# Effectiveness of the vitamin drug Doctovit for correction of clinical symptomatology and restoration of life quality in complex therapy of chronic erosive H. pylori-associated gastritis

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**Key words:** chronic erosive gastritis, H. pylori, vitamin drug, life quality, treatment

**Introduction.** For the treatment of chronic erosive H. pylori-associated gastritis, which is one of the most common nosologies in gastroenterology in the modern world, Maastricht IV offers rational and effective regimens, taking into account the features of regions with low resistance to H. pylori. Standard triple therapy in the first line includes proton pump inhibitors (PPI) in a standard dose 2 times a day, Clarithromycin 500 mg 2 times a day, Amoxicillin 1000 mg 2 times a day. In the case of inefficiency — quadrotherapy: PPI in a standard dose 2 times a day, bismuth of subcitrate of colloidal (De-no etc.) 120 mg 4 times or 240 mg 2 times a day, Metronidazole 500 mg 3 times a day, Tetracycline 500 mg 4 times a day As a second line treatment, a triple therapy regimen with levofloxacin is proposed: PPI in a standard dose 2 times a day, Levofloxacin 250 mg twice daily, Amoxicillin 1000 mg 2 times a day.

Since chronic erosive gastritis (CEG) is considered to be a precancerous condition, according to the recommendations of the leading gastroenterologists, secondary and specific prophylaxis is necessary to prevent the onset of gastric cancer [3, 8]. Secondary prophylaxis of gastric cancer includes balanced nutrition, antioxidants (vitamins A, E), refusal of smoking and concentrated alcohol, as well as preparations of bismuth of subcitrate of colloidal. For the specific prophylaxis for patients with CEG, associated with H. pylori, the above-mentioned eradication course of H. pylori is recommended.

A serious problem in the treatment of H. pylori-associated processes of the gastrointestinal tract (GIT), as well as carcinogens, is the decision to finally

overcome the effects of post-radical therapy — long-term chronic inflammation of the gastric mucosa (SOS). After eradication H. pylori remains inflammatory infiltrate, which produces active forms of oxygen, which in turn, according to researchers, causes damage to DNA, as well as changes in the expression of oncogenes and oncosuppressors [1]. Lymphocytic infiltration, leukocyte neutrophil infiltration, which produces active forms of oxygen and causes oxidative stress, hyperproduction of pepsin, which breaks down the epidermal growth factor, which restores damaged SOS — are residual phenomena post-radical therapy [4], which require additional effects, which provides the appointment of vitamin drug Doctovit.

The doctrine is the first and for today the only comprehensive remedy for the treatment of gastroduodenal diseases (chronic gastritis, erosive and ulcerative digestive tract infections, ulcerous stomach and duodenal ulcer, functional dyspepsia, heartburn, etc.) on the basis of vitamin U and provitamin B5. Vitamin U (methylmethionine), a part of the Doctovit, promotes processes for the synthesis of digestive enzymes and stimulates the healing of lesions of the gastrointestinal mucosa. Provitamin B5 (dexpanthenol), in turn, normalizes digestion due to the effect on the motor activity of the digestive tract and its secretory function, as well as stimulates the regeneration and restoration of mucous membranes, providing the cells with the necessary energy. The combined effect of vitamin U and provitamin B5 ensures normalization of gastric secretion and stimulates the healing of erosive and ulcerative gastrointestinal tract infections. Such a successful vitamin combination combines a number of important clinical effects: metabolic, cytoprotective, reparative, and others.

The combination of dexpanthenol (provitamin B5) and metilmethionine (vitamin U), which has been successfully selected as a part of the doctrine, allows for the efficient flow of important cellular functions necessary for cytoprotection and regeneration [2]. First, the transformation of methionine (vitamin U) into the active form — SAM requires the energy of ATP, and the predator ATP in the Krebs biochemical cycle is pantothenic acid (vitamin B5). Secondly, the important process of decomposition of chromatin occurs during the methylation of individual DNA regions, which is provided by methylmethionine (vitamin U) and to a lesser extent

pantothenic acid (vitamin B5) with obligatory participation of energy of ATP (and again — pantothenic acid (vitamin B5)). . The role of chromatin decondensation at the start of the regenerative cell cycle is very important. It is known that despite the microscopic size of the cell, the total length of the DNA molecules packed in its core reaches 2 km. Compact placement of DNA is provided by the formation of complex and dense spatial "tubes" of chromatin. In this case, the DNA packaged in the chromatin is inactive and only after "unpacking" or decondensation, is subject to replication (doubling), thus ensuring the process of cell division and, consequently, regeneration.

The next aspect is the methylation of the nucleotide residues of the newly created DNA strands (methyl methionine, vitamin U) after completing the replication. The methyl groups are joined to all the adenine residues in the sequence -GATC-, with the formation of N6-methylaldehenine. It is also possible to methylation of cytosine in the sequence -GC- and the formation of N5-methylcytosine. The amount of methylated bases is about 1-8%. Modification occurs with the energy of ATP (pantothenic acid (vitamin B5)). SAM is used as a source of methyl groups. The addition of methyl groups to the adenine and cytosine residues does not violate the complementarity of the chains. The presence of methyl groups in the DNA chains is necessary for the formation of the structure of the chromosomes, as well as for the regulation of gene transcription. For a short time, the DNA molecule of the sequence -GATC-is methylated for adenine only in the matrix, but not in the new chain. This difference is used by reparation enzymes to correct errors that may occur during replication.

An important point is the protein involved in the synthesis. Protein molecules are polypeptide chains, composed of individual amino acids. However, amino acids are not active enough to connect with each other independently. Therefore, before you connect with each other and form a protein molecule, amino acids must be activated. This activation occurs under the action of special enzymes. Each amino acid has its own specific enzyme. The source of energy for this is ATP. After activated, the amino acid becomes more labile and, under the action of the same enzyme, binds to the transport RNA for further stages of cellular metabolism. Each of

the 20 amino acids of the protein is combined with covalent bonds with a certain t-RNA, also using ATP energy. In turn, S-adenosylmethionine is involved in all reactions in which the methyl group is used in biosynthetic reactions (for example, in the synthesis of adrenaline, creatinine, thymine, phosphatidylcholine, betaine, etc.). Formulated after cleavage of the methyl group, S-adenosylmomocystein undergoes hydrolysis on adenosine and homocysteine. The latter is used in the synthesis of serine (this is the main path of transformation). Thus, vitamins B5 and U are needed in the synthesis of protein.

The next important role is transport. Some membrane proteins take part in the transport of small molecules through the cell membrane, changing its permeability. The lipid component of the membrane is waterproof (hydrophobic), which prevents the diffusion of polar or charged (ions) molecules. Membrane transport proteins are divided into protein channels and carrier proteins. Protein-canals contain internal water-filled pores that allow ions (through ion channels) or water molecules (via proteins, aquaphores) to move inside or outside the cell. Many ion channels specialize in transporting only one ion. So, potassium and sodium channels distinguish these similar ions and skip only one of them. Carrier proteins associate each molecule or ion with enzymes and, unlike channels for active transport, require the use of ATP energy. “Cell power station” — ATP synthase, which synthesizes ATP due to the proton gradient, can also be attributed to membrane transport proteins.

It is also important that the synthesis of phosphatidylcholine from phosphatidyl ethanolamine in the cell membrane occurs as a result of two successive stages of methylation carried out by the transfer of methyl groups from S-adenosylmethionine under the control of two enzymes, the so-called phosphomethyltransferases I and II. The first enzyme carries one methyl group, forming phosphatidylmonoetheletanolamine. Both the phosphatidyl ethanolamine substrate and the first methyltransferase enzyme are localized on the cytoplasmic side of the cell membrane. The second enzyme carries two more methyl groups of S-adenosylmethionine to form phosphatidylcholine. Both phosphatidylcholine and the second methyltransferase are located on the outer surface of the membrane. This

asymmetric distribution of enzymes and their substrates contributes to the rapid transfer of phospholipids through the plasma membrane during sequential methylation. Intra-membrane synthesis of an intermediate product — phosphatidylmonomethylethanolamine causes sharp changes in fluidity of the membrane, creating conditions for the accelerated lateral movement of its own membrane proteins. The "polar head" of phosphatidylcholine is converted by the energy of ATP into the active form, phosphocholine, which then is attached to the cytidine triphosphate with the simultaneous removal of the pyrophosphate, which shifts the equilibrium reaction to the right. Cytidinediophosphate-choline is formed — a choline donor for the synthesis of phosphatidylcholine molecules.

Thus, a synergistic combination of vitamins B5 and U together catalyzes these biochemical reactions and a number of others, which also provides a pronounced effect on SOS and duodenum due to the following cumulative effect: stimulation of the division of stem cells of the epithelial layer of SOS; ensuring accelerated differentiation and active functioning of newly created cells. It is important that vitamin U also has antihistaminic properties. By histamine, vitamin U converts it into an inactive form, which helps to reduce the secretion of the stomach, accelerates the healing of ulcers and exerts an additional analgesic effect.

These effects are exacerbated by other physiological mechanisms of action of both vitamins, namely: inhibition of secretory function of the stomach at elevated doses of vitamin B5; stimulation of intestinal peristalsis with vitamin B5 due to activation of acetylcholine synthesis; the deactivation of histamine with vitamin U by its methylation and transformation into an inactive form, which also helps to reduce the secretion of the stomach and accelerate the healing of ulcers; an increase in the synthesis of choline with vitamin U, with the inadequate formation of which there are disturbances in the synthesis of phospholipids from fats and deposits in the liver of neutral fat (fatty liver dystrophy).

Vitamin U is a low-toxic compound. The minimum toxic dose for white mice is 2000 mg / kg. In some patients when taking S-methylmetionin there are phenomena of individual intolerance to this drug: nausea, vomiting, pain, allergic reactions, etc. Characteristically, both for vitamin B5 and for vitamin U there is no

maximum allowable dose level, which indicates their exceptional safety and the possibility of use in broad therapeutic doses.

In the tablet preparation Doctote combines these two unique vitamins. It is intended for adults and children older than 14 years, usually 1-2 tablets per day, after eating. The drug should be washed with a small amount of liquid. At the appointment of a doctor, the daily dosage of the drug can be increased to 3 tablets. The course of admission, as a rule, is 1-2 months. Thus, based on the analysis of the pharmacological properties of the drug Doctovit, as well as on the results of previous clinical trials, one can speak of the pathogenetic validity of its appointment during post-radical period during the type of functional dyspepsia with epigastric pain.

The drug has undergone a series of clinical trials, during which its high therapeutic efficacy was confirmed. Thus, during the first 3 days since the beginning of its application, there was a decrease in pain and dyspepsia (heartburn, acid stings). In 95% of patients receiving the drug, there was a disappearance or a significant reduction in clinical manifestations of gastroduodenal pathology. Four weeks after the course of treatment, the frequency of scarring of ulcers and epithelization of erosions was 95% [1, 2].

**Aim of study** is to to investigate the effectiveness of the use of the Doctovit in the complex therapy of patients with chronic erosive gastritis, associated with H. pylori, for the correction of clinical symptoms and the restoration of quality of life of patients on international scales.

**Materials and methods.** 25 patients were examined for H. pylori-associated CEG, who were on a dispensary record and under the supervision of a family doctor in the conditions of the Ternopil city communal institution "Center of primary health care". The comparison group consisted of 20 practically healthy individuals who did not have clinical anamnestic and instrumental signs of GI disease. The verification of the diagnosis was carried out in accordance with standardized protocols for the diagnosis and treatment of diseases of the digestive system (according to the generally accepted classification in Ukraine proposed by the Research Institute of the NAMS of Ukraine, according to the "Unified clinical protocol of primary, secondary (specialized) medical aid and medical rehabilitation of patients with chronic

gastritis", approved by the attachment to the Order No. 271 of the Ministry of Health of Ukraine dated from 13.06.2005).

The criteria for inclusion of patients in the study were: persons of both sexes; presence of the established diagnosis of H. pylori-associated HCG (according to the International Classification of Diseases X review). All the surveyed signed informed consent to participate in the study in accordance with the protocol approved by the Ethics Committee of the State Pedagogical University "Ternopil State Medical University named after. I. Ya. Gorbachevsky, Ministry of Health of Ukraine".

The criteria for exclusion of patients from the study were: decompensation of cardio-pulmonary diseases, acute myocardial infarction, rhythm disturbances, severe acute surgery during the last month, diabetes mellitus type I and II, chronic hepatitis, chronic pancreatitis, systemic glucocorticosteroids use, chronic renal insufficiency III- V stages, pathology of the thyroid gland, pregnancy, severe exhaustion, predisposition to bleeding, malignant neoplasms (and suspicion of them), blood diseases and hematopoietic organs, infection mental and parasitic diseases, mental and behavioral disorders, congenital anomalies and chromosomal disorders, unstable ischemic heart disease; hypertonic illness II-III centuries, and refusal to participate in the study.

Patients, comparable with clinical, gender criteria, severity of the course of HEM and treatment received, were divided into two groups.

**Group 1** — control (10 patients) — general treatment (GT) for 10 days: PPP pantoprazole (control, nulpase, pentasan, etc.) 40 mg × 2; Amoxicillin 1000 mg (or metronidazole 500) × 2; clarithromycin 500 × 2 without Doctovit.

**Group 2 —** primary (15 patients) — GT + Doctovit for 10 days: PPP pantoprazole (control, nulpase, pentasan, etc.) 40 mg × 2; Amoxicillin 1000 mg (or metronidazole 500) × 2; clarithromycin 500 × 2; Doctovit 2 tablets per day after eating for 2 months.

Mandatory components of medical complexes were ambulatory regimen and normotrophic diet based on the type of diet 5 by Pevzner, which is indicated for all diseases of the gastrointestinal tract in the phase of therapeutic exacerbation, unstable remission and remission. The purpose of this nutrition is the mechanical and chemical

affection of the digestive system, the removal of pain syndrome, and decreased activity of the software. Calories and chemical composition: 2500-2800 kcal, proteins — 130-140 g (low-fat varieties of cheese, hard cheese, meat, fish), fats — 70 g, carbohydrates — 350 g. Mode of food — in small portions 5-6 times day. Characteristics of food: boiled in a steamed form, stewed, with a restriction of fats, sugar, with the exception of products with strong bohemian action (broth, broth cabbage, etc.).

A standardized clinical and laboratory examination was conducted for all patients with CEG. At the entrance and on the control, YGDS + urease test on H. pylori + biopsy with 5 places performed with histological examination was performed.

Clinical and anamnestic research method was used for the analysis of clinical symptoms. Quality of Life (IQ) was determined using adapted general questionnaires SF-36 and GSRS.

The statistical processing of the results was performed on a Pentium Core Duo PC using a single-factor dispersion analysis (Microsoft Office 2007, Microsoft Exel Stadia 6.1/Pro and Statistica, XLSTAT-Pro for MS Excel, Statistical Package for Social Science). The average sample values of the quantitative indicators are given in the form M±m, where M is the arithmetic mean and m is its error.

**Results and discussion.** Table 1 shows the results of the influence of two therapeutic programs on some clinical symptoms and syndromes in patients with CHE. There was a positive trend in clinical manifestations in both groups of patients, but the therapeutic effect in group 2 was more significant: on average, from 88.3% of patients to 17.5% in group 2 compared with 80.6% of patients respectively and 38.1% after treatment in the 1st group of patients with CHE.

Table 1

Dynamics of clinical manifestations under the influence of GT and complex with the inclusion of Doctovit

| Clinical | Number of patients | |
|---|---|---|
| | Group 1 (n=10) | Group 2 (n=15) |

| manifestation | Before treatment | After treatment | Before treatment | After treatment |
|---|---|---|---|---|
| Pain syndrome | 10 (100.0)* | 3 (30.0)** | 15 (100.0) | 3 (20.0) |
| Dyspeptic syndrome | 9 (90.0) | 4 (40.0) | 15 (100.0) | 2 (13.3) |
| Weight loss | 7 (70.0) | 4 (40.0) | 12 (80.0) | 3 (20.0) |
| Anemia | 8 (80.0) | 6 (60.0) | 13 (86.7) | 2 (13.3) |
| Hypovitaminosis | 28 (73.7) | 11 (28.4) | 32 (76.2) | 5 (11.9) |
| Hypotonia | 7 (70.0) | 3 (30.0) | 13 (86.7) | 4 (26.7) |

Notes:

* — in brackets the percentages are given (%);

** — clinical manifestation in patients with chronic CG after treatment was considered to be present in the absence of significant positive dynamics.

The scales of the questionnaire SF-36 examined the physical and psychological components of the YAH of patients with COC as a result of treatment using the Doctovit. A comparison was made between the LAS parameters by the physical component in group 1 before and after treatment (Fig. 1).

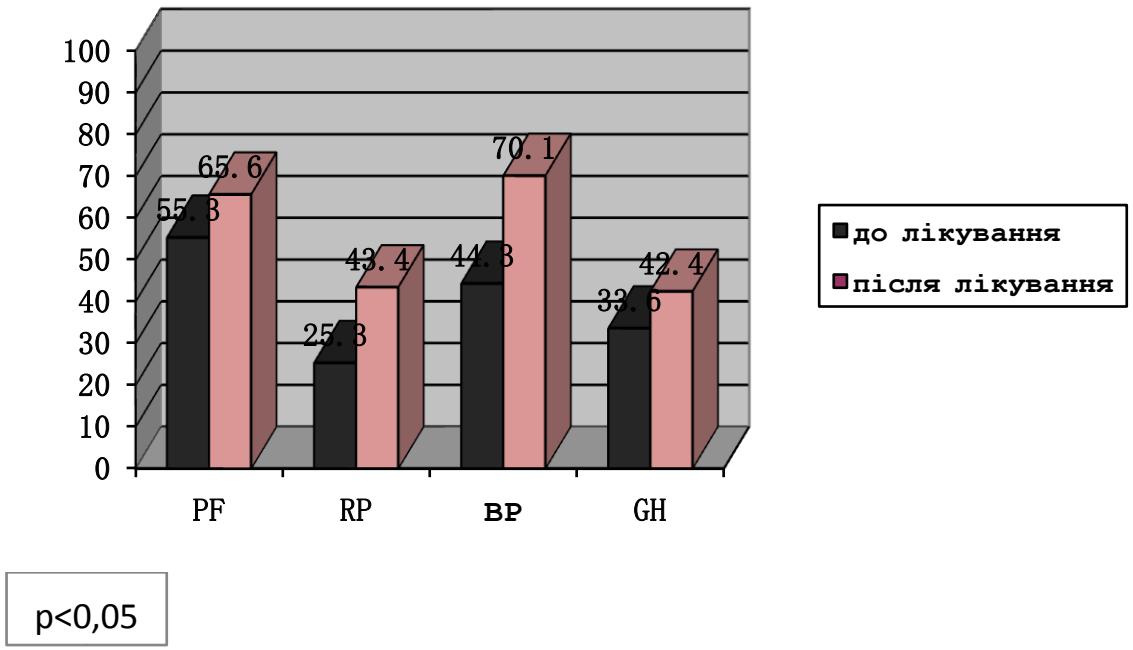
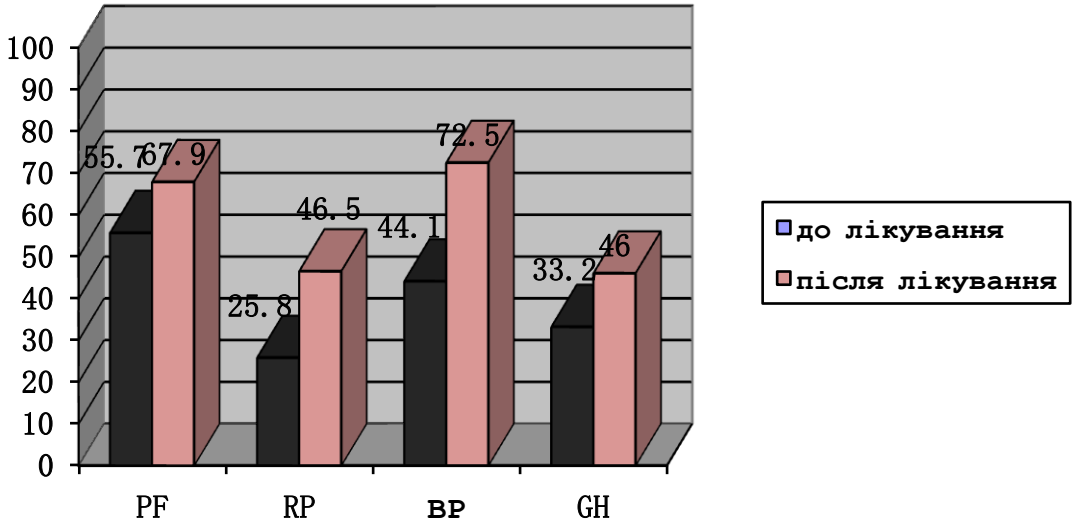



Fig. 1. Physical health indicators in the 1st group of patients with CEG as a result of treatment.

The mean value of YJ on the scale of physical functioning (PF) was (55.3±1.2) points before treatment and (65.6±1.3) points after treatment. According to the scale of functional physical functioning (RP), the score was (25.3±1.7) and (43.4±1.1) points, respectively. The mean value on the pain scale (BP) before the treatment was (44.3±1.5) points and was (70.1±1.1) points after treatment. According to the general health scale (GH), YAH corresponded (33.6±1.4) and (42.4±1.5) points, respectively. Consequently, the difference in the physical components of the QA in the comparison groups was 63, which was 39.7%.

A comparison was also made between the LAS parameters by the physical component in the 2nd group before and after the treatment (Fig. 2).




p<0,05

Fig. 2. Physical health indicators in the 2nd group of patients with CEG as a result of treatment.

In the 2nd group of patients, the mean value of LU on the scale of physical functioning (PF) was before treatment (55.7±1.2) and (67.9±1.3) points after treatment. According to the scale of roles physical functioning (RP), YZH was (25.8±1.7) and (46.5±1.1) points, respectively. On the pain scale (BP), the average before treatment was 44.1±2.8 points and 72.3±1.1 points after treatment. In the general health scale (GH), the scores were (33.2±1.9) points and (46.1±1.6) points, respectively. Consequently, the difference in the physical components of the LAS in the comparison groups was 74.1 points, which was 46.7%.

We also studied the indicators of psychosocial health of patients with CEG in group 1 (Fig. 3).

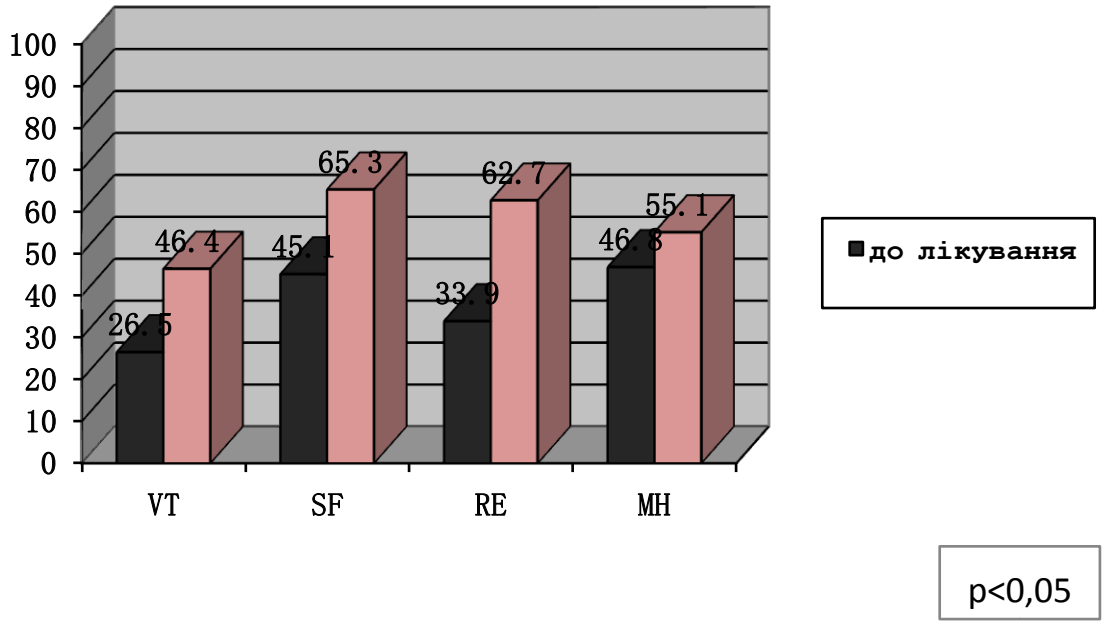



Fig. 3. Indicators of psychological health in the 1st group of patients with CEG as a result of treatment.

During treatment, the median BMD on the viability scale (VT) increased from (26.5±2.4) to (46.4±1.8) points. Improvement of YA on the scale of social functioning (SF) from (45.1±2.3) to (65.3±4.5) points. On the scale of role-playing emotional functioning (RE), the average value for treatment was (33.9±2.4) points and increased to (62.7±1.7) points. According to the MH, the average LH score was 46.8±2.9 and 55.1±2.7 respectively. Thus, according to the analysis of the data obtained, it can be argued that the YAH improvement in patients with CHEM is performed on the background of complex therapy with inclusion of vitamin complex Doctovit. Consequently, the difference in the indicators for the psychological component of QA in the comparison groups was 77.2 points, which is a rock of 50.7%.

Changes in the parameters of QOL by the psychological component in the 2nd group before and after treatment were analyzed (Fig. 4).

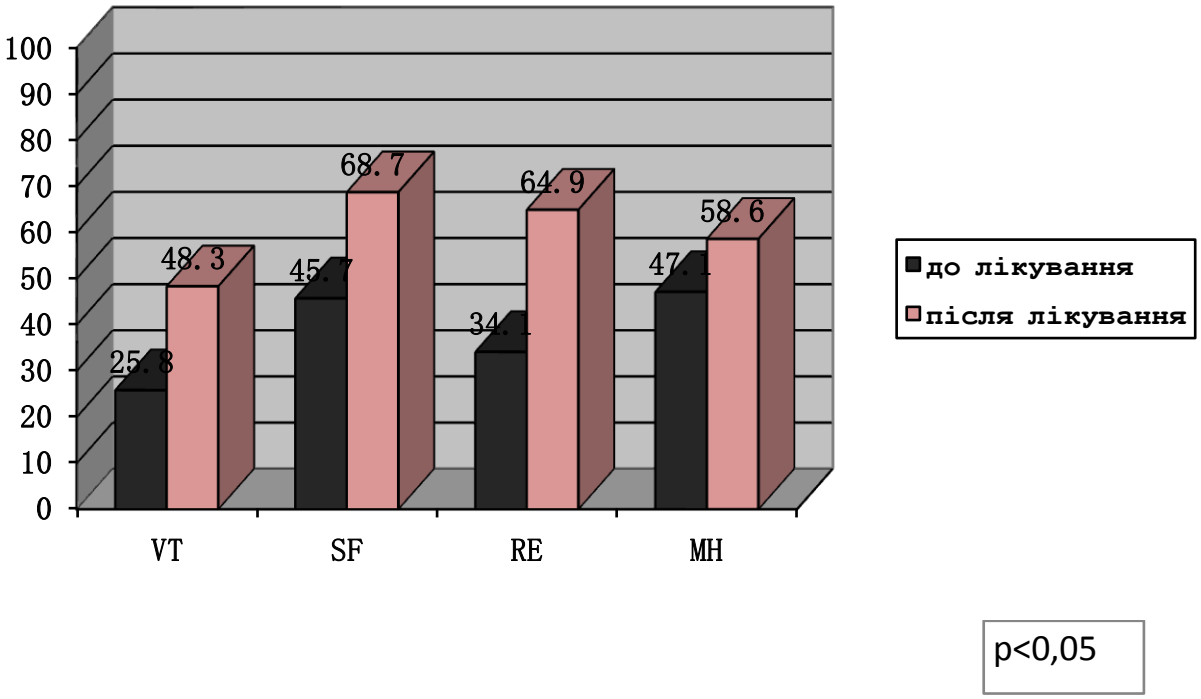



Fig. 4. Indicators of psychological health in the 2nd group of patients with CEG as a result of treatment.

On the viability scale (VT), the mean value of LJ in group 2 during treatment increased from (25.8±1.4) to (48.3±1.4) points. According to the scale of social functioning (SF), I changed from (45.7±1.3) points to (68.7±1.6) points. The average value on the scale of role-playing emotional functioning (RE) was (34.1±1.2) points and increased to the level (64.9±1.4) points. According to the MH, according to the scale of mental health (47.1±1.5) and (58.6±1.7) points. Consequently, analyzing the results, it can be argued that the improvement of the patients with CEG in group 2 (Fig. 4). Consequently, the difference in the indicators for the psychological component of QF in the comparison groups was 87.8 points, which was 57.5%.

The GSRS questionnaire assessed the severity of the symptoms of gastroenterological diseases in the 1st and 2nd groups before and after treatment (Fig. 5).

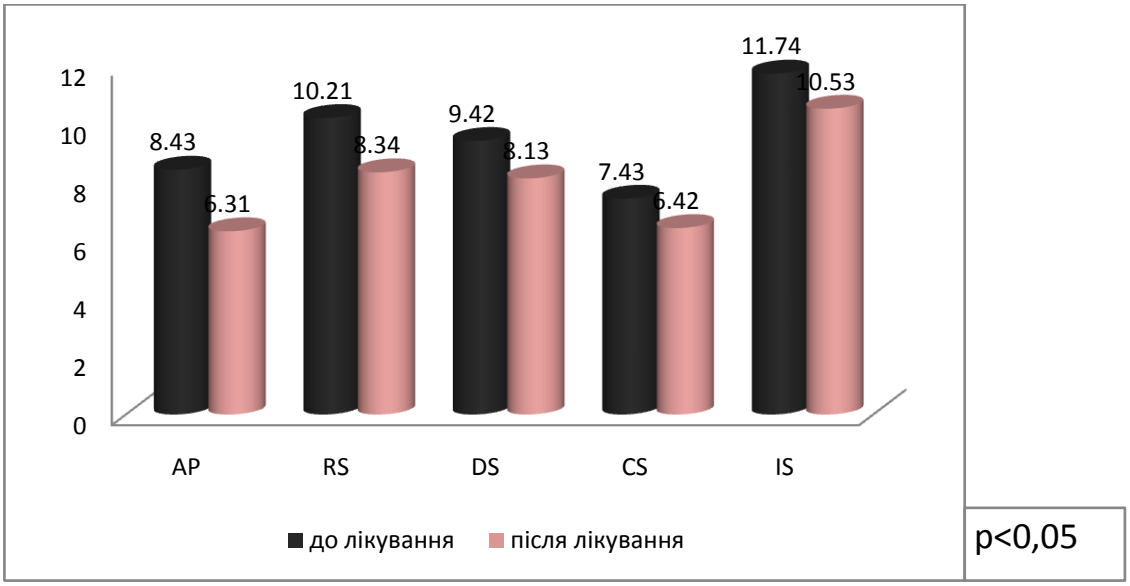



Fig. 5. Indicators of the GSRS questionnaire in the 1st group of patients with CEG as a result of treatment.

According to the abdominal pain score (AP), the average value in the 1st group before treatment was (8.43±0.12), after treatment — (6.31±0.13) points, according to the scale of assessment of the gastroesophageal reflux syndrome (RS ) — (10.21±0.14) and (8.34±0.12) points respectively, on the scale of the assessment of diarrhea syndrome (DS) — (9.42±0.14) and (8.13±0.11) scores, respectively, according to the scale of the assessment of the constipation syndrome (CS), the mean value was at the level (7.43±0.12) before treatment and (6.42±0.16) points after treatment; on the scale of assessment of the dyspepsia syndrome, the level was (11.74±0.13) and (10.53±0.12) points respectively (Fig. 6). Consequently, it can be argued that the symptoms of gastroenterological illness and the improvement of LH in patients with CHEM under the influence of conventional treatment can be regressed. The difference in GSRS questionnaire scores in the 1st group was 7.5 points, which was 15.9% (Fig. 5).

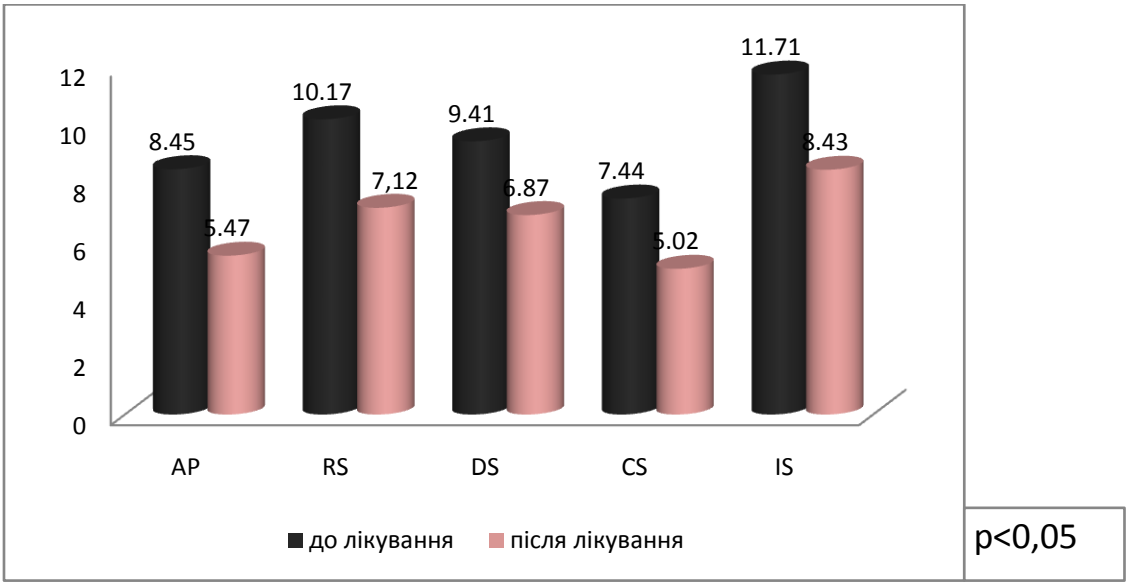



Fig. 6. Indicators of the GSRS questionnaire in the 2nd group of patients with CHE as a result of treatment.

The mean score for abdominal pain (AP) was (8.45±0.12) before treatment and (5.47±0.14) points after treatment, according to the scale of gastric reflux (RS), the level was (10, 17±0.15) before treatment and (7.12±0.14) points after treatment, in the diarrhea syndrome (DS) — (9.41±0.12) and (6.87±0.12) scores for the score for the assessment of the constipation syndrome (CS) — (7.44±0.12) and (5.02±0.15) points, respectively, and according to the assessment scale for the dyspeptic syndrome (IS) — (11.71±0.14) and (8.43±0.16) points, respectively, indicating a more significant regression of the symptoms of gastrointestinal disease and improving QOL in patients under the influence of combined therapy with the inclusion of vitamin complex Doctovit than patients receiving conventional treatment (Fig. 6). The difference in GSRS questionnaire scores in the 2nd group was 14.27 points, which is 30.2%. This is significantly and significantly higher than the effectiveness of the proposed program with the inclusion of the Doctovit in relation to such in the group of commonly accepted treatment — 30.2% vs. 15.9%.

**Conclusions**

1) Inclusion in the complex treatment of patients with CEG vitamin preparation Doctovit contributed to a statistically significant regression of clinical symptoms ($p < 0,05$). This allowed to significantly improve the physical and psychological parameters of quality of life on the scale of the SF-36 questionnaire by an average of 4.9%, according to GSRS questionnaires — by 17.2% ($p < 0.05$), which proved the

effectiveness and feasibility of using vitamin Drug Doctovit in the complex treatment and rehabilitation of patients with CEG.

2) For the correction of polynutrient disorders in the complex treatment of CEG it is expedient to use a vitamin complex Doctovit 2 tablets per day after eating for 2 months.

**The prospect of further research** is the study of the effectiveness of the Doctovit for the correction of trophological disorders

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Inclusion of the vitamin drug Doctovit in the complex treatment of patients with chronic erosive gastritis contributed to a statistically significant regression of clinical symptoms ($p<0.05$). This led to significant improvement of physical and psychological parameters of life quality: according to the SF-36 questionnaire scale — at the average of 4.9%, GSRS questionnaire scale — by 17.2% ($p<0.05$), which proved the effectiveness and reasonability of using the vitamin drug in complex treatment and rehabilitation of patients with chronic erosive gastritis. It is expedient to prescribe 2 tablets of the vitamin complex Doctovit per day after eating during 2 months for the correction of polynutrient disorders in complex treatment of chronic erosive gastritis.