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PHARMACOLOGICAL ASPECTS OF BIOLOGICAL DRUGS FOR THE TREATMENT OF POSTTRAUMATIC STRESS DISORDER

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Aim. To analyze the pharmacodynamic and pharmacokinetic features of the latest biologics for the correction of posttraumatic stress disorder, and to assess their therapeutic potential for personalized medicine.

Materials and Methods. The study employs general scientific approaches, including analysis, synthesis, and abstraction of scientific papers related to neurobiology, psychopharmacology, and microbiology, which were identified through an Internet search using the electronic databases Web of Science, Scopus, PubMed, and Google Scholar.

Results. PTSD is associated with dysregulation of neurotransmitter systems, hyperactivity of the amygdala, reduced activity of the prefrontal cortex, and disorders of the gut-brain axis. The latest biologics, such as BNC210, which modulates the cholinergic system, and probiotics (*Lactobacillus*, *Bifidobacterium*), which affect the microbiome, demonstrate high efficacy. Biologics have a rapid onset of action (6–8 weeks for probiotics) and minimal side effects. However, high cost and limited clinical trial data are significant barriers.

Conclusions. Biologics offer new perspectives for the treatment of PTSD due to their unique mechanisms of action and safety. Their potential in personalized medicine, in particular through modulation of the individual microbiome, is promising. Further research and optimization of dosage will facilitate the integration of biologics into standard treatment protocols, improving treatment efficacy and quality of life for patients.

Key words: posttraumatic stress disorder, biologics, pharmacodynamics, pharmacokinetics, neurobiology, personalized medicine, microbiome, therapeutic potential.

Posttraumatic stress disorder (PTSD) is a complex psychiatric condition resulting from the experience of traumatic events, such as combat, violence, or natural disasters. The disorder is characterized by intrusive memories, anxiety, sleep disturbances, emotional instability, and physiological manifestations that significantly impair quality of life [1].

The relevance of the problem is due to the increasing number of people with PTSD, military personnel, and civilians in conditions of modern conflicts, as well as the limited effectiveness of traditional treatment methods, which often have side effects or insufficient effectiveness. The development of innovative therapeutic approaches, the use of new biological products, is an

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essential scientific and practical task aimed at increasing the effectiveness of PTSD correction and restoring psycho-emotional health.

Recent studies have focused on the neurobiological mechanisms of PTSD, including dysregulation of the serotonergic, dopaminergic, and adrenergic systems, as well as disruption of the gut-brain axis [2]. Traditional pharmacotherapy based on selective serotonin reuptake inhibitors (SSRIs), such as sertraline and paroxetine, has shown some efficacy, but has limitations associated with side effects and slow onset of action. Newer biologics, such as BNC210, which modulate the cholinergic system, and probiotics that affect the microbiome, open new perspectives due to their unique mechanisms of action and minimal side effects [3]. Recent studies highlight the potential of probiotics (*Lactobacillus, Bifidobacterium*) in reducing stress reactivity through the regulation of neuroimmune and neuroendocrine processes [4]. However, insufficient clinical data, high cost of biologics, and the need for personalized approaches remain unresolved aspects that require further study.

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Materials and Methods

Analysis and synthesis to study the pathophysiology of PTSD and the mechanisms of action of biologics; comparison to compare their pharmacodynamic and pharmacokinetic characteristics with traditional agents; systematization to classify types of biologics and their profiles; generalization to formulate conclusions about therapeutic potential; abstraction to highlight key patterns, which ensures a comprehensive analysis and validity of the results. The search for articles and other scientific works was conducted on the Internet, utilizing the electronic databases Web of Science, Scopus, PubMed, and Google Scholar.

Posttraumatic stress disorder (PTSD) is a complex psychiatric condition that results from exposure to highly stressful, traumatic events, such as combat, natural disasters, violence, or bereavement. The pathophysiology of PTSD encompasses complex changes in neurobiological, cognitive, affective, and behavioral systems that result in dysregulation of mental functioning. These changes result from both the acute response to the trauma and the body's long-term adaptation to stressful conditions [5].

At the neurobiological level, PTSD is associated with dysfunction in several key brain systems. Hyperactivity in the amygdala, which is responsible for processing emotions, contributes to the formation of intrusive symptoms, such as intrusive memories or flashbacks. Reduced activity in the prefrontal cortex, which regulates emotional responses and decision-making, makes it difficult to control these memories and emotions [6]. At the neurobiological level, PTSD is associated with dysfunction in several key brain systems. Hyperactivity in the amygdala, which is responsible for processing emotions, contributes to the formation of intrusive symptoms, such as intrusive memories or flashbacks. Reduced activity in the prefrontal cortex, which regulates emotional responses and decision-making, makes it difficult to control these memories and emotions [6]. The hippocampus, which is responsible for contextualizing memories, also changes, leading to difficulties in distinguishing past traumatic events from current reality. Therefore, individuals with PTSD may react to triggers as if the trauma is happening again [7].

Chronic stress leads to dysregulation of the hypothalamic-pituitary-adrenal axis, which is responsible for the release of the stress hormone cortisol. Individuals with PTSD often have reduced cortisol levels, which, paradoxically, is accompanied by hyperactivity of the sympathetic nervous system, causing increased excitability and reactivity. The neurotransmitter systems serotonin, dopamine, and norepinephrine are altered, affecting mood, sleep, and concentration [8].

At the cognitive and affective levels, PTSD is characterized by disturbances in information processing and emotional regulation. Traumatic experiences form negative cognitive schemas, feelings of guilt, shame, or loss of control. These disturbances exacerbate depressive states and anxiety. Avoidance, as one of the symptoms, reflects the brain's attempt to protect itself from painful memories, but this only worsens isolation and complicates social adaptation. The chronic nature of PTSD is due to the fact that traumatic memories are not integrated into standard memory, but remain fragmented, causing repeated experiences [9].

The behavioral manifestations of PTSD, such as irritability, aggression, and hypervigilance, are the result of adaptation to the perception of the world as dangerous. These reactions persist for years, especially if the traumatic experience was prolonged or repeated, as in the case of military personnel in combat zones. PTSD is also associated with an increased risk of psychosomatic disorders, such as headaches, chronic fatigue, and digestive disorders [10].

Pharmacotherapy for PTSD is usually combined with psychotherapeutic approaches, since a comprehensive approach to the psychoemotional and physiological manifestations of the disorder is most effective. The study focuses on several classes of medications used to treat PTSD symptoms, including selective serotonin reuptake inhibitors (SSRIs), other antidepressants, antipsychotics, and mood stabilizers [2]. These drugs act on neurochemical processes in the brain that are disrupted by traumatic stress, on the serotonin, dopamine, and adrenergic systems.

Selective serotonin reuptake inhibitors (SSRIs) are the main class of drugs recommended for the treatment of PTSD, due to their ability to stabilize the level of serotonin in the synapses, which is responsible for regulating mood, anxiety, and sleep. Researchers identify sertraline and paroxetine as the leading drugs in this class. Sertraline received approval from the US Food and Drug Administration (FDA) in 1999 as the only drug officially approved for the treatment of PTSD. Paroxetine, another SSRI, has also shown high efficacy, especially in chronic PTSD, due to its action on serotonin receptors, which helps reduce anxiety and depressive symptoms [11].

According to the order of the Ministry of Health of Ukraine of July 19, 2024, traditionally, psychotherapy (for example, cognitive behavioral therapy, prolonged exposure therapy) and drug treatment, synthetic antidepressants such as sertraline, paroxetine are used to correct PTSD [5]. Unfortunately, biological preparations are not so often used to correct PTSD, since most modern treatment methods are based on synthetic compounds or psychotherapeutic approaches.

One of the newest biologics is BNC210, developed by Bionomics, a company focused on the development of drugs for neuropsychiatric disorders. BNC210 has a unique mechanism of action, based on the modulation of the cholinergic system through the α7 subtype of nicotinic acetylcholine receptors (nAChR). These receptors are cation channels that are permeable to calcium and sodium, serving to shape anxiety-related behavior and fear-related responses. BNC210 acts as a negative allosteric modulator of the α7 nAChR, providing a pronounced anxiolytic effect. The drug does not cause sedation, which is a significant advantage for patients seeking to maintain daily activities. Preclinical studies in animals have shown that BNC210 effectively reduces anxiety in various behavioral paradigms. Early clinical trials have confirmed a favorable safety profile; the drug does not affect appetite and has no sedative effect, making it potentially more comfortable for long-term use [12].

Key efficacy results for BNC210 were obtained in the placebo-controlled phase 2b ATTUNE trial, which was completed in late 2023 [13]. In this trial, BNC210, administered at a dose of 900 mg twice daily, demonstrated significantly superior efficacy compared to traditional selective serotonin reuptake inhibitors (SSRIs) such as sertraline and paroxetine. On the CAPS-5 scale, which assesses the severity of PTSD symptoms, BNC210 reduced the total score by approximately 20 points. In comparison, sertraline achieved a reduction of 6.8–9.8 points and paroxetine attained a decrease of 11–14 points. This result suggests the potential of BNC210 as a new standard of pharmacotherapy for PTSD. In addition to the primary endpoint, the drug also improved secondary outcomes, depressive symptoms (MADRS), sleep quality (ISI), and overall disease severity and functional limitations (CGI-S, PGI-S, and SDS). Based on these data, Bionomics is planning a clinical registration program that could make BNC210 the first approved drug with this mechanism of action for the treatment of PTSD [13]. In parallel, the company is investigating the use

of BNC210 in other anxiety disorders, although results in social anxiety disorder have been less successful.

Newer microbial-based biologics include probiotics (live microorganisms such as *Lactobacillus* and *Bifidobacterium*), prebiotics (substances that promote the growth of beneficial bacteria, such as galactooligosaccharides), and postbiotics (metabolites of microorganisms such as short-chain fatty acids, or SCFAs) [14]. Their specialty lies in their ability to modulate the composition of the intestinal microbiome, which contributes to the regulation of physiological and psychological processes through the gut-brain axis. This axis provides a bidirectional interaction between the gastrointestinal tract and the central nervous system (CNS) through neural, neuroendocrine, and immune mechanisms [15].

Recent studies have shown that probiotics such as *Lactobacillus farciminis*, *Bifidobacterium pseudocatenulatum*, *Lactobacillus helveticus*, and *Bifidobacterium longum* have been shown to reduce the activity of the hypothalamic-pituitary-adrenal (HPA) axis, which is activated during stress and contributes to the development of PTSD [15]. For example, *Lactobacillus farciminis* reduces intestinal permeability and levels of pro-inflammatory cytokines in the hippocampus, which contribute to reduced stress reactivity [15]. Similarly, *Bifidobacterium pseudocatenulatum* minimizes the sensitivity of the HPA axis to stress, and the combination of *Lactobacillus helveticus* R0052 and *Bifidobacterium longum* R0175 modulates the level of glucocorticoid receptors in the hypothalamus, reducing chronic stress-related changes [16].

Prebiotics, galactooligosaccharides, promote the growth of beneficial bacteria, Actinobacteria, which are associated with positive neuroimmune function. They have antimicrobial effects, preventing colonization by pathogenic species and dysbiosis [16]. Postbiotics, such as CLFA (e.g., butyrate), have an immunoregulatory purpose, stimulating the proliferation of regulatory T cells (Treg) and reducing systemic inflammation, which is essential for the correction of PTSD, as this disease is often accompanied by chronic low-grade inflammation [17].

Another example is Mycobacterium vaccae, which, when administered subcutaneously, reduces corticotropin-releasing hormone levels in the amygdala and the nucleus of the stria terminalis, reducing anxiety and fear.

This microorganism prevents stress colitis by creating an anti-inflammatory environment in both peripheral tissues and the brain. Firmicutes-based probiotics, such as *Lactobacillus rhamnosus* JB-1 and *Lactobacillus plantarum*, have shown efficacy in reducing anxiety and immune dysregulation by increasing levels of the anti-inflammatory cytokine interleukin-10 (IL-10) [18].

The unique nature of these biologics and their minimal side effects compared to traditional pharmacological agents make them attractive to patients seeking less invasive approaches, as they can be used as stand-alone therapies or as an adjunct to psychotherapy and medication [19].

The pharmacodynamics of biologics in the context of posttraumatic stress disorder (PTSD) treatment is based on their ability to influence the gut-brain axis by modulating neurotransmitter systems, immune responses, and neuroendocrine processes [20]. The gut microbiome is involved in the synthesis and metabolism of neurotransmitters such as serotonin, gamma-aminobutyric acid (GABA), and glutamate, the disruption of which is associated with intestinal dysbiosis, which affects cognitive and behavioral functions. Probiotics, *Lactobacillus plantarum*, contribute to the normalization of serotonin metabolism, which helps reduce anxiety and depressive symptoms that are characteristic of PTSD [21].

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PTSD is often accompanied by chronic inflammation, manifested by elevated

levels of pro-inflammatory markers such as C-reactive protein, interleukin-1β (IL-1β), IL-6, and tumor necrosis factor (TNF) [22]. Probiotics such as *Lactobacillus* and *Bifidobacterium reduce* the concentration of these markers, creating an anti-inflammatory environment. For example, *Lactobacillus rhamnosus* JB-1 increases the level of the anti-inflammatory cytokine interleukin-PTSD is often accompanied by chronic inflammation, manifested by elevated levels of pro-inflammatory markers such as C-reactive protein, interleukin-1β (IL-1β), IL-6, and tumor necrosis factor (TNF) [22]. Probiotics such as *Lactobacillus* and *Bifidobacterium* reduce the concentration of these markers, creating an anti-inflammatory environment. For example, *Lactobacillus rhamnosus* JB-1 increases the level of the anti-inflammatory cytokine interleukin-10 (IL-10), while short-chain fatty acids (SCFAs) produced by Firmicutes stimulate the proliferation of regulatory T cells (Treg), reducing neuro-inflammation [19].

Probiotics affect the hypothalamic-pituitary-adrenal (HPA) axis, whose hyper-activity is a key factor in the pathogenesis of PTSD. For example, *Lactobacillus farciminis* and *Bifidobacterium pseudocatenulatum* reduce intestinal wall permeability and modulate stress responses by reducing corticosteroid levels, which contributes to reduced stress reactivity [23].

The microbiome influences neuroplasticity, the expression of genes associated with neural activity in the amygdala (anxiety and fear formation). Probiotics, such as *Bifidobacterium longum* NCC3001, reduce activity in the amygdala, frontal cortex, and temporal cortex, which helps alleviate depressive symptoms [4].

The microbiota also produces metabolites such as CLFA, secondary bile acids, and antioxidants that affect physiology. For example, butyrate produced by Firmicutes has neuroprotective properties and reduces neuroinflammation. The microbiota also produces metabolites such as CLFA, secondary bile acids, and antioxidants that affect physiology. For example, butyrate produced by Firmicutes has neuroprotective properties and reduces neuroinflammation. The microbiota modulates tryptophan metabolism, reducing the kynurenine/tryptophan ratio, a marker of intestinal dysfunction, contributing to the improvement of psychoemotional state [24].

The pharmacokinetic characteristics of biologics are less well understood than traditional pharmacological agents, as they are not classical drugs and their behavior in the body depends on the route of administration, survival in the gastrointestinal tract, and interaction with the intestinal microbiome. Probiotics are usually administered orally and must survive the acidic environment of the stomach to reach the intestine, where they temporarily colonize the mucosa or alter the composition of the microbiota. *Lactobacillus* and *Bifidobacterium* strains demonstrate high resistance to gastric juice and the ability to adhere to the intestinal wall, which ensures their functional activity [25].

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Prebiotics, galactooligosaccharides, are not absorbed in the small intestine but are fermented by the microbiota in the large intestine, stimulating the growth of beneficial bacteria such as Actinobacteria. Postbiotics, CLFAs, can be absorbed through the intestinal wall, enter the systemic circulation, and affect distant organs, including the brain, providing their systemic effects [26].

In the gut, probiotics are partially metabolized to produce active metabolites, such as CLFAs, which influence intestinal

permeability, immune response, and neuronal activity. For example, butyrate is metabolized by intestinal epithelial cells or transported to the liver, where it affects systemic metabolism. Prebiotics, when fermented, contribute to the formation of CLFAs and other metabolites that support microbiome homeostasis [17].

Probiotics do not accumulate in the body and are excreted in the feces after discontinuation, requiring regular administration to maintain the therapeutic effect. Metabolites, such as CLFA, are excreted via the kidneys or metabolized in the tissues, which limits their duration of action [26].

The effect of probiotics usually appears after several weeks of regular intake, as changes in the composition of the microbiota and modulation of the gut-brain axis take time. For example, *Bifidobacterium longum* NCC3001 reduced depressive symptoms in patients after 6–8 weeks, depending on the dose, strain of the microorganism, and individual microbiome status [4].

Conclusions

Biologics offer significant therapeutic benefits. They demonstrate high efficacy, with BNC210, which at a dose of 900 mg twice daily, reducing the severity of PTSD symptoms on the CAPS-5 scale by 20 points, exceeding the results of traditional selective serotonin reuptake inhibitors (6.8–14 points). Probiotics, in turn, contribute to the reduction of anxiety and depressive symptoms by normalizing the microbiome. However, despite these advantages, biologics have certain limitations. The high cost of their production and development, for drugs such as BNC210, may limit their availability to a wide range of patients. Also, clinical trial data remain limited, and the long-term effects and safety of many biologics, especially probiotics, require further large-scale trials to form a reliable evidence base.

The prospects for biologics in personalized medicine are on the rise. Further development of this area, optimization of dosage, combination of biologics with psychotherapeutic methods, and expansion of clinical trials will facilitate the integration of biologics into standard PTSD treatment protocols, which, in turn, will increase the effectiveness of therapy and the quality of life of individuals suffering from this disorder.

Conflict of interest

The authors declare that they have no conflict of interest.

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Author Contributions

Lypey I.M. — Conceptualization, Methodology, Literature Search, Data Curation, Formal Analysis, Writing — original draft preparation, Visualization.

Boyko N.V. — Supervision, Validation, Resources, Writing — review & editing, Project administration.

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ФАРМАКОЛОГІЧНІ АСПЕКТИ БІОПРЕПАРАТІВ ЗАДЛЯ ЛІКУВАННЯ ПОСТТРАВМАТИЧНОГО СТРЕСОВОГО РОЗЛАДУ

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Мета. Проаналізувати фармакодинамічні та фармакокінетичні особливості новітніх біопрепаратів для корекції посттравматичного стресового розладу, оцінити їхній терапевтичний потенціал для персоналізованої медицини.

Матеріали та методи. Дослідження містять загальнонаукові підходи, аналіз, узагальнення та абстрагування наукових праць, що стосуються нейробіології, психофармакології та мікробіології, пошук яких здійснювали в мережі *Internet*, використовуючи електронні бази даних *Web of Science, Scopus, PubMed* та *Google Scholar*.

Результати. ПТСР пов'язаний із дисрегуляцією нейротрансмітерних систем, гіперактивністю мигдалеподібного тіла, зниженою активністю префронтальної кори та порушеннями осі «кишечник-мозок». Новітні біопрепарати, такі як BNC210, що модулюють холінергічну систему, та пробіотики (*Lactobacillus, Bifidobacterium*), які впливають на мікробіом, демонструють високу ефективність. Біопрепарати мають швидкий початок дії (6–8 тижнів для пробіотиків) і мінімальні побічні ефекти. Однак висока вартість і обмежені дані клінічних досліджень є основними бар'єрами.

Висновки. Біопрепарати відкривають нові перспективи для лікування ПТСР завдяки унікальним механізмам дії та безпеці. Їхній потенціал у персоналізованій медицині, зокрема через модуляцію індивідуального мікробіому, є обнадійливим. Подальші дослідження та оптимізація дозування сприятимуть інтеграції біопрепаратів у стандартні протоколи терапії, підвищуючи ефективність лікування та якість життя пацієнтів.

Ключові слова: посттравматичний стресовий розлад, біопрепарати, фармакодинаміка, фармакокінетика, нейробіологія, персоналізована медицина, мікробіом, терапевтичний потенціал.