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THERAPEUTIC EFFECT OF SILODOSIN ON ACUTE URINARY RETENTION INDUCED BY BENIGN PROSTATIC HYPERPLASIA

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Abstract
This article explores the use of α-adrenergic blockers in the treatment of acute urinary retention (AUR), a serious complication of benign prostatic hyperplasia (BPH). It highlights clinical findings regarding silodosin, a new generation uroselective α-blocker approved for managing lower urinary tract symptoms due to BPH. Silodosin is distinguished by its high degree of uroselectivity, fast therapeutic onset, and ease of use—a standard 8 mg daily dose that remains consistent regardless of patient age. Furthermore, it is compatible with concurrent use of antihypertensive therapies.

Keywords: Acute urinary retention, prostate adenoma, silodosin, α-blocker, effectiveness, safety

Introduction

According to global statistics, benign prostatic hyperplasia (BPH), or prostate adenoma, is diagnosed in approximately 80% of men aged 60 and older [1]. Data from the United Nations indicate that by the end of the 20th century, the global population aged 60 and above had more than tripled compared to mid-century figures. With continued population aging, the treatment and management of BPH are expected to attract increasing attention worldwide [1, 2].

Acute urinary retention (AUR) is among the most frequent and serious complications of BPH in elderly males [3]. Epidemiological research has demonstrated a direct correlation between prostate volume and the risk of developing AUR [4].

The current optimal approach to managing AUR due to BPH includes conservative measures aimed at restoring natural urination. These typically involve bladder catheterization, administration of α-blockers—preferably selective ones due to their safety profile and the lack of need for dose adjustment—and concurrent diagnostic evaluation [5, 6]. Urologists today have access to a broad selection of α-adrenergic antagonists. Silodosin stands out among them due to its high selectivity for the α1A-adrenergic receptor subtype—162 times greater than for α1B receptors [7–11]—which significantly reduces its hypotensive effects.

One of the key therapeutic advantages of silodosin is its fixed-dose regimen, eliminating the need for dose adjustments. Moreover, it can be used cautiously in combination with antihypertensive agents. In phase III clinical trials conducted in the U.S. and Europe, 32% of participants received silodosin alongside antihypertensive medications—including renin-angiotensin system inhibitors,

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beta-blockers, calcium channel blockers, and diuretics. Importantly, the incidence of orthostatic hypotension in these groups (1.2%) was not significantly different from those taking silodosin alone (1.4%) or placebo (1.0%) [13].

Notably, silodosin provides rapid symptom relief, with improvements in urinary function observed within the first few days of treatment [12], making it particularly valuable for managing AUR associated with BPH.

Study Objective: To evaluate the efficacy and safety of once-daily silodosin at a dose of 8 mg in the treatment of AUR due to BPH.

Study Aims:

- To assess the impact of silodosin 8 mg daily on the restoration of spontaneous urination in patients with AUR caused by BPH.
- To monitor changes in BPH symptom severity using the International Prostate Symptom Score (IPSS) during silodosin therapy.
- To evaluate the extent of bladder outlet obstruction through transrectal ultrasonography, uroflowmetry, and measurements of prostate volume and post-void residual urine during treatment.
- To analyze the tolerability of silodosin based on adverse event reporting and changes in laboratory values from clinical and biochemical blood tests as well as urine analyses.

Materials and Methods

The study was conducted in two phases. In the first phase, 120 male patients over the age of 50 with a confirmed diagnosis of benign prostatic hyperplasia (BPH) and experiencing their first episode of acute urinary retention (AUR) were enrolled. The volume of urine drained during catheterization ranged from 500 to 1500 ml. Participants were divided into two groups: 60 patients received silodosin at a daily dose of 8 mg, while the other 60 received doxazosin at 4 mg per day. The second phase included only those patients who successfully regained spontaneous urination following catheterization and initial treatment with an α-blocker (silodosin or doxazosin). Eligibility criteria for this phase included an International Prostate Symptom Score (IPSS) of 12 or higher, evidence of moderate bladder outlet obstruction (Qmax between 5 and 15 ml/s), and a prostate-specific antigen (PSA) level of 4 ng/ml or lower. These patients continued treatment with the same α-blocker they had received during the first phase.

Exclusion criteria for the initial phase included:

Patients requiring surgical intervention or alternative therapies for BPH;

Patients with previously undiagnosed conditions affecting the kidneys, bladder, prostate (except BPH or prostatitis), urethra, or other urinary tract disorders;

Individuals with severe, decompensated hepatic, renal, or other organ system diseases;

Patients unable to properly communicate with the research team or adhere to study procedures.

Participants were randomly assigned to the treatment groups using typological selection—a method ensuring comparability between groups in terms of age, clinical presentation, comorbidities, AUR duration, and residual urine volume.

Those who restored natural urination in the first phase proceeded to the second phase of observation. In this phase, all patients were evaluated based on IPSS scores for urinary symptoms

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and quality of life. Additional assessments included digital rectal examination of the prostate, transrectal ultrasound to measure residual urine volume, uroflowmetry, routine urinalysis, and serum PSA measurement. These evaluations were performed at the beginning of the second phase and at 1, 3, and 6 months following initiation of treatment.

Primary efficacy endpoints during the second phase included:

Overall therapeutic effectiveness;

Change in symptom severity as measured by the IPSS.

Therapeutic outcomes were assessed through digital rectal exams, transrectal ultrasonography, residual urine volume analysis, and uroflowmetry. The total follow-up and treatment period for both groups lasted six months.

Results and Discussion

To relieve acute urinary retention (AUR), all patients first underwent bladder catheterization followed by administration of α-blockers. Key indicators of restored urination were observed within 8–10 hours after the initial dose of the medication, coinciding with bladder filling. Patients' urination was subsequently monitored over a five-day period. During this time, spontaneous bladder emptying was reestablished in 47 patients (78.3%) from the main group (silodosin) and in 38 patients (63.3%) from the comparison group (doxazosin). This outcome is particularly noteworthy and can be attributed to the rapid onset of action of silodosin within the first few hours of administration [6].

Patients who did not regain the ability to urinate independently underwent a trocar or open cystostomy and were prepared for surgical intervention, such as transurethral resection of the prostate or adenomectomy.

A total of 78 patients proceeded to the second phase of the study—43 from the silodosin group and 35 from the doxazosin group. During this stage, seven participants withdrew (four from the main group and three from the comparison group). The therapeutic efficacy of the two drugs was evaluated using data from transrectal ultrasonography, which served as one of the study's primary outcome measures.

By the second clinical visit, both groups showed a moderate reduction in prostate volume, likely due to decreased edema. A significant reduction in post-void residual urine volume was also observed, suggesting a reduction in bladder outlet obstruction during α-blocker therapy.

Uroflowmetry was employed to evaluate key parameters of urinary function, showing an improvement in the maximum urinary flow rate in both treatment groups.

The total International Prostate Symptom Score (IPSS) was used to quantify the severity of urinary symptoms associated with BPH. A decline in this score reflected therapeutic effectiveness. The analysis revealed that the average IPSS score declined in both groups as early as the second follow-up visit and remained stable throughout the treatment period. These results align with existing evidence that all α-blockers produce a comparable therapeutic effect on urinary symptoms [6].

Any deterioration in patients' general condition, new complaints, or abnormalities in laboratory findings (including clinical and biochemical blood tests and urinalysis) were classified as adverse events. According to Table 2, the incidence of adverse effects was higher in the doxazosin group,

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with the most frequent being hypotension—a side effect that can significantly impair patient quality of life. This adverse event was not reported in the silodosin group.

The findings suggest that silodosin, due to its rapid onset of action, is effective in restoring spontaneous urination in patients with AUR caused by BPH. Given the lack of prior published research on this specific application, the present study was initiated to demonstrate the fast-acting influence of silodosin on the smooth muscle tone of the lower urinary tract

Conclusions

1.Silodosin, a selective α1A-adrenergic receptor blocker, has demonstrated a favorable safety profile and effectively restored spontaneous bladder emptying in 78.3% of patients experiencing acute urinary retention (AUR) due to benign prostatic hyperplasia (BPH).

2.Administering silodosin following the initial resolution of AUR not only alleviates urinary symptoms but may also serve as a preventive strategy against future episodes of AUR in patients with BPH.

3.The drug's rapid onset of action and high therapeutic efficacy make it particularly suitable for managing AUR. Based on the findings of this study, silodosin can be recommended both for the acute restoration of urination in AUR and as part of long-term BPH management. Notably, throughout the study, no cases of blood pressure reduction were observed with the 8 mg daily dose of silodosin, further supporting its safety in this patient population.

References

1. Emberton M., Andriole G.L., de la Rosette J. et al. Benign prostatic hyperplasia: a progressive disease of aging men. Urology 2003;61: 267–273.
2. Marberger M.J., Andersen J.T., Nickel J.C. et al. Prostate Volume and Serum Prostate-Specific Antigen as Predictors of Acute Urinary Retention. Eur. Urol. 2000;38:563–568.
3. Clifford G.M., Farmer R.D.T. Medical therapy for benign prostatic hyperplasia: a review of the literature. Eur. Urol. 2000;38:2–19.
4. Lukacs B., Grange J.C., McCarthy C. et al. Clinical uroselectivity a 3-year follow-up in general practice. BPH Group in General practice. Eur. Urol. 1998;33(Suppl. 2):28–33.
5. Lopatkin N.A. (Eds.). Rational pharmacotherapy in Urology. M., 2006:152.
6. Tkachuk V.N., Al-Shukri S.H., Lukyanov A.E. Drug treatment of patients with benign prostatic hyperplasia. SPb., 2000:104 p.
7. Tatemichi S. et al. Yakugaku Zasshi. 2006;12:209–216.
8. Katzung B.G. Basic and Clinical Pharmacology. 6th ed. Norwalk, CT: Appleton & Lange; 1995.
9. Schwinn D.A. et al. Mayo Clin Proc. 2004;79:1423–1434.
10. Kenny B.A. et al. Br. J Pharmacol. 1996;118:871–878.
11. Akiyama K. et al. J Pharm. Exp. Ther. 1999;291:81–91.
12. Montorsi F. Profile of silodosin. Eur. Urol. 2010;9 (Suppl.):491–495. 13. Marks L.S., Gittelman M.C., Hill L.A. et al. Rapid efficacy of the highly selective α1A-adrenoceptor antagonist silodosin in men with signs and symptoms of BPH: pooled results of two phase 3 studies. J Urol. 2009;181:2634–2640.

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