Succinate-Based Preparation Alleviates Manifestations of the Climacteric Syndrome in Women

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Clinical placebo-controlled study of Enerlit-Clima (bioactive succinate-based food additive) a showed positive effect of the preparation on general clinical and psychoemotional manifestations of the climacteric syndrome. A trend to an increase in estradiol level in early pathological climacteric and normalization of the endometrial status were observed.

Key Words: *Enerlit-Clima; succinates; climacteric syndrome*

Injection of succinate+glutamate mixture to animals reduced the threshold of the feedback signal perception by the hypothalamus in the hormone system and thus reduces the age-associated changes in the regulation of endocrine functions [1]. Enerlit-Clima (EC) preparation contains a composition of substrates (ammonium, magnesium, and calcium succinates, zinc fumarate, glycine, sodium glutaminate, tocopherol acetate). The preparation increased the ratio of the estrus phase in the estrus cycle in old animals from 0.18± 0.02 to 0.35±0.04, *i.e.* to the level characteristic of young adult animals. This paper seems to present the first clinical results of EC treatment.

MATERIALS AND METHOD

Seventy women with climacteric syndrome (CS; age: 9 patients aged 40-45 years, 28 aged 45-50 years, 25 aged 50-55 years, 5 aged 55-60 years, and 3 aged 60-61 years) were observed. The patients were divided into 2 groups receiving EC (2 capsules twice a day, main group, n=50) and placebo (control group, n=20) for 3 weeks. Clinical status of women was evaluated by Kupperman's method modified by E. V. Uvarova including gynecological examination and consultation of a psychiatrist. The level of actual anxiety was evaluated by the Spielberger-Khanin test [2]. Ultrasonic examination of the uterus and ovaries was carried out twice. Serum levels of total cholesterol, A-cholesterol, triglycerides, β-lipoproteins, LDL, and VLDL were measured on a BIOM-01M analyzer. Total protein and glucose were measured on a Hitachi analyzer, follicle-stimulating hormone, luteinizing hormone, and estradiol using GonadotropinIFA-FSH, GonadotropinIFA-LH, and Micropale Steroid Estradiol enzyme immunoassay kits. Prothrombin index was estimated.

The study was carried out by the blind control method. The data were processed using Microsoft Excel software. The results are presented as $M\pm m$ at p=0.05.

RESULTS

Subjective well-being of women receiving EC for 3 weeks improved significantly after a course of treatment. The patients noted alleviation of depression, anxiety, insomnia, and irritability (that is, 4 of 14 symptoms, most characteristic of CS and evaluated in scores from 0 to 3, Table 1).

After EC treatment the level of actual anxiety (Spielberger-Khanin test) decreased from 54.8±3.5 to 47.3±3.3 (p<0.05), while after placebo treatment from 53.1±4.7 to 50.0±3.9 (p>0.05).

Of 9 symptoms evaluated in the Kupperman test, 3 regressed significantly under the effect of EC: mani-

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festations of vestibulopathy decreased, tachicardia attacks became more rare, and the incidence of discomfortable conditions (chill) reduced (Table 2). The time course of blood pressure and headache, that tolerance and dermographism were similar after EC and placebo.

Enerlit-Clima treatment improved 2 of 11 neurovegetative characteristics of Kupperman test: sleeping (from 1.32±0.29 to 0.45±0.27, $p<0.05$ *vs.* placebo group) and the incidence of hot flushes (from 1.12±0.21 to 0.68±0.17, $p<0.05$). On the other hand, the incidence of hot flushes was the same after placebo treatment (1.22±0.25 and 1.05±0.25, $p>0.05$). The score of sleeping disorders in the placebo group was 1.35±0.51 before treatment and 0.95±0.50 after treatment.

The level of glucose in the peripheral blood decreased after a course of EC, other biochemical parameters remaining unchanged (Table 3).

Blood concentration of sex hormones varied in examined women, though blood for analysis was collected on days corresponding to the menstrual cycle

TABLE 1. Characteristics of Subjective Status of Examined Women (*M*±*m*, Score)

Parameter	Placebo		EC	
	before treatment	after treatment	before treatment	after treatment
Irritability	1.50±0.33	1.25±0.34	1.50±0.27	0.60±0.21*+
Depression	0.95±0.41	0.70±0.35	1.06±0.31	0.30±0.16*
Anxiety	1.40±0.38	1.05±0.30	1.64±0.30	0.52±0.20*+
Insomnia	1.55±0.46	1.20±0.48	1.42±0.31	0.44±0.20*+

Note. $p<0.05$ compared to: *value before treatment (comparison by the direct difference method), +placebo.

TABLE 2. Common Clinical Manifestations of the Climacteric Syndrome in Women (Kupperman Score; *M*±*m*)

Parameter	Placebo		EC	
	before treatment	after treatment	before treatment	after treatment
Vestibulopathies	0.55±0.30	0.55±0.30	0.72±0.25	0.38±0.5*
Tachicardia	1.25±0.51	0.90±0.46	1.24±0.29	0.98±0.28*
Chill	1.00±0.47	0.90±0.42	0.96±0.28	0.68±0.25*

Note. Here and in Table 3: *$p<0.05$ compared to the corresponding value before treatment (comparison by the direct difference method).

TABLE 3. Blood Plasma Biochemical Values in Examined Women (*M*±*m*)

Parameter	Placebo		EC	
	before treatment	after treatment	before treatment	after treatment
Total cholesterol, mmol/liter	4.92±0.54	5.55±0.64	4.62±0.31	4.83±0.44
A-cholesterol, mmol/liter	1.20±0.07	1.44±0.10	1.27±0.04	1.34±0.05
Atherogeneity coefficient, units	3.12±0.48	2.98±0.53	2.65±0.19	2.71±0.30
Triglycerides, mol/liter	1.50±0.26	1.41±0.59	1.27±0.11	1.36±0.16
β-Lipoproteins, mmol/liter	4.34±0.82	4.77±0.81	3.82±0.24	4.44±0.33
LDL, mmol/liter	2.95±0.44	3.60±0.49	2.69±0.22	3.38±0.30
VLDL, mmol/liter	0.69±0.12	0.78±0.18	0.57±0.05	0.65±0.07
Total protein, g/liter	68.92±2.23	71.89±2.78	71.08±1.59	75.11±1.23
Glucose, mmol/liter	4.85±0.26	4.68±0.24	4.73±0.14	4.19±0.16*
Prothrombin index, %	90.85±1.91	91.10±2.08	90.30±1.27	90.80±1.11

phase II (if there were menses). EC had virtually no effect on the time course of follicle-stimulating and luteinizing hormones, but a slight trend to an increase of estradiol level was observed, mainly in women with early pathological menopause.

According to ultrasonic findings, EC had no effect on the size of the uterus and ovaries, but slightly thinned the endometrium (from 4.58±0.95 to 3.97±0.83 mm; placebo group: from 3.38±0.99 to 3.62±1.22 mm). The endometrium became more homogeneous in the main group.

Three-week course of EC in women with amenorrhea of 3-9 months promoted restoration of menses-like discharge in 7 of 15 women. No effects of this kind were observed after placebo treatment.

Hence, the course of EC appreciably reduced some clinical psychoemotional and neuroendocrine manifestations of CS.

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