Therapy efficiency of anxiety at patients with adjustment disorder, on glycine therapy model with placebo-sensibility

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Abstract.

The research data, which testify to decrease of anxiety expressiveness at patients with adjustment disorder under therapy by microencapsulated glycine, are provided in article. It is revealed that the average reduction of disturbing symptoms in group of patients taking glycine, upon four weeks of treatment, twice exceeded the corresponding indicators in placebo group (31 vs 15% of average point reduction on Hamilton Anxiety Rating Scale). Under therapy by glycine, such symptoms as mood of anxiety, tension and sleep disturbance underwent the greatest return dynamics.

Key words: stress, anxiety, adjustment disorder, therapy efficiency, glycine

Introduction

In modern society, due to a large number of stresses, adaptation disorders are widespread. One of the most common symptoms of these disorders is anxiety. In the treatment of anxiety conditions, depending on their severity and duration, a whole spectrum of methods is used — both psychotherapy and pharmacological agents (anxiolytics, antidepressants, herbal formulations). At the moment, it is important to find and use drugs that are quite effective, and at the same time devoid of the disadvantages of anxiolytics and antidepressants, which are the risk of drug dependence, delayed onset of effect and poor tolerance. Glycine (tablets for sublingual use containing microencapsulated glycine as an active substance) has long been widely used in medical practice. Many of the conditions and symptoms in which glycine is indicated, are also seen in adaptation disorders. However, the use of glycine in the treatment of adaptation disorders has not previously been deeply studied.

Materials and Methods

The study was conducted in the Department of boundary psychiatry of the State Scientific Center for Social and Forensic Psychiatry named of V.P. Serbsky. The study included patients suffering from an adaptation disorder with mixed anxiety and depressed mood (F43.23 according to ICD-10), with predominant symptoms of anxiety, aged 18 to 65 years, with a general severity on a CGI-S scale of ≤3 points (at the time of inclusion in the study), which were prescribed anxiolytics. A total of 64 patients were examined (Table 1). Criteria for exclusion from the study – severe drug allergies or a history of hypersensitivity, or hypersensitivity to glycine; disorders associated with alcohol or psychoactive substances (according to the ICD-10 criteria); depressive disorders, organic damage of the central nervous system; schizophrenia; the level of anxiety on the Hamilton Scale HAM-A more than 25 points.

After a 7-day wash-out and randomization period, the experimental group (34 people) received only glycine, 1 tablet 100 mg 3 times a day (daily dose of 300 mg) sublingually (or buccally) for 28 days. Patients from the placebo group (30 people) received placebo in the same mode.

Patient dynamics was assessed using the CGI-S General Clinical Impression Scale (severity of condition), CGI-I Clinical General Impression Scale (dynamic of condition), and the Hamilton – Anxiety Scale. Measurements were made weekly (7th, 14th, 21st and 28th days of treatment).

Results and Discussion

Concomitant mental disorders in the patients were not found. A history of psychopathological disorders was recorded in 7 patients (10.9%). Concomitant somatic diseases – in 56 patients (87.5%). Only 13 (20.3%) of the patients at the time of beginning of the study and throughout it needed somatotropic therapy. One patient before inclusion in the study received therapy with a drug that has an effect on the central nervous system (clonazepam) in order to correct sleep disorders.

The average score on the CGI-S scale in the preliminary examination of the group was 2.6 ± 0.5, on the HAM-A scale – 21.6 ± 1.9. The proportion of mental manifestations of anxiety slightly exceeded the somatic ones (12.72 vs 9.4 score on the HAM-A scale). The most severe symptoms of anxiety before starting of the study were anxious mood (2.75 points), insomnia (1.95 points) and tension (1.89 points). The least worried were the genitourinary symptoms (1.06 points), somatic muscular symptoms (1.2 points), cognitive impairments (1.23 points), respiratory (1.28 points), somatic sensory and behavioral symptoms (1.34 points each). The average values of particular symptoms of anxiety are in Table. 2.

At the end of the 4th week of therapy in the glycine group, the average score on the CGI-S scale decreased from 2.59 to 1.29 points, in the placebo group – from 2.63 to 2.28 (Fig. 1). The results of patients in dynamics are shown in Table. 3. After 4 weeks, 28 patients of the experimental group (82.4%) showed significant improvement, 5 patients (14.7%) showed a substantial improvement. In the placebo group, significant improvement was observed only in 14.3% of patients, and substantial - in 21.4% of patients. The placebo result is significantly different from the experimental group.

After 4 weeks, the average total score of HAM-A in the experimental group decreased by 6.59 points (31%), and in the placebo group – by 3.16 points (15%), i.e. half as much as glycine (Fig. 2). Changes in the average score for subscales of mental and somatic anxiety are presented in Tables 4 and 5. In the experimental group, the mental manifestations of anxiety decreased by 38%, and somatic – by 31% (Table 5). These changes are comparable and significantly exceed the reduction in symptoms in the placebo group. The dynamics of individual anxiety symptoms is presented in Table 6 and in Fig. 3.

In general, the placebo results obtained in the study coincides with the available literature data on the placebo effect in anxiety disorders. The superiority of glycine over placebo was shown for most of the studied indicators, excluding the effect on depressive mood (there were no statistically significant differences between the efficacy of glycine and placebo relative to this indicator). The most sensitive to glycine therapy were such symptoms of anxiety as anxious mood, insomnia, tension. Thus, the present study shows the efficacy of microencapsulated glycine in the treatment of mild anxiety in patients suffering from an adaptation disorder with a predominance of other emotions, which opens up the prospect of using this drug for the treatment of boundary mental disorders related to stress.