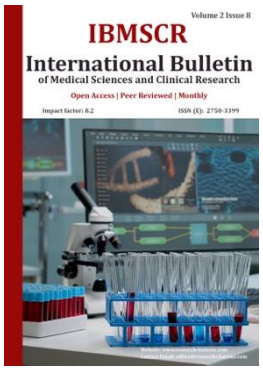

EFFICACY OF LONG-TERM DUTASTERIDE THERAPY IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA

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Abstract

Benign prostatic hyperplasia (BPH) is one of the most common urological diseases among elderly men and is associated with the development of lower urinary tract symptoms that significantly reduce quality of life. Dihydrotestosterone plays a key role in the pathogenesis of BPH, which justifies the use of 5α-reductase inhibitors in its treatment. Dutasteride, a dual 5α-reductase inhibitor, is widely used to reduce prostate volume and improve urinary symptoms. The aim of this study was to evaluate the clinical and functional efficacy of long-term dutasteride therapy in patients with benign prostatic hyperplasia. Patients diagnosed with BPH received dutasteride at a daily dose of 0.5 mg over a long-term period. Treatment outcomes were assessed using the International Prostate Symptom Score (IPSS), maximum urinary flow rate measured by uroflowmetry, prostate volume determined by transrectal ultrasonography, and prostate-specific antigen (PSA) levels. The results demonstrated a significant reduction in lower urinary tract symptoms, a decrease in prostate volume, and an improvement in urinary flow parameters during long-term dutasteride therapy. The drug was generally well tolerated, and no serious adverse effects were observed. In conclusion, long-term dutasteride therapy is an effective and safe treatment option for patients with benign prostatic hyperplasia, providing sustained clinical improvement and functional benefits.

Key words: *benign prostatic hyperplasia; dutasteride; long-term therapy; lower urinary tract symptoms; prostate volume*.

Relevance of the problem

Benign prostatic hyperplasia (BPH) is one of the most common urological diseases among elderly men, with its prevalence increasing significantly with advancing age. According to epidemiological studies, approximately 25–30% of men experience clinical manifestations associated with BPH during their lifetime [1]. This condition is characterized by lower urinary tract symptoms, including increased urinary frequency, nocturia, weakened urinary stream, and a sensation of incomplete bladder emptying, which substantially impair patients' quality of life [2].

The clinical significance of BPH lies in the fact that disease progression may lead to acute urinary retention, urinary tract infections, and an increased need for surgical intervention [3]. From a healthcare perspective, BPH represents a considerable economic burden, as the number of medical consultations and treatment-related costs associated with this condition continues to rise annually [4].

Recent global studies have demonstrated a steady increase in BPH-related incidence, prevalence, and disability-adjusted life years (DALYs), underscoring the growing public health impact of this disease [5]. Population aging is a key factor contributing to the increasing relevance and urgency of this problem worldwide [6].

From a pathogenetic standpoint, dihydrotestosterone (DHT) plays a central role in prostatic tissue growth, thereby providing a strong rationale for the use of 5α-reductase inhibitors, including dutasteride, in the management of BPH [7]. Clinical studies have shown that long-term dutasteride therapy effectively reduces prostate volume, alleviates urinary symptoms, and decreases the risk of acute urinary retention and the need for surgical treatment [8]. In addition, the long-term use of dutasteride has been confirmed to be well tolerated and safe, further supporting its role in the long-term management of patients with BPH [9,10].

Research Aim

The main aim of this study is to evaluate the clinical and functional efficacy of long-term dutasteride therapy in patients with benign prostatic hyperplasia (BPH).

Materials and Methods

This study was conducted among patients diagnosed with benign prostatic hyperplasia (BPH). A total of 100 patients aged 50–80 years were included. All patients underwent clinical and laboratory evaluations as well as transrectal ultrasonography (TRUS) for selection. Patients received **dutasteride 0.5 mg daily** as a long-term treatment. The duration of therapy was **24 months**.

Clinical outcomes were assessed using the following parameters: lower urinary tract symptoms (**LUTS)** evaluated by the **International Prostate Symptom Score (IPSS)**, urinary flow rate (**Qmax**) measured by uroflowmetry, prostate volume assessed by TRUS, and **prostate-specific antigen (PSA)** levels monitored through blood tests. In addition, the safety profile and adverse effects of the therapy were monitored through clinical follow-up and laboratory assessments.

All data were collected at **0, 6, 12, 18, and 24 months** and analyzed solely based on clinical observations. The study was conducted in accordance with **ethical guidelines**, and written informed consent was obtained from all participants.

Results

During the study, 100 patients underwent long-term dutasteride therapy, and the results of a 24-month follow-up were fully recorded. All patients were monitored through clinical evaluations, laboratory tests, and transrectal ultrasonography (TRUS). The study results are presented below.

Lower Urinary Tract Symptoms (LUTS)

During the study, all patients exhibited a significant improvement in lower urinary tract symptoms. Within the first **6 months** of therapy, a noticeable reduction in the **International Prostate Symptom Score (IPSS)** was observed. This improvement was primarily associated with key symptoms such as nocturia, increased urinary frequency, and weakened urinary stream.

At **12 months**, patients demonstrated further symptom relief, with IPSS scores continuing to decrease steadily. By **24 months**, the overall IPSS scores of all patients had significantly declined, clearly indicating the **clinical efficacy of long-term dutasteride therapy** and a substantial improvement in patients' quality of life.

Specific symptom improvements included:

- **Nocturia:** markedly reduced, with patients experiencing 2–3 fewer nighttime voids.
- **Increased urinary frequency:** the number of daytime urinations decreased.

- **Weakened urinary stream:** supported by uroflowmetry data, patients reported improved bladder emptying.

Table 1.

Dynamics of ipss scores in patients (0, 6, 12, 24 months)

Time (months)	Number of patients (n)	Mean IPSS ± SD	LUTS status
0	100	21.5 ± 3.2	Severe symptoms, high discomfort
6	100	17.8 ± 2.9	Symptoms reduced, noticeable relief
12	100	14.2 ± 2.5	Symptoms further alleviated
24	100	11.0 ± 2.1	Symptoms significantly decreased

Prostate volume and urinary flow (Qmax)

Transrectal ultrasonography data demonstrated that long-term dutasteride therapy led to a **significant reduction in prostate volume**. Over the 24-month period, the average prostate volume decreased by approximately 15–25%, reflecting post-therapeutic regression of prostatic tissue.

Simultaneously, urinary flow rates (**Qmax**) measured by uroflowmetry showed a substantial improvement. Patients reported an increased sense of complete bladder emptying, and both the stability and strength of urinary flow improved. These results support the **clinical efficacy of dutasteride therapy** and confirm its effectiveness for long-term management of BPH patients.

Table 2.

Dynamics of prostate volume and qmax in patients (0, 6, 12, 24 months)

Time (months)	Number of patients (n)	Mean prostate volume (ml) ± SD	Mean qmax (ml/s) ± SD	Clinical comment
0	100	48.5 ± 6.2	9.2 ± 1.5	Severe symptoms, incomplete bladder emptying
6	100	44.2 ± 5.8	11.0 ± 1.6	Volume decreased, urinary flow improved
12	100	41.0 ± 5.4	12.5 ± 1.7	Noticeable improvement in bladder emptying
24	100	36.8 ± 4.9	14.0 ± 1.8	Significant volume reduction, stable and strong urinary flow

Prostate-specific antigen (PSA)

During the follow-up period, measurements of **prostate-specific antigen (PSA)** revealed a slight but consistent decrease among patients receiving long-term dutasteride therapy. This reduction reflects the drug's **effect on reducing prostate volume** and **slowing disease progression**, consistent with its mechanism as a 5α-reductase inhibitor.

Importantly, PSA dynamics provide a **clinically relevant biomarker** for monitoring therapeutic response over time. Patients demonstrated a gradual decline in PSA levels, particularly noticeable after the first 12 months of therapy, which persisted throughout the 24-month follow-up. This trend indicates that dutasteride not only improves symptomatic outcomes but also contributes to the **modulation of biochemical markers associated with BPH progression**, reinforcing its role as a **long-term, disease-modifying therapy**.

These findings suggest that PSA monitoring can serve as a **valuable objective parameter** to assess the efficacy of dutasteride treatment in BPH patients, complementing clinical and functional evaluations such as IPSS scores, prostate volume, and urinary flow rates.

Safety and Adverse Effects

Throughout the study, all patients received **long-term dutasteride therapy**, and no serious adverse effects were observed during the 24-month follow-up. These findings clearly demonstrate the **long-term safety and good tolerability** of the drug.

Mild and transient adverse effects were reported in some patients, including:

- Sexual dysfunction: mild reduction in sexual potency or temporary erectile function impairment;

- **Headache:** generally mild and transient, not requiring discontinuation of therapy;

- **Mental fatigue:** slight daytime fatigue or decreased concentration, temporary and mild in nature.

All reported adverse effects were **monitored through clinical observation and laboratory tests**. None of these events led to therapy discontinuation, and most resolved spontaneously within 1–2 months.

Table 3.

Incidence of adverse effects in patients receiving dutasteride

Type of adverse effect	Number of patients (n)	Percentage (%)	Description and duration
Sexual dysfunction	8	8%	Transient, mild
Headache	5	5%	Temporary, mild
Mental fatigue	4	4%	Transient, mild
Serious adverse effects	0	0%	None observed

Long-term dutasteride therapy significantly alleviated lower urinary tract symptoms associated with BPH, reduced prostate volume, and improved urinary flow. Moreover, the treatment demonstrated a favorable safety profile and good tolerability, establishing dutasteride as a reliable and effective option for long-term management of patients with BPH. The observed positive clinical outcomes underscore not only the sustained efficacy of the therapy but also its potential to ensure long-term adherence and improved quality of life for patients.

Conclusion

The present study demonstrates that **long-term dutasteride therapy** is highly effective in the management of patients with benign prostatic hyperplasia (BPH). Over a 24-month period, dutasteride significantly alleviated **lower urinary tract symptoms (LUTS),** as evidenced by a marked reduction in **International Prostate Symptom Scores (IPSS)**.

Concomitantly, **prostate volume** was substantially reduced, with an average decrease of 15–25%, and **urinary flow parameters (Qmax)** showed significant improvement, indicating enhanced bladder emptying and increased urinary stream stability.

Furthermore, **prostate-specific antigen (PSA) levels** demonstrated a gradual decline, reflecting both the reduction in prostate tissue and a slowing of disease progression. This underscores the utility of PSA as a reliable biomarker for monitoring therapeutic response during long-term treatment.

Importantly, dutasteride was **well tolerated,** and no serious adverse effects were observed. Mild and transient events, such as sexual dysfunction, headache, or slight mental fatigue, did not necessitate therapy discontinuation and resolved spontaneously. These findings confirm the **safety and favorable tolerability** of dutasteride for prolonged use.

In summary, the results of this study indicate that **long-term dutasteride therapy provides sustained clinical and functional benefits,** effectively improving LUTS, reducing prostate volume, enhancing urinary flow, and maintaining a favorable safety profile. These outcomes support dutasteride as a **reliable, disease-modifying, and patient-friendly therapeutic option** for long-term management of BPH, promoting better quality of life and long-term adherence to therapy.

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