



Research Article

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Full-Scale Testing of Functional Product in Patients with Vegetative-Vascular Dysfunction and Chronic Cerebrovascular Disorder

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ABSTRACT

Background and Objectives: The long history of traditional medicine clearly demonstrates the role of nutrition in the prevention and treatment of the disease. Of particular importance in modern scientific medicine is the simultaneous use natural biologically active complexes and medicines. The objective of this study is to provide clinical evidence of the effectiveness and functional orientation of a new type of biologically active additives (BAA) in the patients with vegetative vascular dystonia and chronic cerebrovascular disorder. Methodology: The principles of the modern science of nutrition on the role of individual macro-and micronutrients, and minor components of food in the correction of metabolic disorders form the methodological basis of the research. Results: The biologically active additive "Sophia" was introduced in the diet of the patients for 4 weeks at a dose of one tablet, in combination with 50 mg of Trental per day (the 1st main group). The 2nd main group received an additional "Guta-Viva" additive. The 3rd (control) group received Trental only, at the prescribed dosage. The use of BAA had a positive effect on the relief of disease syndromes, and improved overall health. Conclusion: The antioxidant effect of the specialized product, as well as the improvement of metabolic processes in the brain, was noted. A conclusion was made that the test product can be an effective remedy in the treatment of moderately grave vegetative-vascular dystonia. BAA is well tolerated by the patients and does not cause side effects.

Key words: *Biologically Active Supplement, Functional Orientation, Efficiency, Central Nervous System, Complex Therapy.*

INTRODUCTION

The issues of prevention and complex treatment of nervous system diseases with the account of a nutritional factor are of current importance, given their prevalence and negative consequences for society.

The most widely spread pathology in neurological practice is vegetative-vascular dystonia, which is common in both young and older people. Vegetative-vascular dystonia has a wide range of clinical manifestations: headaches, dizziness, arterial pressure fluctuations, memory disturbance, irritability, tearfulness, aggression or depression, physical and psychological fatigue, emotional stress, and insomnia [1–5].

In the human body, 20% of the whole energy received is spent on the functioning of the brain, which cannot tolerate deficiencies of essential nutrients. For instance, a decrease in the glucose level in plasma below the norm (e.g., in diabetes, during prolonged fasting) may cause brain dysfunction [6-9].

Modern therapy employs a significant amount of medicines to improve the functionality of the central nervous system and metabolic processes. At the same time, importance is being increasingly attached to biologically active additives (BAA) based on natural components due to their milder and prolonged effect on the correction of the patient's metabolic disorders, which justifies their wide use in preventive and curative medicine [10-16].

In this paper, we studied the feasibility of using and also the effectiveness of "Sophia" BAA in the patients with the syndrome of vegetative-vascular dystonia. There is a lack of research in this field, which determines their novelty and social importance, given the prevalence of the pathology and its negative consequences for society.

The formulation of the new form of the specialized product intended for the multifactor support of the central nervous system (Table 1) is scientifically grounded.

Table 1. Prescription composition of BAA

Seq. No.	Component name	Content mg/tablet	% of adequate intake
1	Tyrosine	150	-
2	Antioxidant complex (Cifrol-5)	100	-
	Hesperidin	20	-
	Ascorbic acid	12.5	21
	Superoxide dismutase	12.5	-
	Hibiscus extract	11.5	-
	Vitamin E (tocopherol acetate)	5.0	34
	Catechin hydrate	5.0	20
	B-Carotene	1.75	35
	Coenzyme Q ₁₀	1.25	-
3	5-hydroxytryptophan	75	-
4	Glycine	75	-
5	Glutamic acid	75	-
6	P-aminobenzoic acid	75	75
7	Inositol	75	15
8	Schizandra extract	25	70
	Schizandra, NLT	0.35	
9	Motherwort extract	25	-
10	Gingko Biloba extract	20	-
	Flavanone glycosides, NLT	3.0	
11	Valerian extract	10	-
12	Vitamin B3 (nicotinamide)	10	50
13	Vitamin B5 (calcium pantothenate)	2.5	50
14	Vitamin B6 (pyridoxine hydrochloride)	1.0	50
15	Vitamin B1 (thiamine mononitrate)	0.85	57

MATERIALS AND METHODS

The study used data obtained from the examination and monitoring of 105 patients with vegetative-vascular dystonia, where the 1st (main group) consisted of 35 patients who received "Sophia" biologically active additive at a dose of 1 tablet during meals in combination with medicine Trental at a dose of 50 mg once a day. The treatment course was 4 weeks. The 2nd main group consisted of 35 patients who received "Sophia" BAA at a dose of 1 tablet during meals in combination with Trental BAA "Gutta-Viva" (1 g/day. Dissolve in a glass of water, take 1 hour before meals). The treatment course lasted for 4 weeks. The 3rd (control) group included 35 patients who received Trental only at a dose of 1 tablet once a day for 4 weeks. The patients were aged 38 to 50, and the average age was 42.2±5.3 years. The groups were randomized by age and gender, duration of the disease and disease severity. Vegetative-vascular dystonia was diagnosed in all the patients as moderate. All the patients complained about the deterioration of their condition, headache, dizziness, most often the deterioration of memorization and reproduction of the reads, and impaired concentration. Emotional-volitional disorders were recorded.

All the patients underwent a clinical examination. Besides the analysis of complete blood count and urine tests, the biochemical composition of blood was studied, the ECG and the electroencephalogram (EEG) were taken. All the patients were examined by a neurologist who noted that most of them had a neurological status in the form of muscle hypotension, half of them had a hypertensive syndrome and all of them had emotional-volitional disorders.

An examination of the psycho-emotional state was performed using the Beck Depression Inventory, the Zung Self-Rating Depression Scale, as well as the Sheehan Patient-Rated Anxiety Scale. Anxiodepressive disorders (ADD) were detected in 30 patients of the 1st main group, in 29 of the second group and in 30 patients in the control group. The mixed anxiety and depressive disorders dominated in almost 30 patients, both in the 1st, 2nd and 3rd groups. Out of 105 patients of the 3 groups, the ratio of depressive disorders in accordance with the criterion of the Beck Depression Inventory was in 29 patients. The patients that were feeling sad subsequently did not have a satisfaction of what had been before, were disappointed in themselves and needed additional conditions to get down to work. The average level of depression according to the criteria of the Zung Self-Rating Depression Scale was 62 to 63 points (average depression).

The high anxiety, as a stable personality trait, according to the SPRAS criteria was less than 80 points in each patient in each group. The anxiety level of more than 30 points was considered abnormal and was recorded in almost all examined patients in all groups. Herewith, the treatment goal shall be to achieve the anxiety level below 20 points.

The antioxidant effect of "Sophia" BAA in combination with "Gutta Viva" BAA was assessed. The process of free radical oxidation was considered as a universal mechanism of cell damage. In the vast majority of patients (97%) a high level of the final product of lipid peroxidation (LPO) – malondialdehyde was noted.

The result of "Sophia" BAA prescription and its combination with "Gutta Viva" BAA was supposed to be a reduction of vegetative-vascular dystonia signs in the patients: improvement of memory functions, improvement of attention and concentration, and reduction of emotional-volitional disorders. For this purpose, it was necessary to provide nutritional support to the brain functions by means of quantitative and qualitative composition of the formulation components.

The study was performed at the premises of the Department of Therapy of the Advanced and Post-graduate Training Faculty of the Siberian State Medical University under the direction of E.I. Beloborodova, Holder of the Habilitation degree in Medicine, Professor, Honored Doctor of the Russian Federation.

RESULTS AND DISCUSSION

As a result of the treatment of patients with vegetative-vascular dystonia, the main group showed positive dynamics of both the objective and subjective condition of the patients. The tolerability of "Sophia" BAA was satisfactory, no adverse events in the internal organs, as well as the nervous system and skin, were observed (Table 2). Also, the effect was observed in the combination of "Sophia" BAA and "Gutta Viva" BAA.

Table 2. Dynamics of clinical indicators of vegetative-vascular changes in the main and control groups before and after the treatment

Clinical Signs	1 st main group (35 patients)	2 nd main group (patients)	3 rd main group (35 patients)
Improvement of the general condition	30 (85%)	32 (90%)	20 (40%)
Reduction and regress of headache	28 (80 %)	35 (100 %)	25 (50 %)
Improvement of memorization and reproduction of the reads	30 (85 %)	35 (100 %)	20 (40%)
Better attention and concentration	28 (80 %)	30 (85 %)	25 (50 %)
Reduction of emotional-volitional disorders	25 (70 %)	30 (85 %)	30 (60 %)
Improvement of muscle tone	25 (70 %)	32 (90 %)	20 (40%)
Reduction of hypertension syndrome	12 (35 %)	17 (50%)	10 (20%)
Positive dynamics on EEG	25 (70 %)	30 (85 %)	10 (20%)

Table 2 shows positive dynamics as a result of treatment of the patients with vegetative-vascular dystonia in the 1st and 2nd main groups, especially in the 2nd main group ("Sophia" BAA and "Gutta Viva" BAA). The vast majority of patients (90%) demonstrated an improved general condition, all of them had fewer headaches, 80%

showed better memorization and reproduction of the reads, better attention and concentration, and reduction of emotional-volitional disorders (90%).

Two-thirds of the patients in the 1st main group and the majority of patients (85%) in the 2nd main group showed positive dynamics on the electroencephalogram (EEG). As for the patients from the control group, there was some clinical improvement but significantly less than in the main groups. The hypertension syndrome decreased only in 25%, positive dynamics in terms of EEG was observed in 20%, which is over 3 times less than in the 1st and 2nd main groups.

After a 4-week treatment – with "Sophia" BAA in combination with Trental – in the 1st main group, "Sophia" + Trental + "Gutta Viva" BAA – in the 2nd group, and Trental only – in the control group, a decrease in MDA level was observed. This value decreased by 1.4 times on average ($p < 0.05$). In 16 (50%) patients in the 1st and 2nd main groups, the positive decrease was noted to a greater extent – by 1.9 times on average ($p < 0.01$). In the control group, the normalization of MDA level did not occur, a tendency to decrease was observed in 20% (Table 3, Fig. 1).

Table 3. Dynamics of the LPO indicator in VVD patients in the main group after a 4-week treatment course

Parameter	Main group (1 g)		Main group (1 g)		Main group (1 g)	
	Before	After	Before	After	Before	After
Malondialdehyde, $\mu\text{mol/l}$	6.5 \pm 0.55	4.7 \pm 0.18**	7.6 \pm 0.42*	4.2 \pm 0.52	7.01 \pm 0.27	6.2 \pm 0.24

Note: * ($p < 0.05$) ** - $p < 0.01$

Diagrammatic representation of this dynamics in 3 groups is shown in Figure 1.

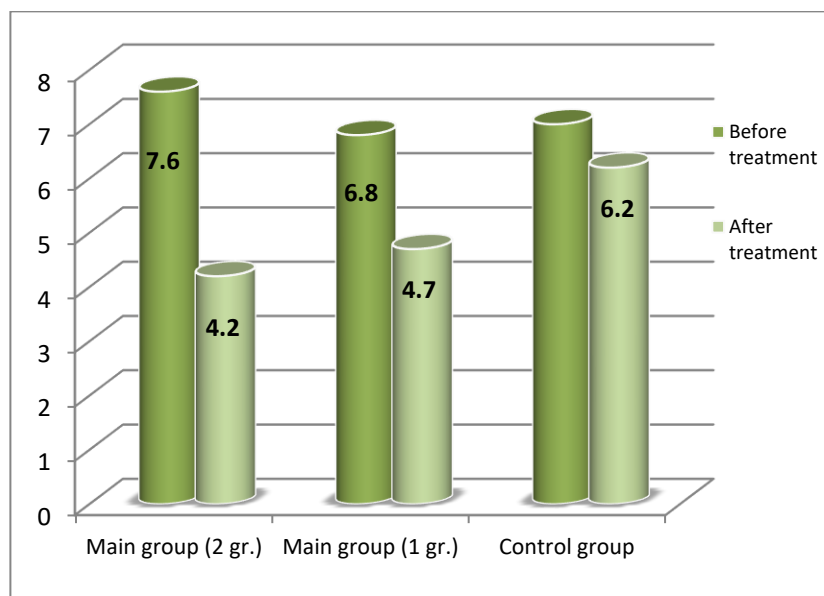


Figure 1. Dynamics of the MDA level in VVD patients after the treatment course

According to the literature, the main substrate of LPO in liver microsomes is arachidonic acid; its decrease in microsomal phospholipids is accompanied by the peroxidation decrease. Based on the data obtained, it can be assumed that there is an inhibitory effect of "Sophia" BBA and the same effect but to the greater extent of "Sophia" BAA in combination with "Gutta Viva" BAA on the synthesis of arachidonic acid. This is probably associated with the inhibiting effect of LPO processes and the activation of the antioxidant protection in the main groups in comparison with the control group.

The results of statistical analysis indicate a significant decrease ($p < 0.05$) in the self-assessment scale value of depression and anxiety in the test groups (in points) (Table 4).

Table 4. Dynamics of psychosomatic disorder indicators in the examined groups after a 4-week treatment course

Treatment period	Groups	Beck scale (points)	Tsung scale (points)	Sheehan scale (points)
Before treatment	Main group (1 g)	28.0 (27.0-29.0)	63.0 (62.0-64.0)	37.0 (34.5-39.0)
	Main group (2 g)	26.0 (25.0-27.0)	63.0 (62.0-64.0)	36.0 (35.0-37.0)
	Control group	28.0 (27.0-29.0)	62.0 (61.0-63.0)	37.0 (34.0-39.0)
After treatment	Main group (1 g)	20.0 (20.0-21.0)	45.0 (44.0-46.0)	19.0 (18.0-19.0)
	Main group (2 g)	16.0 (16.0-17.0)	40.0 (39.0-41.0)	16.0 (15.0-16.0)
	Control group	28.0 (27.0-29.0)	60.0 (61.0-59.0)	27.0 (26.0-28.0)

All the patients of the first two groups demonstrated their psychic health improvement (the average anxiety level by the Beck Depression Inventory), and the Tsung and Sheehan scales showed a significant decrease ($p < 0.05$). The third control group did not show any significant decrease (Table 3).

Thus, we can make a conclusion that "Sophia" food additive intake improves the patients' health condition. We can speak of the headache abatement, better memory retention and information retrieval, better attention and concentration, fewer emotional-volitional sphere disorders. Check-ups also showed lower blood pressure and positive EEG dynamics. The results in the first main group ("Sophia" only intake) were a bit worse than in the second group since 85% of the participants of the first group observed improvement of their general health condition, 80% noted a headache abatement and an increased initiative, 85% showed a better memory retention, and 70% demonstrated fewer emotional-volitional sphere disorders and a better muscle tone.

We can state that biologically active "Sophia" food supplement significantly improves the cerebral blood flow, reduces blood viscosity, and protects cell membranes from damage.

Treatment with "Sophia" can improve brain metabolism, which leads to better memory, concentration, increased initiative, weaker emotional-volitional disorder manifestation in the patients suffering from angioneurosis.

Combination of "Sophia" and "Gutta Viva" food supplements (2nd main group) significantly influences the disease manifestation. It improves the antioxidant protection and stabilizes the psycho-emotional state of the patients with angioneurosis.

The second main group also showed better results concerning clinical manifestations of angioneurosis since 100% observed abated headaches, the majority noted better health condition, memory retention, and information retrieval, and 85% demonstrated positive EEG dynamics.

MDA level dynamics (LPO index) in the main groups were characterized by a significant inhibition of lipid peroxidation process, which proves reduced cell damage.

Psycho-emotional sphere study noted the psychological condition improvement in all patients of the two main groups ($p < 0.05$). The best results were demonstrated by the second main group. The average level of anxiety by the Sheehan scale was about 16 points.

These findings are new since no such studies have been done before. They can be used by other authors to form an appropriate understanding of the way the nutrition factor affects the correction of metabolic processes in the disease under study.

CONCLUSION

The obtained results allow for the following conclusions:

- Food supplement "Sophia" in combination with "Gutta Viva" food supplement facilitates cell membranes stabilization by reducing LPO processes, has a significant antioxidation effect, improves patients' psycho-emotional condition and can be considered as an effective treatment of the patients with angioneurosis of moderate severity.
- "Sophia" food supplement in combination with vascular drug Trental contributes to early relief of the main angioneurosis symptoms. When combined with "Gutta Viva" food supplement, it significantly improves the general health condition, attention, concentration, and initiative aspect, normalizes the psycho-emotional sphere, reduces lipid peroxidation, and has a pronounced antioxidant effect.
- Course treatment with "Sophia" in combination with Trental provides a more pronounced therapeutic effect on the disease progression, decreases LPO, improves the psycho-emotional sphere;

- Course treatment with "Sophia" in combination with Trental improves brain metabolic processes, attention, memory, normalizes blood pressure and muscle tone.
- The tested food supplement is characterized by good tolerability.
- "Sophia" can be recommended as an additional antioxidant source.

The developed product has the following competitive advantages.

- cifrol-5 provides a 24-hour persistent antioxidant protection.
- Scientifically valid food supplement formulation provides a prolonged targeted effect.
- Pelletized form of the ingredients makes it possible to release tablet active substances in a certain order.
- A single intake of the complex (one tablet a day) makes its use convenient and affordable.
- Physiological dosage of active substances prevents addiction and other side-effects.

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Conflict of Interest

There was no conflict of interest among the authors.

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