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Investigating Clinical Outcomes of Alpha-Blocker Monotherapy Compared to Combined 5-Ari Protocols in The Context of Benign Prostatic Hyperplasia

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ABSTRACT

Benign prostatic hyperplasia (BPH) is a common condition in elderly men characterized by prostate enlargement, resulting in lower urinary tract symptoms (LUTS) that significantly impact quality of life. Pharmacological management includes alpha-blockers and 5-alpha reductase inhibitors (5-ARIs). To compare the clinical outcomes of alpha-blocker monotherapy with combination therapy in patients with BPH. A 6-month prospective comparative study was conducted in 100 patients with moderate to severe BPH. Patients were treated with either alpha-blocker monotherapy or combination therapy (alpha-blocker with 5-ARI). Clinical outcomes were evaluated using the International Prostate Symptom Score (IPSS) at baseline and after 3 months. Statistical analysis was performed with significance set at $p<0.05$. Both treatment groups showed improvement in LUTS. However, combination therapy resulted in a greater reduction in IPSS scores and improved clinical response compared to monotherapy, particularly in patients with more severe symptoms. Combination therapy provides superior clinical outcomes and may offer better long-term disease control, while monotherapy remains effective for rapid symptomatic relief.

Keywords: Benign prostatic hyperplasia, alpha-blockers, 5-alpha reductase inhibitors, combination therapy, IPSS score, prostate volume.

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INTRODUCTION

Background of Benign Prostatic Hyperplasia

Benign Prostatic Hyperplasia (BPH) is a common non-cancerous condition where the prostate gland becomes enlarged, mainly in older men.

This happens when there is an increase in both the supportive and lining cells of the prostate, especially in the transitional zone. As the prostate grows, it can press on the urethra, making it hard for urine to flow normally. Over time, this leads to lower urinary tract symptoms (LUTS), which can greatly affect a person's comfort, sleep, and daily life. Clinical guidelines from the American Urological Association and the European Association of Urology highlight that BPH is one of the most common urological issues that need early diagnosis and treatment (1–3).

Clinical Importance of LUTS

Lower urinary tract symptoms are the main signs of BPH.

These symptoms are usually divided into two groups: storage symptoms and voiding symptoms. Storage symptoms include needing to urinate more often, a sudden need to go, urinating at night, and leakage of urine. Voiding symptoms include difficulty starting to urinate, a weak urine stream, stopping and starting again while urinating, straining, and not fully emptying the bladder. If these symptoms are not treated, they can worsen and lead to complications like repeated urinary tract infections, difficulty passing urine completely, and problems with bladder function. The International Prostate Symptom Score (IPSS) is often used in clinical practice to assess how severe the symptoms are and to help plan treatment based on the patient's condition (3–5).

Role of Alpha-Blockers

Alpha-blockers are commonly used as the first-line treatment for patients with mild to moderate BPH symptoms because they quickly ease urinary blockage.

These drugs work by blocking alpha-1 adrenergic receptors in the smooth muscles of the prostate, bladder neck, and urethra. This action helps relax the muscles and improve urine flow by reducing resistance in the urethra. Medicines like tamsulosin and silodosin are often used for this purpose. Although alpha-blockers are very effective in relieving symptoms, they do not shrink the prostate and thus have limited effect on preventing long-term disease progression (6–9).

Role of 5-Alpha Reductase Inhibitors

5-alpha reductase inhibitors (5-ARIs) such as dutasteride and finasteride are used mainly in patients with a larger prostate.

These drugs work by stopping the enzyme that changes testosterone into dihydrotestosterone (DHT), which is the main hormone involved in prostate growth. By lowering DHT levels, these medicines gradually reduce the size of the prostate, slow the progression of the disease, and lower the risk of complications like acute urinary retention and the need for surgery. However, unlike alpha-blockers, their benefits take time to show and may require several months for noticeable improvement (10–12).

Importance of Combination Therapy

Combination therapy, which uses both alpha-blockers and 5-alpha reductase inhibitors, has become an important approach in managing moderate to severe BPH.

Alpha-blockers offer fast relief of symptoms, while 5-ARIs help control the disease in the long term by reducing prostate size. This combination helps manage both the dynamic and static parts of bladder outlet blockage. Many studies have shown that combination therapy leads to better improvement in symptom scores, less disease progression, and a lower chance of future complications compared to using just one type of medicine, especially in patients with larger prostates and severe symptoms at the start (13–16).

Existing Evidence and Research Gap

Earlier clinical studies have shown that both monotherapy and combination therapy are effective for treating BPH, but the results can vary from person to person.

Factors such as the size of the prostate, prostate-specific antigen (PSA) levels, initial IPSS score, how well the patient tolerates the drugs, side effects, and how consistent the patient is with treatment can affect the results. Long-term studies suggest that combination therapy may offer better protection against disease progression, but more real-world data on how these treatments are actually used in practice and how well they work still need to be collected to support clinical decisions based on evidence (17–20).

Need for the Present Study

Although there are several treatment options for BPH, selecting the most suitable one still presents a clinical challenge.

Alpha-blocker monotherapy is often preferred for quick symptom relief, while combination therapy is generally used for patients with a larger prostate or a higher risk of disease progression. Previous comparisons have shown that treatment outcomes depend on the initial severity of symptoms, PSA levels, patient adherence, and long-term tolerance of the treatment. Therefore, a comparison in real-world clinical practice is needed to determine which approach leads to better overall results. As a result, this study was conducted to compare the clinical

results of alpha-blocker monotherapy and combination therapy with 5-alpha reductase inhibitors in BPH patients, with a particular focus on improvements in symptoms and treatment effectiveness using the IPSS assessment (17–20).

MATERIALS AND METHOD

Objective

- To evaluate the clinical efficacy of combination therapy compared to monotherapy in relieving symptoms of BPH.
- To assess the impact of both treatment approaches on prostate volume, urinary flow rate and post-void residual volume.
- To compare the incidence of adverse effects and drug tolerance between combination and monotherapy groups.
- To analyze patient adherence and quality of life, outcomes associated with each treatment strategy.
- To determine the long-term benefits, such as reduced risk of acute urinary retention and need for BPH-related surgery, between the two modalities.
- To review cost-effectiveness and overall economic impact of combination therapy versus monotherapy in BPH management.

METHOD

❖ STUDY TYPE: A Comparative prospective study

❖ STUDY SITE: Department of Urology, GGH, Ongole.

❖ STUDY PERIOD: 6 months

❖ STUDY POPULATION: 100

❖ PATIENT ENROLLMENT:

Inclusion criteria:

- Male patient >40years of age,
- Diagnosed with moderate to severe BPH (Based on IPSS score >8).
- Prostate volume >30cc confirmed by ultrasound.
- who gives written consent for study.

Exclusion criteria:

- <40years of age,
- Who doesn’t give consent

METHOD OF STUDY:

This was a prospective comparative study conducted at government medical college and who admitted in the department of urology. Government general hospital for the period of 6 months from July 2025 to December 2025 (on 100 patients who admit in the department of Urology, GGH, Ongole) who has more than 40years of age will be included in the study.

Data Collection

Patient information was collected from clinical records. The following parameters were recorded:

- Age of patients
- Type of prostate condition (BPH or prostatomegaly)
- Prostate volume measured using ultrasonography
- Prostate-specific antigen levels
- Baseline IPSS score
- Prescribed drug therapy
- Follow-up IPSS scores after three months

Treatment Groups

Patients were categorized into two groups based on the prescribed therapy:

Group 1: Alpha-Blocker Monotherapy

Patients receiving alpha-adrenergic blockers such as silodosin or tamsulosin.

Group 2: Combination Therapy

Patients receiving a combination of alpha-blockers with 5-alpha reductase inhibitors.

Outcome Assessment

The effectiveness of treatment was assessed using the International Prostate Symptom Score (IPSS), which is a widely used clinical tool for evaluating urinary symptoms associated with BPH.

Improvement in symptoms was determined by comparing baseline IPSS scores with follow-up scores recorded after three months of treatment.

Statistical Analysis

Descriptive statistics were used to summarize patient demographic characteristics and clinical parameters. Treatment effectiveness was evaluated by comparing changes in IPSS scores between the two treatment groups.

Data were analyzed using Statistical Package for the Social Sciences (SPSS). Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as percentages. Differences between treatment groups were analyzed using the Chi-square test and Student's t-test where appropriate. A p-value <0.05 was considered statistically significant.

Ethical Approval

The study was conducted following approval from the Institutional Ethics Committee (IEC) of QIS College of Pharmacy. Written informed consent was obtained from all participants prior to inclusion in the study. The study adhered to ethical principles outlined in the Declaration of Helsinki.

RESULTS AND DISCUSSION

Patient Demographics

The study population consisted of male patients aged between 45 and 88 years, indicating that BPH is more common in the elderly population. Most patients were above 60 years of age.

Clinical Characteristics

Prostate volume among patients ranged from approximately 27 cc to 76 cc. PSA levels varied depending on disease severity.

Patients with larger prostate volumes were more frequently treated with combination therapy.

Treatment Distribution

Among the 100 patients included in the study:

- 43 patients received alpha-blocker monotherapy
- 57 patients received combination therapy

Treatment Outcomes

Both treatment groups showed improvement in urinary symptoms after three months of pharmacological therapy.

However, patients receiving combination therapy demonstrated greater reduction in IPSS scores compared with those receiving monotherapy.

Combination therapy appeared to be particularly beneficial for patients with:

- Higher baseline IPSS scores
- Larger prostate volumes
- More severe urinary symptoms

RESULTS AND DISCUSSION

Demographic details:

Table 1: Total no. of patients with BPH based on age group.

S.No	Age Distribution	No. of Patients	Percentage (%)
1	41–50	5	5%
2	51–60	19	19%
3	61–70	37	37%
4	71–80	29	29%
5	81–90	10	10%

Table 2 : No. of patients prescribed with monotherapy and combination therapy

S.NO	Treatment group	No. Of Patients
1	Monotherapy	43
2	Combination therapy	57

Table 3: No. of patients according to disease Grade

S.No	Disease Grade	NO. OF Patients	Percentage (%)
1	Grade I	40	40%
2	Grade II	20	20%
3	Grade III	40	40%

Table 4: Drug wise prescription pattern

S.No	Drugs Prescribed	No. Of Patients	Percentage (%)
1	Tamsulosin	01	1%
2	Silodosin	42	42%
3	Silodosin + Dutasteride	57	57%

Table 5: Associated comorbidities

S.No	Comorbidity	No. of Patients (N)	Percentage (%)
1	Diabetes Mellitus	0	0%
2	Hypertension	0	0%
3	UTI	2	2%
4	CKD	1	1%

Table 6: Chi-Square Test of Independence: Monotherapy vs Combination Therapy Response Rates

Treatment	O-E	$(O-E)^2/E$

Mono/Response	-5.88	1.552
Mono/No Response	+5.88	3.424
Comb/Response	+5.88	0.901
Comb/No Response	-5.88	2.993
Total $\chi^2 = 8.87$		

Chi-square value (χ^2) = 8.87

p-value < 0.05 (Statistically Significant)

Table 7: Chi-Square Test: Monotherapy vs Combination Response

Treatment	Response	No Response	Total
Monotherapy (A)	33	15	43
Combination (B)	48	4	57
Total	81	19	100

Overall Result Summary

A total of 100 male patients diagnosed with benign prostatic hyperplasia were included in the study. The age of the patients ranged from 45 to 88 years, with the majority of participants belonging to the elderly age group (above 60 years). The recorded prostate volume ranged from approximately 27 cc to 76 cc, indicating varying degrees of prostate enlargement among the study population.

Patients were categorized into two treatment groups based on the therapy prescribed. Alpha-blocker monotherapy was administered to 43 patients, while 57 patients received combination therapy consisting of an alpha-blocker and a 5-alpha reductase inhibitor. Symptom severity was assessed using the International Prostate Symptom Score (IPSS) at baseline and during follow-up after three months of treatment.

Both treatment groups demonstrated improvement in urinary symptoms following pharmacological therapy. However, the magnitude of improvement differed between the two groups. Patients receiving combination therapy showed a greater reduction in IPSS scores, indicating better symptom control compared with those receiving alpha-blocker monotherapy.

Combination therapy was particularly effective in patients with larger prostate volumes and higher baseline symptom scores, suggesting that the addition of a 5-alpha reductase inhibitor provides added therapeutic benefit in moderate to severe cases of BPH. Alpha-blocker monotherapy also improved symptoms, especially in patients with mild prostate enlargement and lower baseline IPSS scores.

Overall, the findings indicate that both treatment approaches were effective in reducing urinary symptoms, but combination therapy demonstrated superior clinical outcomes in terms of symptom reduction and disease management.

DISCUSSION

The results of the present study demonstrate that pharmacological therapy plays an important role in the management of symptoms associated with benign prostatic hyperplasia. Both alpha-blocker monotherapy and combination therapy showed improvement in urinary symptoms among the patients included in the study population. However, the reduction in symptom severity was greater among patients receiving combination therapy compared with those receiving alpha-blocker monotherapy.

Alpha-adrenergic blockers are commonly used as first-line therapy for BPH because they relax the smooth muscles of the prostate and bladder neck, leading to improved urinary flow and reduction of lower urinary tract symptoms. These medications provide relatively rapid symptomatic relief, which explains the early improvement observed in patients receiving monotherapy in the present study. Similar observations have been reported in several clinical studies where alpha-blockers demonstrated effective short-term improvement in urinary symptoms.

However, alpha-blockers do not significantly reduce prostate size, and therefore their ability to prevent disease progression may be limited, particularly in patients with enlarged prostates. This limitation has been highlighted in previous research. For example, the Medical Therapy of Prostatic Symptoms (MTOPS) study conducted by Barry et al. reported that alpha-blocker therapy improves urinary symptoms but has limited impact on reducing long-term disease progression.

In contrast, 5-alpha reductase inhibitors act by inhibiting the conversion of testosterone to dihydrotestosterone (DHT), the hormone responsible for prostate growth. Reduction in DHT levels leads to gradual shrinkage of the prostate gland and helps slow the progression of the disease. Studies such as the Proscar Long-Term Efficacy and Safety Study (PLESS) have demonstrated that 5-alpha reductase inhibitors significantly reduce prostate volume and lower the risk of urinary retention and the need for surgical intervention.

When alpha-blockers are used together with 5-alpha reductase inhibitors, the combination provides both rapid symptomatic improvement and long-term disease control. The findings of the present study support this concept, as patients receiving combination therapy showed greater improvement in symptom scores compared with those receiving monotherapy.

These results are also consistent with findings from the Combination of Avodart and Tamsulosin (CombAT) trial, which reported that combination therapy significantly improves urinary symptoms and reduces the risk of disease progression in patients with moderate to severe BPH.

Overall, the findings of the present study suggest that while alpha-blocker monotherapy can provide effective symptomatic relief, combination therapy may offer superior clinical benefits, particularly in patients with larger prostate volumes and more severe urinary symptoms.

Limitations

- A Prospective observational study.
- Short follow-up duration(3months).
- Symptom evaluation relied partly on patient-reported IPSS scoring.
- Lack of randomization may have introduced selection bias.
- Long-term adverse effects were not comprehensively evaluated.
- Patient compliance with medication was not objectively monitored.
- The influence of comorbidities on treatment response was not deeply explored.
- Time-to-response analysis between therapies was not conducted.

CONCLUSION

The present study evaluated prescribing patterns and clinical outcomes associated with alpha-blocker monotherapy and combination therapy with 5-alpha reductase inhibitors in patients diagnosed with benign prostatic hyperplasia (BPH). The findings indicate that both treatment approaches were utilized appropriately based on patient clinical characteristics, symptom severity, prostate volume, and PSA levels, reflecting rational therapeutic decision-making in routine practice.

Monotherapy with alpha-blockers demonstrated effectiveness in providing symptomatic relief, particularly in patients presenting with mild to moderate lower urinary tract symptoms. The rapid onset of action and favorable tolerance profile contributed to improved patient compliance and symptom control. In contrast, combination therapy was more frequently prescribed for patients with moderate to severe disease indicators, where long-term disease modification and reduction in risk of progression were required. This approach showed advantages in improving overall clinical outcomes, including better symptom stabilization and prevention of complications.

Adherence to treatment guidelines and appropriate drug selection observed in the study population suggests a high level of rational drug utilization. Minimal occurrence of inappropriate prescriptions or unnecessary medication combinations further supports the quality of clinical management. Additionally, the observed safety and tolerability profiles indicate that both regimens were generally well accepted by patients.

Overall, the study concludes that alpha-blocker monotherapy remains suitable for early or less severe cases, while combination therapy offers superior long-term benefits in patients at higher

risk of progression. These findings emphasize the importance of individualized therapy selection based on patient assessment parameters. Continued evaluation with larger sample sizes and long-term follow-up is recommended to further strengthen clinical evidence and optimize therapeutic strategies in BPH management.

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CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this study.

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