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Multifactorial prediction of adverse outcome of acute coronary syndrome combined with post-COVID syndrome

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Abstract

Aim – to build a multivariate model for predicting adverse outcomes of acute coronary syndrome with and without ST segment elevation in patients with post-COVID syndrome.

Material and methods. The study included 118 patients (61 men and 57 women) with acute coronary syndrome and post-COVID syndrome. All patients underwent medical history review, clinical examination, laboratory tests, coronary angiography, echocardiography, electrocardiography, and molecular genetic marker testing. The influence of each factor on the probability of developing a combined endpoint, including the total number of cardiovascular complications and fatal outcomes, was assessed using logistic regression analysis. The statistical significance of the model was determined by the χ^2 test. The sensitivity and specificity of the model were assessed using ROC analysis.

Results. The constructed multivariate regression model showed that the development of an unfavorable outcome in patients with acute coronary syndrome in combination with PCS is associated with the presence of chronic heart failure, elevated soluble fms-like tyrosine kinase-1, hypokinesis zones on echocardiography, carrier status of the *TT/AA* genotype of the genetic marker rs2285666 of the *ACE2* gene (χ^2 = 38.416, p <0.001). The sensitivity of the model is 93.5%, and the specificity is 21.8%, the accuracy is 76.6%, the area under the curve (AUC) = 0.8.

Conclusion. A multivariate regression model was constructed and tested to predict, with high accuracy, the development of an unfavorable outcome of acute coronary syndrome in combination with post-COVID syndrome.

Keywords: acute coronary syndrome, multivariate regression model, genetic markers, post-COVID syndrome.

Conflict of interest: nothing to disclose.

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Многофакторное прогнозирование неблагоприятного исхода острого коронарного синдрома в сочетании с постковидным синдромом

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Аннотация

Цель – построить многофакторную модель для прогнозирования неблагоприятного исхода острого коронарного синдрома с подъемом и без подъема сегмента ST у пациентов с постковидным синдромом.

Материал и методы. В исследование вошли 118 пациентов, из них 61 мужчина и 57 женщин с острым коронарным синдромом в сочетании с постковидным синдромом. Всем пациентам проводились сбор анамнеза, клинический осмотр, забор лабораторных анализов, коронароангиография, эхокардиография, электрокардиография, диагностика молекулярно-генетических маркеров. Оценивалось влияние каждого из факторов на вероятность развития комбинированной конечной точки, включающей суммарное количество кардиоваскулярных осложнений и летальных исходов, с помощью применения логистического регрессионного анализа. Статистическая значимость модели определялась критерием χ^2. Чувствительность и специфичность модели оценивались с помощью ROC-анализа.

Результаты. Построенная многофакторная регрессионная модель показала, что с развитием неблагоприятного исхода у пациентов с острым коронарным синдромом в сочетании с постковидным синдромом связаны наличие хронической сердечной недостаточности, наличие растворимой fms-подобной тирозинкиназы-1, зоны гипокинеза по эхокардиографии, носительство генотипа *TT/AA* генетического маркера rs2285666 гена *ACE2* (χ^2 = 38,416, p<0,001). Чувствительность модели составила 93,5%, специфичность – 21,8%, точность – 76,6%, площадь под кривой (AUC) = 0,8.

Выводы. Получена и апробирована многофакторная регрессионная модель, прогнозирующая с высокой точностью развитие неблагоприятного исхода острого коронарного синдрома в сочетании с постковидным синдромом.

Ключевые слова: острый коронарный синдром, многофакторная регрессионная модель, генетические маркеры, постковидный синдром.

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ОКС – острый коронарный синдром; ПКС – постковидный синдром; НКИ – новая коронавирусная инфекция; ЭКГ – электрокардиография; ЭхоКГ – эхокардиография; КАГ – коронароангиография; ИБС – ишемическая болезнь сердца; САД – суточное артериальное давление; ЧСС – частота сердечных сокращений; ВНП – вариант нуклеотидной последовательности.

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INTRODUCTION

According to global registries, acute coronary syndrome (ACS), including both ST-segment elevation and non-ST-segment elevation myocardial infarction, represents the leading cause of morbidity and mortality in Russia and worldwide [1]. Various prognostic risk stratification tools for adverse outcomes in ACS are currently available. The GRACE risk model is among the most widely recognized. In addition to predicting in-hospital complications of ACS, it enables assessment of long-term adverse outcomes. Furthermore, the discriminant power of the GRACE model significantly surpasses that of models based on randomized clinical trial data. However, emerging evidence highlights important limitations of the GRACE model, particularly its failure to incorporate biochemical blood markers, electrocardiographic (ECG) and echocardiographic (EchoCG) parameters, and genetic indicators being a significant shortcoming that diminishes its alignment with contemporary scientific and clinical practice standards [2]. In particular, the COVID-19 pandemic has adversely impacted the course and outcomes of cardiovascular diseases [3]. The World Health Organization has classified post-COVID syndrome (PCS) as a distinct clinical entity - a condition characterized by signs and symptoms that emerge during or following COVID-19 infection, persist for over 12 weeks, and cannot be attributed to alternative diagnoses [3]. The development and implementation of a multifactorial risk assessment model is clinically imperative, as even highly experienced practitioners often focus solely on PCS diagnosis. In contrast, a comprehensive risk stratification model incorporates numerous predictive factors and should therefore become an essential clinical tool for all physicians, enabling routine identification of patients at risk for adverse outcomes.

Thus, patients with ACS and concomitant PCS require a comprehensive prognostic model for assessing ACS-related adverse outcomes to guide targeted prevention strategies and personalized rehabilitation programs.

AIM

To build a multivariate model for predicting adverse outcomes of acute coronary syndrome with and without ST segment elevation in patients with post-COVID syndrome.

MATERIAL AND METHODS

The prospective cohort study included 118 patients (61 men, 57 women). The average age of women was 57.5±6.2 years; the average age of men was 53.7±8.3 years. The comparison group included 121 patients (62 men, 59 women) with ACS, without PCS (the history had no diagnosis of the COVID-19 infection confirmed by a PCR test from a swab or identification of A, M, G immunoglobulins (IgA, IgM, IgG) for SARS-CoV-2 by immunochemical assay.

The patients were matched by sex and age. All were emergently transported to the regional vascular center by emergency medical services. Upon admission, all patients were diagnosed with ACS. The diagnosis was established based on current clinical guidelines "Acute coronary syndrome with ECG ST segment elevation"[1] and "Acute coronary syndrome without ECG ST segment elevation"[2], approved by the Scientific Practical Council of the Ministry of Health of the Russian Federation.

Inclusion criteria: history of COVID-19 meeting the criteria of the "Post-COVID syndrome" diagnosis as per the recommendations of the Methodological recommendations "Features of long-COVID infection clinical course. Therapeutic and rehabilitation measures" [4]. According to the updated International Classification of Diseases (ICD-10), post-COVID syndrome (PCS) develops in individuals with confirmed SARS-CoV-2 infection three months after COVID-19 onset. For study participants, prior COVID-19 diagnosis was confirmed using laboratory diagnostic methods specified in the provisional clinical guidelines "Prevention, Diagnosis, and Treatment of COVID-19" (Version 18, 26.10.2023) approved by the Scientific and Practical Council of the Ministry of Health of the Russian Federation[3].

To predict the risk of adverse ACS outcomes, logistic regression analysis was employed. The logistic regression model was constructed using the following equation (1)

$$P = 1 / (1 + e^{-y}), \quad (1)$$

where P is the probability of development of the index event; e is the base of natural logarithms (Euler's number, 2.718), and y represents the standard regression equation.

The standard regression equation is presented as follows (2)

$$y = a + b1X1 + b2X2 + ... + bnXn, \quad (2)$$

where a is the constant; b are regression factors; X are initial variables.

[1] Acute coronary syndrome without ECG ST segment elevation. Clinical guidelines. 2024. Available online: https://scardio.ru/content/Guidelines/2024_09_26.pdf
[2] Acute myocardial infarction with ECG ST segment elevation. Clinical guidelines. 2024. Available online: https://russjcardiol.elpub.ru/jour/article/view/6306
[3] Provisional clinical guidelines "Prevention, Diagnosis, and Treatment of the new coronavirus infection COVID-19" (Version 18, 26.10.2023). Available online: https://static-0.minzdrav.gov.ru/system/attachments/attaches/000/064/610/original/%D0%92%D0%9C%D0%A0_COVID-19_V18.pdf

The X value was represented with quantitative or qualitative variables. The qualitative variables were taken as binary values, where 1 means the presence of the factor and 0, its absence.

A prognostic model was developed using stepwise logistic regression analysis incorporating statistically significant factors (variables).

The statistical significance of the model was assessed using the χ^2 test. With $p < 0.05$, the null hypothesis of model insignificance was rejected. A cutoff threshold of 0.5 was established for predicting the index event after model development. The model's sensitivity and specificity were evaluated through ROC analysis. Results were interpreted by constructing ROC curves with calculation of the area under the ROC curve (AUC).

The study was approved by the Local Ethics Committee of Novosibirsk State Medical University (Protocol No. 155 dated November 29, 2023) and by the Problem Commission (Protocol No. 1 "Current Issues in Prevention, Diagnosis and Treatment of Internal Diseases" dated October 25, 2023). All patients provided written informed consent to participate in the study.

RESULTS

The analysis included the following baseline variables: clinical and anamnestic parameters (sex, age, weight, obesity grade (if any), duration, localization and character of pain, presence of arterial hypertension, coronary artery disease, chronic heart failure, presence/absence of prior COVID-19 infection, disease severity, variant wave (Alpha, Delta, Omicron), treatment modality, smoking status, severity of prior cardiovascular events); instrumental parameters: electrocardiogram (ECG), Holter ECG monitoring, 24-hour blood pressure monitoring (BP), findings of coronary angiography (CAG (multi-vessel or single-vessel involvement, post-catheterization complications)), echocardiography (hypokinesis/akinesis areas, left ventricular ejection fraction (quantitative and qualitative assessment); laboratory parameters: cholesterol fractions (total cholesterol, high-density lipoproteins, low-density lipoproteins, triglycerides), endothelial dysfunction factors (Soluble fms-like tyrosine kinase-1 and anti-endothelial antibodies), biochemical markers (C-reactive protein, lactate dehydrogenase, ferritin, blood glucose, high-sensitivity troponin I); molecular-genetic markers (*ACE2* gene variant rs2285666, *ACE* gene variant rs1799752, *TMPRSS2* gene variant rs12329760).

The prognostic model was developed using stepwise logistic regression incorporating statistically significant factors (variables). Model significance was assessed using the χ^2 test, with the null hypothesis of model insignificance rejected at $p < 0.05$. A cutoff threshold of 0.5 was established for predicting the index event following model development.

Based on the Wald criterion, the most statistically significant predictors were the degree of hypokinesis and the combination of ACS with PCS (**Table 1**). These were followed by tyrosine kinase levels, presence of the ACE2 TT/AA genotype, and presence of chronic heart failure in terms of predictive strength.

Thus, the predicted probability of developing the combined endpoint encompassing the total number of cardiovascular complications and fatal outcomes was expressed by the following formula (3):

$$P = 1 / (1 + 2{,}718^{-(13{,}153 - 1{,}689 \times X1 + 0{,}039 \times X2 + 0{,}870 \times X3 + 0{,}082 \times X4 - 1{,}286 \times X5)}), \quad (3)$$

where X1 means belonging to the "ACS with PCS" group, X1 = 0 – patient with ACS without PCS, X1 = 1 – patient having ACS and PCS, X2 – soluble fms-like tyrosine kinase-1 (X2), pg/mL, X3 – belonging to the "CHF" group, X3 = 0 – patient without signs of CHF, X3 = 1 – patient with signs of CHF, X4 – hypokinesis, X5 – presence of ACE2 TT/AA gene polymorphism, X5 = 0 – patient does not have this gene, X5 = 1 – patient has this gene.

For clarity of interpretation, the final result is multiplied by 100%.

The Hosmer-Lemeshow goodness-of-fit test for this predictive model yielded $\chi^2 = 38.416$, $p = 0.0000$, indicating extremely high statistical significance.

Subsequently, a ROC curve was constructed. Based on the ROC curve analysis, the area under the ROC curve was 0.8 (**Figure 1**), indicating good model quality - an acceptable model. The model's sensitivity (proportion of correctly classified patients with adverse ACS outcomes) was 93.5%, while specificity (proportion of correctly classified patients without adverse ACS outcomes) was 21.8%. The overall accuracy for predicting complications was 76.6%. Thus, the developed model demonstrates excellent predictive capability for adverse ACS occurrence but poor performance for predicting its absence.

DISCUSSION

To date, the literature describes only a few prognostic models designed to assess ACS outcomes [5].

One of the earliest prognostic models was a scoring system proposed in 1962 [6]. It was based on calculating a prognostic index using characteristics of the acute phase of ACS. The resulting data predicted the likelihood of adverse disease progression within 28 days of symptom onset.

Predictor	B (regression factor)	MSE (mean square error)	Wald (Wald criterion, X^2)	P (significance level)	Exp (B)
ACS/PCS group (X1)	-1.689	0.48	12.362	0.0004	0.185
Soluble fms-like tyrosine kinase-1 (X2), pg/ml	0.039	0.01	8.237	0.004	1.04
Chronic heart failure (X3)	0.870	0.39	4.894	0.027	2.388
Hypokynesia (X4), damage of segments of myocardium	0.082	0.02	17.983	0.00002	1.085
Polymorphism of the *ACE 2 TT/AA* gene (X5)	-1.286	0.51	6.419	0.011	0.276

Table 1. *Main results of the analysis of binary logistic regression of the prognosis of the development of unfavorable ACS*
Таблица 1. *Основные результаты анализа бинарной логистической регрессии прогноза развития неблагоприятного ОКС*

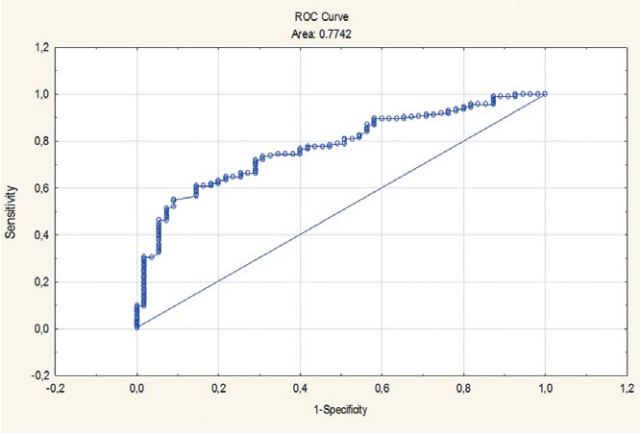

Figure 1. *ROC curve graph for predicting the development of adverse ACS in patients with PCS.*

Рисунок 1. *График ROC-кривой прогнозирования развития неблагоприятного ОКС у пациентов в сочетании с ПКС.*

Modern prognostic models include one developed through regression analysis using data from the GRACE IM registry [6, 7]. This model incorporates eight parameters identified through registry data analysis: patient age, Killip classification of heart failure, systolic blood pressure level, heart rate, creatinine level, diagnostic levels of myocardial necrosis biomarkers, ST-segment changes, and presence of at least one cardiac arrest episode [3].

The TIMI (Thrombolysis In Myocardial Infarction) risk score, developed through clinical trials, incorporates seven variables: age over 65; presence of at least three risk factors of coronary artery disease (CAD) (hypercholesterolemia, family history of CAD, diabetes mellitus, hypertension); previously documented 50%+ stenosis of the coronary artery; ST-segment deviation; at least two angina episodes within 24 hours; aspirin use within the past week; elevated serum cardiac biomarkers. TIMI predicts the 14-day risk of mortality and myocardial infarction [9] and has demonstrated high efficacy in assessing 30-day and 1-year mortality rates in ACS patients.

The PREDICT score (Predicting Risk of Death in Cardiac Disease Tool) is based on a retrospective analysis of MI/unstable angina patients that included the following parameters: age, 24-hour arterial blood pressure (BP), heart rate (HR), ECG data, signs of heart failure, serum urea level, and accounted for comorbidities [10]. This model has demonstrated prognostic efficacy in assessing 6-year mortality post-hospitalization.

The PURSUIT (Platelet Glycoprotein IIb/IIIa in Unstable Angina: Receptor Suppression Using Integrilin Therapy) risk model enables assessment of 30-day mortality risk, as well as the likelihood of primary or recurrent myocardial infarction, using the following parameters: age, heart rate, systolic blood pressure, status of ST-segment elevation, heart failure status, and serum cardiac biomarkers [11, 12].

Russian medical literature has also described several prognostic models [13-15]. These models evaluated one-year outcomes in acute coronary syndrome using the following criteria: status of diabetes mellitus in the case history, C-reactive protein level, left ventricular ejection fraction, rs1376251 SNP of the *TAS2R50* gene. The approach demonstrated 82% sensitivity for predicting adverse outcomes, and 80% sensitivity for predicting favorable outcomes.

A prognostic model exists for assessing in-hospital mortality risk in patients with acute coronary syndrome [15]. This model incorporates parameters recorded at hospital admission: urea level, Killip class, age, ST-segment elevation in lateral leads, diagnostic elevation of CK/CK-MB, systolic blood pressure level, and others. Using this model, patients can be stratified into risk groups during hospitalization, from minimal (mortality <1%) to very high (mortality >40%).

Another Russian prognostic model for assessing adverse outcomes in patients with ST-segment elevation myocardial infarction incorporates renal function parameters [8]. According to the authors, renal dysfunction represents one of the key factors determining poor prognosis in myocardial infarction.

Among the first registries established in the Russian Federation were RECORD, RECORD-2, and RECORD-3 [16-18]. These registries served as the foundation for developing a prognostic risk scale assessing adverse ACS outcomes within 6 months post-discharge. The registries enabled evaluation of treatment efficacy and identification of key patient clusters. The 7-point scoring system included hemoglobin levels below 100 g/l, presence of diabetes mellitus, age over 65, Killip class III-IV heart failure, blood pressure below 100 mmHg, ST segment elevation over 1 mm above the baseline. It reliably predicts 6-month mortality following ACS onset [16-18].

At the same time, none of the existing prognostic models for assessing adverse outcomes in ACS account for post-COVID syndrome in patients: a critical limitation that distinguishes our multifactorial regression model.

CONCLUSION

We have developed a multifactorial predictive model for assessing the risk of adverse outcomes in ACS patients (both with and without ST segment elevation) with post-COVID syndrome. The inclusion of the post-COVID syndrome status as a variable significantly differentiates this model from existing risk scores and previously developed prognostic systems.

ADDITIONAL INFORMATION	ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ
Study funding. The study was the authors' initiative without external funding.	***Источник финансирования.*** Работа выполнена по инициативе авторов без привлечения финансирования.
Conflict of interest. The authors declare that there are no obvious or potential conflicts of interest associated with the content of this article.	***Конфликт интересов.*** Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с содержанием настоящей статьи.
Compliance with Ethical Standards. The study was approved by the local ethics committee of the Novosibirsk State Medical University (protocol No. 155 dated November 29, 2023), and also approved at a meeting of the problem commission (protocol No. 1 "Current issues of prevention, diagnosis and treatment of internal diseases" dated October 25, 2023).	***Соответствие нормам этики.*** Исследование одобрено локальным этическим комитетом ФГБОУ ВО НГМУ Минздрава России (протокол №155 от 29.11.2023 г.), а также одобрено на заседании проблемной комиссии (протокол №1 «Актуальные вопросы профилактики, диагностики и лечения внутренних болезней» от 25.10.2023 г.).

Contribution of individual authors.

Shpagina L.A.: development of the study concept, text editing. Kozik V.A., Shpagin I.S.: collection and processing of scientific material, writing of the text.

The authors gave their final approval of the manuscript for submission, and agreed to be accountable for all aspects of the work, implying proper study and resolution of issues related to the accuracy or integrity of any part of the work.

Участие авторов.

Л.А. Шпагина – разработка концепции исследования, редактирование текста. В.А. Козик, И.С. Шпагин – сбор и обработка научного материала, написание текста.

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