made to identify the source; if unresolved, a random-effects model (REM) was applied. For binary variables, odds ratios (ORs) were utilized, with 95% confidence intervals (CIs); for continuous variables, mean differences (MD) with 95%CI were reported. Subgroup analyses were performed to compare treatment efficacy across different drugs, with statistical significance at $p < 0.05$.

Results and Discussion

Search outcome

Four hundred twenty-nine articles related to Alfuzosin treatment for BPH were retrieved. After the removal of 158 duplicate articles, 271 articles remained for initial screening. Following review of titles and abstracts, 210 articles categorized as reviews, basic experiments, retrospective studies, conference papers, or case reports were excluded, leaving 61 articles for detailed screening. After downloading and reviewing full texts, 46 papers were further excluded due to their focus on combination therapies, inability to access full texts, or incomplete data. Ultimately, 15 articles (11-25) were included in this MA (Figure 1).

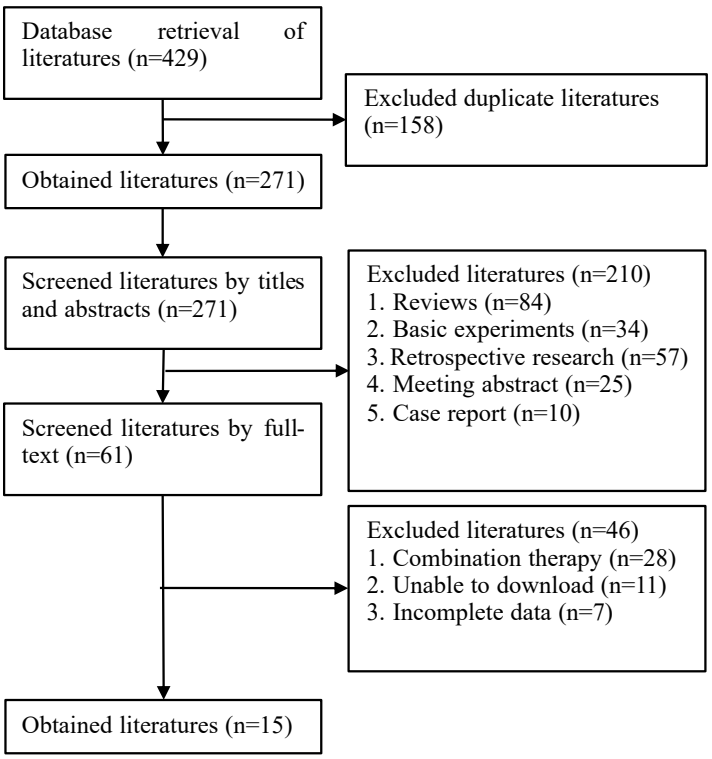

Figure 1.
Screening process

Basic characteristics of the included literatures

This MA included 15 relevant studies (11-25), encompassing 4264 patients. Specifically, there were ten studies comparing the efficacy of Alfuzosin *versus* placebo (11, 12, 14, 17, 19, 20, 21, 23, 24, 25), seven studies comparing Alfuzosin *versus* Tamsulosin (13, 14, 15, 16, 17, 18, 22) and four studies comparing Alfuzosin *versus* Silodosin (15, 16, 18, 22), as illustrated in Table I.

Table I

Summary of studies basic characteristics

Author	Year	Alfuzosin	Control group	Follow-up time	Study indicators
Jalo [11]	2020	45, Not described	placebo	12 weeks	IPSS and drug safety-related indicators
Jardin [12]	1991	251,10mg/d	placebo	12 weeks	IPSS, DAN-PSSsex, QOL, and adverse events
Lapitan [13]	2005	36, 10mg/d	Tamsulosin (0.2mg/d)	12 weeks	IPSS, Qmax, DAN-PSSsex, and adverse events
Maldonado-Ávila [14]	2014	34, 10mg/d	placebo, Tamsulosin (0.4mg/d)	2 months	TWOC success rate and adverse events

Author	Year	Alfuzosin	Control group	Follow-up time	Study indicators
Manjunatha [15]	2016	30, 10mg/d	Tamsulosin (0.4mg/d), Silodosin (8mg/d)	28 days	IPSS, QLS, Qmax, and adverse events
Manohar [16]	2017	87, 10mg/d	Tamsulosin (0.4mg/d), Silodosin (8mg/d)	12 weeks	IPSS, QoL, Qmax, PVR, and adverse events
Nordling [17]	2005	154,10mg/d	placebo, Tamsulosin (0.4mg/d)	28 days	IPSS, Qmax, and adverse events
Parikh [18]	2020	15, 10mg/d	Tamsulosin (0.4mg/d), Silodosin (8mg/d)	2 days	TWOC success rate, IPSS, Qmax, and adverse events
Resnick [19]	2007	185,10mg/d	placebo	12 weeks	Qmax, Acute IPSS, and adverse events
Roehrborn [20]	2003	473,10mg/d	placebo	12 months	IPSS, PFR, QoL, and adverse events
Rosen [21]	2007	185,10mg/d	placebo	Only mention that the patient has been taking medication for at least one month	DAN-PSSsex, Qmax, IPSS, QOL, and adverse events
Sokhal [22]	2018	56, 10mg/d	Tamsulosin (0.4mg/d), Silodosin (8mg/d)	26 weeks	IPSS, QOL, IIEF (EF), OS, and SVV
Tiong [23]	2009	33, 10mg/d	placebo	12 weeks	IPP and adverse events
van Kerrebroeck [24]	2000	143,10mg/d	placebo	12 weeks	IPSS, Qmax, and QOL
van Kerrebroeck [25]	2002	94, 10mg/d	placebo	12 weeks	IPSS, Qmax, (QOL), and adverse events

Note: IPSS: International Prostate Symptom Score; DAN-PSSsex: Danish Prostate Symptom Score Sex; QOL: Quality of Life index; TWOC: Trial Without Catheter; PVR: Post-Void Residual volume; Acute IPSS: Acute International Prostate Symptom Score; PFR: Peak Flow Rate; IIEF: International Index of Erectile Function; EF: Erectile Function; OS: Overall Satisfaction; SVV: Seminal Vesicle Volume.

Methodological quality evaluation of literature

Among the 15 studies included in this MA (11-25), 3 studies (11, 22, 25) did not clearly describe randomization methods for group allocation. However, the remaining studies did not have issues related to unclear allocation concealment or blinding procedures, and reasons for participant loss to follow-up were adequately reported. Overall, the paper quality was considered good and met the criteria (Figure 2 and Figure 3).

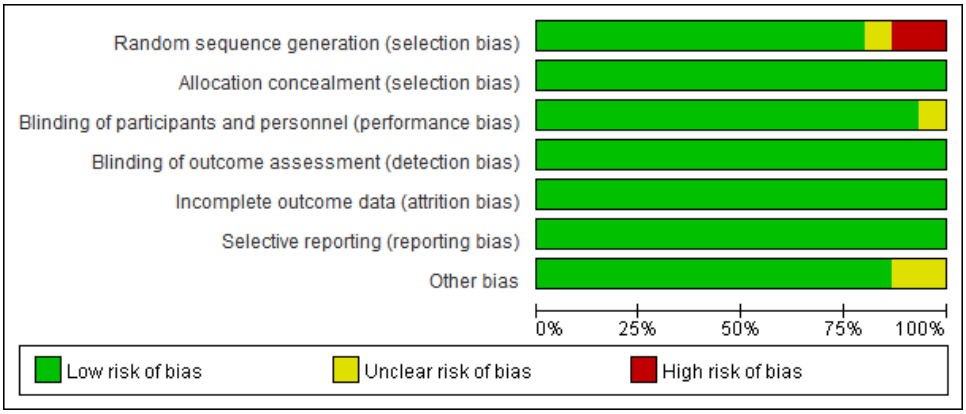

Figure 2.
Proportion of total risk of bias in included papers

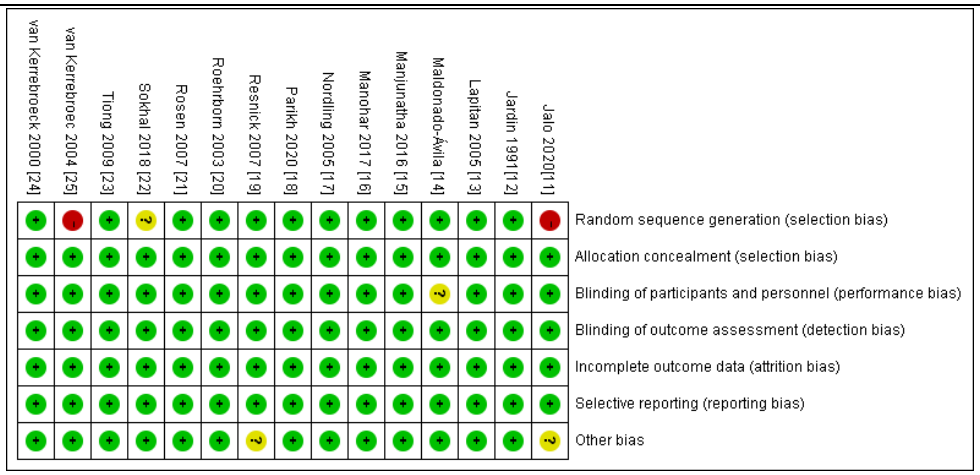

Figure 3.
Risk assessment of bias in included papers

Meta-analysis (MA)
Residual urine volume

Three studies (11, 12, 14) reported changes in residual urine volume after treatment with Alfuzosin versus placebo, two papers (14, 16) reported changes versus Tamsulosin, and one (16) reported changes versus Silodosin. Heterogeneity analysis indicated marked heterogeneity among the studies (I^2 = 99%, $p < 0.00001$), thus a REM was employed for MA. MA results suggested neglectable difference in residual urine volume between Alfuzosin and placebo, Tamsulosin, or Silodosin treatments (MD=-5.68, 95%CI = -25.11 ~ 13.75, p = 0.57) (Figure 4). The observed heterogeneity may be attributed to variations in dosage (alfuzosin 10 mg *vs*. 15 mg), follow-up duration (4-24 weeks), or population characteristics (age, baseline symptom severity).

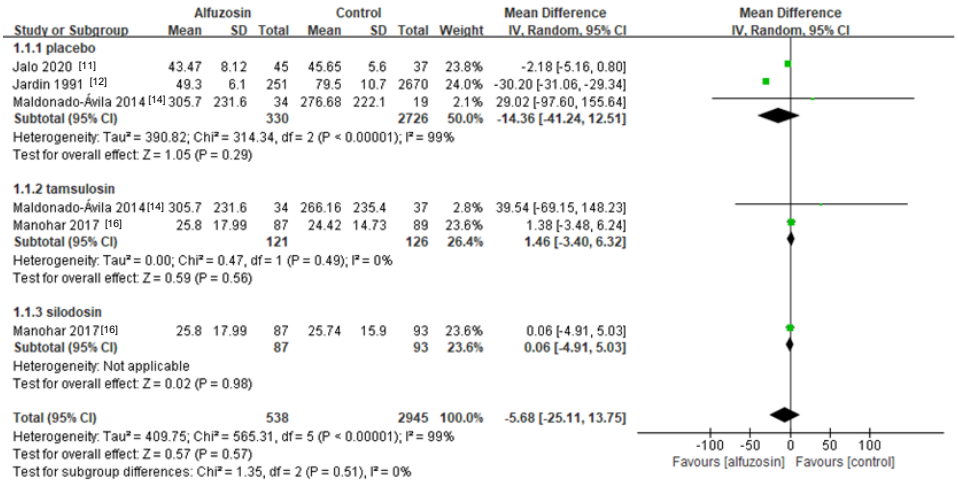

Figure 4.
MA forest plot of residual urine volume comparison among groups

International Prostate Symptom Score (IPSS)

Eight studies (11, 17, 19, 20, 21, 23, 24, 25) reported differences in IPSS after treatment with Alfuzosin versus placebo, six studies (13, 15, 16, 17, 18, 22) reported differences *versus* Tamsulosin, and four studies (15, 16, 18, 22) reported differences versus Silodosin. Heterogeneity analysis implied marked heterogeneity across papers (I^2 = 80%, $p < 0.00001$), therefore a REM was used for MA. MA results showed that Alfuzosin significantly reduced IPSS *versus* placebo (MD = -1.99, 95%CI = -2.59 ~ - 1.40, $p < 0.00001$). However, there existed negligible difference in IPSS between Alfuzosin and Tamsulosin treatments (MD = -0.15, 95%CI = -0.61 ~ 0.31, p = 0.51) or between Alfuzosin and Silodosin treatments (MD = 1.21, 95%CI = -1.23 ~ 3.65, p = 0.33). The inclusion of zero within the confidence interval supports the conclusion of "no significant difference" (Figure 5).

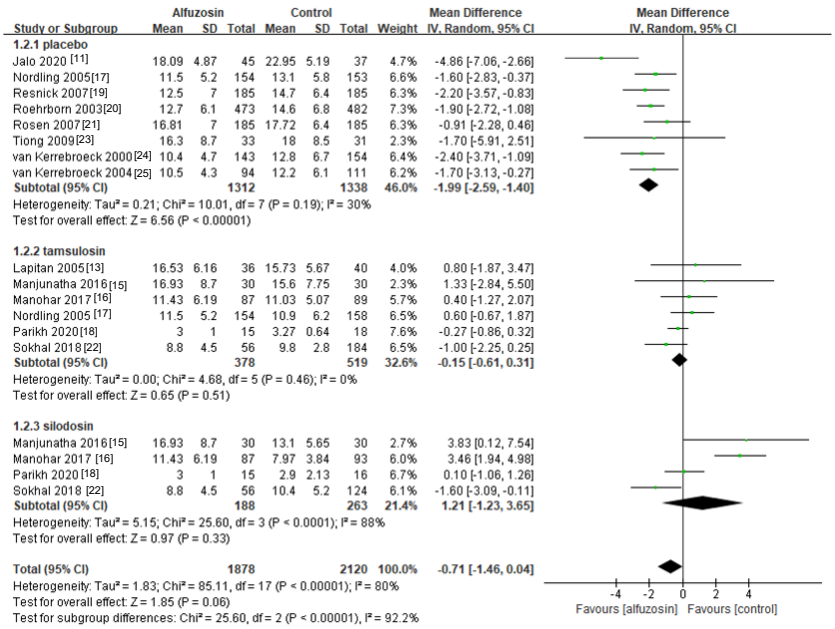

Figure 5.
MA forest plot of IPSS comparison among different groups

Peak urine flow rate

Six studies (17, 19, 20, 21, 24, 25) reported marked differences in peak urine flow rate between Alfuzosin and placebo treatments, and five studies (13, 15, 16, 17, 22) reported differences in that between Alfuzosin and Tamsulosin treatments, while three studies (15, 16, 22) reported differences between Alfuzosin and Silodosin treatments. Heterogeneity analysis indicated substantial variability across studies (I^2 = 87%, p < 0.00001), prompting the use of a REM for MA. MA revealed that Alfuzosin treatment notably increased peak urine flow rate versus placebo (MD = 1.49, 95%CI = 0.76 ~ 2.22, p < 0.0001), whereas negligible differences were found between Alfuzosin and Tamsulosin (MD = 0.37, 95%CI = -0.55 ~ 1.29, p = 0.43) or between Alfuzosin and Silodosin treatments (MD = 0.38, 95%CI = -0.69 ~ 1.46, p = 0.49) (Figure 6).

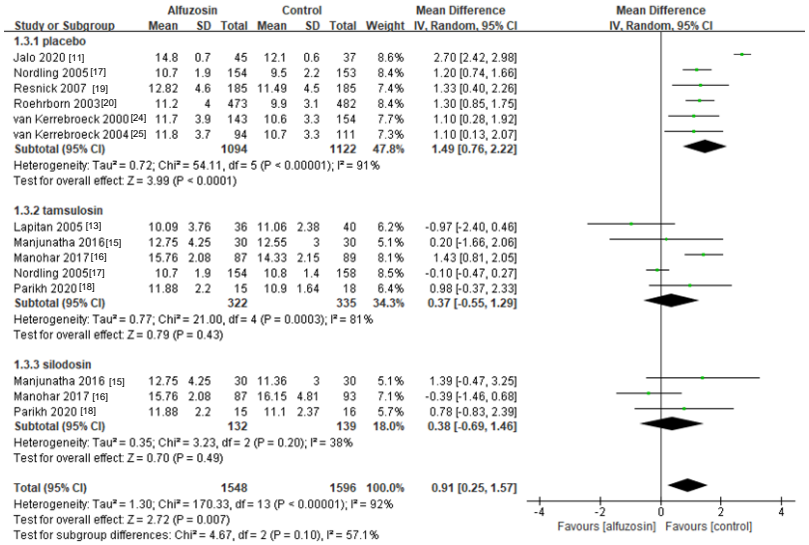

Figure 6.
MA forest plot comparing peak urine flow rates among different groups

QoL scores

Two studies (12, 24) reported differences in QoL between Alfuzosin and placebo treatments. Three studies (15, 16, 22) reported differences between Alfuzosin and Tamsulosin treatments, and three studies (15, 16, 22) reported differences between

Alfuzosin and Silodosin treatments. Heterogeneity analysis indicated great variability across studies (I^2 = 90%, p < 0.00001), thus a REM was used for MA. MA results suggested neglectable differences in QoL outcomes between Alfuzosin and placebo, Tamsulosin, or Silodosin treatments (MD = -0.01, 95%CI = -0.30 ~ 0.28, p = 0.97), as depicted in Figure 7.

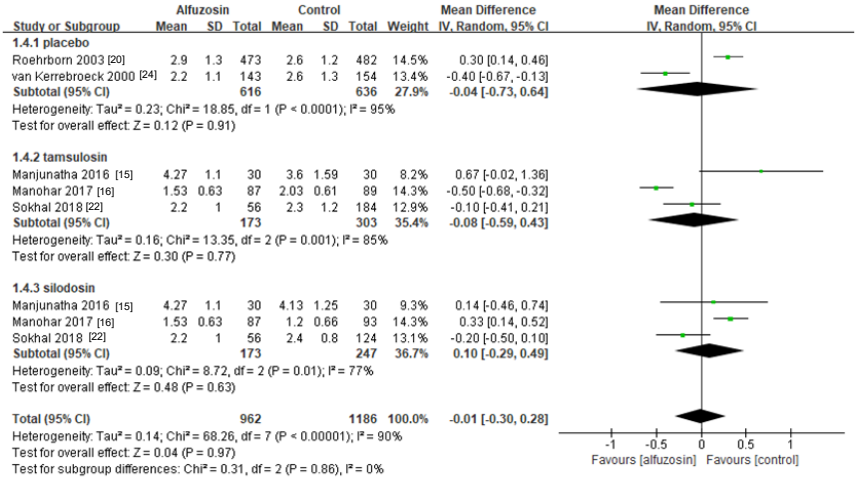

Figure 7.
MA forest plot of QoL comparison among groups

Adverse events

Seven studies (12, 17, 19, 20, 21, 24, 25) reported differences in adverse events between Alfuzosin and placebo treatments. Five studies (13, 15, 16, 17, 22) reported differences between Alfuzosin and Tamsulosin treatments, and three studies (15, 16, 22) reported differences between Alfuzosin and Silodosin treatments. Heterogeneity analysis indicated marked variability across studies (I^2 = 73%, p < 0.00001), thus a REM was employed for MA. MA results indicated neglectable differences in adverse events between Alfuzosin and placebo (OR = 1.15, 95%CI = 0.96~1.39, p = 0.14) or between Alfuzosin and Tamsulosin treatments (OR = 0.88, 95%CI = 0.50 ~ 1.57, p = 0.67). However, Alfuzosin treatment resulted in notably fewer adverse events versus Silodosin (OR = 0.20, 95%CI = 0.06 ~ 0.63, p = 0.006) (Figure 8).

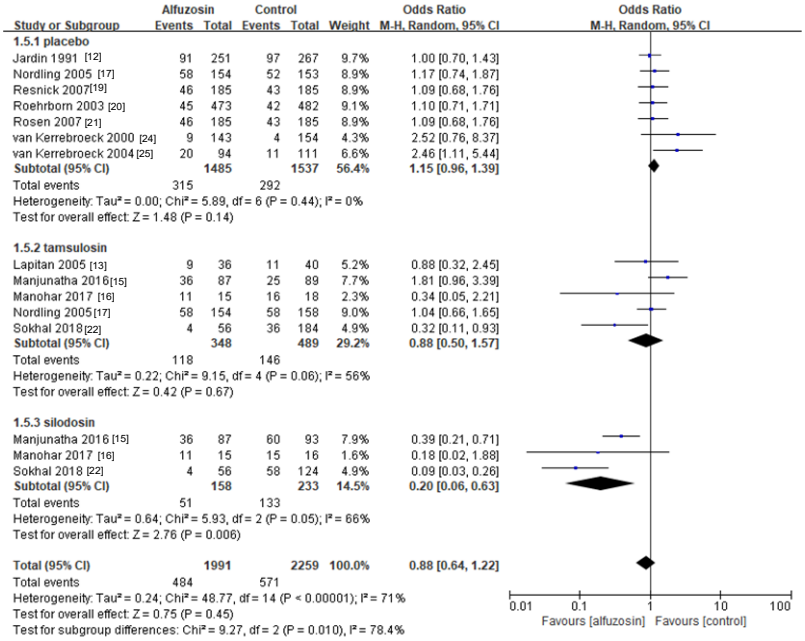

Figure 8.
MA forest plot comparing adverse events among different groups

Publication bias analysis

The asymmetrical appearance of the funnel plot generated for the IPSS indicator suggests potential publication bias. This asymmetry, characterized by a spread-out and symmetric distribution of estimated true values around the effect estimates of individual studies, may indicate larger biases possibly due to factors such as inadequate sample sizes in included studies (Figure 9).

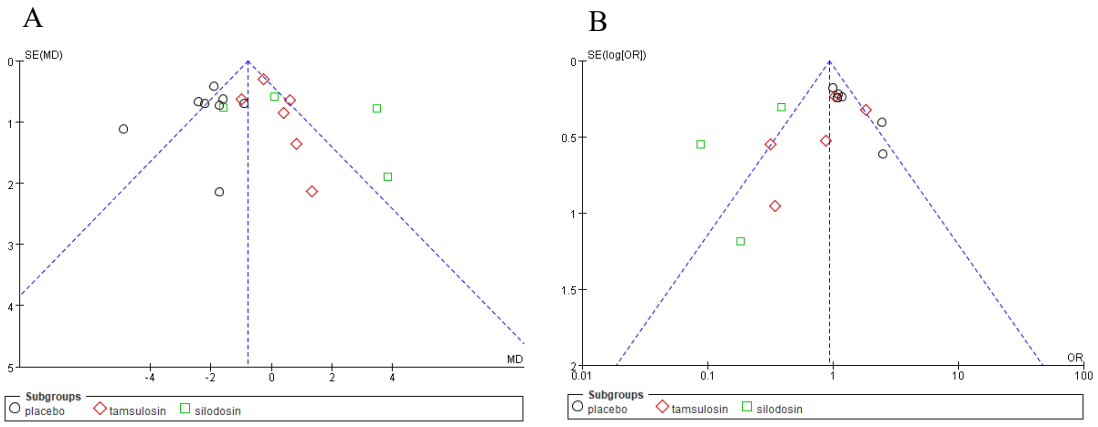

Figure 9.
MA funnel plot of publication bias. A: IPSS indicator; B: adverse events indicator

This MA investigated the efficacy of Alfuzosin in treating BPH and compared it with a placebo. The results indicated that Alfuzosin can effectively reduce IPSS scores versus placebo and increase peak urine flow rate. BPH is a chronic disease characterized by prolonged progression and difficulty in cure. Alfuzosin achieves these effects by blocking α1A-adrenergic receptors, thereby reducing bladder smooth muscle tone, alleviating urinary frequency, improving voiding difficulties, lowering the risk of urinary retention due to prostate enlargement, and relieving nocturia symptoms (26). IPSS is internationally recognized as the optimal tool for assessing the severity of symptoms in patients with BPH, representing their subjective response to lower urinary tract symptoms (27, 28). Peak urine flow rate serves as a valuable indicator to assess whether there is obstruction at the bladder outlet and can assist in the diagnosis of conditions such as prostatitis or urinary obstruction disorders (29). The results of this MA indicated that Alfuzosin, versus placebo, reduces IPSS and increases peak urine flow rate in patients with BPH, suggesting superior therapeutic efficacy of Alfuzosin in this context. However, the MA also finds negligible differences in IPSS and peak urine flow rate between Alfuzosin and other α1-adrenergic receptor blockers such as Tamsulosin and Silodosin. This contrasts with findings by Mari *et al*. (2021) (30), who conducted a MA comparing the efficacy of 10mg Alfuzosin in treating BPH-related urinary tract symptoms, demonstrating that Alfuzosin is more effective in improving secondary lower urinary tract symptoms and has a lower incidence of sexual dysfunction versus other α1-adrenergic receptor blockers. Tamsulosin functions by binding to α1A-adrenergic receptors and blocking the action of norepinephrine, thereby improving voiding difficulties caused by prostate enlargement (31). Silodosin blocks the activation of α1A-adrenergic receptors, thereby relaxing the smooth muscle of the urethral sphincter, facilitating urine voiding. It also increases blood flow and potentially improves erectile function (32). This may explain why Alfuzosin, Tamsulosin, and Silodosin, all being α1A-adrenergic receptor blockers, have similar mechanisms of action in the body, leading to comparable therapeutic efficacy. Furthermore, the MA included a limited number of studies comparing Alfuzosin with Tamsulosin and Silodosin, possibly due to insufficient sample sizes and other factors. Additionally, IPSS relies on subjective patient assessments, which may introduce bias when evaluating the therapeutic effects of treatments for BPH. The substantial heterogeneity warrants cautious interpretation of results. Subgroup analyses revealed that heterogeneity in IPSS improvement was associated with dosage ($I^2 = 68\%$) and treatment duration ($I^2 = 72\%$), though the limited number of included studies necessitates further validation.

Clinical treatment options for BPH include surgical and pharmacological approaches. In pharmacological treatment, the use of α1-adrenergic receptor blockers alone or in combination with 5α-reductase inhibitors is the preferred therapeutic modality for this condition (33, 34). The results of this MA indicated that Alfuzosin, Tamsulosin, and Silodosin did not show considerable differences in residual urine volume and QoL in patients treated for BPH. Alfuzosin, Tamsulosin, and Silodosin are all α1-

adrenergic receptor blockers that act by blocking adrenergic receptors located on the smooth muscle surfaces of the prostate and bladder neck. This blockade inhibits the transmission of signals through neuromuscular junctions, leading to relaxation of smooth muscle and dilation of the prostatic urethra, ultimately relieving dynamic obstruction of the urethra (35-37). Therefore, it is inferred that since Alfuzosin, Tamsulosin, and Silodosin share similar mechanisms of action in treating BPH, the differences in therapeutic efficacy are not significant. The induction of adverse events by α1-adrenergic receptor blockers primarily depends on their affinity for α1-adrenergic receptors. While demonstrating comparable efficacy, the pharmacological differences between alfuzosin (selective α1A/D-adrenoceptor antagonist) and tamsulosin (highly selective α1A-adrenoceptor antagonist) or silodosin (ultra-selective α1A-adrenoceptor antagonist) may account for their distinct safety profiles (38).The results of this MA indicated that Alfuzosin suggested neglectable difference in adverse event rates versus placebo or Tamsulosin treatments, but greatly lower adverse event rates versus Silodosin. This finding aligns with the results reported by Liu *et al*. (2015) through a MA, which found similar adverse reaction rates for Alfuzosin and Tamsulosin in the treatment of ureteral stones with a diameter smaller than 10mm. A retrospective analysis also demonstrated that Alfuzosin, Tamsulosin, and Silodosin all improve clinical symptoms in BPH patients, with adverse event rates of 21%, 22%, and 39%, respectively (39, 40). Additionally, a minority of patients using Alfuzosin may experience transient elevation of serum transaminases, though the incidence of acute liver injury does not markedly differ from placebo (41). Ejaculatory dysfunction is a common and specific adverse effect following Silodosin treatment, and the associated liver function impairment is more severe versus Alfuzosin (42). Therefore, it is considered that Alfuzosin offers relatively higher safety in the treatment of BPH versus Silodosin.

However, this study has several limitations. Most included studies (12/15) were conducted in Western populations, with limited data from Asian cohorts (n = 3), warranting cautious extrapolation of findings. Certain outcomes (*e.g.,* postvoid residual volume) had insufficient data (≤ 3 studies), compromising statistical power. The subjective nature of IPSS may introduce cultural bias. Future research should: i) conduct multicentre studies, particularly in Asian populations, to address geographical bias; ii) extend follow-up durations or incorporate composite endpoints to enhance statistical power; iii) implement cross-cultural validation protocols for subjective measures; and iv) explore mechanistic studies and novel therapeutic approaches.

Conclusions

Monotherapy with Alfuzosin is more effective in treating BPH than placebo, while the efficacy of Alfuzosin, Tamsulosin and Silodosin appears similar. However, Alfuzosin monotherapy has a superior safety profile for treating BPH compared to Silodosin. In conclusion, this meta-analysis provides an objective evaluation of alfuzosin's effectiveness in treating BPH and serves as a reference for selecting clinical treatment options for BPH medications.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Not applicable.

AI use disclosure

Not applicable.

Conflict of interest

The authors declare no conflict of interest.

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