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COMPREHENSIVE ASSESSMENT OF CLINICAL AND IMMUNOLOGICAL PARAMETERS IN THE TREATMENT OF ALLERGIC DERMATOSES WITH BILASTINE MOLECULE

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One of the most pressing problems in dermatology and venereology is allergic dermatoses. Over recent decades, the incidence of allergic skin diseases has increased significantly. The high prevalence of allergic dermatoses and the insufficient effectiveness of the proposed therapy necessitate the development of new drugs that directly or indirectly affect various stages of the pathological process through their influence on mediator systems. A comprehensive assessment of clinical and immunological indicators was conducted during bilastine treatment of allergic dermatoses. Against the background of bilastine administration, the therapeutic effect in the vast majority of patients began to manifest within the first 4–5 days of treatment. After bilastine use, mild pruritus rated 3–5 points persisted in 16 patients (19.82 %), whereas in 64 patients (79 %) it was observed only periodically and rated 0–2 points. In addition, after bilastine use, 76 patients (93.8 %) reported practically normal sleep (0–2 points), and only 5 patients reported mild sleep disturbances (3–5 points). As a result of complex treatment with bilastine, the absolute and relative numbers of CD4 cells decreased by approximately 30 %, while the number of CD8 cells increased slightly, leading to normalization of the immunoregulatory index, that is, indicators of T-cell immunity. Clinical observations and immunological status assessments in patients with allergic dermatoses confirmed the effectiveness of bilastine and enabled its recommendation as part of the complex therapy for this group of dermatoses.

Key words: allergic dermatoses, immunoglobulin E, bilastine, T-cell immunity.

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КОМПЛЕКСНА ОЦІНКА КЛІНІЧНИХ ТА ІМУНОЛОГІЧНИХ ПОКАЗНИКІВ ПРИ ЗАСТОСУВАННІ МОЛЕКУЛИ БІЛАСТИНУ В ЛІКУВАННІ АЛЕРГОДЕРМАТОЗІВ

Однією з найбільш актуальних проблем дерматовенерології є проблема алергодерматозів. Останні десятиліття істотно почастішали алергічні захворювання шкіри. Поширеність алергодерматозів, недостатня ефективність запропонованої терапії зумовлюють створення нових препаратів, які безпосередньо чи опосередковано впливають на різні стадії патологічного процесу шляхом впливу на медіаторні системи. Проведено комплексну оцінку клінічних та імунологічних показників при застосуванні молекули біластину в лікуванні алергодерматозів. Терапевтичний ефект на фоні застосування біластину у переважної більшості пацієнтів почав виявлятися в перші 4–5 днів лікування. Після застосування біластину незначний свербіж 3–5 бали зберігався у 16 (19.82 %) пацієнтів, свербіж 0–2 бали у 64 (79 %) відзначався лише періодично, також після застосування препарату біластин практично здоровий сон (0–2 бали) відмітило 76 (93.8 %) пацієнтів і лише 5 – незначне порушення сну (3–5 балів). В результаті комплексного лікування із застосуванням біластину абсолютна та відносна кількість CD4 зменшилися приблизно на 30 %, а кількість CD8 незначно збільшилася, що призвело до нормалізації імунорегуляторного індексу, тобто показників Т-клітинного імунітету. Клінічні спостереження та оцінка імунологічного статусу у хворих з алергодерматозами підтвердили ефективність біластину та дозволили рекомендувати його у комплексній терапії цієї групи дерматозів.

Ключові слова: алергодерматози, імуноглобулін Е, біластин, Т-клітинний імунітет.

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One of the most pressing problems in dermatology and venereology is allergic dermatoses. The high prevalence of allergic dermatoses and the insufficient effectiveness of existing therapies have driven the development of new drugs that directly or indirectly affect various stages of the pathological process by modulating mediator systems. A distinctive clinical feature of allergic dermatoses is persistent or paroxysmal pruritus, which primarily justifies the use of antihistamines in standard treatment protocols [7].

The pathogenesis of allergic dermatoses is characterized by the activation of mast cells and basophils, leading to degranulation via interaction between membrane-bound immunoglobulin E (IgE) and its corresponding antigen. Cross-linking of IgE initiates a cascade of intracellular signaling events, resulting in the release of a wide range of inflammatory mediators. In particular, the secretion of histamine, heparin, and other biologically active compounds triggers immediate-type immune reactions, with subsequent effects on target organs [4].

Allergic dermatitis develops in individuals with increased sensitivity to a specific allergen. Both delayed-type and immediate-type hypersensitivity mechanisms contribute to the pathogenesis of contact sensitivity. The functional state of the nervous and endocrine systems also plays an important role in the development of contact sensitivity. Immune complexes bind to the surface of mast cells and basophils [8, 15].

The eczematous process is believed to result from a complex interplay among neuroallergic, endocrine, metabolic, and exogenous factors. Exogenous triggering factors may include chemical agents, biological agents, bacterial allergens, physical factors, medications, and food products. Monovalent allergy, characteristic of the initial stage of eczema, eventually progresses to polyvalent allergy. Eczema is characterized by suppression of T-suppressor function and a decrease in the number of T-helper cells. The development of eczema in genetically predisposed individuals, which depends on the presence of immune response genes in lymphocytes, creates conditions for its inheritance in subsequent generations [1, 6].

In recent years, allergic dermatosis (AD) has been recognized as a hereditary disease with a chronic course and distinct age-related dynamics, characterized by eczematous and lichenified lesions, abnormalities in cutaneous cellular immunity, and dysregulation of T-cell interactions [5].

The etiology of the disease is not fully understood; however, the influence of genetic factors and environmental triggers remains indisputable [14].

In recent years, specific fragments of genetic material and chromosomal regions, known as epitopes, have been identified as responsible for genetic susceptibility to atopic pathology. IgE-mediated reactions play a leading role in the development of AD. In patients with AD, activation of the synthesis and secretion of anti-inflammatory cytokines, including interleukin-4 (IL-4), interleukin-5 (IL-5), and interleukin-13 (IL-13), has been observed. IL-4 suppresses the production of interferon gamma and promotes increased IgE synthesis [9]. IL-5 stimulates eosinophil differentiation and adhesion to the endothelium. The ratio of these cytokines determines the nature of cutaneous inflammation. IL-13 also enhances IgE synthesis. In patients with AD, excessive expression of interleukin-10 (IL-10) has been observed not only in cutaneous lesions but also in the peripheral immune system following specific mitogenic stimulation [2].

In patients with allergic dermatoses, the number of mast cells is significantly increased and further increases upon allergen exposure. During degranulation, mast cells release mediators critical to allergic inflammation, including serotonin, prostaglandin E, and histamine [11].

Antihistamines are traditionally included in standard treatment regimens for allergic dermatoses. Most of them act as competitive histamine antagonists, competing with histamine for receptor binding on target organs. Antihistamines also alleviate pruritus [14]. This study examined the clinical and pathogenetic efficacy of bilastine. In terms of its pharmacological properties, bilastine is a histamine H_1-receptor blocker and also exhibits serotonin-antagonist activity. This aspect of bilastine pharmacodynamics is particularly important because, during exacerbations of allergic dermatoses, a substantial amount of serotonin is released from mast cells [10].

The purpose of the study was to comprehensively evaluate clinical and immunological parameters during treatment with the bilastine molecule for allergic dermatoses.

Materials and methods. The study was conducted by the staff of the Department of Skin and Venereal Diseases at Poltava State Medical University and was carried out at the Center of Dermatology and Venereology of the Sklifosovsky Regional Clinical Hospital. The study was conducted from January 2025 to November 2025.

The diagnosis of patients with allergic dermatoses was performed in accordance with the medical and technological documents for the standardization of medical care in atopic dermatitis, approved by Order No. 670 of the Ministry of Health of Ukraine dated July 4, 2016.

A total of 81 patients aged 18 to 71 years with pruritic dermatological diseases were enrolled. Among them, 22 patients had atopic dermatitis, 8 had microbial eczema, 14 had eczema, 24 had allergic dermatitis, 6 had seborrheic dermatitis, and 7 had toxicoderma. The mean age of the patients was 39.06±4.41 years. The study group included 52 women and 29 men.

Patients were included in the study if they met the following criteria: a clinically confirmed diagnosis of allergic dermatosis (atopic dermatitis, allergic contact dermatitis, eczema) established by a dermatologist in accordance with the unified clinical protocol for medical care; age between 18 and 71 years; presence of clinical manifestations of the disease (erythema, papules, vesicles, lichenification, pruritus); presence of disease exacerbation at the time of inclusion in the study; signed informed consent for participation; and absence of systemic antihistamine or immunosuppressive therapy for a defined period prior to study initiation (if necessary, 7–14 days).

Patients were excluded from the study in the presence of the following factors: severe concomitant somatic diseases (decompensated cardiovascular, hepatic, renal, or endocrine disorders); presence of other dermatological diseases that could affect the clinical picture (psoriasis, fungal skin infections, infectious dermatoses); pregnancy or lactation; individual hypersensitivity or contraindications to the medications used in the study; use of systemic glucocorticosteroids, immunosuppressants, or biological therapy during a period that could influence the study results; presence of acute infectious diseases at the time of examination; refusal to participate in the study or withdrawal of informed consent.

The study included patients of different ages and both sexes, with a predominance of female

participants. The primary aim of the study was to evaluate the overall clinical and pathogenetic effectiveness of bilastine in patients with allergic dermatoses under real-world clinical conditions. Therefore, stratification of patients by age and sex was not performed in the present study.

In addition, the absence of a separate control group is due to the practical realities of the observational study design, which was aimed at assessing the therapy's efficacy in real-world clinical settings rather than comparing it.

In addition to conventional therapy (detoxification agents, vitamins, biogenic stimulants, and topical therapy), patients received bilastine 20 mg (1 tablet) three times daily for 7–10 days.

As part of detoxification therapy, Reosorbilact infusion solution was administered (1 mL of solution contains: sorbitol 60.0 mg, sodium lactate (calculated as 100 % substance) 19.0 mg, sodium chloride 6.0 mg, calcium chloride dihydrate (calculated as calcium chloride) 0.1 mg, potassium chloride 0.3 mg, magnesium chloride hexahydrate (calculated as magnesium chloride) 0.2 mg; Yuria-Pharm LLC, Ukraine). The solution exhibits rheological, anti-shock, detoxifying, and alkalizing effects and stimulates intestinal peristalsis. The main pharmacologically active components are sorbitol and sodium lactate. Reosorbilact was administered intravenously via drip infusion at a dose of 200 mL at 60 drops per minute once daily for 3 days.

In addition, the enterosorbent Atoxil (silicon dioxide with pronounced sorption properties) (Orisil-Pharm LLC, Ukraine) was used. Atoxil adsorbs endogenous and exogenous toxic substances of various origins from the gastrointestinal tract and facilitates their elimination, including food and bacterial allergens, microbial endotoxins, and other toxic compounds, as well as toxic products formed during protein putrefaction in the intestine. Atoxil gel was administered as one stick pack with a glass of water three times daily after meals for five days.

B-group vitamins (B6 and B12) were prescribed as adjunctive therapy to reduce pruritus, improve skin condition, and normalize neural regulation. Vitamin B6 (pyridoxine) (Farmak JSC, Ukraine) was administered as intramuscular injections of 1 mL. Vitamin B12 (cyanocobalamin) (Halychpharm PJSC, Ukraine) was administered intramuscularly at a dose of 200–500 μg every other day for a total of 10–15 injections.

As a biogenic stimulant, Aloe extract injections (Lubnypharm JSC, Ukraine) were administered subcutaneously at a dose of 1 mL daily for 20–30 injections to enhance metabolism, stimulate tissue regeneration, and improve skin trophism.

Topical therapy included 0.1 % mometasone furoate cream (Elocom, Schering-Plough Labo N.V., Belgium), applied as a thin layer once daily for up to 4 weeks.

As part of basic skin care, emollients were used, including Lipikar cream (La Roche-Posay, France) and Aquatopic cream (Zandra Life Sciences Pvt. Ltd., India), which moisturize, soften the skin, and restore its protective barrier. These were applied twice daily, regardless of symptom presence, immediately after bathing on damp skin.

As antihistamine therapy, patients received bilastine (Nixar, Menarini–von Heyden GmbH, Germany) 1 tablet (20 mg) three times daily for 7–10 days.

All laboratory investigations were performed at the clinical diagnostic laboratory of the Dermatovenereologic Center of the Municipal Enterprise “Poltava Regional Clinical Hospital named after M.V. Sklifosovsky of Poltava Regional Council” (Poltava, Ukraine). Immunological parameters were assessed using a flow cytometer (Epix XL-MCL; Beckman Coulter, USA).

Biological samples (blood, urine, feces) were collected in accordance with national standards and methodological guidelines. Analytical measurements were performed using certified equipment, including a hematology analyzer (Sysmex XN-1000, Japan); a blood glucose analyzer (Cobas 6000, Roche Diagnostics, Switzerland); and a urinalysis analyzer (Urised 3, Japan). Parasitological examination of fecal samples was conducted using conventional microscopy.

When indicated, patients were consulted by a gastroenterologist, an otorhinolaryngologist, a dentist, an endocrinologist, and an ophthalmologist. In some patients, fibrogastroduodenoscopy, abdominal organ ultrasound, and electrocardiography were performed.

The effectiveness of bilastine therapy was evaluated by changes in T-cell immune parameters. For this purpose, immunological blood testing was performed before and after treatment. Parameters of the T-cell system were assessed by lymphocyte phenotyping using rosette formation assays with particles coated with monoclonal antibodies (CD3 T lymphocytes, CD4 T-helper cells, CD8 T-suppressor cells) (Ukraine) [13].

To assess the severity of dermatosis at baseline and during follow-up, signs characterizing the intensity of the cutaneous process (objective symptoms) were evaluated, including erythema (hyperemia), edema/papule formation, oozing/crust formation, excoriations, lichenification, and skin dryness. To characterize subjective symptoms, the severity of pruritus and sleep disturbances was assessed using a 10-point scale (0–10) before bilastine administration and after completion of treatment.

The study was conducted in accordance with the applicable laws of Ukraine regulating clinical research, the Code of Ethics of the Physician of Ukraine, the Code of Ethics of the Scientist of Ukraine, and the Declaration of Helsinki of the

World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects." The study protocol was approved by the Commission on Ethics and Biomedical Ethics of Poltava State Medical University (Approval No. 234, January 23, 2025).

Results of the study and their discussion. The treatment outcomes demonstrated that, in most patients, the therapeutic effect of bilastine began to manifest as early as days 4–5 of therapy. Regression of skin lesions was observed, including reduced erythema, resolution of inflammatory signs, and decreased infiltration and lichenification. Pruritus was significantly reduced, which had a positive impact on patients' psycho-emotional state and sleep quality. During this period, a pronounced regression of acute eruptions was noted, with the disappearance of erythema, reduction of signs of infection, and attenuation of lichenification. Sleep gradually normalized, and pruritus progressively subsided, directly contributing to a decrease in the number of excoriations and an overall improvement in skin condition. Patients reported a marked improvement in comfort, with reduced irritation and burning, enabling them to resume daily activities more actively and reducing the psychological stress associated with chronic itching.

During the course of treatment, subjective parameters showed significant changes, as illustrated in the table below (Table 1).

Table 1

Assessment of subjective parameters before and after bilastine treatment

Subjective parameter		Score			
		0–2	3–5	6–8	9–10
Before treatment	Sleep disturbance	4	11	48	18
	Pruritus	4	4	57	16
After treatment	Sleep disturbance	76	5		
	Pruritus	64	16		1

Severe pruritus (6–8 points) was reported in 57 patients (70.3 %) and 16 patients (19.8 %), while significant sleep disturbances before treatment were observed in 48 patients (59.3 %), with 18 patients (22.2 %) reporting severe impairment (9–10 points). After administration of bilastine, mild pruritus (3–5 points) persisted in only 16 patients (19.8 %), whereas in 64 patients (79 %), pruritus was reported only occasionally (0–2 points). In addition, after treatment, normal sleep (0–2 points) was observed in 76 patients (93.8 %), and only 5 patients had mild sleep disturbances (3–5 points). It should be noted that in one patient, pruritus persisted even after 4 weeks of bilastine therapy; however, sleep normalized, indicating a positive effect of the drug on quality of life even in more challenging cases. The mean values of subjective complaints also demonstrated significant improvement. The level of sleep disturbance in patients before treatment was 6.85±2.12, whereas after treatment it decreased to 1.19±0.86 ($P<0.05$), indicating a statistically significant difference. Similarly, the mean pruritus score before treatment was 7.05±1.78, which decreased to 1.70±1.23 after treatment ($P<0.05$). These findings indicate the high effectiveness of bilastine in the comprehensive therapy of allergic dermatoses.

Evaluation of patients' immunological status also revealed significant changes in the structure of T-cell immunity during the course of treatment. These changes are presented in Table 2.

Table 2

Changes in immunological parameters following bilastine therapy (n=81)

Parameter	Before treatment	After treatment
CD3, %	48.11±3.29	39.10±2.66*
CD3, $\times10^9$/L	1024.00±61.30	900.20±77.34
CD4, %	31.33±2.27	21.10±1.29*
CD4, $\times10^9$/L	692.07±45.41	489.09±20.56*
CD8, %	17.78±1.80	19.10±1.70
CD8, $\times10^9$/L	392.76±36.01	442.74±27.09
CD4/CD8	1.84±0.02	1.12±0.07*
CIC	0.258±0.04	0.155±0.02*

Note: * – significantly different from the corresponding values before treatment ($P<0.05$).

Before treatment, the absolute CD3 count in patients with allergic dermatoses was 1024±61.30×10^9/L, while the relative count was 48.11±3.29 %. After comprehensive treatment with bilastine, the relative CD3 level decreased to 39.1±2.66 %, and the absolute count decreased to 900.20±77.34×10^9/L.

As a result of comprehensive therapy, both absolute and relative CD4 counts decreased by approximately 30 %, while CD8 levels increased slightly, resulting in normalization of the immunoregulatory index and reflecting improved T-cell immunity parameters. Before treatment, the CD4/CD8 ratio was 1.84±0.02, whereas after bilastine therapy it decreased to 1.12±0.07.

In addition, patients demonstrated an almost twofold decrease in circulating immune complexes (CIC), with a mean of 0.155±0.02 after treatment. These changes indicate normalization of immune regulation, reduction of allergic inflammation, and

restoration of the functional activity of T lymphocytes.

Thus, the use of bilastine in the comprehensive treatment of pruritic dermatoses results in a rapid reduction in pruritus intensity, normalization of sleep, and improvement in objective clinical manifestations, including erythema, exudation, lichenification, and excoriations. At the same time, restoration of immunological balance occurs, as evidenced by significant changes in T-cell subpopulations and circulating immune complexes.

The drug's effectiveness was observed in patients with various dermatoses, including atopic dermatitis, allergic dermatitis, microbial eczema, seborrheic dermatitis, toxicoderma, and other chronic dermatoses. The results indicate that bilastine is an effective agent for improving patients' quality of life, reducing clinical manifestations of the disease, and stabilizing the immune response, making it an appropriate component of comprehensive therapy.

Due to its effect on sleep quality and reduction of pruritus, the drug enables patients to return to active daily life, improves psycho-emotional status, and reduces the risk of complications associated with chronic dermatoses, such as secondary infections and persistent lichenification. In addition, bilastine therapy demonstrates high safety and tolerability, making it suitable for widespread clinical use.

Limitations. The limitations of the study include a relatively small sample size and a short follow-up period, which restrict the assessment of the long-term efficacy and safety of bilastine. In addition, the absence of a control group and the heterogeneity of dermatoses within the sample limit the generalizability of the findings to a broader population.

Conclusion

The choice of pharmacological therapy should take into account the patient's needs and capabilities, as well as the evidence base supporting the specific drug. Diagnosis and treatment of allergic dermatoses of any etiology using modern medications allow for rapid symptom relief, improving patients' quality of life and significantly reducing the risk of complications. Bilastine, a non-sedating, long-acting antihistamine, exhibits a high affinity for H_1 receptors. Based on the data obtained in this study, bilastine demonstrated high efficacy in controlling symptoms of hyperreactivity in various pathologies, was well tolerated by patients, and improved their quality of life.

Summarizing the results of clinical observation (objective symptoms) and patients' subjective assessments, it can be concluded that the inclusion of bilastine in the comprehensive therapy of patients with pruritic dermatoses led to clinical remission in 48 patients (59.25 %) and significant improvement in 10 patients (12.35 %). Only one patient with microbial eczema reported virtually no change in their condition.

Thus, clinical observations and immunological evaluations in patients with allergic dermatoses confirmed the effectiveness of bilastine and support its recommendation as part of comprehensive therapy for this group of dermatoses.

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COMPARATIVE ANALYSIS OF THE EFFECTIVENESS OF NOVEL PROGNOSTIC MARKERS OF POSTPARTUM INFLAMMATORY COMPLICATIONS

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Postpartum inflammatory complications remain a significant medical and social problem and significantly affect maternal morbidity rates. The purpose of this study was to evaluate the effectiveness of Raman spectroscopy as a prognostic marker for inflammatory complications in the postpartum period, compared with traditional laboratory parameters. The study included 300 women in labor (250 women with inflammatory complications and 50 women in the control group). A reliable gradation dependence of the frequency and intensity of spectral peaks on the clinical severity of the inflammatory process has been established. High values of spectral parameters correlated with an increase in C-reactive protein, procalcitonin, IL-6, fibrinogen, neutrophil-lymphocyte ratio, and erythrocyte sedimentation rate ($p<0.001$). The analysis of clinical, laboratory, and spectroscopic data indicates the high diagnostic and prognostic significance of Raman spectroscopy in assessing inflammatory complications of the postpartum period. It was found that changes in the intensity of characteristic spectral bands (Amide I, Amide III, phenylalanine ~1003 cm^{-1}, lipid bands 1445 and 2850-2930 cm^{-1}) correlate with increased levels of CRP, procalcitonin, IL-6, fibrinogen, as well as with an increase in the NLR index and ESR. The sequential increase in protein and lipid peaks, accompanied by an increase in the frequency of complications, reflects activation of the cytokine cascade, synthesis of acute-phase proteins, and the development of oxidative stress. This confirms Raman spectroscopy's ability to detect molecular changes preceding the clinical manifestation of severe inflammation. Thus, Raman spectroscopy can be considered an effective additional prognostic marker of systemic inflammatory response in the postpartum period and a potential basis for developing rapid diagnostic algorithms for early detection of complications.

Key words: postpartum inflammatory complications, Raman spectroscopy, prognostic markers, C-reactive protein, procalcitonin, interleukin-6, neutrophil-lymphocyte ratio, fibrinogen, oxidative stress, early diagnosis.

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ПОРІВНЯЛЬНИЙ АНАЛІЗ ЕФЕКТИВНОСТІ НОВИХ ПРОГНОСТИЧНИХ МАРКЕРІВ ПОСЛЯПОЛОГОВИХ ЗАПАЛЬНИХ УСКЛАДНЕНЬ

Післяпологові запальні ускладнення залишаються значною медико-соціальною проблемою та суттєво впливають на показники захворюваності матерів. Метою даного дослідження була оцінка ефективності спектроскопії комбінаційного розсіювання як прогностичного маркера запальних ускладнень післяпологового періоду у порівнянні з традиційними лабораторними показниками. До дослідження було включено 300 породіль (250 жінок із запальними ускладненнями та 50 як контрольна група). Встановлено достовірну градаційну залежність частоти та інтенсивності спектральних піків від клінічної вираженості запального процесу. Високі значення спектральних показників корелювали з підвищенням рівня С-реактивного білка, прокальцитоніну, ІЛ-6, фібриногену, нейтрофільно-лімфоцитарного співвідношення та швидкості осідання еритроцитів ($p<0,001$). Таким чином, раман-спектроскопія може розглядатися як ефективний додатковий прогностичний маркер системної запальної реакції в післяпологовому періоді та потенційна основа для розробки експрес-діагностичних алгоритмів раннього виявлення ускладнень.

Ключові слова: післяпологові запальні ускладнення, раман-спектроскопія, прогностичні маркери, С-реактивний білок, прокальцитонін, інтерлейкін-6, нейтрофільно-лімфоцитарне співвідношення, фібриноген, оксидативний стрес, рання діагностика.

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A modern urgent task of obstetrics is the careful management of pregnancy and its final stage – the birth act [4, 6]. It is known that the peculiarities of the course of labor largely determine the perinatal outcomes for the mother and fetus [3, 8].

Early prognostic assessment of postpartum inflammatory complications, identification of effective predictors, and the introduction of modern diagnostic methods and rapid tests are of great clinical importance [8, 13]. The definition of prognostic criteria, the development of effective algorithms, and the development of prognostic scales are essential for the identification of risk factors and