OXYETHYLAMMONIUM METHYLPHENOXYACETATE, IMMUNOMODULATOR AND ADAPTOGEN: CLINICAL USE REVIEW

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Oxyethylammonium methylphenoxyacetate is an adaptogenic immunomodulator with a complex mechanism of action. It can be successfully used for treatment, prevention and restoration in case of flu and cold, and to improve working capacity in asthenia, including conditions developed following COVID-19. Clinical investigation of the effect produced by oxyethylammonium methylphenoxyacetate demonstrates its effectiveness under extreme climate and geographic conditions, during physical and mental overload, exercise, viral infections, severe infectious pathology, and all diseases associated with a weakened immune system. Based on conducted clinical trials of oxyethylammonium methylphenoxyacetate, no adverse effects were found and good tolerability was observed. Due to good compatibility of oxyethylammonium methylphenoxyacetate with other agents, it can be included into complex rehabilitation programs as an independent or/and complementary agent. This increases effectiveness of the conducted treatment and improves the diagnosis.

Keywords: oxyethylammonium methylphenoxyacetate, immunomodulator, adaptogen, efficacy, safety

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ИММУНОМОДУЛЯТОР И АДАПТОГЕН ОКСИЭТИЛАММОНИЯ МЕТИЛФЕНОКСИАЦЕТАТ: ОБЗОР ПРИМЕНЕНИЯ В КЛИНИЧЕСКОЙ ПРАКТИКЕ

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Оксиэтиламмония метилфеноксиацетат — адаптогенный иммуномодулятор комплексного действия, который можно с успехом использовать для лечения, профилактики и восстановления при простуде и гриппе, для повышения и поддержки работоспособности при астенических состояниях, в том числе после COVID-19. Клиническое изучение действия оксиэтиламмония метилфеноксиацетата свидетельствует о его эффективности в экстремальных климатогеографических условиях, при перегрузках в физическом и умственном труде, спорте, вирусных простудных заболеваниях, тяжелой инфекционной патологии, при всех заболеваниях, связанных с понижением иммунитета. На основании проведенных клинических исследований применения оксиэтиламмония метилфеноксиацетата не было выявлено побочных эффектов, отмечалась хорошая переносимость препарата. Благодаря хорошей совместимости оксиэтиламмония метилфеноксиацетата с другими препаратами он может быть включен в комплексные реабилитационные программы в качестве самостоятельного или/и дополняющего средства, что позволит повысить эффективность проводимого лечения и улучшить прогноз.

Ключевые слова: оксиэтиламмония метилфеноксиацетат, иммуномодулятор, адаптоген, эффективность, безопасность

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A principal problem that arises during the use of adaptogens is a lack of proven effectiveness, i. e., effectiveness in the trials conducted following strict rules. Effectiveness of adaptogens is most commonly a consequence of small trials (which, unfortunately, are not always correctly conducted) or experience of using traditional medicine which can sometimes be rejected with the help of evidence-based medicine.

It should be taken into account that from a chemical point of view, an adaptogenic agent is a complex combination of different substances which is difficult to analyze and reproduce. That's why the effect can vary lot-to-lot and is not always predictable.

A lack of proven effects observed during the use of adaptogens doesn't mean a complete lack of effects. Thus, some plant-based agents can influence metabolism of other medicinal agents and increase the risk of adverse effects. Wide use of plant-based agents in the absence of convincing evidence is related to ethical issues. Thus, further trials are required to obtain convincing evidence of adaptogen effectiveness and safety in clinical practice.

In recent years, oxyethylammonium methylphenoxyacetate, a biostimulator with immunomodulating and good adaptogenic properties, has been used in practical medicine. Its spectrum of action is similar to that of natural adaptogens (magnolia vine, ginseng, golden root, Eleuterococus, etc.). Nevertheless, in case with oxyethylammonium methylphenoxyacetate, these properties are pronounced to a significant extent [1].

Oxyethylammonium methylphenoxyacetate promotes interferon production, improves and corrects the immune status due to activation of cellular and humoral immunity links, promotes the phagocytic activity of macrophages, improves physical and mental endurance, decreases exposure to various toxins, enhances tolerance to hypoxia, low and high temperatures and other unfavorable environmental factors; has a marked antitoxic activity during intoxication with ethanol, organic solvents, and salts of heavy metals.

Oxyethylammonium methylphenoxyacetate produces immune- and hemostimulating effects, increasing tolerance to intensive physical and mental activities, hypoxia, overheating, overcooling, immobilization and pain stress, being an

adaptogen with a broad spectrum of action, and having marked antioxidative, antitoxic and membrane-stabilizing actions, anti-inflammatory, gonadotropic and anti-blast properties [2, 3].

Oxyethylammonium methylphenoxyacetate is approved for use in medicine as a broad spectrum adaptogen and in agriculture as a regulator of productivity and adaptive properties of plants, and also to improve reproducibility and productivity of animals, birds and beneficial insects [4–7].

The agent with low toxicity has antioxidative, reparative, anti-inflammatory, antitoxic, and energy-stabilizing (antiasthenic) effects [8–11].

According to the conducted trials, oxyethylammonium methylphenoxyacetate has demonstrated its effectiveness in combined therapy of out-patients (with cold, ARVI, flu, etc.) and in patients with severe somatic pathologies, including tuberculosis [7, 8].

Taking into account good compatibility of oxyethylammonium methylphenoxyacetate with other medicinal agents (MA), it can be included into rehabilitation programs as an independent or/and supplementary agent, increasing effectiveness of the conducted treatment and improving the prognosis.

Effectiveness of oxyethylammonium methylphenoxyacetate was shown during a complex therapy of patients with tuberculosis [12]. In the course of treatment of 30 patients with infiltrative pulmonary tuberculosis (17 men and 13 women who were administered 200 mg oxyethylammonium methylphenoxyacetate 3 times a day for 35 days) it has been found out that 13 men and 11 women had scarring and significant resorption of pulmonary tissue infiltrates; they had improved well-being and appetites, normal temperature and increased weight. In the control group, similar effects were found only in 3 men and 2 women during the same period of treatment.

The effect of 0.2 g of oxyethylammonium methylphenoxyacetate 3 times a day for 20 days was examined in a complex therapy of 37 patients with tuberculosis. Meanwhile, 19 patients with pulmonary tuberculosis had significantly accelerated absorption of infiltrates and earlier scarring of the pulmonary tissue during an X-ray examination. Improved hepatic function, increased appetites, higher body mass and normalized temperature were observed. 18 patients with extrapulmonary tuberculosis had improved health, better general tone, absence of weakness, more severe fatigue, and improved body mass. In all the cases, no worsened condition of the patients was observed, demonstrating effectiveness of oxyethylammonium methylphenoxyacetate for treatment of patients with tuberculosis [12].

During the next series of observations of 31 patients with fibrous and cavernous tuberculosis (17 men and 14 women who were administered 200 mg of oxyethylammonium methylphenoxyacetate 3 times a day for 90 days) it has been established that 10 men and 7 women had significant cavern scarring and less fibrosis, better well-being, less amount of produced sputum, better appetites, normal temperature and increased body mass. During the same period of treatment, similar effects were observed among 5 men and 4 women in the control group [7, 8].

In the complex treatment of 33 patients with posttuberculosis pyelonephritis (14 men and 19 women who were administered oxyethylammonium methylphenoxyacetate for 25 days) it has been shown that 8 men and 9 women had lower body temperatures with less pronounced or even vanishing clinical and laboratory signs of pyelonephritis. In the control group (30 patients), only 4 men and 1 woman had similar effects during the same period of treatment.

Kuznetsov IA et al. [13] have shown that clinical examination of the action produced by oxyethylammonium methylphenoxyacetate demonstrates effectiveness of this agent under extreme climatic and geographic conditions, physical and mental overload, exercise, viral infections, severe infectious pathology, and in case of all diseases related to immune deficiency.

Oxyethylammonium methylphenoxyacetate is used to prevent oncological diseases, and correct the psychoemotional status of narcological patients. It doesn't cause any complications, is well combined with many other medicinal agents, has no contraindications and builds up no tolerance [1].

Use of 0.2 g of oxyethylammonium methylphenoxyacetate a day for 20 days normalizes T- and B-cell-mediated immunity, increases both physical and mental working capacity. The sportsmen who took 0.3 g of oxyethylammonium methylphenoxyacetate a day for three weeks of training that uses speed and force experienced improved working capacity [14].

22 patients with neurocirculatory dystonia who were administered 0.1 g of oxyethylammonium methylphenoxyacetate 3 times a day for 20 days as a complex therapy had decreased weakness and fatigue during physical and mental stress. Use of 0.1 g of oxyethylammonium methylphenoxyacetate 3 times a day for 20 days as a complex therapy given to 28 patients with neurotic disorders also improved their quality of life. 24 patients from a psychiatric hospital and clinic of neurosis had normalized emotional background, improved motor activity and decreased weakness and fatigue. Treatment effect was manifested already on day 3–5 and augmented by the end of week 2 of using 0.3 g/day of oxyethylammonium methylphenoxyacetate for 20 days in combination with tranquilizers. On the other hand, asthenic and astheno-depressive states appear during abstinence and remission in patients with alcohol addiction.

Use of 0.6 g/day of oxyethylammonium methylphenoxyacetate for 20 days in patients with alcohol addiction who underwent treatment at a narcological clinic demonstrated a positive effect in all cases: headache, feeling unrested, heaviness in the head and other psychogenic disorders were decreased [13, 15–17].

Positive results were obtained when 0.1 g of oxyethylammonium methylphenoxyacetate was administered twice a day for three weeks to treat viral hepatitis (n = 32, hepatitis A as established diagnosis). Clinical and laboratory observations have shown that 30 patients from the control group who were not administered oxyethylammonium methylphenoxyacetate developed hepatomegaly on day 10–14 and were discharged on day 20–21. Two of them had elevated transaminase levels. All patients with hepatitis A who were administered oxyethylammonium methylphenoxyacetate were discharged on day 17–18 with normal biochemical values. Bilirubin level reduced twice or thrice on day 5, liver volumes were normalized by day 7–10, no allergic and toxic reactions were found [7].

In the subsequent observations, clinical effectiveness of oxyethylammonium methylphenoxyacetate and its effect on parameters of the immune system were examined in 38 patients who had moderate acute virus hepatitis B with an anticipated chronic outcome. 100 mg of oxyethylammonium methylphenoxyacetate were given to patients 3 times a day for 21 days from day 15–16 of the disease.

Oxyethylammonium methylphenoxyacetate normalized biochemical parameters during early recovery, whereas in patients from the control group, the values became normal only three months after discharge and remained high even at 12 months after discharge in case of a chronic stage. Use of oxyethylammonium methylphenoxyacetate resulted in significantly increased levels of T-killers, decreased production of interleukin 1β, and reduced levels of circulating immune

complexes, DNA antibodies; 78.9% of patients had 50–300 pg/ml of serum interferon α. Treatment with oxyethylammonium methylphenoxyacetate resulted in DNA virus levels reduced 10 times and more. Within 12 months after discharge, 89.5% of patients who were administered oxyethylammonium methylphenoxyacetate had negative virus DNA testing results, and only 5.3% of patients had traces of virus DNA, whereas 5.3% (2 people) of patients with chronic hepatitis had rather high concentrations of it (the latter was observed in 12.4% of patients from the control group).

Moreover, effectiveness of oxyethylammonium methylphenoxyacetate was examined in 39 patients with viral hepatitis B and aggravated occupational history (long-term contact with toxic and chemical substances) and secondary immunodeficiency. Oxyethylammonium methylphenoxyacetate was administered in the presence of markers of viral replication (0.1 g twice a day for 2–3 weeks starting from the period of maximum viral replication against the background of generally accepted pathogenetic treatment). Within the course of treatment, the majority of patients (86.2%) significantly improved their condition manifested as reduced intoxication, decreased jaundice intensity and reduced liver volumes, and distinct management of the syndrome of cytolysis. Tolerance of oxyethylammonium methylphenoxyacetate was good, no adverse effects were found. 35 patients had no signs of immunodeficiency after treatment; significant reduction in serologic markers of HBV infection was noted following treatment and during the restoration period as compared to the control group.

Remote outcomes in patients with aggravated anamnesis who had viral hepatitis B and were not administered oxyethylammonium methylphenoxyacetate seemed less satisfactory (chronic hepatitis and bile duct damage were registered 4 and 2 times as frequently, respectively) as compared to patients who used agents for pathogenetic therapy in combination with oxyethylammonium methylphenoxyacetate [18].

Use of 0.6 g/day of oxyethylammonium methylphenoxyacetate for 20 days as a complex therapy in patients with infectious hepatitis resulted in an icteric period reduced for 5–6 days, more rapidly restored volumes of the liver, lack of nausea, vomiting, sensation of heaviness in the epigastrium and right subcostal area. Oxyethylammonium methylphenoxyacetate administered for 7 days decreased serum bilirubin levels in the majority of patients. The patients had normalized biochemical values 4–6 days earlier than those from the control group, the length of stay in hospitals was reduced on Day 3–4.

The obtained data show that the agent is effective in treatment of hepatitis A and B as an adaptogen and probably as an inducer of interferonogenesis. Oxyethylammonium methylphenoxyacetate reduces the need in other hepatoprotectors and immunomodulators [7].

Moreover, oxyethylammonium methylphenoxyacetate ensures effective treatment for herpes. Observations of 32 out-patients with herpetic fever and 22 out-patients with genital herpes have shown that 0.6 g/day of oxyethylammonium methylphenoxyacetate for 20 days combined with antiviral and symptomatic agents reduced objective signs of the disease 5–6 days earlier than in 40 patients in the control group. It means that oxyethylammonium methylphenoxyacetate can correct the immune status during the secondary herpetic infection, prolong the period of remission and improve the clinical picture [19].

Oxyethylammonium methylphenoxyacetate also produced a stimulating effect on the cardiac function of patients with acute myocardial infarction (AMI) and chronic heart failure (CHF), potentiated and prolonged the action of cardiac medications (Neoton, Preductal) [12, 20–22].

Use of 0.6 g/day of oxyethylammonium methylphenoxyacetate for 20 days in 44 patients with chronic heart failure during combination treatment reduced peripheral vascular resistance, improved ECG parameters and increased the quality of life of patients based on the results of conducted psychological tests. Similar results were obtained in patients with acute myocardial infarction [12, 13, 16, 17, 20, 23–27].

Patients with CHD (primary acute myocardial infarction) aged 30 to 75 have been under observation. Oxyethylammonium methylphenoxyacetate has been used in the background therapy. They started at 100 mg once a day before increasing the dose to 200 mg three times a day. The control group included those patients who had not taken oxyethylammonium methylphenoxyacetate. Examination of patients who were given 100 mg of oxyethylammonium methylphenoxyacetate 3 times a day for 20 days against the background of traditional therapy has shown a significant improvement of hemodynamic parameters already on Day 10 [7].

A dramatic decline in immunity was found in patients with purulent and necrotic wounds, especially during the postoperative period. This promoted effectiveness trials of oxyethylammonium methylphenoxyacetate in surgical practice. It has been found out that 37 patients operated on for pancreonecrosis who obtained 0.2 g of oxyethylammonium methylphenoxyacetate 3 times a day for 10 days during a combination therapy experienced better restoration with significantly reduced length of stay at the intensive care unit [13, 28–31].

In the article of Shabanov PD, Ganapolsky VP, et al. [4, 6] it has also been shown that oxyethylammonium methylphenoxyacetate normalizes the values of physical and mental working capacity and metabolic state during exposure to the cold. The medicinal agent has frigoprotective properties and can be recommended for use as a meteoadaptogen for stimulation, preservation and restoration of working capacity during exposure to the cold (in cold climate). It effectively corrected cardiovascular changes induced by cold stress, including Ruffier test results. The working capacity of those tested was ultimately improved. Endurance of the muscular system (dynamic dynamometry results) and PWC170 statoergometric test results (indirect values of physical working capacity) were improved while taking oxyethylammonium methylphenoxyacetate. Coordination of movements (fine motor skills), values of static and dynamic dynamometry, were preserved at the level of thermal comfort.

No statistically significant changes in mental capacity were found with oxyethylammonium methylphenoxyacetate. While taking placebo, mean values of physiological parameters were significantly similar to those from the control group. During exposure to the cold, the metabolic status of test subjects had high prooxidant readiness expressed as increase in malondialdehyde levels by 99% and diene conjugates levels by 62%, decreased activity of superoxide dismutase by 55% and reduced glutathione levels by 47%. During exposure to the cold, volunteers had increased levels of lactate by 54% with decreased levels of pyruvic acid by 37% demonstrating a change in effectiveness of oxygen-dependent utilization of carbohydrate metabolites with activated anaerobic glycolysis.

In the group of volunteers who received placebo, the nature of metabolic changes was similar to one in the control group. Test subjects who received oxyethylammonium methylphenoxyacetate developed less pronounced metabolic changes during exposure to the cold as compared to those in the control and placebo groups. Thus, compared with the

control group, the level of malondialdehyde was higher by 48% only, whereas the level of conjugated dienes was higher by 29% ($p < 0,05$). Activity of creatine phosphokinase dropped by 29%. Activity of superoxide dismutase, levels of reduced glutathione, lactate and pyruvate weren't different from the values measured under thermal comfort conditions [4–6].

Thus, oxyethylammonium methylphenoxyacetate acts at the level of cells (tissues), and effectively corrects metabolic changes when it's cold. The action is universal as it prevents and mitigates the effect of environmental unfavorable factors on any organ [4–6].

In the work of Rasulov MM et al. [10] it was noted that oxyethylammonium methylphenoxyacetate enhances resistance to unfavorable climate and toxic effects in an integrated manner, increases resistance to cold-related infections during prevention and treatment of patients with acute viral respiratory infections. Oxyethylammonium methylphenoxyacetate reduces protein degradation and generation, accelerates its synthesis, decreases toxic and drug load, risk of complications, corrects postinfectious asthenia, and prevents immunodeficiency after anti-infective therapy [2, 10, 32].

The purpose of another trial was to examine a possible use of oxyethylammonium methylphenoxyacetate within a complex program of physical rehabilitation of patients with arterial hypertension (AH) combined with abdominal obesity [33].

Use of oxyethylammonium methylphenoxyacetate in addition to background therapy with enalapril resulted in a significant decrease in the levels of triglyceride, low density lipoprotein cholesterol as compared to the control group, and a significant reduction in the end-diastolic volume, end-systolic volume, left ventricular myocardial mass and left ventricular myocardial mass index based on echocardiography data.

Use of oxyethylammonium methylphenoxyacetate in addition to background therapy of patients with AH and obesity significantly decreased the level of metabolic disturbances and produced a positive effect on cardiac hemodynamic parameters. Due to good tolerability with other agents, oxyethylammonium methylphenoxyacetate can be included in complex rehabilitation programs for patients with arterial hypertension and obesity as a complimentary agent improving exercise tolerance [33].

Thus, pursuant to evidence base, oxyethylammonium methylphenoxyacetate as a complex adaptogenic immunomodulator can be successfully used for treatment, prevention and restoration during cold and flu, to increase and support working capacity in asthenic conditions, including the ones after COVID-19. This is particularly relevant in the view of the epidemiological situation and can aid in adaptation to new climatic conditions [1].

Clinical investigation of the effect produced by oxyethylammonium methylphenoxyacetate demonstrates its effectiveness under extreme climate and geographic conditions, during physical and mental overload, exercise, severe infectious pathology, and all diseases associated with a weakened immune system. Oxyethylammonium methylphenoxyacetate is needed to prevent oncological disorders and correct psychoemotional status in narcological patients.

Oxyethylammonium methylphenoxyacetate increased resistance to acute respiratory diseases (ARD), activated immune processes, increased effectiveness of protein synthesis, normalized lipid exchange, somatometric and physiometric data. That's why oxyethylammonium methylphenoxyacetate can be recommended for broad application both in therapeutic, and preventive purposes [34].

Based on the conducted clinical trials of oxyethylammonium methylphenoxyacetate, no adverse effects were found, and good tolerability of the drug was observed. Oxyethylammonium methylphenoxyacetate leads to no complications, has no contraindications and causes no addiction [13]. Due to good compatibility of oxyethylammonium methylphenoxyacetate with other agents, it can be included into complex rehabilitation programs as an independent or/and complementary agent. This increases effectiveness of the conducted treatment and improves the diagnosis.

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