Clinical Use of Afala in the Therapy of Chronic Prostatitis

V. N. Tkachuk

Translated from *Byulleten' Eksperimental'noi Biologii i Meditsiny*, Vol. 148, Suppl. 1, pp. 61-63, August, 2009
Original article submitted August 1, 2008

The efficiency of afala in the therapy of chronic abacterial prostatitis was demonstrated. The preparation considerably improved urodynamics, reduced pain syndrome and inflammation, decreased prostate volume, improved patient's quality of life, and restored microcirculation in the prostate. No changes in blood, urine, and ECG parameters were noted. No side effects requiring afala withdrawal were recorded.

Key Words: *prostatitis; prostate; afala*

Chronic prostatitis is now a prevalent disease; 20-70% men of reproductive age suffer from this disease [1,2,6,9]. Chronic prostatitis considerably decreases patient's quality of life and is often accompanied by psychosomatic disorders, neuroses and depression [6, 8,12]. According to modern views, chronic abacterial prostatitis (CAP) and chronic bacterial prostatitis are now diagnosed in 90 and 10% cases, respectively [3,6,11].

Therapy of patients with CAP is a complex and not completely solved problem. More than 20 groups of drugs are now proposed for the treatment of CAP [4,6], but no substantiated approaches to the therapy of this disease are developed yet.

At the same time, afala was never used for the treatment of CAP.

Patients with CAP have increased serum level of prostate-specific antigen (PSA) [5], which is determined by increased permeability and impaired integrity of tissue barriers, but not increased production of PSA by epithelial cells of the prostate. Serum level of PSA reflects activity of the inflammatory process in the prostate [7].

The acting matter of afala is affinity-purified antibodies to PSA in ultralow doses (a mixture of homeopathic dilutions C12, C30, and C200). The effect of the preparation is based on modulation of physiological activity of endogenous PSA. Afala normalizes metabolic processes in the prostate, increases zinc concentration, reduces manifestations of aseptic inflammation and edema, and normalizes functional state of the prostate [10], which was the reason for application of this preparation in patients with CAP.

Here we evaluated the efficiency and safety of afala in patients with CAP.

MATERIALS AND METHODS

The study included 25 men aging 20-46 years (mean age 28.9 years); CAP history varied from 4 to 9 years (mean 2.9 years); the diagnosis was verified by clinical, laboratory, ultrasonic, and Doppler investigations.

All patients completed the course of afala treatment (2 sublingual tablets 4 times a day, independently of meals). The duration of treatment was 30 days.

The study planned 2 visits (before and after treatment), which included history taking, physical examination, symptom recording using International NIH-CPSI scale, transrectal ultrasonography of the prostate (TRUS), analysis of the ejaculate with measurement of citric acid concentration, and bacteriological analysis of the ejaculate. For evaluation of urination functions, uroflowmetry was performed. Blood flow in the prostate was measured by color Doppler ultrasonography on an Aloka-Prosaund-4000 apparatus. Sexual life of patients before and after treatment was evaluated.

Urology Hospital, I. P. Pavlov State Medical University, St.Petersburg

0007-4888/09/1482-0312

RESULTS

Symptomatic improvement after therapy was attained in 24 patients.

Afala had a positive effect on pain syndrome and urination disorders in CAP patients. For instance, the intensity of the pain syndrome by NIP-CPSI scale decreased by 2.5 times compared to the initial level (Table 1). Urination disorders were reduced by 2.8 times. This pronounced symptomatic effect determined considerable improvement of patient's quality of life (Table 1).

The severity of the main symptoms (IPSS score) also considerably decreased after treatment. Afala treatment improved urination; the maximum uroflow rate increased (Table 1).

Blood circulation in the prostate appreciably increased after afala treatment (according to transrectal ultrasonography with color Doppler mapping). Depletion of the vascular pattern and reduced circulation in arteries and veins of the prostate were typical of CAP patients, while after treatment considerable improvement of circulation was noted. The density of vascular plexuses, peak systolic blood flow rate in arteries, linear blood flow velocity in veins of the prostate and blood flow volume appreciably increased after treatment.

Circulation improvement reduced edema in the prostate, alleviated pain syndrome, and decreased the severity of urination disturbances.

Normalization of echostructure of the prostate against the background of afala treatment was observed in 22 patients, whereas before treatment normal homogenous echostructure of the prostate was found in only one patient. The decrease in the volume of the prostate by 4.6 cm^3 (Table 1) can be explained by alleviation or disappearance of edema and normalization of circulation in the prostate.

In 12 patients with CAP, decreased motility of spermatozoa in the ejaculate was revealed before afala treatment, while after treatment this symptom was diagnosed in 6 patients. The volume of ejaculate increased, its viscosity and the time of ejaculate liquefaction decreased, and, most important, the concentration of citric acid increased, which attested to functional improvement of the prostate in patents with CAP after afala treatment.

Before treatment, 20 CAP patients complained of sexual dysfunction, in 17 patients this was the main cause of their visit to a doctor. After treatment, the sexual function improved in 15 of 20 patients.

The level of PSA before treatment varied from 0.9-4.2 ng/ml, while after treatment this parameter

TABLE 1. Effect of Afala on the State of CAP Patients (*M*±*m*)

Parameter	Before treatment	After treatment
Intensity of pain syndrome, score	11.59±0.88	4.67±0.72***
Urination disorders, score	12.25±0.56	4.42±0.32***
Quality of life (parameters of dysfunctions), score	11.05±0.81	4.11±0.45***
Symptoms by IPSS scale, score	12.2±0.9	5.3±0.8***
Maximum uroflow rate, ml/sec	10.9±2.2	17.8±1.2**
Density of vascular plexus in the prostate, per 1 cm^2	0.920±0.007	1.44±0.15**
Peak systolic blood flow rate in arteries of the prostate, cm/sec	8.86±0.91	12.95±1.31*
Linear blood flow rate in veins of the prostate, cm/sec	3.29±0.55	5.46±0.44**
Volume blood flow, liter/min	0.015±0.003	0.026±0.004**
Volume of prostate, cm^3	24.9±2.2	20.3±2.5
Volume of ejaculate, ml	3.3±0.5	4.7±0.9**
Viscosity of ejaculate, ml	18.0±2.5	14.2±1.2*
Time of ejaculate liquefaction, min	25.9±4.5	15.2±4.0**
Concentration of citric acid in ejaculate, mol/liter	17.5±1.9	24.8±2.1*
PSA, ng/ml	3.6±0.7	2.1±0.5*

Note. *p<0.05, **p<0.01, ***p<0.001 compared to the corresponding values before treatment.

decreased by 1.7 times. However, we believe that definite conclusions about the level of PSA can be made not immediately after 30-day afala course, but in a more delayed period.

No undesirable events were recorded against the background of afala therapy.

Thus, our clinical study demonstrated high efficiency and safety of afala in the therapy of patients with CAP. Clinical effect of afala developed by the end of the first month of treatment. Afala therapy for 30 days (8 tablets per day) led to a considerable alleviation of the pain syndrome, produced a positive effect on urination parameters, improved patient's quality of life, normalized circulation in the prostate, led to decrease or disappearance of edema in this organ, increased motility of spermatozoa in the ejaculate, and improved sexual function in CAP patients.

Afala is a principally new pathogenetic means for the treatment of patients with CAP.

REFERENCES

1. N. A. Lopatkin, *Manual in Urology* [in Russian], Moscow (1998), Vol. 2, 400-439.
2. O. B. Loran and A. S. Segal, *Proceedings of X Russian Urologist Congress* [in Russian], Moscow (2002), pp. 209-222.
3. D. Yu. Pushkar', *Proceedings of Plenary Session of Administration of Russian Urologist Society* [in Russian], Moscow (2004), pp. 289-314.
4. A. V. Sivkov, V. N. Oshchepkov, and A. A. Egorov, *Ibid.,* pp. 216-230.
5. V. N. Tkachuk, *Proceedings of Plenary Session of Administration of Russian Urologist Society* [in Russian], Perm' (1994), pp. 4-9.
6. V. N. Tkachuk, *Chronic Prostatitis* [in Russian], Moscow (2006), p. 112.
7. S. Al-Shykri and V. N. Tkachuk, *Abstracts of First Russian-Finnish Symposium on Urology.* St.Petersburg (1998), pp. 13-17.
8. J. J. de la Rosette, M. R. Hubregste, E. J. Meuleman, *et al*., *Urology,* **41**, No. 4, 301-307 (1993).
9. S. A. Kaplan, M. A. Volpe, A. E.Te, *J. Urol.,* **171**, No. 1, 284-288 (2004).
10. A. Martyushev-Poklad, V. Petrov, J. Dugina, *et al*., *Abstracts of 8th International Congress of Andrology.* Seoul (2005), pp. 183-188.
11. A. Schaeffer, W. Weidner, G. A. Barbalias, *et al., Eur. Urol. Suppl*.**2**, No. 2, 1-4 (2003).
12. K. Wenninger, J.R. Heiman, I. Rothman, *et al., J. Urol.,* **155**, No. 3, 965-968 (1996).