Efficiency of Afala in Complex Therapy of Patients with Chronic Prostatitis

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The use of afala in complex treatment of patients with chronic prostatitis improves the efficiency of therapy and prolongs its positive results. The preparation is well tolerated, has no contraindication, and can be combined with other drugs. Afala is indicated for patients with stages II and IIIa chronic prostatitis from the first day of therapy.

Key Words: *chronic prostatitisl prostate-specific antigen; afala*

Preparations containing ultralow doses of antibodies are the mildest drugs for pathogenetic therapy of patients with chronic prostatitis (CP) and benign hyperplasia of the prostatic gland (PG). These preparations have practically no side effects and contraindications. Afala, one of the newest preparations in this class, contains ultralow doses of affinity-purified antibodies to prostate-specific antigen (PSA).

PSA, a marker of prostatic diseases, is a glycoprotein belonging to the class of proteases with chymotrypsin-like activity. PSA is produced by secretory epithelium of PG, is secreted into the urethra, and liquefies the ejaculate; 0.1% of the total amount of PSA penetrates through the basal membrane into the blood.

Elevated serum content of PSA can be a result of PG cancer, acute and chronic prostatitis, malignant hyperplasia of PG, ischemia or infarction of PG, and ejaculation 24 h before the study.

Elevated PSA level in prostatitis is a result of impaired barrier functions of prostatic epithelial cells, their basal membrane, and basal membrane and endothelium of blood vessels [3]. Active inflammation (acute or chronic at the sage of exacerbation) impairs the integrity and increases permeability of the prostatic epithelium. Being a highly active proteolytic enzyme, PSA released into tissues aggravates inflammation. Afala produces a normalizing effect on the epithelium of PG, which implies its efficiency in complex therapy of patients with prostatitis.

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MATERIALS AND METHODS

We analyzed the results of therapy of 78 patients with CP (stages II and IIIa) aging 28-54 years (mean 32.8±3.4 years); history of CP varied from 2-14 years (mean 6.4±2.1 years). In all patients, uroflowmetry and complex clinical, laboratory, X-ray, bacteriological, and ultrasonic examinations (directed among other things, to exclusion of tuberculosis) were performed before the start of treatment. Other exclusion criteria were oncological diseases of any localization, diabetes mellitus and cardiovascular diseases at the stage of decompensation, urolithiasis, benign hyperplasia of PG, developmental abnormalities of the urinary bladder and PG, and the presence of foreign bodies in the urinary bladder.

The patients were divided into 3 groups: group 1 patients (n=28) received etiotropic therapy with levofloxacin and standard pathogenetic treatment; group 2 patients (n=32) received complex etiopathogenetic therapy as in group 1 and afala (2 sublingual tablets 4 times a day); group 3 patients (n=18) received standard etiopathogenetic therapy and placebo.

Complex etiopathogenetic therapy was administered for 1 month; patients of groups 2 and 3 received afala/placebo for one more month after completion of the basic course.

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The efficiency was evaluated by the following parameters: decrease in leukocyte count in PG secretion, increase in secretion saturation with lecithin corpuscles; bacteria-negative smears, parameters of uroflowmetry and transrectal ultrasonic examination, alleviation of pain, and changes in spermogram parameters. The severity of dysuria (stranguria, nicturia, pollakiuria, decreased uroflow rate) was evaluated by a 6-point scale (0: no symptom, 1: weak symptom; 2: moderate symptom; 3: pronounced symptom); the mean and maximum uroflow rates were taken into account.

RESULTS

Bacterial CP (stage II) and abacterial CP (stage IIIa) with signs of inflammation were diagnosed in 37 and 41 patients, respectively. We believe that IIIa stage CP is usually latent bacterial (infection) prostatitis, because it is difficult to imagine another reliable cause of pronounced aseptic inflammation. Our previous studies [1,2] confirmed this hypothesis, which was the reason for administration of antibacterial therapy to all patients with pronounced signs of active inflammation in PG.

Initially, microbial flora was detected in gonadal exprimates from 73 patients: *E.coli* in 18 patients (CFU 1×10^4 ml), *Staphylococcus aureus* and *Staphylococcus epidermidis* in 19 patients (CFU 1×10^5 ml each). Gram-positive and gram-negative flora was visualized in stained smears from 62 patients (79.5%). In 29 patients, DNA of intracellular sexually-transmitted infections (mycoplasma, ureaplasma, and chlamydia) was detected.

The most common complain was pain in the perineum (in 63 patients, 80.8%) and in the perineum and testes (in 15 patients, 19.2%). No painless forms of CP were observed. All patients complained of urination disturbances, the mean IPSS score was 9.7, the average uroflow rate (Q_{ave}) was 11.4 ml/sec, and the mean uroflow rate (Q_{max}) was 16.2 ml/sec. The volume of PG was on average 28.4 ml; in none patients residual urine was observed. Heterogeneity of PG echostructure was noted in all patients, prostatolithiasis was diagnosed in 4 patients.

Twenty-four patients (30.8%) complained of decreased libido, weak or painful erection was noted in 18 (23.1%) and 7 (8.9%) patients, respectively. Analysis of ejaculate revealed pyospermia in 59 patients (75.6%), oligospermia in 39 patients (50%), and teratozoospermia in 29 patients (37.2%). Microscopy of native PG secretion showed increased leukocyte count (from 35 to complete covering of the visual field). The results of therapy were evaluated after 10, 30, and 60 days from the start of treatment.

Afala exhibited a pronounced analgesic effect (Fig. 1) comparable to that of nimesulide: by day 10, weak pain persisted in 4 (12.5%) patients of group 2, while after 4 weeks none patients complained of pain in this group. This result remained throughout

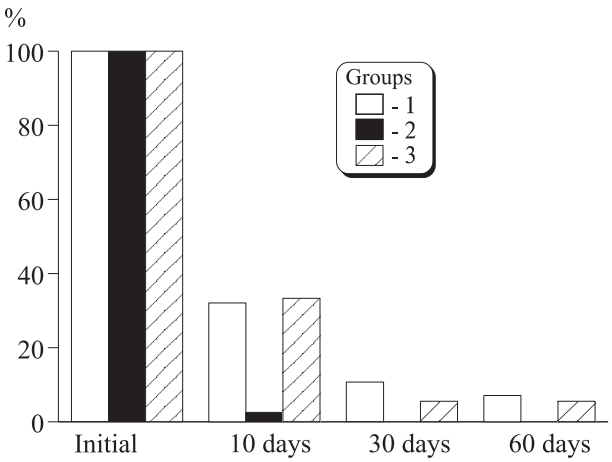

Fig. 1. Dynamics of pain in CP patients.

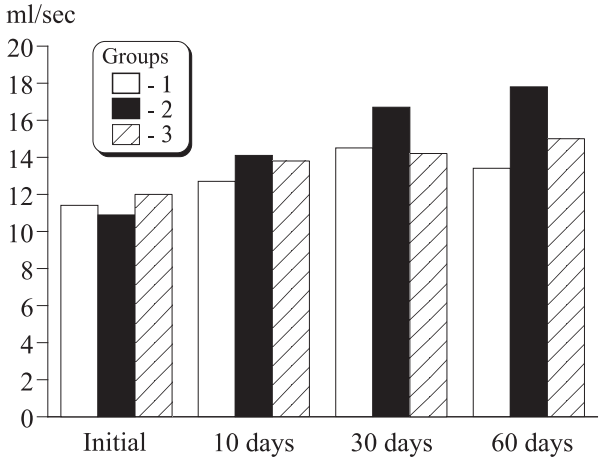

Fig. 2. Dynamics of Q_{ave} in CP patients.

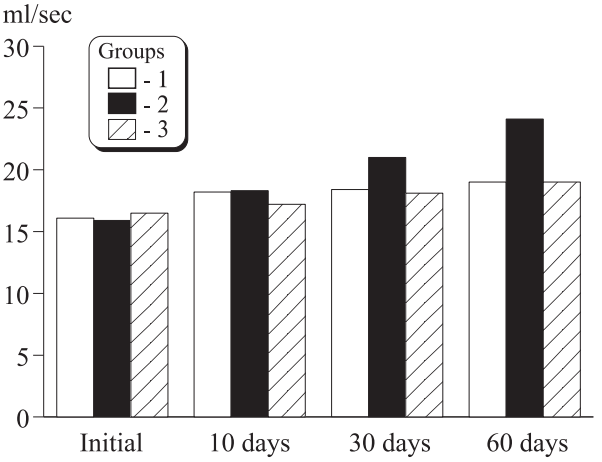

Fig. 3. Dynamics of Q_{max} in CP patients.

TABLE 1. Efficiency of Therapy in CP patients (*M*±*m*)

Sign	Group 1		Group 2		Group 3	
	initial	after 30 days	initial	after 30 days	initial	after 30 days
Pain, score	2.80±0.07	0.40±0.08	2.90±0.07	0	2.90±0.06	0.30±0.04
Dysuria, score	2.4±0.1	0.30±0.08	2.30±0.09	0	2.5±0.1	0.30±0.06
Erectile dysfunction, score	1.90±0.09	0.80±0.05	2.00±0.09	0.70±0.04	1.80±0.07	0.90±0.03
Number of leukocytes per field of view	58.3±7.8	14.1±1.1	64.2±5.6	9.2±3.7	61.7±6.4	10.3±4.9
Lecithin grains, score	0.7±0.1	2.7±0.2	0.7±0.1	2.9±0.1	0.6±0.1	2.7±0.1
Microbial flora (culture and/or microscopy)	+	—	+	—	+	—

the observation period. At the same time, 9 patients in groups 1 (32.1%) and 6 patients in group 3 (33.3%) still complained of pain after 10-day treatment, the difference from group 2 was significant.

The antibacterial effect of levofloxacin was similar in all groups, after 1-month therapy no microflora was detected by bacteriological and cultural methods (Table 1).

The uroflow rate considerably increased in group 2 patients and this effect remained throughout the observation period (Figs. 2 and 3).

In none groups, transrectal ultrasonography of PG revealed no appreciable changes in PG echostructure after treatment. In group 2 patients, toxic effects of antibacterial therapy on spermogram parameters were reduced by afala treatment (by 57.4%): terato- and oligozoospermia were significantly less frequent in this group by the end of treatment; by day 60, the quantitative and qualitative parameters of ejaculate surpassed the initial values in group 2, which was not attained in groups 1 and 3. No complications or side effects of afala treatment were noted.

The final result (with consideration for clinical and laboratory signs of CP) was defined as excellent (the absence of pain and dysuria, normalization of PG secretion, negative smears, improvement of functional parameters) good, and satisfactory. In group 1 patients, excellent and good results were attained in 23 patients (82.1%). In group 2 patients, excellent and good results were attained in 30 (93.8%) and 2 (6.2%) patients, and in group 3 in 15 (83.3%) and 3 patients (16.7%), respectively.

Thus, the use of afala in complex treatment of patients with chronic prostatitis improves the efficiency of therapy and prolongs its positive results.

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