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Results of the use of silodosin in acute urinary retention caused by Benign prostatic hyperplasia

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Abstract. The article provides .α-blockers are widely used to treat one of the most serious complications of benign prostatic hyperplasia (BPH), acute urinary retention (AUR). Experience with the use of a new uroselective α-adrenergic blocker, silodosin, approved for the treatment of patients with urinary disorders caused by BPH, is presented. Its pharmacological profile has a number of advantages, including the highest uroselectivity to date, rapid onset of effect, the ability to take a standard dose of 8 mg once a day, which does not require adjustment depending on age; possibility of simultaneous use with antihypertensive drugs.
Key words: acute urinary retention, prostate adenoma, silodosin, α-blocker, effectiveness, safety

Introduction.

According to international statistics, prostate adenoma (BPA) is diagnosed on average in 80% of men aged 60 years and older [1]. According to the UN, by the end of the twentieth century. The population aged 60 years has increased more than 3 times compared to the middle of the century. According to forecasts, due to the aging of the population, more and more attention will be paid to the problems of treating BPH around the world [1, 2].

Acute urinary retention (AUR) is one of the most common and serious complications of BPH in older men [3]. The results of epidemiological studies have shown that the risk of developing AUR increases as the volume of the prostate gland increases [4].

The optimal treatment strategy for AUR in BPH includes a set of conservative measures aimed at restoring urination: bladder catheterization, use of α-blockers (preferably selective, since they do not require dose selection and are the safest) with simultaneous examination of the patient [5, 6]. Currently, urologists have a wide range of α-blocker drugs in their arsenal. The affinity of silodosin for the α1A-adrenergic receptor subtype is much higher (162 times) than for α1B-adrenergic receptors [7–11]. That is why the hypotensive potential of silodosin is minimized. A significant therapeutic advantage of silodosin is that there is no need for dose adjustment. Silodosin can be used (with caution) concomitantly with drugs that lower blood pressure. In the American and European phase III studies of silodosin, 32% of patients were concomitantly taking silodosin and antihypertensive drugs (renin-angiotensin system blockers, beta-blockers, calcium channel blockers and diuretics). There was no statistically significant difference in the incidence of orthostatic hypotension between the groups receiving silodosin, concomitant silodosin and antihypertensive drugs and placebo (1.4%, 1.2% and 1%, respectively) [13].

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A decrease in the severity of urinary disorders occurs already in the first days of taking silodosin [12], which is of particular importance for the treatment of AUR associated with BPH.

The purpose of this study was to study the effectiveness and safety of silodosin at a dose of 8 mg per day for the treatment of patients with AUR due to BPH.

To achieve the goal of the study, we set the following tasks:

• assessment of the effect of silodosin 8 mg per day on the restoration of natural bladder emptying in patients with AUR associated with BPH;

• assessment of the dynamics of BPH symptoms according to the International Prostate Symptom Score (IPSS) during treatment with silodosin 8 mg per day;

• determination of the severity of bladder outlet obstruction caused by BPH, based on data from transrectal echography, uroflowmetry, determination of prostate volume and residual urine volume during treatment with silodosin 8 mg per day;

• assessment of the tolerability of silodosin based on the analysis of registered adverse effects and changes in laboratory parameters in clinical and biochemical blood tests and clinical urine analysis.

Materials and methods.

The study consisted of two phases. The first phase included 120 patients over 50 years of age (60 patients received silodosin 8 mg per day, 60 patients received doxazosin 4 mg per day) with diagnosed BPH, who first developed AUR, urine volume during bladder catheterization ranged from 500 to 1500 ml. The second phase of the study continued with patients who had restored natural bladder emptying after catheterization and use of an α-blocker (doxazosin or silodosin) and who met the following criteria: IPSS score ≥12, moderate bladder outlet obstruction (5<Qmax ≤ 15 ml/s) and PSA level≤4 ng/ml. In the second phase of the study, patients who regained spontaneous urination after AUR received silodosin or doxazosin.

Exclusion criteria for the first phase of the study:

• patients who required surgery or received any other treatment for BPH;

• patients with previously undiagnosed diseases of the kidneys, bladder, prostate gland (except for BPH and prostatitis), urethra and other diseases that can cause urination disorders;

• patients with severe decompensated diseases of the liver and/or kidneys and/or other vital organs;

• patients who were unable to adequately answer the researcher's questions, fill out the necessary documents and administer medications.

Patients were randomized by typological selection into two equal groups, similar in age, clinical manifestations, results of laboratory and instrumental studies. Typological selection is a method of forming groups comparable in age, severity of clinical manifestations, concomitant diseases, duration of AUR and residual urine volume. Patients in the main group received silodosin 8 mg, 1 capsule once a day, patients in the comparison group received doxazosin 4 mg, 1 tablet once a day.

Patients who successfully completed the first phase, i.e. those who regained natural bladder emptying were included in the second phase of observation. IPSS scores for voiding disorders and quality of life were taken into account for all patients; In addition, additional examinations

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were carried out: digital rectal examination of the prostate gland, transrectal echography of the prostate gland with determination of residual urine volume and uroflowmetry. A urine test was also performed and the level of prostate-specific antigen (PSA) in the blood serum was determined. These examinations were carried out at inclusion in the second phase of observation, 1, 3 and 6 months after the start of treatment.

In the second phase of the study, the efficacy endpoints were:

• therapeutic effect;

• severity of BPH symptoms according to the IPSS scale.

To assess the therapeutic effect, we used data obtained from digital rectal examination of the prostate gland, transrectal echography of the prostate gland with determination of the volume of residual urine, and uroflowmetry. The duration of follow-up and treatment in both groups was 6 months.

Results and discussion.

To relieve AUR, all patients underwent bladder catheterization, then α-blockers were prescribed. The main data indicating the restoration of urination in patients was obtained within 8–10 hours after taking α-blockers (during the accumulation of urine in the bladder). Subsequently, urination patterns were monitored for 5 days. During this period, natural bladder emptying was restored in 47 (78.3%) patients in the main group and in 38 (63.3%) in the comparison group. This fact is important and is explained by the rapid action of silodosin in the first few hours after its administration [6].

For patients whose independent urination was not restored, a trocar, or open, cystostomy was performed, followed by preparation for surgery - transurethral resection of the prostate gland or adenomectomy.

The second phase of the study included 78 patients, 43 of them from the main group, 35 from the comparison group. Subsequently, 7 patients dropped out of the study (4 from the main group and 3 from the comparison group). At this stage, the therapeutic effect of the drugs used was assessed based on the results of transrectal echography of the prostate gland, which were used as efficacy endpoints.

At the second visit, patients in both groups showed a moderate decrease in prostate volume due to a decrease in edema. In addition, a significant decrease in the volume of residual urine was noted. Apparently, this fact is explained by a decrease in bladder outlet obstruction while taking α-blockers.

The uroflowmetry method was used to assess the main parameters of urination and revealed an increase in the average value of the maximum urine flow rate in both groups.

The total IPSS score was used to assess the severity of symptoms of bladder outlet obstruction due to BPH, with a decrease in the absolute value of this indicator indicating the effectiveness of treatment.

Analysis of the results of the second phase of the study showed that the average IPSS score decreased in both groups already at the second visit and remained at the achieved level during treatment. This confirms the well-known fact: the effect of all α-blockers on urination is approximately comparable [6].

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Unfavorable changes in the general condition of patients, the appearance of new complaints, deviations in laboratory parameters (clinical and biochemical blood tests and clinical urine analysis) were considered as undesirable effects of treatment.

As follows from the table. 2, the frequency of adverse effects while taking doxazosin was higher than in patients taking silodosin; undesirable effects most often manifested themselves in the form of a decrease in blood pressure, which significantly affects the quality of life of patients. This undesirable effect was not observed in the main group.

The observation showed that due to the rapid onset of action of silodosin, its use can effectively restore the natural emptying of the bladder in patients with AUR due to BPH. Since there are no published data on this issue, therefore, the decision to conduct this study is related to showing the effect of silodosin on the smooth muscle tone of the lower urinary tract and that it develops quite quickly.

conclusions

• The α1A-adrenergic blocker silodosin is a safe drug that helps restore natural bladder emptying in 78.3% of patients with AUR caused by BPH;

• taking silodosin after successful relief of AUR in patients with BPH serves as prevention of AUR in the future; This treatment relieves and eliminates urinary disorders.

• silodosin is characterized by a rapid onset of action and high efficiency, which facilitates its use in cases of AUR. The results of this study allow us to recommend silodosin both for the restoration of urination in patients with AUR arising from BPH, and for the routine treatment of patients with BPH. During the study, no decrease in blood pressure was observed while taking silodosin at a dose of 8 mg per day, which indicates the safety of its use in patients with AUR caused by BPH.

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