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CLINICAL EFFICACY AND SAFETY OF THE DRUG NEUROOXIDOL-ZOMMER (250 MG/5 ML) IN PATIENTS WITH ISCHEMIC CEREBROVASCULAR ACCIDENTS

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Abstract

Objective of the study. To study the efficacy and safety of sequential therapy with Neurooxidol-Zommer (250 mg/5 ml), administered intravenously by drip for 14 days, in elderly patients with chronic cerebral ischemia (CCI) against the background of arterial hypertension and atherosclerosis.

Material and methods. The open prospective observational study included 60 patients with an established diagnosis of CCI, confirmed by the results of neuroimaging. All patients were examined to assess the neuropsychological status (MoCA test), severity of asthenia (MFI-20 scale), emotional state (Hamilton Anxiety and Depression Scale), motor functions (Tinetti Formalized Clinical Scale for Assessing the Motor Activity of the Elderly). The effectiveness of the therapy was assessed using the quality-of-life questionnaire (SF-36). The study results showed high efficacy and safety of sequential therapy with Neurooxidol-Zommer (250 mg/5 ml) in relieving asthenic and emotional disorders, improving cognitive functions, and increasing the quality of life of patients. The maximum effect occurred after the completion of the full course of therapy. High patient compliance with the therapy and a low incidence of adverse events were shown. Sequential use of intravenous administration of Neurooxidol-Zommer (250 mg/5 ml) is an effective and safe method of treating patients with CCI.

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Keywords: Chronic cerebral ischemia, arterial hypertension, atherosclerosis, ethylmethylhydroxypyridine succinate, Neurooxidol-Zommer (250 mg/5 ml), cognitive impairment.

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Introduction

Cerebrovascular diseases are a pressing issue in modern medicine. With the increasing proportion of elderly people in the world population, this problem is becoming increasingly important in both medical and social aspects [1]. In the Republic of Uzbekistan, there are more than 3 million patients suffering from chronic cerebrovascular accidents, which, according to the latest statistics, is twice as many as ten years ago [2]. The main clinical manifestations of chronic cerebral ischemia (CCI) are various neurological and cognitive disorders caused by cerebral microangiopathy. The results of prospective studies indicate the progression of cognitive impairment from mild and moderate changes to severe dementia in patients with CCI, especially in the elderly. Given the trend toward increasing life expectancy in most countries, the growth in the proportion of elderly and senile people, it is important to maintain sufficient social activity in the elderly with CCI in order to reduce the risk of severe dementia [2, 3].

The issue of the mechanisms of CCI formation has been discussed for a long time. The main factors initiating pathomorphological disorders of the brain substance in CCI are arterial hypertension (AH), arteriolosclerosis, lipogyalinosis of small cerebral arteries, atherosclerotic lesions of the main arteries of the head, etc. The most important risk factor for damage to the vascular system of the brain is hypertension and symptomatic AH, which, with an increase in blood pressure, are accompanied by a breakdown in autoregulation of cerebral circulation and increasing ischemic damage to neurons [3, 4].

The emergence of high-tech methods of lifetime diagnostics, assessment of the state of the brain and cerebrovascular system have shown that the long-term pathological influence of hypertension, diabetes mellitus, arteriolosclerosis initiates diffuse changes in the deep subcortical structures of the brain, leading to white matter hyperintensity (WMH). The presence of WMH, expansion of perivascular spaces, foci of various ages of past lacunar infarctions and microbleeds are currently considered one of the neuroimaging criteria of CCI [5, 6]. Despite the diversity of pathogenetic pathways for the development of CCI, the mechanisms of damage to brain structures are largely universal. A decrease in cerebral perfusion leads to hypoxia and oxidative stress, which causes the formation of not only lacunar foci in the white matter of the brain, but also damage to neuroglia and apoptosis. The vulnerability of brain tissue to damaging factors increases with age, and therefore the focus of therapeutic measures in an elderly patient with CCI should include the use of a universal neurocytoprotector with a powerful antioxidant antihypoxant effect - Neurooxidol-Zommer [3,5]. Treatment of CCI should be comprehensive, based on the identified cardiovascular risk factors and pathobiochemical processes occurring in the brain, and aimed at preventing disease progression. Impact on CCI risk factors includes correction of blood pressure, dyslipidemia, hyperglycemia, and administration of antiplatelet agents, which is considered as basic therapy [2, 4, 5]. Neuroprotective therapy will reveal its maximum potential only when the main risk factors for the development of CCI are eliminated [6, 7].

Neurooxidol-Zommer (250 mg/5 ml) (2-ethyl-6-methyl-3-hydroxypyridine succinate) causes an increase in compensatory activation of aerobic glycolysis and reduces the degree of inhibition of oxidative processes in the Krebs cycle under hypoxic conditions with an increase in the formation of ATP and creatine phosphate, activates the energy-synthesizing functions of mitochondria and stabilizes cell membranes. The value of Neurooxidol-Zommer is that in addition to the direct effect on the processes occurring in the Krebs cycle, the drug has a multimodal effect, in particular, a positive effect on the state of the rheological properties of the blood and the aggregation capacity of platelets [8, 9]. A number of studies indicate the antiatherogenic effect of Neurooxidol-Zommer, developing due to the ability to inhibit lipid peroxidation and have a protective effect on local vascular mechanisms of atherogenesis [7, 8].

The aim of the study was to investigate the efficacy and safety of sequential therapy with the administration of Neurooxidol-Zommer intravenously by drip (250 mg once a day) for 14 days in elderly patients with CCI against the background of hypertension and atherosclerosis.

Material and Research Methods

A prospective observational study of patients with CCI against the background of hypertension and cerebral atherosclerosis was conducted.

Inclusion criteria: the presence of chronic myocardial infarction confirmed by neuroimaging (MRI of the brain) according to the diagnostic criteria for chronic myocardial infarction, laboratory-instrumental confirmed hypertension and atherosclerosis of extra- and intracranial arteries, maintaining an active social and work status (all patients included in the study continued to work).

Exclusion criteria: history of ischemic or hemorrhagic stroke, Alzheimer's disease, neurodegenerative diseases of the brain, Parkinson's disease, multiple sclerosis and other demyelinating diseases of the nervous system, hereditary degenerative diseases of the central nervous system, developmental abnormalities of the nervous system, uncontrolled epilepsy, other neurological disorders that seriously affect motor and cognitive functions, mental disorders (schizophrenia, schizotypal states, delusional disorders), depression level of no more than 14 points on the Hamilton scale, severe somatic diseases and conditions that do not allow the patient to be regularly monitored within the framework of the protocol.

The patients were divided into two groups. Group 1 included 30 patients (16 women, mean age 67.0±2.5 years, and 14 men, mean age 66.8±2.3 years), and group 2 included 30 patients (15 women, mean age 66.8±3.8 years, and 15 men, mean age 65.6±2.8 years). The groups were comparable in age, gender, nature of concomitant diseases, and basic therapy (antihypertensive, lipid-lowering, and antiplatelet therapy). In addition to basic therapy, patients in group 1 received Neurooxidol-Zommer intravenously by drip (250 mg-5 ml once a day) as infusions for 14 days. Patients in group 2 received only basic therapy. During the present study, several visits were conducted to assess the patient's condition before the start of treatment (visit 1), on the 14th day (visit 2) - completion of parenteral administration of Neurooxidol-Zommer, - 74±5 days from the start of therapy.

Patients in both groups remained socially active at the start of the study and continued working in intellectual occupations (engineers, teachers, architects, doctors). All patients underwent examination with a detailed assessment of neuropsychological status (Montreal Cognitive Assessment Scale (MoCAtest) [10], severity of asthenia (subjective asthenia assessment scale MFI-

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20 [11]), emotional state (Hamilton Anxiety and Depression Scale [12]), motor functions (Tinetti Formalized Clinical Scale for Assessing Motor Activity in the Elderly [13]). The effectiveness of the therapy was assessed using the quality of life questionnaire (TheShortForm-36 — SF-36), which provides an assessment of the physical, psychological, and social state of the subjects and consists of 36 questions grouped into scales: physical functioning, role functioning due to physical condition, pain intensity, general health ("Physical component of health"); psychological health, role functioning due to emotional state, social functioning, life activity ("Mental component of health") [14]. During visits 2 and 3 were assessed for adverse events. The study was approved by the local ethics committee.

Statistical processing of the results was carried out using the SPSS21.0 program. The results are presented as M±m, where M is the arithmetic mean, m is the representativeness error (standard deviation). The significance of differences between the compared samples was assessed using the parametric Student t-test at a 95% confidence interval [15].

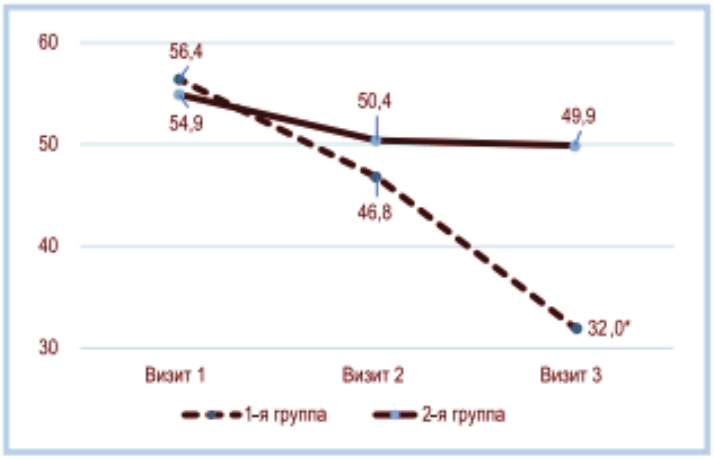

Рис. 1. **Динамика показателей по шкале MFI-20 у пациентов двух групп.**
* — различия между группами статистически достоверны ($p<0,05$).

Results and Discussion

Despite the intellectual nature of the work activity, all patients included in the study complained of memory loss, impaired concentration, rapid physical and mental fatigue, difficulty switching activities, mood lability, sleep disorders, most often of the early awakening type. In both groups, at the beginning of the study, mild to moderate cognitive impairments were detected, there were no signs of significant mental disorders (anxiety and depression) and signs of asthenia were detected. In both groups, changes in the indicators of neurodynamic, visual-spatial functions were detected. Thus, the MoCA test indicators in the 1st group at the beginning of the study were 24.0 ± 2.4 points, in the 2nd - 24.6 ± 2.6 points. During the treatment in the 1st group, significant positive dynamics were noted, reaching the level of reliability for most indicators (to a greater extent this concerned attention, short-term memory, executive functions). A positive effect of therapy was also found in terms of anxiety reduction according to the Hamilton Anxiety Scale, according to which, by the end of the observation period, a significant decrease in this indicator occurred in Group 1. By the end of the study, at Visit 3, patients in Group 1 showed a significant improvement in motor functions according to the Tinetti scale (stability and gait) when compared with Group 2.

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Table 2. Dynamics of quality of life indicators according to the SF-36 questionnaire, points

Визит	Компоненты опросника SF-36	2-я группа (n=30)	1-я группа (n=30)	p
1	Физический	42,3±4,3	43,6±5,3	0,623
	Психический	43,7±5,6	44,3±6,8	0,101
2	Физический	48,2±10,9	47,1±10,4	0,164
	Психический	52,6±6,3	48,2±4,1	0,069
3	Физический	57,1±3,9	47,3,0±4,3	0,001
	Психический	57,3±4,1	52,6±3,5	0,003

Примечание. * — различия между группами статистически достоверны (p<0,05).

The dynamics of the examination indicators on the MFI-20 scale deserve special attention: in the 1st group, already by visit 2, there was a tendency towards a decrease in asthenic manifestations of a more pronounced nature than in the 2nd group, which reached the level of statistical significance by visit 3 (Fig. 1).

The most pronounced improvement was noted in the structure of physical and mental asthenia, as well as decreased activity (Fig. 2). It should be emphasized that a statistically significant decrease in the manifestation of decreased activity and a decrease in the manifestation of physical asthenia were noted by patients of the 1st group already at visit 2, after the end of infusion therapy with the study drug, which indicates the advisability of initiating therapyNeurooxidol-Zommerwith injection. The results obtained were expected, showing further improvement in the indicators of decreased activity and physical asthenia by the end of the study. A significant reduction in the phenomena of mental asthenia was observed only after the end of the full course of therapy. Neurooxidol-Zommer

Quality of life indicators (SF-36 questionnaire) at visit 1 were low, indicating a negative impact of CIM on the patient's daily life. At visit 2, the patients of group 1 had significantly better physical and mental health indicators than those in group 2. Patients tolerated physical and intellectual stress better, their mood and emotional status improved. When analyzing quality of life indicators (average assessment) after the treatment, it was found that they statistically significantly increased only in group 1, indicating a positive impact of the therapy.Neurooxidol-Zommer(Table 2).

Significant differences between the groups appeared only by visit 3, which demonstrates the feasibility of using sequential therapy, in which parenteral administration of the drug is necessary for more rapid initiation of antihypoxic and antioxidant effects, and continued therapy with the tablet form ensures maximization of the positive effect of treatment and achievement of the main goal - stopping or slowing the progression of cognitive impairment, reducing the manifestations of asthenia, improving motor function and, as the main goal of our interaction with the patient, improving the quality of life of an elderly socially active patient.

Positive dynamics in relation to neurological symptoms of CCI associated with the influence of sequential drug therapy Neurooxidol-ZommerThe 1st group of patients was accompanied by a low level of development of unpleasant sensations (in 2 patients), none of which were serious. All adverse outcomes were manifested by a feeling of sore throat during intravenous drip administration of the drug, the possibility of which is noted in the instructions for use of the drug. In one case, it

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was stopped by reducing the rate of administrationNeurooxidol-Zommer, the second patient had a transient sore throat sensation that resolved on its own. High level of safetyNeurooxidol-Zommerand its good tolerability have been noted previously [5, 8, 16]

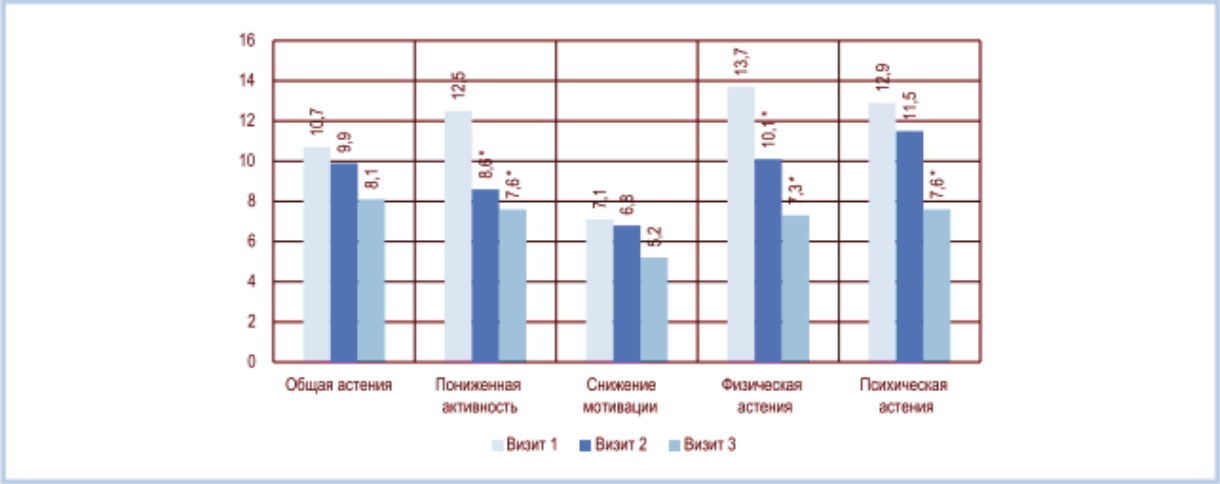

***Рис. 2.* Динамика отдельных показателей шкалы MFI-20 у пациентов 1-й группы.**
* — различия статистически достоверны по сравнению с исходным уровнем ($p<0,05$).

Conclusion

The appearance of a dosage form on the pharmaceutical market and the studies conducted using a double dose of the drug demonstrated a significant role in the correction of energy metabolism in patients with cerebrovascular pathology, in particular, with CCI. Sequential therapy with parenteral administration of 250 mg - 5 ml Neurooxidol-Zommerwithin 14 days, allows to compensate for the pathophysiological processes of hypoxia and oxidative stress, which in clinical practice is manifested by an increase in the quality of life due to an improvement in the subjective well-being and stabilization of the cognitive functions of a patient with CCI.

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