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Gender-specific features of the prognostic value of pro-inflammatory biomarkers in patients with type 2 diabetes and COVID-19

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Gender-specific features of the pro-inflammatory response in patients with type 2 diabetes (DT2) during COVID-19 are an urgent problem of modern medicine, due to the high prevalence of metabolic disorders, adverse course of infection and differences in the immune response depending on gender. Of particular importance are pro-inflammatory biomarkers that reflect the intensity of systemic inflammation, allow predicting the severity of the disease course, the development of complications, and can be used for risk stratification in men and women with DT2.

Aim – to carry out a systematic analysis of modern scientific data on sex-specific features of the prognostic value of pro-inflammatory biomarkers in patients with DT2 in the presence of COVID-19 and to determine their role in predicting the severity of the course and clinical consequences of the disease.

Summarizing the results of modern research shows that the levels of interleukin-6, C-reactive protein, ferritin, tumor necrosis factor alpha, D-dimer, and neutrophil-to-lymphocyte ratio are closely associated with the severity of the course of COVID-19 in patients with DT2. The presence of sex-specific features of the immune and inflammatory response, which can influence the prognostic value of certain biomarkers regarding the risk of hospitalization to the intensive care unit, the development of multiple organ failure, and fatal outcomes, has been established. The analysis of literature sources confirms the expediency of a comprehensive assessment of biomarkers, taking into account the gender of patients, to increase the accuracy of predicting the clinical course of COVID-19.

Conclusions. The prognostic value of pro-inflammatory biomarkers in patients with DT2 depends not only on the severity of systemic inflammation, but also on sex-specific features of the immune response. The use of a comprehensive approach to the assessment of laboratory indicators, taking into account gender, can contribute to early prediction of the adverse course of COVID-19, optimization of clinical monitoring and personalization of treatment tactics.

The authors declare no conflict of interest.

Keywords: COVID-19, type 2 diabetes, proinflammatory biomarkers, gender differences, systemic inflammation, prognosis, systematic review.

Статево-специфічні особливості прогностичної цінності прозапальних біомаркерів у пацієнтів із цукровим діабетом 2 типу та COVID-19

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Статево-специфічні особливості прозапальної відповіді в пацієнтів із цукровим діабетом 2 типу (ЦД2) під час COVID-19 є актуальною проблемою сучасної медицини, що обумовлено високою поширеністю метаболічних порушень, несприятливим перебігом інфекції та відмінностями імунної відповіді залежно від статі. Особливе значення мають прозапальні біомаркери, які відображають інтенсивність системного запалення, дають змогу прогнозувати тяжкість перебігу захворювання, розвиток ускладнень та можуть використовуватися для стратифікації ризику в чоловіків і жінок із ЦД2.

Мета – провести систематичний аналіз сучасних наукових даних щодо статево-специфічних особливостей прогностичної цінності прозапальних біомаркерів у пацієнтів із ЦД2 при COVID-19 та визначити їхню роль у прогнозуванні тяжкості перебігу і клінічних наслідків захворювання.

Узагальнення результатів сучасних досліджень свідчить, що рівні інтерлейкіну-6, С-реактивного білка, феритину, фактора некрозу пухлин альфа, D-димеру та нейтрофільно-лімфоцитарного співвідношення тісно асоціюються з тяжкістю перебігу COVID-19 у пацієнтів із ЦД2. Встановлено наявність статево-специфічних особливостей імунної та запальної відповіді, які можуть впливати на прогностичну цінність окремих біомаркерів щодо ризику госпіталізації до відділення інтенсивної терапії, розвитку поліорганної недостатності та летальних наслідків. Аналіз літературних джерел підтверджує доцільність комплексної оцінки біомаркерів із урахуванням статі пацієнтів для підвищення точності прогнозування клінічного перебігу COVID-19.

Висновки. Прогностична цінність прозапальних біомаркерів у пацієнтів із ЦД2 залежить не лише від вираженості системного запалення, а й від статево-специфічних особливостей імунної відповіді. Використання комплексного підходу до оцінки лабораторних показників із урахуванням статі може сприяти ранньому прогнозуванню несприятливого перебігу COVID-19, оптимізації клінічного моніторингу та персоніфікації лікувальної тактики.

Автори заявляють про відсутність конфлікту інтересів.

Ключові слова: COVID-19, цукровий діабет 2 типу, прозапальні біомаркери, статеві відмінності, системне запалення, прогноз, систематичний огляд.

Introduction

The COVID-19 pandemic significantly changed the understanding of the pathogenesis of viral infections, demonstrating the leading role of systemic inflammation in the formation of the severe course of the disease and the development of multiple organ dysfunction. Despite significant progress in prevention and treatment, infection caused by the SARS-CoV-2 virus continues to be an important public health problem, especially among patients with chronic non-communicable diseases [6,15,19]. One of the most vulnerable categories is patients with type 2 diabetes, in whom impaired carbohydrate metabolism is combined with chronic low-intensity inflammation, endothelial dysfunction, oxidative stress, and immune disorders, which significantly increase the risk of an adverse course of COVID-19 [16,17].

It is known that hyperglycemia, insulin resistance, and metabolic disorders contribute to the activation of pro-inflammatory signaling pathways, increased cytokine production, and the development of a dysregulated immune response [1,3,7]. In such patients, high concentrations of interleukin-6 (IL-6), C-reactive protein (CRP), ferritin, tumor necrosis factor alpha (TNF-α), D-dimer and other laboratory indicators that reflect the intensity of the systemic inflammatory reaction are more often registered. Today, these biomarkers are considered potential predictors of the severity of the disease, the development of acute respiratory distress syndrome, thrombotic complications, the need for an intensive care unit, and mortality [4,6,8,12].

In recent years, more and more attention has been paid to the study of sex-specific features of the course of COVID-19. Accumulated clinical and experimental data indicate that men and women may differ in the nature of the immune response, the level of expression of ACE2 receptors, the activity of pro-inflammatory cytokines, the influence of sex hormones on the regulation of inflammation, and the frequency of complications [6,14,16]. Patients with type 2 diabetes are of particular interest, since the combination of metabolic disorders with hormonal and immunological differences can determine the individual characteristics of the clinical course of the infection and the prognostic value of laboratory parameters [5,6].

Despite a significant number of publications, research results remain ambiguous. Some authors report a higher prognostic value of certain biomarkers in men, while others note a more pronounced association between systemic inflammation and adverse clinical outcomes in women, especially in the postmenopausal period [1,2,8,11]. In addition, there is no unified approach to the interpretation of laboratory indicators, taking into account the gender of patients and the characteristics of the course of type 2 diabetes. This necessitates the systematization of current scientific data on the prognostic value of pro-inflammatory biomarkers and the assessment of their role in risk stratification depending on gender, which is important for personalizing the clinical management of patients with COVID-19.

Aim – to carry out a systematic analysis of modern scientific data on sex-specific features of the prognostic value of pro-inflammatory biomarkers in patients with type 2 diabetes in the presence of COVID-19 and to determine their role in predicting the severity of the course and clinical consequences of the disease.

The study was conducted in the format of a systematic review of the scientific literature using the principles of evidence-based medicine and PRISMA 2020 recommendations for the preparation of review studies. Information search was carried out in international scientometric databases PubMed, Scopus, Web of Science, and Google Scholar. The analysis included scientific articles published in English and Ukrainian during 2020–2025 that highlighted the features of the pro-inflammatory response, the prognostic value of laboratory biomarkers, gender differences in the course of COVID-19, and clinical aspects of type 2 diabetes.

Literature sources were searched using combinations of keywords and their synonyms: COVID-19, SARS-CoV-2, type 2 diabetes mellitus, inflammatory biomarkers, IL-6, CRP, ferritin, D-dimer, neutrophil-to-lymphocyte ratio (NLR), sex differences, gender differences, prognosis. Original clinical studies, systematic reviews, meta-analyses, and international clinical guidelines were considered during selection.

The inclusion criteria were the presence of data on the prognostic value of one or more pro-inflammatory biomarkers in patients with type 2 diabetes confirmed by COVID-19, as well as the analysis of gender characteristics of the course of the disease. Publications with incomplete results, duplicates, clinical cases, conference abstracts, and papers without full text were excluded.

The processing of literary sources was carried out by bibliosemantic analysis, systematization, critical evaluation, comparison and generalization of the obtained data. Special attention was paid to the assessment of the prognostic significance of IL-6, CRP, ferritin, D-dimer, TNF-α, and NLR, taking into account sex-specific features of the immune response and the clinical course of COVID-19 in patients with type 2 diabetes.

An analysis of modern scientific publications proved that type 2 diabetes is one of the most important risk factors for the adverse course of COVID-19. Most studies have noted that a combination of metabolic disorders, chronic systemic inflammation, endothelial dysfunction, and disorders of innate and adaptive immunity contributes to the development of severe clinical forms of the disease, increases the frequency of hospitalizations in intensive care units, the need for respiratory support, and the risk of death [2,7,16]. The study of pro-inflammatory biomarkers, the concentration of which reflects the activity of the systemic inflammatory response and can be used to predict the clinical course of COVID-19, attracts the special attention of researchers [1,11].

The largest number of scientific works is devoted to IL-6, which is one of the key mediators of the cytokine cascade. Summarizing the results of research shows that an increase in the concentration of IL-6 is reliably associated with an increase in the risk of developing acute respiratory distress syndrome, multiple organ failure, and mortality in patients with type 2 diabetes [17]. It has been established that chronic hyperglycemia stimulates the production of pro-inflammatory cytokines, increases the activation of macrophages and endothelial cells, creating prerequisites for the development of an excessive immune response after SARS-CoV-2 infection. That is why the level of IL-6 is considered not only as a marker of inflammatory activity, but also as an independent prognostic factor of the severe course of COVID-19 [3,8].

C-reactive protein (CRP) occupies an equally important place among laboratory predictors. According to the results of most clinical studies, a direct relationship between its concentration and the severity of clinical manifestations of the disease has been established [10]. High CRP levels are associated with significant lung tissue damage, the development of a systemic inflammatory response, prolonged hospital stay, and an increased risk of adverse clinical outcomes [4,9]. In patients with type 2 diabetes, the concentration of this indicator, as a rule, exceeds similar values in individuals without carbohydrate metabolism disorders, which is explained by the presence of chronic subclinical inflammation even before the development of an acute viral infection [14].

A significant number of studies confirm the prognostic value of ferritin as a marker of hyperinflammation. Hyperferritinemia reflects not only a violation of iron metabolism but also an indicator of the activation of the macrophage system and the development of a cytokine storm [5,19]. In patients with type 2 diabetes, an increase in ferritin concentration is more often combined with pronounced insulin resistance, oxidative stress, and endothelial dysfunction, which potentiates the development of a severe course of COVID-19. Many authors consider ferritin to be one of the most informative laboratory indicators for early risk stratification, especially if it is comprehensively evaluated together with IL-6 and CRP [12,18].

Particular attention is paid to D-dimer and NLR, which reflect the relationship between inflammatory processes, activation of the coagulation cascade, and immune dysregulation [5]. An increase in the D-dimer level is associated with the development of thromboembolic complications, impaired microcirculation, and worsening of the disease prognosis. At the same time, the increase in NLR is considered a simple and accessible indicator of the intensity of systemic inflammation, which can be used for early prediction of the severe course of COVID-19 in patients with concomitant type 2 diabetes [13,15].

In recent years, researchers have been particularly interested in the analysis of sex-specific features of the immune response to COVID-19. Summarizing the results of clinical studies shows that the prognostic value of pro-inflammatory biomarkers can differ significantly in men and women [6]. Such differences are associated with the influence of sex hormones, genetic factors, features of the expression of angiotensin-converting enzyme 2 (ACE2) receptors, as well as differences in the functioning of cells of innate and adaptive immunity [1,7,12].

Most publications indicate that women are characterized by a more effective early antiviral response, which is ensured by higher activity of plasmacytoid dendritic cells, T-lymphocytes, and production of type I interferons [4,15,19]. At the same time, estrogens are able to suppress the excessive production of pro-inflammatory cytokines, re-

ducing the intensity of the systemic inflammatory reaction. Such mechanisms partially explain the lower frequency of severe forms of COVID-19 among women of reproductive age compared to men of a similar age [17,18].

However, in women with type 2 diabetes, especially in the postmenopausal period, there is a gradual loss of the protective effect of estrogens. A decrease in their concentration is accompanied by an increase in insulin resistance, accumulation of visceral adipose tissue, activation of chronic systemic inflammation, and an increase in the concentration of IL-6, CRP, and ferritin [2,8,9]. This may increase the risk of developing a severe course of COVID-19 and reduce the prognostic difference between men and women of older age groups [10].

Some authors report that it is in women with decompensated type 2 diabetes that CRP and IL-6 levels are more closely correlated with the duration of hospitalization and the risk of multiple organ failure. At the same time, other researchers point to the greater prognostic significance of D-dimer and ferritin among men [5,11]. Such contradictions can be explained by the heterogeneity of the studied populations, different patient inclusion criteria, differences in the age structure, the frequency of obesity, the level of diabetes compensation, and the applied drug therapy [3,14].

Special attention is paid to the NLR as one of the most accessible indicators of the systemic inflammatory response. The majority of studies confirm its high informativeness regardless of the gender of the patients [6]. However, some authors indicate that in women, the predictive accuracy of NLR can increase when body mass index, HbA1c level, and CRP concentration are taken into account simultaneously, while in men, the combination of NLR with D-dimer and ferritin shows the greatest diagnostic value [13]. This indicates the expediency of using combined models of risk assessment, which take into account not only individual laboratory parameters but also gender, age, metabolic status, and concomitant pathology.

A systematic review of the literature confirms that pro-inflammatory biomarkers take a leading place among laboratory indicators that predict the clinical course of COVID-19 in patients with type 2 diabetes [16]. Despite a significant number of studies, there is no universal biomarker that would be characterized by an equally high prognostic value for all categories of patients. That is why the majority of modern authors recommend using a comprehensive assessment of several indicators at the same time, which provides higher accuracy in predicting adverse clinical consequences [8,17]. The obtained results are consistent with modern ideas about the pathogenesis of COVID-19, according to which the severity of the disease is determined not only by the direct replication of the virus, but also by the intensity of the systemic inflammatory response, endothelial dysfunction, hemostasis disorders, and metabolic changes characteristic of type 2 diabetes [1,3]. Chronic hyperglycemia contributes to the activation of pro-inflammatory signaling pathways, which significantly enhances the development of a cytokine storm and causes a high risk of severe complications [2].

Of particular interest are the results of studies devoted to sex-specific aspects of the prognostic value of pro-inflammatory biomarkers. The generalization of modern literary data shows that gender is an important biological factor that affects the intensity of the immune response, the features of cytokine activation, and the nature of the clinical course of COVID-19 [1,8]. At the same time, gender differences are not limited to the level of individual laboratory indicators, but include complex relationships between hormonal status, genetic mechanisms, metabolic disorders, and the functioning of the immune system [13,16].

It has been established that estrogens are capable of modulating the activity of pro-inflammatory cytokines, reducing the expression of certain inflammatory mediators and maintaining the functional activity of the endothelium. That is why women of reproductive age more often show a less pronounced systemic inflammatory reaction after infection with SARS-CoV-2 [15]. However, with the onset of the postmenopausal period, the protective effect of estrogens gradually decreases, which is accompanied by an increase in insulin resistance, an increase in the mass of visceral adipose tissue, the development of dyslipidemia and chronic low-intensity inflammation [14]. In the presence of type 2 diabetes, these processes mutually potentiate each other, contributing to an increase in the concentration of IL-6, CRP, ferritin and other markers of the systemic inflammatory response [5,11].

At the same time, the analysis of published works proved the absence of a single approach to the assessment of gender differences in the prognostic value of biomarkers. A significant part of clinical studies considered gender only as one of the demographic characteristics of the sample, without performing a se-

parate statistical analysis for men and women [6,8,9]. Many studies did not stratify outcomes by age, menopausal status, level of diabetes compensation, disease duration, or obesity. This significantly limits the possibility of forming convincing conclusions regarding the clinical significance of sex-specific features of systemic inflammation [4,7].

Significant methodological heterogeneity of available studies remains an important problem. The authors used different criteria for assessing the severity of COVID-19, different threshold values of laboratory indicators, different time intervals for the determination of biomarkers, and different statistical forecasting models [10]. In addition, the results could depend on the dominant variants of SARS-CoV-2, the level of vaccination of the population, the specifics of the applied antiviral and anti-inflammatory therapy, which must also be taken into account when interpreting the obtained data [18].

Despite the mentioned limitations, the majority of modern publications confirm the feasibility of using a complex panel of pro-inflammatory biomarkers instead of evaluating a separate laboratory indicator [19]. The combination of concentrations of IL-6, CRP, ferritin, D-dimer, and NLR provides a higher prognostic accuracy for the development of a severe course of COVID-19 than the use of each marker alone. The inclusion in such models of the patient's clinical characteristics, in particular age, sex, body mass index, HbA1c level, concomitant cardiovascular pathology and the functional status of the kidneys, allows for significantly improved risk stratification [12].

A promising direction of further research is the development of sex-oriented prognostic algorithms that will combine laboratory, clinical and metabolic indicators. This approach corresponds to the modern concept of personalized medicine and can contribute to the timely identification of patients with a high probability of developing adverse consequences. This is especially relevant for postmenopausal women with type 2 diabetes, in whom the combination of age-related hormonal changes, chronic systemic inflammation, and metabolic disorders creates additional prerequisites for a severe course of COVID-19.

Systematization of modern scientific data shows that sex-specific analysis of pro-inflammatory biomarkers is a promising direction of clinical research. Taking biological sex into account during the interpretation of laboratory parameters may increase the accuracy of prediction, optimize clinical monitoring of patients with type 2 diabetes mellitus, and contribute to the implementation of more personalized approaches to the management of patients with COVID-19.

Conclusions

A systematic analysis of modern scientific sources confirmed that pro-inflammatory biomarkers play an important role in predicting the clinical course of COVID-19 in patients with type 2 diabetes. Interleukin-6, CRP, ferritin, D-dimer, and NLR demonstrated the greatest prognostic value, the increase of which is associated with an increase in the risk of a severe course of the disease, the development of multiple organ failure and adverse clinical consequences.

The generalization of the results of published studies indicates the presence of sex-specific features of the immune and inflammatory response, which can affect the diagnostic and prognostic informativeness of individual laboratory indicators. At the same time, the available literature remains heterogeneous due to differences in study design, sample characteristics, and insufficient consideration of patients' hormonal and metabolic status.

A promising direction for further research is the development of standardized sex-oriented prognostic models that will combine the assessment of pro-inflammatory biomarkers with clinical and metabolic characteristics of patients. This approach will contribute to more accurate risk stratification, timely identification of patients with a high probability of developing complications, optimization of clinical monitoring, and implementation of personalized approaches to the management of patients with type 2 diabetes and COVID-19.

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