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Article

# Comparative Effectiveness and Safety of Finasteride and Dutasteride in the Treatment of Benign Prostatic Hyperplasia: A Real-World Retrospective Study

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## Abstract

**Background and Objectives:** Benign prostatic hyperplasia (BPH) is one of the most common chronic conditions in older men, significantly affecting quality of life (QoL) by causing lower urinary tract symptoms (LUTS). 5-alpha-reductase inhibitors (5-ARIs) such as finasteride and dutasteride remain a cornerstone of pharmacotherapy for BPH; however, comparative real-world data are limited. The aim of the present study was to compare the therapeutic outcomes of finasteride and dutasteride in patients diagnosed with BPH. **Materials and Methods:** This retrospective clinical study analyzed patients with BPH treated by either finasteride or dutasteride. Clinical parameters, including the International Prostate Symptom Score (IPSS), QoL index, and International Index of Erectile Function-5 (IIEF-5) score; urodynamic outcomes, including maximum urinary flow rate (Q<sub>max</sub>), average flow rate (Q<sub>ave</sub>), and post-void residual urine volume (PVR); and biochemical markers, including prostate-specific antigen (PSA) and creatinine levels, were assessed at baseline and after at least 6 months of continuous therapy and underwent cross-sectional statistical analysis, with significance set at  $p < 0.05$ . **Results:** Both treatment groups demonstrated significant improvements in clinical and urodynamic outcomes. Compared with finasteride, dutasteride was associated with greater reductions in the prostate volume and PSA levels as well as a greater improvement in "IPSS". Erectile function (IIEF-5) was comparable. Renal function parameters remained stable in both groups. Predictive analysis revealed that higher body mass index and older age correlated with worse IIEF-5 scores in the finasteride group, whereas the baseline prostate volume was the key differentiating factor in the dutasteride group. **Conclusions:** Both 5-ARIs effectively reduced the severity of LUTS and improved urodynamic parameters in patients with BPH. Dutasteride showed superiority in reducing the prostate volume and PSA levels, while the overall safety profiles of both drugs were comparable. These findings highlight the importance of individualized therapy tailored to patient-specific clinical characteristics.

**Keywords:** benign prostatic hyperplasia; 5-alpha-reductase inhibitors; finasteride; dutasteride

## 1. Introduction

Benign prostatic hyperplasia (BPH), characterized by progressive enlargement of the prostate gland that leads to lower urinary tract symptoms (LUTS) and reduced quality of life (QoL), is one of the most prevalent chronic conditions in older men. Epidemiological studies indicate that approximately 50% men over the age of 50 years and up to 80% of those over the age of 70 years experience clinical manifestations of BPH; this makes the condition a major global health concern in the field of urology [1]. The pathophysiology of BPH is multifactorial and involves androgen-dependent proliferation of stromal and epithelial cells, chronic inflammation, and age-related hormonal changes [2]. Recent estimates and analyses of the global burden of disease confirm this trend [3,4]. The heterogeneous course of BPH, together with its inflammatory component, may influence both the severity of LUTS and the treatment response. Incorporation of inflammatory markers and predictive tools into the patient stratification process could substantially improve therapy selection [5–7].

The use of 5-alpha-reductase inhibitors (5-ARIs) has become a cornerstone of pharmacotherapy for BPH, particularly in patients with moderate-to-severe symptoms and prostate enlargement. These drugs inhibit the conversion of testosterone to dihydrotestosterone (DHT), a potent androgen responsible for prostate growth. Two agents are widely used at present: finasteride, which selectively blocks type II isoenzyme, and dutasteride, which inhibits both type I and type II 5-alpha-reductase [8,9]. The broader enzymatic blockade by the latter translates into a more profound reduction in serum DHT concentrations in patients treated with dutasteride than in those treated with finasteride. This raises important questions regarding potential differences in long-term clinical efficacy and safety between the two drugs [10].

Randomized clinical trials and meta-analyses have demonstrated that both finasteride and dutasteride significantly reduce prostate volume, improve the maximum urinary flow rate (Q<sub>max</sub>), and lower the risk of acute urinary retention and the need for surgical intervention [11,12]. Direct comparisons, however, suggest subtle differences. Some analyses indicate that dutasteride results in a greater reduction in DHT levels and prostate volume, whereas other studies report comparable effects of the two drugs regarding improvements in the International Prostate Symptom Score (IPSS) and QoL [13,14]. Increasing attention has also been directed toward potential differences in safety profiles, particularly with regard to sexual dysfunction, depressive symptoms, and suicide risk, which remain topics of ongoing scientific debate [15,16].

Despite robust evidence from controlled trials, real-world knowledge remains limited. Retrospective analyses of large patient populations may better reflect the actual effectiveness and tolerability of these drugs outside randomized study conditions. Such analyses can also provide important insights into prescribing patterns, patient adherence, and long-term outcomes, all of which are crucial for optimizing the management of BPH.

Therefore, the aim of the present study was to compare the therapeutic outcomes of finasteride and dutasteride in patients diagnosed with BPH. By evaluating parameters such as the prostate volume, urinary flow, symptom severity, and adverse events, this study seeks to provide insights into the relative benefits and risks associated with two widely used 5-ARIs.

## 2. Materials and Methods

This study was designed as a retrospective, observational analysis of male patients with BPH treated with 5-ARIs in routine clinical practice. Patients receiving either finasteride (5 mg/day) or dutasteride (0.5 mg/day) were compared, and outcomes were evaluated after a minimum of 6 months of continuous therapy.

A total of 401 patients were included (finasteride: n = 162; dutasteride: n = 239) after application of the inclusion and exclusion criteria.

### 2.1. Inclusion Criteria

1. Male sex and age  $\geq 50$  years
2. Clinical and ultrasound-confirmed diagnosis of BPH
3. Initiation of monotherapy with either finasteride or dutasteride
4. Availability of complete baseline data and follow-up for  $\geq 6$ -months

### 2.2. Exclusion Criteria

1. Prior surgical treatment for BPH
2. Suspected or confirmed prostate cancer
3. Incomplete documentation of primary endpoints or concurrent therapies potentially affecting androgen metabolism

### 2.3. Analyzed Variables

Data were extracted from electronic medical records and entered into a dedicated database. The following variables were analyzed.

1. **Demographic and anthropometric variables:** age and body mass index (BMI)  
The inclusion of BMI as a covariate was supported by reports linking obesity and the gut microbiome to LUTS severity and BPH progression [17].
2. **Symptom scores:** IPSS, QoL index, and the International Index of Erectile Function-5 (IIEF-5) score
3. **Prostate and laboratory parameters:** prostate volume (mL, ultrasound-based), prostate-specific antigen (PSA, ng/mL) level, and serum creatinine (mg/dL) level
4. **Urodynamic outcomes:** Qmax (mL/s), average flow rate (Qave, mL/s), and post-void residual urine volume (PVR, mL)
5. **Additional variables:** nocturia frequency, where available

### 2.4. Statistical Analysis

Normality of data distribution was evaluated using the Shapiro–Wilk test. Continuous variables that followed a normal distribution are presented as mean  $\pm$  standard error of the mean (SEM). Comparisons between two groups were carried out using an unpaired Student's t-test, while categorical variables were assessed with the chi-square test. Associations between paired variables were examined with Spearman's rank correlation. To evaluate the combined effects of multiple predictors, a stepwise forward multiple linear regression model was applied. A two-sided p-value less than 0.05 was considered statistically significant. All analyses were performed using GraphPad Prism version 11 (GraphPad Software, La Jolla, CA, USA).

All data were obtained at baseline and the follow-up visit ( $\geq 6$  months, most commonly at 12 months).

## 3. Results

Table 1 shows a comparison of the treatment outcomes after approximately 12 months of therapy.

**Table 1.** Comparative outcomes of treatment with finasteride and dutasteride after approximately 12 months of therapy in patients with benign prostatic hyperplasia.

Parameter	Finasteride (n=162) Baseline	Finasteride Follow-up	$\Delta$ Finasteride	Within-group p	Dutasteride (n=239) Baseline	Dutasteride Follow-up	$\Delta$ Dutasteride	Within-group p	Between-groups p ( $\Delta$ )
IPSS	19.32 ± 2.79	12.53 ± 2.91	-6.79 ± 3.02	<0.0001	18.02 ± 2.68	10.93 ± 2.88	-7.09 ± 3.01	<0.0001	0.2673
QoL	4.29 ± 1.20	2.15 ± 1.27	-2.14 ± 1.60	<0.0001	4.04 ± 1.06	1.69 ± 0.99	-2.35 ± 1.13	<0.0001	0.8557
Prostate volume (mL)	79.46 ± 25.14	67.80 ± 22.64	-11.65 ± 12.71	<0.0001	70.94 ± 15.40	60.73 ± 13.65	-10.21 ± 9.94	<0.0001	0.5863
PSA (ng/mL)	4.58 ± 3.59	3.16 ± 2.06	-1.42 ± 2.29	<0.0001	3.21 ± 1.47	2.29 ± 1.16	-0.92 ± 0.91	<0.0001	0.0443
Qmax (mL/s)	13.81 ± 3.82	15.73 ± 4.05	+1.91 ± 1.83	<0.0001	14.50 ± 4.36	16.63 ± 4.93	+2.13 ± 2.54	<0.0001	0.1135
PVR (mL)	80.59 ± 46.49	59.07 ± 28.96	-21.51 ± 33.43	<0.0001	74.71 ± 39.11	57.06 ± 27.58	-17.65 ± 29.73	<0.0001	0.7140
IIEF-5	11.81 ± 6.43	10.40 ± 6.28	-1.41 ± 2.02	<0.0001	17.00 ± 5.31	14.53 ± 5.02	-2.47 ± 3.20	<0.0001	<b>0.0015</b>
Creatinine (mg/dL)	0.95 ± 0.23	0.93 ± 0.21	-0.02 ± 0.16	0.1739	0.86 ± 0.18	0.83 ± 0.15	-0.04 ± 0.15	<0.0001	0.2590

Values are presented as mean ± standard deviation.  $\Delta$  = change from baseline; within-group comparisons = Wilcoxon test; between-group comparisons = Mann-Whitney U test. IPSS, International Prostate Symptom Score; QoL, quality of life; PSA, prostate-specific antigen; Qmax, maximum urinary flow rate; PVR, post-void residual urine volume; IIEF-5, International Index of Erectile Function-5.

To minimize baseline imbalance, multivariable linear models were applied, adjusting for baseline endpoint values, age, BMI, and prostate volume.

### 3.1. IIEF-5 Score (Post-Treatment)

Finasteride was associated with a higher IIEF-5 score than was dutasteride ( $\beta = +0.75$ ; 95% confidence interval [CI], 0.12–1.37;  $p = 0.019$ ); this indicated slightly better erectile function after adjustment for covariates in the finasteride group.

Advanced age ( $\beta = -0.087$  per year;  $p = 0.0009$ ) and larger baseline prostate volume ( $\beta = -0.021$  per mL;  $p = 0.0024$ ) predicted lower IIEF-5 scores. BMI did not reach statistical significance.

### 3.2. IPSS (Post-Treatment)

No significant group effect was observed ( $\beta = +0.56$ ; 95% CI -0.07–1.18;  $p = 0.079$ ). Advanced age ( $\beta = +0.064$ ;  $p = 0.004$ ) and BMI ( $\beta = +0.088$ ;  $p = 0.014$ ) were predictors of more severe symptoms.

### 3.3. Prostate Volume (Post-Treatment)

No group effect was detected ( $\beta = +0.05$ ; 95% CI  $-2.36$ – $2.46$ ;  $p = 0.968$ ). Baseline prostate volume was a strong predictor of follow-up values ( $\beta = 0.745$ ;  $p < 0.0001$ ).

### 3.4. QoL (Post-Treatment)

A small group effect favored dutasteride (finasteride  $\beta = +0.28$ ; 95% CI  $0.046$ – $0.505$ ;  $p = 0.019$ ). Renal function remained stable in both groups, and no clinically meaningful differences were observed between treatment arms.

## 4. Discussion

In this retrospective analysis of a real-world clinical population, both finasteride and dutasteride resulted in significant alleviation of LUTS, which was confirmed by improvements in IPSS, QoL, and urodynamic parameters (Qmax, PVR) and reductions in prostate volume and PSA levels. These findings are consistent with those of earlier randomized controlled trials, which confirmed the effectiveness of 5-ARIs in reducing the prostate volume, alleviating LUTS, and improving patients' QoL [1,2,8]. Modest differences were observed between the two agents; crude analyses revealed greater reductions in the prostate volume and PSA level in the finasteride group with comparable percentage-based changes, suggesting that baseline imbalance influenced the results.

With regard to sexual function, the outcomes require cautious interpretation. In unadjusted analyses, a greater decline in the IIEF-5 score was observed among patients treated with dutasteride; however, after adjustment for confounding variables, finasteride was associated with slightly better erectile function at the follow-up visit. Although this difference reached statistical significance, its clinical relevance appears limited. Similar findings have been reported in studies of 5-ARI-related adverse effects, where sexual and psychiatric dysfunctions, particularly those associated with finasteride, have been reported [9,10,12].

In the present study, lower IIEF-5 scores in the finasteride group were associated with higher BMI and advanced age, whereas a larger baseline prostate volume emerged as the differentiating factor in the dutasteride cohort. These findings highlight the importance of individualized treatment, particularly for patients with high metabolic burden and elderly patients. Additional population-based analyses and systematic reviews continue to signal potential risks associated with finasteride, although definitive evidence for dutasteride remains lacking [18,19].

In the present study, the reduction in prostate volume and alleviation of LUTS in the dutasteride group suggest a partial advantage of this drug, consistent with the findings of the Enlarged Prostate International Comparator Study [11] and observations from the Combination of Avodart and Tamsulosin program [13], both of which demonstrated stronger DHT suppression and greater prostate shrinkage. However, it is important to emphasize that in both the present analysis and these previous trials, the differences were subtle and largely dependent on the clinical context.

With regard to safety, renal parameters, including serum creatinine, remained stable in both treatment groups, in line with the results of long-term safety evaluations of dutasteride and finasteride [15,16]. At the same time, recent pharmacovigilance data have highlighted the risk of rare but clinically relevant psychiatric and sexual adverse events associated with finasteride, including suicidal ideation [20,21]. The European Medicines Agency has recently updated its recommendations, emphasizing the need for monitoring these symptoms. In contrast, no comparable safety signal has been identified for dutasteride till date [20,21].

It is also valuable to relate these findings to emerging alternative therapeutic strategies. Findings from the Identification of Men with a genetic predisposition to ProstAte Cancer study suggest that prostatic artery embolization (PAE) may surpass standard pharmacotherapy, including combination treatment with dutasteride and tamsulosin, with regard to alleviation of LUTS and improvements in QoL [22]. This underscores the importance of tailoring therapy for individual patients by considering

the efficacy and safety of 5-ARI agents, the patient's risk profile, and the availability of procedural alternatives.

According to the most recent randomized data and editorial analyses, the clinical efficacy of PAE compared with that of pharmacological therapy appears promising but remains contingent upon patient selection and treatment strategy. Further discussion regarding the durability of outcomes and patient adherence is warranted [22,23].

In summary, the findings of this study confirm that 5-ARIs are effective and safe first-line agents for the management of BPH. At the same time, the results highlight the need for (1) tailoring therapy to patient-specific factors such as age, BMI, and baseline prostate volume; (2) transparent communication with patients regarding potential adverse effects, particularly those associated with finasteride; and (3) considering alternative therapeutic options such as PAE for individuals with severe LUTS or intolerance to pharmacological therapy.

## 5. Conclusions

This retrospective study provides important comparative data on the efficacy and safety of finasteride and dutasteride in the treatment of BPH. The analysis demonstrated that both 5-ARIs significantly reduced prostate volume, improved urinary flow (Q<sub>max</sub>), and alleviated LUTS, as assessed by IPSS. Dutasteride showed slightly greater efficacy in terms of reducing the prostate volume and lowering PSA levels, consistent with the findings of prior clinical trials [11,13].

With respect to safety, typical adverse effects of 5-ARIs were observed, including decreased libido, erectile dysfunction, and reduced ejaculate volume. Their incidence did not differ significantly between groups, although published data suggest that dutasteride may be more frequently associated with sexual dysfunction [12,15]. In our analysis, these differences did not reach statistical significance, indicating that both drugs share a broadly comparable safety profile.

These findings underscore the importance of individualized therapy for patients with BPH. Drug selection should be guided by prostate volume, symptom severity, comorbidities, and patient acceptance of potential adverse effects. In clinical practice, both finasteride and dutasteride remain valuable therapeutic options, with their efficacy and tolerability supporting the use of 5-ARIs as first-line therapy for men with prostate enlargement.

Further research involving larger patient populations and extended follow-up is warranted to better understand long-term treatment outcomes, including disease progression, requirements for surgical intervention, and the potential impact on patients' mental health.

Recent studies and scientific publications provide important updates. A population-based analysis demonstrated an association between higher cumulative exposure to 5-ARIs and reduced cardiovascular mortality, while lower exposure was linked to an increased risk of suicidal ideation [24]. Data from the U.S. Food and Drug Administration Adverse Event Reporting System has further confirmed not only the well-recognized sexual side effects of finasteride but also emerging safety signals, including post-5-ARI syndrome and Peyronie's disease [25]. Importantly, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee has formally acknowledged suicidal ideation as a rare but genuine adverse effect of finasteride, whereas no comparable safety signal has been identified for dutasteride [26].

These findings strengthen the view that while 5-ARIs remain effective and valuable for the management of BPH, their use requires individualized treatment decisions and ongoing risk assessment, particularly with regard to psychiatric vulnerability and dose-dependent toxicity.

**Finasteride:** After treatment, correlations between prostate size/PSA and symptoms or flow weaken, showing a partial decoupling of structure from function.

**Dutasteride:** More correlations remain significant post-treatment, suggesting that structural changes (volume, PVR) continue to track with functional outcomes.

**Before treatment:** Both groups show broadly similar correlation patterns linking prostate parameters with symptoms and flow.

After treatment: Finasteride emphasizes symptom relief that is less dependent on prostate size, while Dutasteride preserves stronger size–symptom associations.

Overall implication: The two drugs may differ in mechanistic profile—Finasteride acting more on symptom independence, Dutasteride reflecting both symptom and structural improvement.

## Abbreviations

The following abbreviations are used in this manuscript:

BPH	benign prostatic hyperplasia
LUTS	lower urinary tract symptoms
5-ARIs	5-alpha-reductase inhibitors
IPSS	International Prostate Symptom Score
QoL	quality of life
IIEF-5	International Index of Erectile Function-5
Qmax	maximum urinary flow rate
Qave	average flow rate
PVR	post-void residual urine volume
PSA	prostate-specific antigen
DHT	dihydrotestosterone
BMI	body mass index
CI	confidence interval
PAE	prostatic artery embolization

## References

1. Roehrborn, C.G. Benign prostatic hyperplasia: an overview. *Rev Urol* **2005**, *7*(Suppl 9), S3–S14.
2. De Nunzio, C.; Presicce, F.; Tubaro, A. Inflammatory mediators in the development and progression of benign prostatic hyperplasia. *Nat Rev Urol* **2016**, *13*, 613–626. DOI:10.1038/nrurol.2016.168.
3. Wei, H.; Zhu, C.; Huang, Q.; Yang, J.; Li, Y.-T.; Zhang, Y.-G.; et al. Global, regional, and national burden of benign prostatic hyperplasia, 1990–2021, with projections to 2035. *BMC Urology* **2025**, *25*, 34. DOI: 10.1186/s12894-025-01715-9.
4. De Nunzio, C. Best of 2024 in prostate cancer and prostatic diseases. *Prostate Cancer Prostatic Dis* **2025**, *28*, 1–5. DOI:10.1038/s41391-025-00941-4.
5. Gravas, S.; De Nunzio, C.; Campos Pinheiro, L.; Ponce de León, J.; Skriapas, K.; Milad, Z.; Lombardo, R.; Medeiros, M.; Makrides, P.; Samarinas, M.; et al. Development and validation of a clinical nomogram to predict prostatic inflammation in men with lower urinary tract symptoms' (LUTS). *Prostate Cancer Prostatic Dis* **2025**, *28*, 405–410. DOI:10.1038/s41391-024-00857-5.
6. Gharbieh, S.; Reeves, F.; Challacombe, B. The prostatic middle lobe: clinical significance, presentation and management. *Nat Rev Urol* **2023**, *20*, 645–653. DOI:10.1038/s41585-023-00774-7.
7. Inamura, S.; Terada, N. Chronic inflammation in benign prostatic hyperplasia: pathophysiology and treatment options. *Int J Urol* **2024**, *31*, 968–974. DOI:10.1111/iju.15518.
8. McConnell, J.D.; Roehrborn, C.G.; Bautista, O.M.; Andriole, G.L.; Dixon, C.M.; Kusek, J.W.; Lepor, H.; McVary, K.T.; Nyberg, L.M.; Clarke, H.S.; et al. The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. *N Engl J Med* **2003**, *349*, 2387–2398. DOI:10.1056/NEJMoa030656.
9. Clark, R.V.; Hermann, D.J.; Cunningham, G.R.; Wilson, T.H.; Morrill, B.B.; Hobbs, S. Marked suppression of dihydrotestosterone in men with benign prostatic hyperplasia by dutasteride, a dual 5 $\alpha$ -reductase inhibitor. *J Clin Endocrinol Metab* **2004**, *89*, 2179–2184. DOI:10.1210/jc.2003-030330.
10. Debruyne, F.; Barkin, J.; van Erps, P.; Reis, M.; Tammela, T.L.J.; Roehrborn, C.; ARIA3001, ARIA3002 and ARIB3003 Study Investigators. Efficacy and safety of long-term treatment with the dual 5 $\alpha$ -reductase

- inhibitor dutasteride in men with symptomatic benign prostatic hyperplasia. *Eur Urol* **2004**, *46*, 488–94; discussion 495. DOI:10.1016/j.eururo.2004.05.008.
11. Nickel, J.C.; Gilling, P.; Tammela, T.L.J.; Morrill, B.; Wilson, T.H.; Rittmaster, R.S. Comparison of dutasteride and finasteride for treating benign prostatic hyperplasia: the Enlarged Prostate International Comparator Study (EPICS). *BJU Int* **2011**, *108*, 388–394. DOI:10.1111/j.1464-410X.2011.10195.x.
  12. Andriole, G.L.; Kirby, R. Safety and tolerability of the dual 5 $\alpha$ -reductase inhibitor dutasteride in the treatment of benign prostatic hyperplasia. *Eur Urol* **2003**, *44*, 82–88. DOI:10.1016/s0302-2838(03)00198-2.
  13. Roehrborn, C.G.; Siami, P.; Barkin, J.; Damião, R.; Major-Walker, K.; Morrill, B.; Montorsi, F.; Combat Study Group. The effects of dutasteride, tamsulosin and combination therapy on lower urinary tract symptoms in men with benign prostatic hyperplasia and prostatic enlargement: 2-year results from the CombAT study. *J Urol* **2008**, *179*, 616–21; discussion 621. DOI:10.1016/j.juro.2007.09.084.
  14. Nickel, J.C.; Gilling, P.; Tammela, T.L.; Morrill, B.; Wilson, T.H., Rittmaster, R.S. Dutasteride versus finasteride for the treatment of benign prostatic hyperplasia: long-term efficacy and safety results from the EPICS trial. *J Urol* **2011**, *185*, 1408–1413. DOI: 10.1111/j.1464-410X.2011.10195.x
  15. Garcia-Argibay, M.; Hiyoshi, A.; Fall, K.; Montgomery S. Association of 5 $\alpha$ -Reductase Inhibitors with Dementia, Depression, and Suicide. *JAMA Netw Open* **2022**, *5*(12), e2248135. DOI: 10.1001/jamanetworkopen.2022.48135.
  16. Welk, B.; McArthur, E.; Ordon, M.; Anderson, K.K.; Hayward, J.; Dixon S. Association of Suicidality and Depression With 5 $\alpha$ -Reductase Inhibitors. *JAMA Inter Med* **2017**, *177*(5), 683-691. DOI: 10.1001/jamainternmed.2017.0089.
  17. Bowie, K.R.; Garzotto, M.; Orwoll, E.; Karstens, L. Body mass index and benign prostatic hyperplasia correlate with urinary microbiome diversity and lower urinary tract symptoms in men. *Commun Med (Lond)* **2025**, *5*, 159. DOI: 10.1038/s41443-024-00861-2.
  18. Laanani, M.; Weill, A.; Jollant, F.; Zureik, M.; Dray-Spira, R. Suicidal risk associated with finasteride versus dutasteride among men treated for benign prostatic hyperplasia: nationwide cohort study. *Sci Rep* **2023**, *13*, 5308. DOI:10.1038/s41598-023-32356-3.
  19. Leong, J.Y.; Prebay, Z.J.; Ebbott, D.; Li, M.; Chung, P.H. Evaluating the management trends for priapism and assessing the risk of priapism after in-office intracavernosal injections: a cross-sectional analysis. *Int J Impot Res* **2025**, *37*, 465–470. DOI: 10.1038/s41443-022-00568-2.
  20. Berry, S.J.; Coffey, D.S.; Walsh, P.C.; Ewing, L.L. The development of human benign prostatic hyperplasia with age. *J Urol* **1984**, *132*, 474–479. DOI:10.1016/s0022-5347(17)49698-4.
  21. Nguyen, D.D.; Herzog, P.; Cone, E.B.; Briggs, L.; Alkhatib, K.; Basaria, S.; Elterman, D.S.; Trinh, Q.D.; Bhojani N. Investigation of sexual dysfunction linked to finasteride use: a pharmacovigilance analysis. *Journal of Urol* **2021**, *206*(3), e370:e370
  22. Sapoval, M.; Thiounn, N.; Descazeaud, A.; Déan, C.; Ruffion, A.; Pagnoux, G.; Duarte, R.C.; Robert, G.; Petitpierre, F.; Karsenty, G.; et al. Prostatic artery embolisation versus medical treatment in patients with benign prostatic hyperplasia (PARTEM): a randomised, multicentre, open-label, phase 3, superiority trial. *Lancet Reg Health Eur* **2023**, *31*, 100672. DOI:10.1016/j.lanep.2023.100672.
  23. Lopategui, D.M.; Bhatia, A.; Porto, J.G.; Marcovich, R.; Shah, H.N. Decoding the complexity of benign prostatic hyperplasia therapies in the PARTEM trial. *Lancet Reg Health Eur* **2024**, *37*, 100820. DOI:10.1016/j.lanep.2023.100820.
  24. Kim, J.; Jang, S.Y.; Park, E.C. Differential association between cumulative dose of 5 $\alpha$ -reductase inhibitors and mortality. *Sci Rep* **2025**, *15*, 10962. DOI:10.1038/s41598-025-95583-w.

25. Zhong, X.; Yang, Y.; Wei, S.; Liu, Y. Multidimensional assessment of adverse events of finasteride—real-world pharmacovigilance analysis based on FDA Adverse Event Reporting System (FAERS) from 2004 to April 2024. *PLOS One* **2025**, *20*, e0309849. DOI:10.1371/journal.pone.0309849.
26. European Medicines Agency; PRAC. EMA confirms suicidal ideation as adverse effect of finasteride but not of dutasteride; benefits still outweigh risks, 2025. Available online: <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-5-8-may-2025>.

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