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Experience of Long-Term Use of Afala in Benign Prostatic Hyperplasia

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ABSTRACT

The use of ultra-low doses of antibodies to the prostate-specific antigen (afala) for long-term treatment of benign prostatic hypertrophy in patients with moderately severe symptoms can quickly and effectively reduce irritative and obstructive symptoms, significantly reduce the volume of residual urine, and increase the speed of urination. Afala therapy is indicated for patients with stage I-II benign prostatic hyperplasia with moderately severe symptoms.

Benign prostatic hyperplasia (BPH) occurs in almost all older men. According to autopsy data, morphological signs of BPH are recorded at the age of 40-50 years in approximately 25% of men, 50-60 years old - in 50%, 60-70 years old - in 65%, 70-80 years old - in 80% and 80-90 years old - in 90% [1,6,8]. However, it is believed that the clinical manifestations of the disease occur only in 25-50% of patients with micro or macroscopic signs of BPH, and only 50% of them seek medical help [7,9]. Symptoms of the disease may vary. To assess their severity, the international system of total assessment of symptoms in diseases of the prostate gland (IPSS) is used. Although it does not allow diagnosing BPH and is a subjective indicator, nevertheless, its results and data from other research methods (digital rectal examination, ultrasound of the kidneys, bladder and prostate, uroflowmetry, urinalysis, assessment of creatinine levels, prostate-specific antigen (PSA) in serum and, sometimes, cystoscopy and biopsy of the prostate) make it possible to create various algorithms for medical tactics in BPH, as well as to objectively assess the patient's condition and monitor the results of treatment. Based on them, the urologist can recommend expectant management, prescribe medication, suggest minimally invasive treatments, or refer the patient for surgery. In recent years, there has been a steady downward trend in the number of patients requiring surgical interventions for BPH. This is facilitated by the widespread introduction of medical and minimally invasive methods of treatment. However, as interventions become less invasive, the number of patients receiving treatment increases [10]. Among drug treatments, α1-blockers (AB) and 5α-reductase inhibitors have found the most widespread use. α1-ABs used to treat BPH differ in selectivity for α1-adrenergic receptors and duration of action. The clinical efficacy against BPH and the safety of all original α1-ABs are approximately the same. They increase the maximum urinary flow rate by 1.3-3.5 ml/s (20-30%) and reduce the IPSS score by 1.3-4.7 (2050%) compared with placebo [4]. When prescribing a1-

AB to patients with BPH, it is necessary to take into account the effect of these drugs on other organs and systems, in particular, blood vessels and the central nervous system. At the same time, such side effects of the action of a:-AB as hypotension, especially orthostatic, dizziness, fatigue, fatigue, nasal congestion and ejaculation disorders, in some cases encourage patients to stop taking the prescribed drugs. Finasteride is a competitive selective inhibitor of type II 5-a-reductase. Many studies have convincingly proven that finasteride significantly reduces the volume of the prostate by about 20%, increases the maximum urination rate by 0.2-1.8 ml / s and reduces the total IPSS score by 0.6-2.2. The PSA level under the influence of finasteride decreases by about 2 times. Compared with placebo, regular use of finasteride for 2 years reduced the incidence of acute urinary retention by 75% and reduced the indication for surgical treatment by a third [10]. At the same time, 12% of patients have a side effect of the drug on the genital area: in 3.4–3.7% of patients, libido decreases, in 2.7%, ejaculation is disturbed, and in 1.7–3.7%, erectile dysfunction develops [4]. The known disadvantages and side effects of the use of a1-AB and finasterides, both in monotherapy and in combination, contributed to the development and creation of a drug that does not cause the described negative effects. This drug was afala. The drug has biological activity due to the potentiation of ultra-low doses of antibodies. It contains affinity-purified antibodies to PSA and excipients (lactose, crystalline cellulose, calcium stearate / magnesium stearate, aerosil). A mixture of homeopathic dilutions of C12, C30 and C200 - 0.003 g. According to the developers, the action of afala is based on the ability of antibodies to the endogenous regulator not to block, but to modify the activity of the target molecule. Experimental studies have shown that afala is able to regulate the balance of growth factors in the prostate tissue. The drug stimulates the antiproliferative and angiostatic activity of PSA. The mechanism of action of afala presumably lies in the modification of the functional activity of endogenous PSA, which regulates the balance of growth factors responsible for the metabolism and normal growth of prostate tissue. Given that PSA is a factor in the pathogenesis of BPH, the modulating effect of ultra-low doses of anti-PSA antibodies is used to normalize the physiological activity of PSA in the presented chain. Afala normalizes the balance of growth factors in the prostate tissue, which leads to an increase in the concentration of zinc and the normalization of metabolic processes, a decrease in proliferation, a decrease in aseptic inflammation and the restoration of diuresis. The pathogenetic mechanism of action of the drug provides a complex effect of afala on all clinical components of BPH (inflammation, proliferation, impaired diuresis), comparable to the combined therapy of a1-AB and 5-a-reductase inhibitors [5].

Purpose of the study: The aim of the study was to investigate the safety, tolerability and clinical efficacy of afala oral tablets in patients with BPH during long-term treatment.

Metirals and methods: The study involved 30 people aged 53-86 years (average 71.1+3.4 years) with clinical manifestations of BPH stage I-II. Patients with a PSA level <4 ng/ml and a total IPSS score of <7 or >18 were selected for the study.All patients received afala 2 tablets 2 times a day per os as monotherapy for 7 months. The maximum observation period is 10 months.Simultaneous use of a:-AB and 5-a-reductase inhibitors was excluded. All patients underwent a comprehensive examination, including history taking; physical examination, measurement of blood pressure; filling out questionnaires (IPSS, IIEF-5); digital rectal examination; transabdominal ultrasound examination of the kidneys and bladder; uroflowmetry; transrectal ultrasound (TRUS) of the prostate; laboratory research (general blood and urine tests, biochemical blood tests: total protein, glucose, creatinine, urea, bilirubin, PSA); consultations of related specialists; ECG; multifocal biopsy of the prostate (according to indications). The clinical efficacy of afala was determined in accordance with the positive dynamics of the main diagnostic criteria and parameters, such as: the patient's overall subjective assessment of his condition during the study (improvement, deterioration, no change, side effects); dynamics of the

total score on the IPSS and IIEF questionnaires; quality of life (QoL); blood pressure control; uroflowmetry; determination of the volume of residual urine; TRUS of the prostate; PSA level.

Results of the study: Dynamics of the studied parameters in patients who took afala and the effectiveness of treatment (M±m)

Parameter	Observation period, months					Efficiency, %
	initially	1	3	6	7	
IPSS	14.5±2.4	8.3±0.5*	8.2±0.5	8.3±0.4	8.2±0.2**	+56.7
QoL points	4.8±0.5	2.8±0.2*	2.7±0.2	2.5±0.1	2.5±0.1**	+53
Maximum urination rate, ml/s	8.2±2.9	12± 1.8*	11.8±1.9	12.3±2.1	13.8±2.5**	+68
Volume of residual urine,	156±47	114±56*	96.4±48	87.2±39	70.2±35**	+56.3
Prostate volume, cm3	57.8±14.6	54.6±15.9	57.8± 15.1	58.5±14.2	56.9±15.7	+0.1
PSA, ng/ml	2.0±1.7	1.8±0.6	2.1±1.1	2.3±1.2	2.5±1.1	-25

Note. *p<0.05, **p<0.001 compared to baseline.

The results of the primary examination made it possible to give the initial characteristics of the study group of patients. The largest number of patients (60%) was aged 60-80 years. The duration of the disease was 2-20 years (average 7.0+6.3 years). The severity of clinical symptoms according to IPSS was 11-18 (mean score 14.5+2.4) and the quality of life score (Pob) was 3-6 (mean 4.8+0.5). At the same time, nocturia was observed in all patients from 1 to 8 times (on average 4.8+2.8 times). The volume of the prostate, according to TRUS, was 14-120 cm3 (mean 57.8+14.6 cm3). According to this indicator, patients with a prostate volume of 40-80 cm3 prevailed (70%). The amount of residual urine varied from 0 to 230 ml (mean 156+47 ml). In 16.7% of patients there was no residual urine, in 63.3% it was determined up to 100 ml and in 20% more than 100 ml. All patients complained of a weakening of the urine stream. With uroflowmetry, the maximum urination rate was 5-12 ml/s (mean 8.2±2.9 ml/s), the level of total PSA was 0-4.7 ng/ml (mean 2.0±1.7 ng/ml). We considered it possible to include one patient in the study group with a PSA value >4 ng/ml with a large prostate gland, who had a multifocal prostate biopsy several months ago and no malignant growth was detected. Of the comorbidities, 36.7% of patients had hypertension, 20% had chronic prostatitis, 10% had type 2 diabetes mellitus, and 3.3% had hemiparesis after a hemorrhagic stroke. In addition, 1 patient underwent palliative transurethral resection of prostate adenoma 10 years ago. Prior to the start of the study, 10% of patients had been taking a:-AB for a long time (more than 2 years), the rest of the patients did not receive treatment for BPH. Patients taking a:-ABs were advised to refrain from taking them for the duration of the study. The effectiveness of treatment was assessed monthly, comparing the obtained data with the initial data (table). Patients subjectively noted the positive effect of afala on the 5-7th day after the start of treatment. The volume of residual urine during the observation period decreased by 56.3%. Already after 4 weeks, the following indicators significantly changed and remained approximately at the same level in the future: IPSS decreased by 56.7%, nocturia decreased by 47.4%, pob improved by 53%, maximum urination rate increased by 68.5%. No statistically significant change in prostate volume was found. By the end of the study, an increase in the level of total PSA was noted, but these data are not statistically significant. During the observation period, no patient dropped out of the study,

complications or side effects were not observed. Patients who previously received a:-AB and stopped taking them, did not notice a deterioration in their condition during treatment with afala. In 17% of patients who started and completed the course of treatment 3 months earlier than others and did not receive any subsequent treatment, the disease progression did not occur during dynamic monitoring. After the end of the study, one patient underwent transurethral resection of prostate adenoma, despite the fact that as a result of treatment with afala, not only stabilization of the process occurred, but also some subjective and objective improvement. However, the volume of residual urine remained relatively large (150 ml), and the patient was not completely satisfied with his quality of life.

The results of our work largely confirm the data of other researchers [2, 3]. In 3 patients, the level of serum PSA increased progressively. By the end of the study, it increased by 2-3 times and exceeded 4 ng/ml, in 1 patient it was 5.7 ng/ml. At the same time, the dynamics of clinical manifestations was positive. These patients were extensively examined for prostate cancer, including polyfocal prostate biopsy and contrast-enhanced MRI, and no malignancy was found. Thus, long-term use of afala is effective in the treatment of patients with stage I-II BPH, reduces irritative and obstructive symptoms, significantly reduces the volume of residual urine, and increases the rate of urination. No side effects or complications have been reported with Afala. Nevertheless, further study of the drug is required in terms of selecting the optimal dose and duration of treatment, as well as the effect on PSA levels.

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