This model of phlebothrombosis can be used in experimental studies of structural and ultrastructural changes with subsequent choice of optimal terms of thrombectomy.

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Immunological Aspects of Alisat in Patients with Diabetes Mellitus

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The effect of long-term (12 months) therapy with the garlic-containing preparation Alisat on some parameters of immunity is studied in 52 patients with noninsulin-dependent diabetes mellitus (type II). It was found that Alisat increases natural resistance in the beginning of therapy and induces no remote immunopathological responses.

Key Words: *Alisat; diabetes mellitus; immune system*

Garlic-containing preparations produce various effects in numerous pathological states [1-3]. The information regarding the use of these preparations in patients with diabetes mellitus (DM) is scarce [4]. We failed to find any data on the effect of garlic preparations on the immune system of DM patients.

In the present study we investigated the time course of some immunity parameters in patients with type II DM (noninsulin-dependent) treated with Alisat, a garlic-containing preparation of prolonged action.

MATERIALS AND METHODS

The study enrolled 52 patients with type II DM (18 men and 34 women) aged 42-66 years (mean age 52±1.5 years). The duration of the disease varied from 1 to 20 years. Ten patients had mild DM, 41 patients had moderate DM, and 1 patient had severe DM. In 8 patients diet was used as sugar-reducing monotherapy; other 44 patients received oral hypoglycemic preparations. In all patients, carbohydrate metabolism was compensated or subcompensated. Alisat was prescribed as 1 tablet (300 mg garlic powder) 2 times daily at a 12-h interval. The patients received no special diet or other medication. The immune status was assessed by the factors of nonspecific resistance and specific humoral immunity. The activity of phagocytosis was expressed as the phagocytic index. The intensity of phagocytosis was represented as phagocytic number in experiment with nitro blue tetrazolium (NBT) with evaluation of spontaneous and stimulated phagocytosis. The contents of M, G, and A immunoglobulins were determined by Mancini immunodiffusion technique. The concentration of circulating immune complexes was measured by precipitation in the presence of 4% polyethylene glycol-600. The patients were examined

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TABLE 1. Immune Parameters of Healthy Subjects and Patients with Type II DM (*M±m*)

Parameter	Healthy subjects (*n*=14)	DM patients (*n*=52)
Phagocytic index	51.05±6.25	40.0±4.71
Phagocytic number	4.71±0.92	5.15±0.55*
NBT test:		
spontaneous	8.66±1.55	6.97±1.09
stimulated	29.85±5.48	24.27±4.26
Immunoglobulins:		
M	1.04±0.24	1.13±0.34
G	7.94±1.36	9.41±0.77
A	1.82±0.34	2.09±0.46
Circulating immune complexes	93.33±1.72	94.02±4.33

Note. *$p<0.05$ compared with healthy subjects.

before therapy, 1 (*n*=49), 3 (*n*=30), 6 (*n*=42), 9 (*n*=43), and 12 (*n*=40) months of the therapy. Control group consisted of age-matching 14 healthy subjects and 14 male and female patients with type II DM.

Data were processed by the methods of variational statistics.

RESULTS

In DM patients, the mean phagocytic index was lower than the mean physiological value (Table 1). In 25 patients (48%), the phagocytic number was significantly lower than in healthy subjects. The intensity of phagocytosis was minimal, remaining within physiological norm. Phagocytic number significantly decreased in 36 patients (69.2%). A simultaneous decline in the activity and intensity of phagocytosis was observed in 18 patients (34.8%).

The mean values of the NBT test were within the norm in all DM patients. In 32 patients (61.5%), the index of stimulated phagocytosis in NBT test was lower than in healthy subjects. In 24 patients (46.1%) a decrease in this index coincided with suppression of phagocytosis.

The contents of IgM and IgA were at the upper level and that of IgG at the lower level of physiological norm. Individual analysis revealed considerable dysimmunoglobulinemia in 27 patients (51.9%).

Blood concentration of circulating immune complexes in patients did not differ from that in healthy subjects.

Alisat therapy improved general condition of all DM patients, reduced the occurrence of acute viral

TABLE 2. Effect of Alisat on Immune Parameters of Patients with Type II DM (*M±m*)

Parameter	Therapy, months				
	1 (*n*=49)	3 (*n*=30)	6 (*n*=42)	9 (*n*=43)	12 (*n*=40)
Phagocytic index	45.70±5.36	30.0±9.01	45.60±8.68	44.73±6.15	45.66±5.57
	60.85±7.27	64.45±2.14*	52.04±4.57	52.04±2.66	45.25±3.47
Phagocytic number	6.07±0.80	3.74±0.91	5.51±0.79	5.06±0.58	4.74±0.67
	5.69±1.67	5.82±0.50*	5.82±0.37	5.57±0.20	4.93±0.26
NBT test:					
spontaneous	6.55±2.12	7.33±2.87	6.80±1.07	7.04±0.53	6.37±0.46
	18.85±2.86**	10.63±1.48	10.80±3.39	8.94±1.38	7.46±1.45
stimulated	17.33±4.46	14.14±4.11	23.85±2.69	24.97±1.76	21.22±4.45
	36.20±4.56**	33.65±3.65**	31.28±6.56	23.40±4.07	27.34±2.10
Immunoglobulins: M	1.09±0.36	1.12±0.40	1.26±0.45	1.19±0.33	1.23±0.56
	1.08±0.39	0.90±0.23	1.08±0.39	1.10±0.37	1.13±0.46
G	8.64±1.40	8.76±1.15	9.05±1.41	9.70±1.30	9.09±1.74
	7.87±1.52	8.05±1.55	7.72±1.50	7.93±1.45	7.64±1.46
A	1.84±0.51	1.99±0.53	2.27±0.35	2.30±0.60	2.10±0.76
	1.80±0.48	1.68±0.49	1.81±0.42	1.75±0.48	1.76±0.50
Circulating immune complexes	93.82±4.37	93.30±4.40	93.60±4.59	93.80±4.40	91.05±5.12
	92.41±5.42	92.61±2.92	92.23±3.42	92.74±2.69	92.46±1.75

Note. Numerator is the value before therapy, denominator is the value after therapy. *n* is the number of patients. *$p<0.05$, **$p<0.01$ compared with the value before therapy.

infections and myalgias, and stimulated phagocytosis (Table 2). The phagocytic index and phagocytic number increased after 3 months of the therapy, remaining practically unchanged throughout the entire observation period. Both after 1 and 3 months of the therapy, the intensity of stimulated phagocytosis in the NBT test increased, and remained practically unchanged after 6 and 12 months of Alisat treatment. Positive dynamics of this parameter was observed in 21 patient (40.4%).

There were no statistically significant changes in the contents of immunoglobulins and circulating immune complexes during 12 months of the therapy.

In control DM patients, the analyzed parameters of immunity did not change significantly throughout the entire observation period.

Thus, reduction of phagocytosis and stimulated phagocytic activity in the NBT test occurring in patients with type II DM may lead to the development of pyo-inflammatory processes. This possibility is indirectly confirmed by dysimmunoglobulinemia. Alisat improved general condition of DM patients and their immunological status, stimulating nonspecific resistance within the first 3 months. There were no negative immunological consequences in remote periods. These results imply that Alisat can be recommended for the use in the complex treatment of patients with type II DM.

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