

GOUVPO ST. PETERSBERG STATE MEDICAL AKADEMY
IM I.I. MECHNIKOVA OF THE FEDERAL AGENCY OF
PUBLIC HEALTH AND SOCIAL DEVELOPMENT

**Research of in-patient efficaciousness
of the biologically active addition to food
Glisodin®
in therapeutic practice**

St. Petersburg, 2005

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Approve

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Scientific Report
"Research of in-patient efficaciousness
of the biologically active addition
to food Glisodin® in therapeutic practice

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PREAMBLE

Redox reactions are important in the mechanisms of resistance. Reactions of an organism on different stimulus at the molecular level is characterized by oxidation of the diverse important bio-substrates and formation of the superoxide radicals of the peroxidate compounds.

It is widely known, that the free radical is an atom, a molecule, a particle of the substances without twinned electron at the external orbit and therefore the particles - free radicals are highly "aggressive" in oxidizing the compounds that differ on chemical structure and biological activity. As a consequence, characteristics of these compounds change significantly and the oxidizing stress comes. A multicomponent system rises to protect normal metabolic processes against this aggressive free-radical oxidation. Free radical aggression increases in conditions of inconsistency of the antioxidant protection that inevitably leads to development of various pathological states and illnesses of different systems of an organism.

Metabolic disorders underlie injury of cells, tissues and organs, affected by the ischemic stress and, for example, occur in cardiovascular diseases. Currently there are no doubts in importance of the various disturbances of cardiovascular system, digestive system, skin diseases from oxidizing stress in pathogenesis after the ability of an organism to self-protection against such influence decreases. As a result, conditions for adverse clinical courses and their synchronization occur, arises predisposition to new diseases, the status combined, coupling, compromised pathologies is formed.

Use of a complex treatment of antioxidants and antihypoxic medications allows breaking this vicious circle down.

Antioxidants block activation of the free radical processes (formation of active forms of oxygen) and lipid peroxidation of the cellular membranes. Their effect is realized through restoration of free radicals into a stable molecular formula that is incapable of auto-oxidization.

Primary antioxidants, produced in the organism, include SOD, catalase and glutation peroxidase. Secondary antioxidants received with food - vitamins A, C, E; minerals (selenium, zinc, copper, magnesium) and other substances, including polyphenols of vegetable origin. These food antioxidants assist in maintenance of the antioxidant reserve, therefore performing secondary role in the system. Establishing the connection between the balance of prooxidants and antioxidants in the organism, development of the oxidative stress and increase of the risk of a number of chronic and age degenerative diseases has whetted interest to the natural antioxidants recently.

Using BAAs that containing antioxidants is an efficient form of primary and secondary prophylaxis of a number of nosologic formations. It is also a measure of complementary therapy of chronic diseases. The extractions containing SOD is the most valuable among the antioxidants of vegetable origin, as it assists to increase of protection against cellular destruction and revealing the ability of direct neutralization of the superoxid, one of the most harmful free radical substances.

First characteristics of the superoxiddismutase has been described by McCord and Fridovic in 1968. SOD is an enzyme that assists removal of the superoxid radical and therefore creates a system that protects from negative impact of the radical that can originate from atmosphere oxygen in normal conditions. The enzyme also has a major role in preventing harmful effect of the atmospheric O₂

on cellulose and organisms. Like most other protective components that are created in the organism, SOD synthesis decreases with age, while cellular oxidant susceptibility increases. All these lead to senility and diseases. Reception of the antioxidants, in particular - SOD, with food or as biologically active addition increases the existing individual reserve and can prevent intensification of those chronic sufferings, pathology of which is affected by the oxidizing process. It is known that such diseases include disorders of cardiovascular system (ischemic disorders, idiopathic hypertension), rheumatic diseases, chronic diseases of respiratory organs, ulcer, and skin diseases.

Natural antioxidants are represented by multicomponent systems with compound and varied interaction between its components. Such components often appear to be unstable. Half-life period of natural SOD (of human, vegetable and animal nature) in plasma is significantly different. However all the forms possess a common disadvantage - poor absorption at peroral intake and destruction by the hydrochloric acid.

BAA "Glisodin" is a capsule with melon extract, containing superoxydismutase, gliadine, maltodextrine, extracted from wheat, mannitol 60, magnesium stearate, aerosil. In order to minimize its destruction in the stomach we have included albumen of wheat seeds (gliadin) into the "Glisodin" preparation. Gliadin prevents destruction of the SOD of melon by digestive juices and assists better absorbability in small intestine. Magnesium is viewed as a protector from cardiovascular diseases, it is a co-factor of more than 250 ferments involved in the carbohydrate and energy metabolism. Its lack results in increase of calcium scurf in vessels, heart and kidneys. All components are of natural origin and not modified genetically. Every BAA capsule weights 250 mg.

Carrying out the research of clinical efficiency of the new biologically active addition "GLISODIN" for cure of patients with chronic gastrointestinal disturbances, allergy-driven skin diseases is the purpose of the report.

Goals of the research:

1. Evaluate the dynamics of the clinic indicators when using the biologically active addition (BAA) Glisodin for medical patients ;
2. Define the influence of the BAA "Glisodin" on the basic metabolism activities (protein, carbohydrate and lipid metabolism) and the immunological status;
3. Define cognitive functions of the patients before and after the cure with BAA "Glisodin"
4. Compare efficaciousness of different doses of the medication.

Object of the research:

30 patients, complying the correspondent requirements of the inclusion and exclusion criteria

Inclusion criteria

1. Age 18-65 years;
 2. Chronic diseases, i.e. ischemic disorder, idiopathic hypertension, vascular dystonia, ulcer or combination of them;
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3. Skin diseases, i.e. psoriasis, allergy-driven skin diseases (neurodermatitis, urticaria);
4. Combination of the above mentioned in pp. 2 and 3 diseases with lipid metabolism disorder, pancreatic diabetes, biliary disorders, hypermotile stomach syndrome;
5. Consent of the patient on examination .

Exclusion criteria

1. Complicated ulcer at the moment of inclusion into the research (evidences of bleeding in the digestive system, stenosis of antral part of the stomach or pyloroduodenitis zone, malignant transformation);
2. Enzymopathy, gluten enteropathy in particular;
3. Intolerance of the preparation components

Materials and methods of the research:

1. Standard questioning of the patient including detection of evidence of the main symptoms of disease, defining quality of life (questioning form SF-36), and cognitive functions before and after the course ;
2. Daily determination of basic hemodynamic parameters, evaluation of the somatic status;
3. Standard clinic minimum, including clinic blood test, bulk urine analysis, coprogram;
4. Full-scaled biochemical blood test before and after the therapy;
5. Determination of immunologic blood indexes before and after the course;
6. Electrocardiogram before and after the course.
7. Fibreozofagogastroduodenoscopy (FEGDS) before and after the cours

Before entering into the research, the patient passed the interview in order to reveal and specify the complaints, define the quality of life; psychological tests; blood and urine tests, coprogram, ECG. After the screening, the patient passed a course of treatment: BAA "Glisodin" has been prescribed on the basic therapy background. During 30 days the patients received one capsule twice a day or 2 capsules twice a day on random-distribution method. On the day 14 and 30 of the therapy, the patient have passed the standard interview again. Evaluation of quality of life, psychological tests has passed again on the 30-31 day from the therapy start date. The patient evaluated clinical presentations of their disease and filled the self-estimation diary every day. Somatic status and basic hemodynamic parameters of the patients had been carried every day.

Recurring tests of blood (clinical, biochemical, immunological), urine, feces, ECG, FEGDS has been taken on the days 25-31 of the course.

The following examinations has been carried for the patients with stomach ulcer: examination of bioptic material for urease activity and pathohistologic examination of the biopants (two from the stomach body, one from the antral department). Presence of infiltration by neutrophilic granulocytes, lymphocytes and plasmatic cells, atrophy intensity, presence and type of metaplasia, presence of sclerous changes have been considered during estimation of changes in mucous membrane. All the above mentioned parameters have been estimated according to their intensity semiquantitatively, in points (weak (1 point), moderated (2 points), significant (3 points)). Diagnostics of the *Helicobacter pylori* (HP) has been done by and

morphological method by L.I.Aruin's technique (Aruin L.I. and coauthors, 1993). HP sowing has been differentiated in three degrees in points.

Immunoparameters have been estimated by immunofluorescence method using sets of monoclonal antibodies to various CD - antigens, have investigated the functional condition of the lymphocytes (RTML with PHA), have defined a level of the antibodies and circulating immune complex (CIC) in blood serum.

The level of total cholesterol (TC), triglycerides, high density lipoproteids (LPVP), low and very low density lipoproteids (LPNP and LPONP) have also been diagnosed during the biochemical analysis of the lipidogram. The atherogenic factor (KA) has been counted under A.N.Klimov's formula: $KA = (GH-HLVP)/HLVP$.

Evaluation of the treatment efficiency has been defined by the following parameters: speed of disappearance of subjective clinical symptoms, dynamics of the ECG data, dynamics of FEGDS data and morphological examination of the biopants, dynamics of immunoparameters of blood and lipidogram.

Results and discussion

1. Distribution of patients by nosologic forms

The total number of examined patients is 30: 10 patients with cardiovascular pathology (ischemic disorder in combination with idiopathic hypertension), 10 patients suffering stomach ulcer with antro-duodenal localization of the ulcer, 10 patients with skin diseases. Age of patients varied from 20 to 70 years. All patients have been receiving basic therapy in combination with BAA "Glisodin".

Patients with combination of ischemic disorder and idiopathic hypertension have been receiving AGC inhibitors, nitrates and β -blockers, proton pump inhibitors (PPI), anti-helicobacterial therapy as basic treatment. Patients with skin diseases received antihistamines and local treatment. Distribution of patients by nosologic forms and age is represented in the Table 1 and Diagram 1.

Diagram 1
Distribution of patients into groups

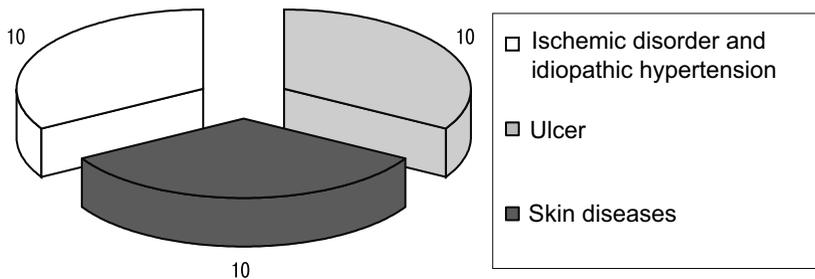


Table 1

Distribution of patients, receiving BAA "Glisodin" by nosologic forms and age

Nosologic form	Number of patients	Average age
Cardiovascular diseases: Exertional angina II functional class. Exertional angina III functional class. Idiopathic hypertension II st Total	5 5 10 10	65,17±3,41 years
Ulcer Ulcer of antral department of stomach Duodenal ulcer Total	4 6 10	43,11±2,08 years
Skin diseases Atopic dermatitis Chronic recurrent urticaria Psoriasis Total	4 3 3 10	30,16±3,44 years

2. Results of use of the preparation "Glisodin" for patients with cardiovascular diseases.

Patients suffering ischemic disorder (exertional angina of II-III functional classes) combined with idiopathic hypertension have passed the basic therapy including extended nitrates, β - adrenoceptor blocking drugs, AGC inhibitors. 10 of the patients have been receiving BAA "Glisodin" in addition to basic therapy by 1 capsule 2 times a day within 30 days. Other 10 patients have been receiving only basic therapy (group of comparison). Efficiency of the treatment have been estimated according to dynamics of subjective symptoms (pain syndrome, palpitation, shortness of breath, headaches, change of tolerance to exercise stress, sleep disturbances), data of dynamics of cognitive functions, changes of hemodynamic parameters (cardiac beat rate, arteriotony), ECG data.

2.1. Evaluation of subjective data

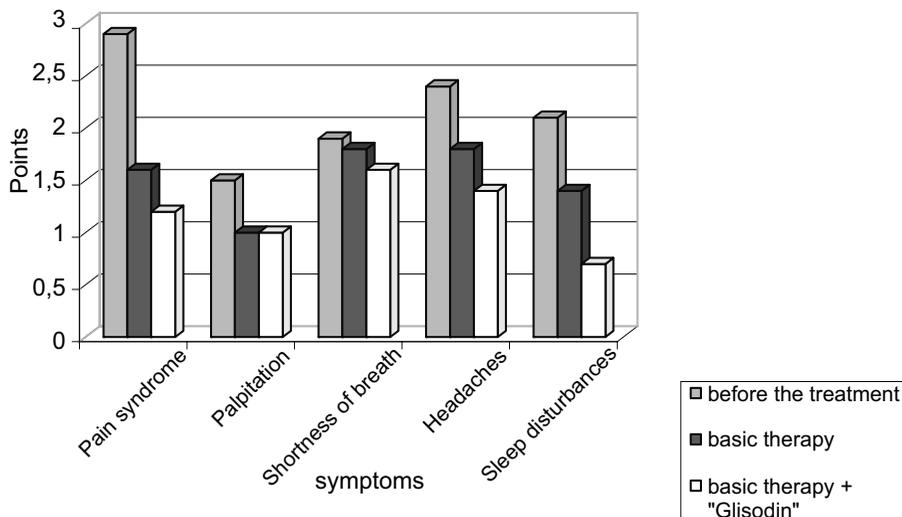
Evaluation of subjective symptoms has been done on five-ball scale in a range from 0 (no evidence) to 4 (apparent symptoms). Results of the estimation of subjective symptoms before treatment are presented in table 2.

According to the presented data, the patients from both groups have shown positive dynamics of subjective symptoms on a background of the carried therapy. More apparent changes have been received in the group of patients receiving

Table 2
Dynamics of subjective symptoms in points during the course treatment
at patients with cardiovascular diseases

	Before the treatment	Group of comparison	Group receiving BAA "Glisodin"
		Points	
Pain syndrome	2,9±0,10	1,6±0,009	1,2±0,09
Palpitation	1,5±0,08	1,0±0,09	1,0±0,09
Shortness of breath	1,9±0,10	1,8±0,09	1,6±0,10
Headaches	2,4±0,09	1,8±0,09	1,4±0,08
Change of tolerance to exercise stress	2,7±0,10	2,0±0,12	1,8 ±0,11
Sleep disturbances	2,1±0,08	1,4±0,10	0,7±0,10

Diagram 2
Dynamics of complaints from patients with ischemic heart disorder
and idiopathic hypertension before and after use of BAA "Glisodin"



"Glisodin": reduction of intensity of the pain syndrome, reduction of shortness of breath, headaches, improvement of sleep and increase of tolerance to exercise stress. According to the diaries of a self-estimation, 80 % of the patients of the group receiving "Glisodin" have noted improval of the night sleep and quieter attitude to stressful influences. The need for short action nitrates time for patients of this group has decreased in one and a half during the period of examination, while the need for nitroglycerine for the patients of group of comparison has decreased only in 1,2 times The patients receiving BAA "Glisodin" in addition to therapy have shown earlier and proof stabilization of the arteriotony, they have rare episodes of

increase of arteriotony in evening and night hours. Patients of this group have shown smaller lability of figures of arteriotony under impact of various external stimulants.

2.2. Change of blood lipid spectrum parameters

Body weight index of the patients has comprised 28 kg/m² - overweight both before and after the treatment. All patients have shown moderate increase of level of the total cholesterol, γ -lipoproteids, very low little density lipoproteids in blood plasma; the level of triglycerides and low density lipoproteids has been at the top border of norm, and the quantity of high density lipoproteids decreased. Both groups showed high level of total cholesterol after the treatment. At the patients receiving BAA "Glisodin", has shown in 30 days improvement of lipid fractions parameters of plasma: decrease of the level of little and very low little density, tendency to decrease of the level of γ -lipoproteids, increase of the high density lipoproteids level that promoted to reduction of the atherogenic factor.

Information on changes of the lipid structure of blood is represented in the Table 3 and Diagram 3.

2.3. Changes in electrocardiogram

According to the electrocardiography, all the patients have shown signs of improvement of coronary blood circulation after the therapy, expressed in reduction of ST segment depression and absence of changes in T wave.

*Table 3
Influence of BAA "Glisodin" on parameters of lipid exchange
for patients with cardiovascular diseases*

	Before the treatment	After the treatment		Normal value
		The group receiving "Glisodin"	The group of comparison	
Total cholesterol, mMoll/l	6,4±0,11	6,1±0,16	6,5±0,16	3,9_5,4
Triglycerides, mMoll/l	1,58±0,05	1,60±0,05	1,52±0,05	0,56_1,54
LPVP, mMoll/l	0,95±0,04	1,18±0,04	1,02±0,04	0,78_1,69
LPNP, mMoll/l	4,9±0,18	4,18±0,10	4,85±0,10	1,81_4,90
LPONP, mMoll/l	0,95±0,02	0,81±0,02	0,89±0,02	0,13_0,90
β -lipoproteids, units	66	59	61	35_55
Atherogenic coefficient	5,37±0,05	4,2±0,10	5,31±0,10	2,7_4,0

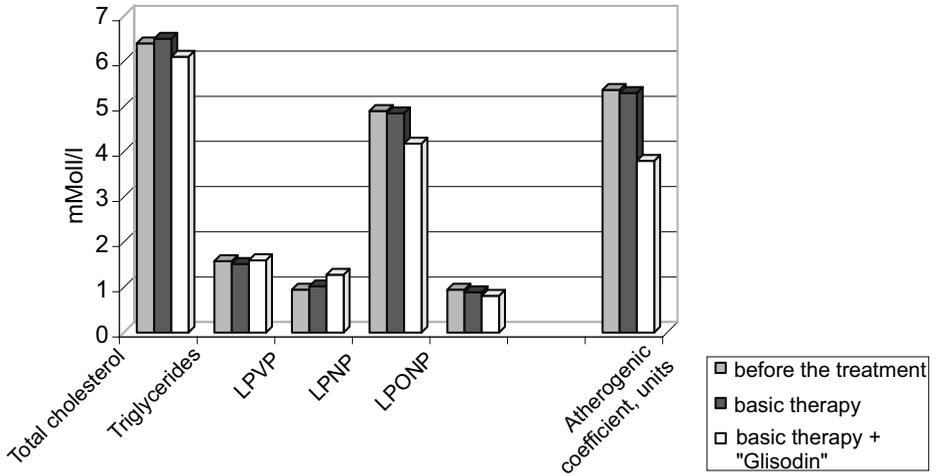
$p < 0.01$

3. Results of use of the preparation "Glisodin" for patients with ulcer

The total number of examined patients suffering stomach ulcer with antro-duodenal localization is 10. All patients have been receiving BAA "Glisodin" in addition proton pump inhibitors (PPI) during 30 days - 1 capsule 2 times day.

Diagram 3

Change of lipid spectrum of blood for patients with ischemic heart disorder and idiopathic hypertension after use of BAA "Glisodin"



3.1. Results of the subjective research

At the beginning of the research all the patients suffered pain syndrome (localization in the very epigastric area or right hypochondrium), pains had night character more often or started in 1,5-3 hours after meal. 50 % of the patients have reported hunger pains.

All the patients under examination, has shown high degree of intensity gastric indigestion signs and presence of such symptoms as swelling and rumbling in the

Table 4

Dynamics of clinical presentations for patients with ulcer

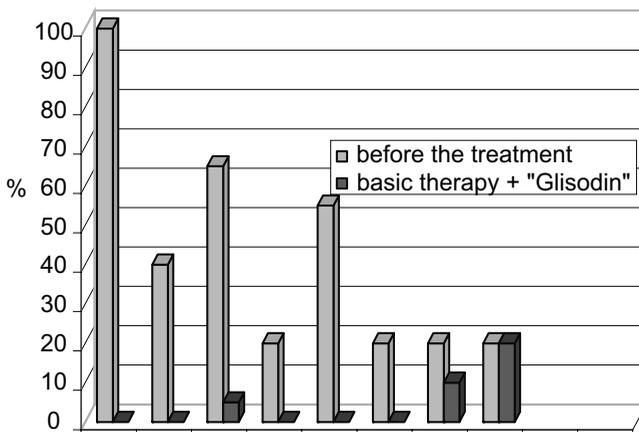
	Before the treatment	15th day of treatment	30th day of treatment
Pain in stomach	100%	0%	0%
Nausea	40%	20%	0%
Heartburn	65%	30%	0%
Vomiting	20%	0%	0%
Eructation	55%	30%	0%
Dry mouth	20%	10%	0%
Epigastric heaviness	20%	20%	0%
Borborygmus	30%	60%	10%
Pains in large intestine	10%	30%	0%
Abdominal swelling	20%	45%	20%
Stool frequency	0,5 times a day	1,8 times a day	1.1 times a day

$p < 0.01$

stomach, dency of constipation (stool 1 time in 2-3 days). Body weight index for such patients comprised 21 kg/m² that corresponds to the normal value. The information obtained by inquiring the patients and dynamics of clinical parameters are represented in table 4 and on the diagram 4.

During the treatment intensity of the pain syndrome decreased by the second or third day of the therapy, 50 % of the patients have reported that pain disappeared. By the seventh day of the therapy the pain syndrome has been stopped at all patients. The patients have also shown fast reduction of the phenomena of gastric and intestinal indigestion, normalization of stool frequency.

*Diagram 4
Dynamics of clinical presentations for patients with ulcer
before and after receiving BAA "Glisodin",*



3.2. Results of the endoscopy and histological examination

According to the endoscopy, all the patients have shown ulcer defect with localization in a bulb of the duodenum, average diameter 0.53 mm before the treatment. Everyone had evidences of a gastritis and duodenitis. Cicatricial deformity of the bulb of the duodenum has been evident in 90 % of the cases. Erosion either in antral or bulbar zones has been discovered at 5 patients (50 %).

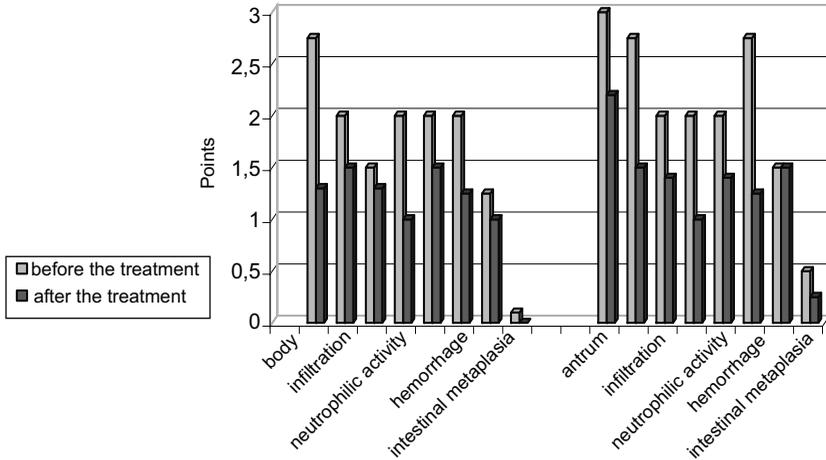
The ulcer has closed up at all the patients by the 25-30th day of the therapy. Erosion has disappeared after treatment at 100 % of the patients receiving therapy with BAA. Hypostasis of the mucous has decreased at endoscopy, and hyperemia of mucous remained at all the patients Urease test has been positive for all the patients and comprised the average of 2.19 points before the treatment (moderate degree). After the treatment the urease test has become negative at 8 (80 %) patients, and 20 % has shown 1,1 (weak degree).

The patients had evident chronic inflammatory changes (hypostasis, leucocytic infiltration, hypersecretion) and presence of intestinal metaplasia, fibrous changes before the treatment. After the treatment the patients has shown decrease in activity and intensity of the inflammatory changes, signs of intestinal metaplasia and fibrous changes. As to intensity of atrophic changes, they have not undergone serious changes during the treatment.

Results of the histologic examination of the biopstants of the mucous membrane of a body and antrum of the patients suffering ulcer, received BAA "Glisodin" are shown on the Diagram 5.

Diagram 5

Results of the histologic examination of the patients suffering ulcer before and after using BAA "Glisodin"



During the retrospective analysis of the data received from clinical and endoscopy examination of the patients suffering ulcer of similar localization, receiving standard eradication therapy and PPI therapy without any antioxidant therapy, has been established, that the majority of patients shows longer preservation of gastric indigestion after the treatment course. E. g., by the 15th day of the therapy 40 % of patients has reported epigastric heaviness after meal, 50-60 % - swelling and rumbling in a stomach, only 40-50 % of patients had shown healing of erosions after the course of treatment.

During the histologic research of the pilorithic helicobacter 80 % of the patients receiving BAA has reached eradication of the HP by 21st day of the therapy while the analysis of histologic preparations of the patients with ulcer not receiving BAA, have verified lack of HP in biopsats of the antral department of 60 % of the patients, and the degree of HP sowing at histologic research have been higher in this group of patients.

3.3. Results of blood lipid spectrum examination

The results of examination of the blood lipid spectrum are represented in Table 6.

	Before the treatment	After the treatment	Normal value
Total cholesterol, mMoll/l	4,80±0,11	4,95±0,16	3,9-5,4
Triglycerides, mMoll/l	1,22±0,05	0,89±0,05	0,56-1,54
LPVP, mMoll/l	1,15±0,04	1,42±0,04	0,78-1,69
LPNP, mMoll/l	2,4±0,18	2,45±0,10	1,81-4,90
LPONP, mMoll/l	0,72±0,02	0,69±0,02	0,13-0,90
Atherogenic coefficient	3,17±0,05	2,45±0,10	2,7-4,0

p < 0.01

Level of the total cholesterol both before and after the treatment remained low. The authentic changes of decrease in the level of triglycerides, increase of the level of high density lipoproteids has been registered during receiving the BAA.

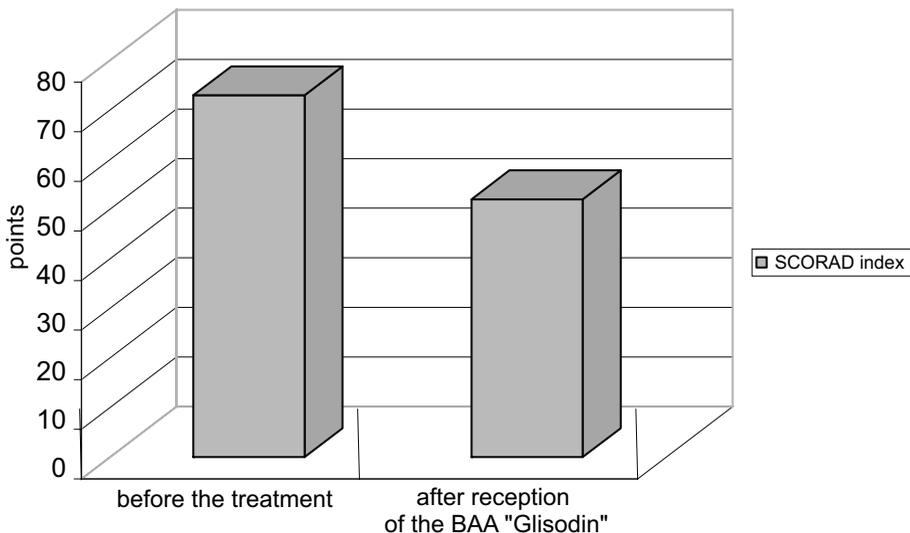
4. Results of use of the preparation "Glisodin" for patients suffering skin diseases

Supervised 10 patients with skin diseases. 7 of the patients had allergic lesions of skin. 3 patients has been diagnosed psoriasis.

Patients with allergic demonstrations on the skin expressed complaints to intensive skin itch, skin rashes (primary localized on the face and members; 2 patients had the rash was localized on the belly), skin blushings, sleep disturbances. SCORAD index of the patients with atopic dermatitis comprised 73 before the treatment. The patients with chronic recurrent urticaria in has shown urticarial rash in 100 % of cases. Patients with stable local psoriasis en plaque has also been examined. The patients had psoriasis plaques mainly localized in the area of forehead skin, genus and elbows skin. All the patients complained xerodermia and skin itch.

Dynamics of the disease symptoms before treatment is shown on Diagrams 6 and 7

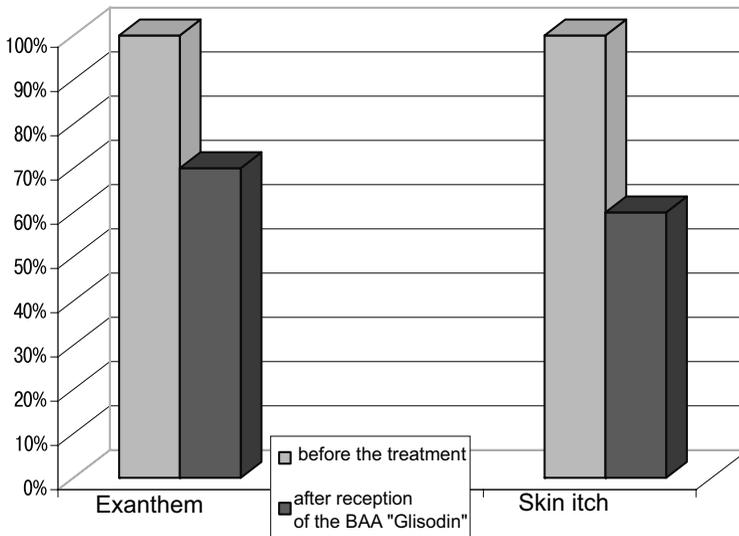
Diagram 6
SCORAD index for patients with allergic skin demonstrations
before and after receiving the BAA "Glisodin"



As shown by the presented data, after reception of the BAA "Glisodin" within 30 days the state of health of patients has considerably improved: 30 % of the patients have shown relief from skin rashes, 70 % its reduction, 60% reported reduce of skin

Diagram 7

Change of the symptoms of the patients suffering skin diseases before and after receiving the BAA "Glisodin"



itch. All the patients reported improvement of the sleep. SCORAD index for patients with atopic dermatitis has been 52 by the end of the therapy. After the treatment all patients suffering psoriasis reported some reduction of the plaque sizes, lack of their tendency to merge, reduction of intensity of the skin itch

Research of the immunoparameters of blood of the patients suffering skin diseases is represented in Table 7.

After the course of BAA "Glisodin" treatment, the patients has shown increase of values of the immunoregulation index (CD4/CD8) with decrease of the T-surpressors level (CD8); increase of the level of natural killers (CD16), of functional activity of lymphocytes (increase of IM in RTML with PHA before the treatment start and normalization after the treatment). The tendency of decrease of the level of the CIC in blood serum has been registered after the treatment. The blood serum of the patients both before and after the treatment has shown raised level of serum antibodies of A class.

5. Changes of neuro-psychological status of the patients after receiving the BAA "Glisodin"

Most of the patients (83%) have complained headaches, depression, fatigue, loss of willingness to work before the treatment. 93 % reported sleep disturbances (frequent awakenings, shortening the sleeping time). The symptoms decreased at 50% of patients by the 21 day of the therapy including BAA "Glisodin". By the end of the treatment all the patients (100%) reported improvement of willingness to work, vivacity feeling, decrease of meteorological sensitivity, improvement of quality and time of sleeping. It is significant that 60% of examined women of childbearing age that complained increase of disturbances of the vegetative nervous system (hyperhidrosis, mood instability, somnolence, irritability, tearfulness) before the beginning of menstua-

tion or during the menses period reported decrease of premenstrual tension, reduction of the abdominal discomfort and pains during menses after the medication course.

Dynamics of symptoms driven by the nervous system at the patients after reception of the BAA "Glisodin" are represented on the Diagram 8.

Table 7
Change of immunogram parameters of the patients suffering skin diseases after the treatment with the BAA "Glisodin"

	Norm	Before the treatment	After the treatment	
Leukocytes x 10 ⁹	4,0-8,0	5,2±0,2	5,1	
TLF x 10 ⁹	1,2-3,0	2,35±0,05	1,98±0,06	
CD3: %/ avs	60-80%	65,8±2,0	64±1,5	
		1,54±0,12	1,26±0,05	
CD4: %/ avs	33-50%	41,7±1,5	41,4±1,0	
		0,97± 0,12	0,84±0,05	
CD8: %/ avs	16-39%	29±1,0	22,2±0,6	
		0,68±0,06	0,43±0,05	
CD4\CD8	1,5-2	1,45±0,06*	1,9±0,08*	
CD16(NK_cell):%/avs	3,0-20%	18,7±0,5*	20,6±0,5*	
		0,46±0,02	0,40±0,02	
CD19: %/ avs	5-22%	14±1,0	13±2,0	
		0,37±0,05	0,34±0,02	
RTML with PHA	SM	2,0-4,0 un	2,63±0,03	2,4±0,13
	IM	30-75%	76,8±0,1*	58,4±1,2*
CIC units	50-80%	102	93	
Antibodies A	1,20-1,50	2,03±0,15	2,62±0,12	
Antibodies M	0,65-1,65	1,62±0,08	1,61±0,06	
Antibodies	7,5-15,5	11,29±1,1	12,47±2,1	

*p<0,01

Asthenia level of every patient has been estimated according to the MMPI scale. 100 % of the patients moderately expressed increase of the asthenia level before the treatment. Parameters of dynamics are shown in the table.

The asthenia level has decreased during the treatment period.

Psychological research has also proved positive effect of the antioxidant preparation "Glisodin" on the cognitive functions. Authentic improvement of psychological characteristics, attention and intellectual working capacity above all, has been marked. Examination of memory and calculation operations has shown, that these functions have improved in comparison to the initial level. The data received are presented in the Table 9.

Good bearableness of the preparation "Glisodin" have been proved during the treatment course. Undesirable by-effects have not been discovered.

Diagram 8
Dynamics of psychoasthenic demonstrations
of the patients treated with the BAA "Glisodin"

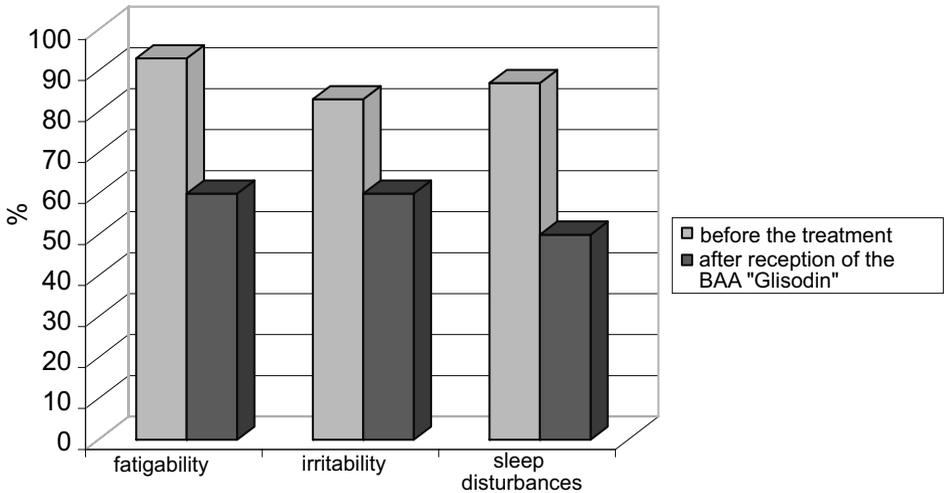


Table 9
Dynamics of the psychological functions before and after the treatment

Parameters	After the treatment	After intake of the BAA "Glisodin"
MMPI scale	115,3±5,1	105,2±2,2*

*p<0,005

Table 8
Dynamics of the astheny level affected by the "Glisodin"

Parameters	After the treatment	After intake of the BAA "Glisodin"
Memory:		
short-term memory capacity, number of words	7,0±0,2	8,0±0,3
main memory, number of words	5,6±0,1	6,8±0,1
Counting, time, sec,	66,0±0,1	44,2±1,3
Faults, %	2,3±0,2	0,5±0,1
Free association, faults,%	4,1±0,2	1,3±0,3
Kinetic, faults%	7,3±0,3	2,3±0,2

p<0,01

Conclusions

1. Treatment by the BAA "Glisodin" with antioxidant effect promotes faster knocking over the symptoms and improvement of the general somatic status of the patients suffering ischemic disorder and idiopathic hypertension, ulcer, skin diseases.

2. Therapeutic effects on the patients receiving the BAA "Glisodin" with antioxidant action in addition to the basic treatment are reached earlier and they are more stable.

3. After inclusion of the BAA "Glisodin" into the basic treatment schemes, the psychological status of the patients improves, the astheny level decreases, functions of attention, memory, the counting, associations, kinetics improve, sleep quality improves.

4. Treatment with BAA "Glisodin" increases resistibility to environmental factors.

5. Applying the BAA "Glisodin" in antiulcer therapy leads to faster healing of the erosion defeats of the mucous stomach membrane, normalization and acceleration of the reparative processes.

6. Inclusion of the antioxidant BAA "Glisodin" into the structure of therapy of ulcer, results in reduction of the HP sowing of the mucous stomach membrane.

7. The BAA "Glisodin" positively influence on the lipid exchange, promotes increase of the anti atherogenic fraction of the high density lipoproteids and reduction of the level of the little and very little density lipoproteids, including for the patients with the level of the specified parameters within the limits of referencial meanings.

8. For the patients suffering skin diseases the BAA "Glisodin" promotes regress of skin lesion reducing the sizes of the skin lesion, reduces intensity of pathological processes, renders positive immunomodulating action owing to increase in quantity of natural killers, decrease in quantity of T-surpressors, improvement of the immunoregulator index, and functional activity of lymphocytes.

Conclusion

In conditions of inconsistency of the antioxidant protection in the majority of diseases of the organs and skin pathology to correct a complex of oxidizing reactions is prescribed to use it in complex treatment by antioxidants. Application of the BAA "Glisodin", with antioxidant action, has shown its therapeutic efficiency. Using the present BAA can be done in the course of treatment from ischemic disorder and idiopathic hypertension, ulcer and skin diseases to reduce the of symptoms of disease and increase clinical efficiency of the therapy.

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SOURCES

1. Arutjunjan V.M., Grigoryan E.G. Efficiency of application of immunomodulators in complex treatment of patients suffering chronic gastritis and ulcer. // Clinical medicine. - 2003. - 15. - p.33_35
 2. Doronin A.F., Shenderov V.A. Functional nutrition. -, Grant, 2002 - p.296
 3. Dubtsova E.A. Some immunological aspects of ulcer creation (review of the literature). // Experimental gastroenterology. - 2002, № 4, p. 9-13
 4. Immunopathology and allergology. Edited by Acad. of the Russian Academy of Medical Science Prof. R.M.Haitova. - M, GEOTAR-MED, 2001. -96 p.
 5. Kon I.Y. Prooxidizers and antioxidants in food. Materials of the Vth International Conferense "Bioantioxidant". - M. - 1998. - p .20-21
 6. Majmulov V.G., Shabrov A.V., Dadali V.A. Methodological basis of use of biological active additives to food in the program of sanitation of the population. // Mat. of the IVth Intern. Simp. " BAA to food ". - SPb, 2000, - p.144_145
 7. Rakitskaya E.V. Dietary opportunities of decrease in speed of the atherosclerosis evolution. // Clinical feed. -2002, № 2, p.18-22.
 8. Rumjantseva O.I., Tuteljan V.A., Pogozheva. BAA in complex therapy of patients with IHD, IH resulting from overweight. // Food matters. - 2000. p.194-195
 9. Scheme of neuro-psychological examinations. - M.: MGU publishing house 1973
 10. Timofeeva T.V., Maliarevsky A. A. Studying the structure of infringements of hearing and vocal memory // Psychological magazine. - 1980, Vol.1, № 5, p. 82-92
 11. Tkachenko E.I. Theory of an adequate nutrition and trophology as a methodological basis of treatment and prevention of diseases of internal organs // Russian magazine of gastroenterology, hepatology and coloproctology. Appendix № 14 Materials of the16th Sessions of School - seminar of the Acad. A.M.Ugolev. - 2001, № 3, p. 15-21
 12. Tkachenko E.I. Holistic theory of food. // Clinical feed. - 2004.,№ 1, p. 2-5
 13. Shenderov V. A. Microcenosis of a human and a functional nutrition //Russian magazine of gastroenterology, hepatology and coloproctology. Appendix № 14 Materials of the16th Sessions of School - seminar of the Acad. A.M.Ugolev. -2001, № 3, p. 78-90.
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