

Endocrine Modulators in BPH Management: From Androgen Blockade to Phytosterol-Based Inhibitors

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ABSTRACT

Benign prostatic hyperplasia (BPH) is a common endocrine-dependent condition among aging men, primarily driven by androgenic stimulation, particularly through dihydrotestosterone (DHT). Endocrine modulation remains a key therapeutic target in BPH management, with approaches ranging from synthetic 5-alpha-reductase inhibitors (5-ARIs) to naturally occurring phytosterol-based agents. This review explores the mechanistic underpinnings, clinical efficacy, and safety profiles of various endocrine modulators, including finasteride, dutasteride, gonadotropin-releasing hormone (GnRH) analogs, and plant-derived compounds such as *Serenoa repens* and β -sitosterol. While 5-ARIs effectively reduce prostate volume and prevent disease progression, their use is limited by delayed onset and adverse sexual effects. In contrast, phytosterol-based agents offer mild but consistent symptom relief with excellent tolerability. This article also highlights emerging therapies, including selective androgen receptor modulators (SARMs) and nanotechnology-enhanced phytotherapy, and underscores the need for biomarker-driven, personalized treatment. Future strategies will likely integrate endocrine modulation into a broader, more individualized and safer framework for long-term BPH management.

Keywords: benign prostatic hyperplasia, endocrine modulators, dihydrotestosterone, 5-alpha-reductase inhibitors, phytosterols, androgen blockade, hormonal therapy

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a chronic, non-malignant enlargement of the prostate gland characterized by the proliferation of stromal and epithelial elements, predominantly within the transition zone [1]. It is a highly prevalent condition affecting more than 50% of men aged 60 years and up to 90% of men over 80 [2]. Clinically, BPH presents with lower urinary tract symptoms (LUTS), which include increased urinary frequency, nocturia, weak stream, hesitancy, incomplete emptying, and urgency [3]. These symptoms significantly impair quality of life and may lead to complications such as urinary retention, recurrent urinary tract infections, bladder stones, and renal dysfunction if left untreated [2]. The pathophysiology of BPH is complex and multifactorial, but androgenic stimulation, particularly through the potent androgen dihydrotestosterone (DHT) is central to its development and progression [4]. Testosterone, produced mainly in the testes and in smaller quantities in the adrenal glands, is converted into DHT in prostatic cells via the enzyme 5-alpha-reductase [5]. DHT has a significantly higher affinity for androgen receptors (ARs) and promotes the transcription of genes involved in prostatic cell proliferation and differentiation [6]. Given the centrality of hormonal signaling in BPH pathogenesis, endocrine modulation represents a rational and targeted therapeutic strategy. Androgen blockade through pharmacological inhibition of DHT synthesis or AR binding can reduce prostate volume, improve urinary flow, and relieve symptoms [4]. The most widely used pharmacologic agents in this category are the 5-alpha-reductase inhibitors (5-ARIs), including finasteride and dutasteride, which inhibit DHT production [7]. In recent years, there has been growing interest in plant-derived compounds—particularly phytosterols—that exhibit endocrine-modulating properties. These natural agents may act through several mechanisms, including mild inhibition of 5-alpha-reductase, interference with AR signaling, and reduction of prostatic inflammation [8]. Phytosterol-rich extracts, such as *Serenoa repens* (saw palmetto), β -sitosterol, and *Pygeum africanum*, are widely used, especially in patients seeking alternatives to

synthetic drugs due to side effects or a preference for natural treatments [9]. This review provides a comprehensive analysis of endocrine modulators in BPH therapy, tracing the development from traditional androgen blockade to the incorporation of phytotherapeutic options. The aim is to evaluate the molecular mechanisms, clinical efficacy, safety, and future potential of these agents within an integrative framework for BPH management.

Androgen Axis and BPH Pathogenesis

The androgen signaling axis is central to both the physiological growth and pathological enlargement of the prostate. While testosterone is the primary circulating androgen, its more potent metabolite, dihydrotestosterone (DHT), exerts the strongest influence on prostatic tissue [10]. Within prostatic cells, testosterone is converted to DHT by the enzyme 5-alpha-reductase [10]. DHT binds with high affinity to androgen receptors (ARs), initiating transcriptional activity that stimulates cell proliferation and inhibits apoptosis [6].

There are two isoenzymes of 5-alpha-reductase: type I and type II. Type II is predominantly expressed in the prostate [11]. In BPH, the activity of this enzyme remains elevated, resulting in persistently high levels of DHT in the gland even as systemic testosterone declines with age [12]. This intraprostatic DHT excess drives stromal and epithelial hyperplasia, contributing to prostate enlargement and the development of lower urinary tract symptoms (LUTS) [2].

Estrogens also modulate prostatic growth, particularly through estrogen receptors ER α and Er β [13]. ER α tends to promote inflammation and proliferation, while ER β exerts anti-proliferative effects [14]. An imbalance favoring ER α activity, often due to increased aromatase activity in aging men, may contribute to BPH progression [15].

Additionally, growth factors such as IGF, FGFs, and TGF- β interact with androgen signaling to further enhance tissue growth [16]. Inflammatory cytokines, oxidative stress, and disrupted stromal-epithelial interactions amplify this hormonal crosstalk, accelerating disease progression [17].

Understanding these endocrine mechanisms has guided the development of therapies targeting DHT synthesis and AR activity. Moreover, phytotherapeutics with similar molecular actions are emerging as complementary approaches to conventional pharmacologic interventions.

Pharmacologic Androgen Blockade

Pharmacologic androgen blockade represents the cornerstone of endocrine therapy for BPH. It primarily involves the use of agents that either inhibit the synthesis of DHT or block its interaction with androgen receptors, thereby mitigating the proliferative stimulus on prostatic tissue [18]. The main classes of pharmacologic agents include 5-alpha-reductase inhibitors (5-ARIs), gonadotropin-releasing hormone (GnRH) analogs, and investigational compounds such as selective androgen receptor modulators (SARMs) [19].

5-Alpha-Reductase Inhibitors (5-ARIs)

Finasteride and dutasteride are the most commonly used 5-ARIs in clinical practice [20]. Finasteride selectively inhibits the type II isoenzyme of 5-alpha-reductase, while dutasteride inhibits both type I and type II isoenzymes, leading to a more profound suppression of DHT synthesis [21]. These agents reduce intraprostatic DHT levels by over 90%, resulting in approximately 20–25% reduction in prostate volume and significant improvement in urinary flow rates [21]. The efficacy of 5-ARIs has been confirmed in landmark trials such as the Medical Therapy of Prostatic Symptoms (MTOPS) study and the Combination of Avodart and Tamsulosin (CombAT) trial [22]. These studies demonstrated that 5-ARIs not only improve LUTS but also decrease the risk of acute urinary retention and the need for surgical intervention.

Despite their benefits, 5-ARIs have several limitations. Their onset of action is delayed, with clinical improvement often requiring 3 to 6 months. Moreover, they are associated with adverse effects such as decreased libido, erectile dysfunction, reduced ejaculate volume, and gynecomastia [23]. A small subset of patients reports persistent sexual dysfunction even after discontinuation—a condition termed post-finasteride syndrome, though its pathophysiology remains controversial [23].

GnRH Analogs

GnRH analogs such as leuprolide and goserelin suppress the hypothalamic-pituitary-gonadal axis, leading to decreased luteinizing hormone (LH) and testosterone production [24]. While effective in reducing androgen levels, these agents are rarely used for BPH alone due to systemic side effects including hot flashes, decreased bone mineral density, and loss of libido [25]. They are typically reserved for cases with concomitant prostate cancer.

Selective Androgen Receptor Modulators (SARMs)

SARMs represent an emerging class of endocrine modulators that selectively bind to androgen receptors in specific tissues such as muscle and bone while sparing others like the prostate and skin [26]. Although not yet approved for BPH, preclinical studies suggest that SARMs may offer the therapeutic benefits of androgen modulation without the undesirable side effects of traditional anti-androgens [27].

Phytosterol-Based Endocrine Modulators

Phytosterols are naturally occurring plant sterols that closely resemble cholesterol in structure. Found in fruits, vegetables, nuts, seeds, and various herbal extracts, phytosterols exhibit a range of biological activities relevant to prostate health, including anti-androgenic, anti-inflammatory, and anti-proliferative effects [28]. Their role in BPH management has gained significant attention as patients increasingly seek effective but well-tolerated alternatives to synthetic pharmaceuticals [29]. Among the most studied phytosterol-containing agents in BPH are *Serenoa repens* (saw palmetto), β -sitosterol, and *Pygeum africanum* [30]. These agents exert multiple actions on endocrine and inflammatory pathways within the prostate. *Serenoa repens* extract is derived from the fruit of the American dwarf palm tree and has been used extensively in Europe and North America for treating LUTS associated with BPH. Its proposed mechanisms include inhibition of both type I and II 5-alpha-reductase isoenzymes, interference with DHT binding to androgen receptors, inhibition of cyclooxygenase and lipoxygenase pathways, and modulation of apoptosis and growth factors [31]. Clinical trials have reported modest improvements in IPSS (typically 4–6 points) and increases in Qmax (approximately 1.5–2.5 mL/s), though results have been inconsistent due to variations in extract standardization and dosage [32]. β -Sitosterol, the principal active compound in many phytotherapeutic blends, has shown promising results in double-blind, placebo-controlled trials [33]. It is believed to compete with DHT for binding to androgen receptors and may also inhibit prostaglandin synthesis and leukotriene activity. β -Sitosterol has been associated with improvements in symptom scores and flow rates with minimal side effects [34]. *Pygeum africanum*, extracted from the bark of the African plum tree, has a long history of use in traditional African medicine. It appears to inhibit prostatic fibroblast proliferation, downregulate 5-alpha-reductase activity, and reduce inflammatory cell infiltration [35,36]. Several studies suggest it improves nocturia and voiding symptoms, although larger trials are needed. Compared to synthetic agents, phytosterol-based treatments are generally well tolerated, with minimal gastrointestinal complaints and rare reports of sexual dysfunction. However, challenges remain due to the lack of standardization, regulatory oversight, and long-term safety data. Further research is required to determine optimal dosing, synergistic effects with other agents, and the identification of responders using molecular profiling.

Comparative Efficacy and Safety Profiles

Endocrine modulators used in BPH management vary considerably in efficacy, mechanism of action, side effect profiles, and patient suitability. Synthetic agents such as 5-alpha-reductase inhibitors (5-ARIs) demonstrate robust efficacy, particularly in patients with larger prostate volumes and more advanced symptoms [37]. These agents, by reducing intraprostatic DHT levels, achieve significant reductions in prostate size (up to 25%) and symptom scores (IPSS reductions of 6–8 points), with additional benefits including decreased risk of urinary retention and delayed need for surgical intervention [37]. However, the adverse effects associated with 5-ARIs—especially sexual dysfunction such as erectile dysfunction, loss of libido, and ejaculatory disorders—can affect patient adherence [38]. Approximately 5–15% of patients may experience some degree of sexual side effect. Moreover, delayed therapeutic onset (3 to 6 months) is a common concern among symptomatic patients seeking faster relief [23]. In contrast, phytosterol-based endocrine modulators offer modest symptom relief but an excellent safety profile. Meta-analyses indicate that β -sitosterol and *Serenoa repens* produce IPSS reductions of 3–6 points and Qmax improvements of 1.5–2.5 mL/s [39]. While these values are lower than those achieved by synthetic drugs, the side effect burden is minimal. Sexual adverse effects are rare, and most patients tolerate these agents well even with long-term use. Importantly, the degree of symptom relief from phytotherapy may be sufficient for patients with mild-to-moderate LUTS who prefer non-pharmaceutical approaches or who have contraindications to androgen blockade [40]. In addition, the possibility of combining phytosterols with alpha-blockers or even low-dose 5-ARIs opens new avenues for individualized, combination therapy approaches that optimize efficacy while minimizing risks [41]. One of the key limitations in comparing efficacy lies in the heterogeneity of phytotherapeutic studies. Differences in extract standardization, patient populations, and study designs hinder direct comparisons [42]. Nonetheless, the general trend favors synthetic agents for greater symptomatic control and phytosterols for safety and tolerability. Overall, the choice between synthetic and phytosterol-based endocrine modulators should consider symptom severity, prostate volume, patient comorbidities, sexual activity, and personal preferences. A balanced, patient-centered strategy that incorporates both efficacy and safety is essential for long-term management success.

Emerging Trends and Future Directions

As the therapeutic landscape for BPH evolves, there is a clear shift toward personalized, minimally invasive, and integrative approaches. Within the domain of endocrine modulation, several emerging trends are shaping the future of treatment, from pharmacogenomics to novel delivery systems. One promising area is the use of nanotechnology to enhance the bioavailability and targeted delivery of phytosterols. Phytosterol absorption is generally poor due to their lipophilic nature, but nanoparticle encapsulation or lipid-based carriers may enhance gastrointestinal uptake and tissue specificity [43]. These technologies could improve the potency and consistency of plant-based endocrine modulators, making them more competitive with synthetic therapies. Combination therapy is another frontier,

where phytosterols are used alongside established medications such as alpha-blockers or low-dose 5-ARIs. This strategy may harness complementary mechanisms while mitigating side effects. For example, combining Serenoa repens with tamsulosin may improve symptom control while preserving sexual function better than tamsulosin-finasteride combinations [44]. The application of pharmacogenomics and molecular diagnostics in BPH is also gaining interest. Identifying genetic polymorphisms in androgen receptors, 5-alpha-reductase isoenzymes, or inflammatory markers could help predict responsiveness to different endocrine modulators, allowing for tailored therapy selection. Emerging drug classes such as selective androgen receptor modulators (SARMs) and estrogen receptor modulators (ERMs) also offer promise. SARMs aim to achieve the benefits of androgen blockade in a tissue-selective manner, reducing systemic side effects. ERMs may provide dual modulation of prostatic estrogen signaling, which plays an increasingly recognized role in BPH pathogenesis. Furthermore, machine learning and artificial intelligence may soon support treatment decisions by integrating symptom scores, imaging data, hormonal profiles, and comorbidities into predictive algorithms. This would help clinicians choose the most appropriate endocrine modulator for individual patients.

CONCLUSION

Endocrine modulation remains a central pillar in BPH management, with androgen blockade and phytosterol-based inhibitors offering complementary advantages. While synthetic agents like 5-ARIs deliver powerful reductions in DHT and prostate volume, phytosterols provide safer alternatives for long-term symptom control. Personalized endocrine therapy, integrating molecular insights with clinical profiles, will likely define the future of BPH treatment in a more holistic and patient-centered paradigm.

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