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Mathematical model for predicting adverse perinatal outcomes in women with COVID-19

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The aim: to create a mathematical model for predicting adverse perinatal outcomes in women with COVID-19.

Materials and methods. To build a mathematical prediction model, candidate indicators were selected whose frequency significantly differed in the groups of pregnant women with significant perinatal disorders (group O1, n=50) and without such disorders (group O2, n=150), and odds ratio (OR) calculations were performed. To assess the significance of the indicators in points and assign threshold values, the expert evaluation method, the Delphi method, was used.

Results. The most statistically significant indicators for predicting perinatal disorders in pregnant women with COVID-19 are laboratory indicators associated with COVID-19, indicators of disease severity, stress, the presence of anxiety and depression, and endocrine pathology. The constructed model (scale) for predicting perinatal disorders in pregnant women with COVID-19 includes 24 indicators and can be used in 2 stages: 1 – at the prehospital stage and/or at the beginning of hospitalization 9 indicators), 2 – in the dynamics of the disease at the hospital stage (15 indicators). The ease of use (scoring), as well as the established fairly high accuracy (86.7%), sensitivity (87.5%), and specificity (86.4%) of the prediction model, allow us to recommend it for use in clinical practice.

Conclusions. The implementation of a model for predicting perinatal disorders in pregnant women with COVID-19 for the purpose of early identification of high-risk patients, their timely hospitalization, and treatment will reduce the incidence of perinatal complications, morbidity, and mortality of the mother and child.

The research was carried out in accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the Local Ethics Committee of the institution mentioned in the paper. The informed consent of the patient was obtained for conducting the studies.

No conflict of interests was declared by the authors.

Keywords: pregnancy, COVID-19, perinatal disorders, prediction, prevention

Математична модель прогнозування несприятливих перинатальних наслідків при COVID-19 у жінки

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Мета: створити математичну модель прогнозування несприятливих перинатальних наслідків при COVID-19 у жінки.

Матеріали і методи. Для побудови математичної моделі прогнозування відібрали показники-кандидати, частота яких достовірно розрізнялась у групах вагітних із суттєвими перинатальними розладами (група О1, n=50) та без таких розладів (група О2, n=150), провели розрахунки відношення шансів (ВШ). Для оцінки значимості показників у балах та призначення порогових значень застосовано метод експертного оцінювання – метод Дельфі.

Результати. Найбільш статистично значимими показниками прогнозування перинатальних порушень у вагітних із COVID-19 є лабораторні показники, асоційовані з COVID-19, показники тяжкості захворювання, стреси, наявність тривоги та депресії, ендокринна патологія. Побудована модель (шкала) прогнозування перинатальних порушень у вагітних із COVID-19 охоплює 24 показники і може застосовуватись у 2 етапи: 1 – на догоспітальному етапі та/або на початку госпіталізації 9 показників), 2 – в динаміці перебігу захворювання на госпітальному етапі (15 показників). Простота застосування (підрахунок балів), а також встановлена досить висока точність (86,7%), чутливість (87,5%) та специфічність (86,4%) моделі прогнозування дають змогу рекомендувати її для застосування у клінічній практиці.

Висновки. Впровадження моделі прогнозування перинатальних порушень у вагітних із COVID-19 з метою раннього виявлення пацієнток високого ризику, їхньої своєчасної госпіталізації та лікування, дасть змогу знизити частоту перинатальних ускладнень, захворюваність та смертність матері та дитини.

Дослідження виконано відповідно до принципів Гельсінської декларації. Протокол дослідження ухвалено локальним етичним комітетом зазначеної в роботі установи. На проведення дослідження отримано інформовану згоду жінок.

Автори заявляють про відсутність конфлікту інтересів.

Ключові слова: вагітність, COVID-19, перинатальні порушення, прогнозування, профілактика

The physiological maternal adaptations to pregnancy, such as expansion of blood volume, increase of insulin resistance, and immunological changes, can unmask a latent predisposition in a woman to cardiovascular and cardiometabolic complications, such as pre-eclampsia, gestational hypertension, and gestational diabetes. These complications can, in turn, affect fetal development, leading to growth restriction (as for pre-eclampsia), overgrowth (associated with gestational diabetes), and preterm birth, often requiring medical intervention and increasing the risk of stillbirth [3]. Additional viremia and inflammatory phases of respiratory virus-related infections, such as H1N1 influenza, and more recently COVID-19, may further hamper maternal adaptation, inducing a pro-coagulation state, affecting uteroplacental circulation and, consequently, fetal growth [4,7,9,10].

Studies investigating COVID-19 in pregnant women showed that pregnant women diagnosed with COVID-19 are more likely to experience pre-eclampsia [9], gestational hypertension [12], and preterm birth [1,5,11].

The main finding of analysis of E. Raffetti et al. [8] was that COVID-19 diagnosis during pregnancy was associated with higher risk of common adverse pregnancy outcomes, including gestational diabetes, hypertensive disorders, preterm birth and small for gestational age, as well as rare outcomes including very preterm, pre-eclampsia, venous thrombosis and stillbirth (only within 14 days after COVID-19 diagnosis). These risks were more pronounced within 14 days of COVID-19 diagnosis and when COVID-19 diagnosis occurred in the 3rd trimester of pregnancy. These risks were less pronounced after the vaccination rollout in England and Wales. There was no evidence to suggest that COVID-19 vaccination during pregnancy was associated with higher risks of adverse pregnancy outcomes.

The consequences of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during pregnancy have been studied intensively. Risk factors for developing severe coronavirus disease (COVID-19) include increasing maternal age and body mass index (BMI), minority ethnicity, comorbidities, and infection in late pregnancy. SARS-CoV-2 infection is associated with preterm delivery, pre-eclampsia, cesarean delivery, and stillbirth. However, risk estimates vary according to country, testing strategy, population, and comparison group and, more recently, virus variant and vaccination status [1].

Although some researchers have attempted to build mathematical prediction models, most of them have focused on predicting severe COVID-19 and Intensive Care Unit admission [2,6].

Several studies have used machine learning and AI to predict perinatal outcomes. In particular, a group of authors from Canada, the United States, and Europe presented a COVID-19 predictive pipeline specifically for pregnant patients using a large repository of SARS-CoV-2 data during pregnancy [13]. The model accurately identifies those at risk of severe disease or clinical deterioration, which is a promising tool for the development of personalized medicine in pregnant patients with COVID-19. However, the authors do not provide a clear algorithm for practical application.

A study of the relationship between the level of certain minerals, immune factors, and perinatal outcomes in women with COVID-19 conducted in Iraq is theoretically interesting [14], but there are also no recommendations for practical application.

Therefore, there is no sufficiently simple tool or scale that could be widely used in everyday clinical practice of perinatal care.

The aim of the study: to create a mathematical model for predicting adverse perinatal outcomes in women with COVID-19.

Materials and methods of the study

To build a mathematical model for predicting (risk scale) adverse perinatal outcomes in women with COVID-19, candidate indicators were selected, the frequency of which significantly differed in the groups of pregnant women with significant perinatal disorders (group O1, n=50) and without such disorders (group O2, n=150), and odds ratio (OR) calculations were performed.

All examined women underwent a general clinical and special obstetric examination, treatment according to the diagnostic and treatment protocols approved by the Ministry of Health of Ukraine.

To assess the significance of the indicators in points and assign threshold values, the expert evaluation method, the Delphi method, was used. This method of the group questioning is carried out in several sequential procedures to form a group opinion. The method is characterized by anonymity and controlled feedback. The feedback is implemented as follows: the results of each round are processed by statistical methods and reported to the experts, the experts present their arguments, and in the following

Table 1

Results of calculating OR for indicators of somatic pathology of pregnant women with COVID-19

Candidate indicator	P1	P2	OR	95% CI	
Obesity of II-III degree	24.0	9.3	3.07*	1.31	7.18
Chronic respiratory diseases	30.0	17.3	2.04	0.98	4.28
Gastrointestinal diseases	16.0	17.3	0.91	0.38	2.16
Diabetes mellitus	18.0	6.0	3.44*	1.28	9.23
Inflammatory diseases of the urinary system	12.0	14.7	0.79	0.30	2.08
Pathology of the cardiovascular system	20.0	10.0	2.25	0.94	5.39

Notes: P1, P2 – frequency of the indicator in the groups O1 and O2; OR – odds ratio, 95% CI – confidence interval; * – OR is statistically significant.

Table 2

Results of calculating the OR for COVID-19 characteristics in pregnant women at the time of hospitalization

Candidate indicator	P1	P2	OR	95% CI	
3rd trimester of pregnancy at the time of illness	80.0	81	3.41*	1.59	7.31
Duration of symptoms of the disease before hospitalization more than 5 days	52.0	25.3	3.19*	1.64	6.21
Fever (above 38°C)	42.0	18.0	3.30*	1.64	6.64
Cough	72.0	59.3	1.76	0.88	3.54
Headache	62.0	38.0	2.66*	1.38	5.15
Myalgia	28.0	15.3	2.15*	1.00	4.59
Difficult breathing	68.0	24.0	6.73*	3.33	13.58
Saturation less than 93%	32.0	18.0	2.14*	1.04	4.43
Change in mental status	16.0	7.3	2.41	0.91	6.37
Pneumonia	30.0	15.3	2.37*	1.12	5.01
Severe degree of disease	32.0	18.0	2.14*	1.04	4.43

Notes: P1, P2 – frequency of the indicator in the groups O1 and O2; OR – odds ratio, 95% CI – confidence interval; * – OR is statistically significant.

rounds, they can review them. From round to round, the results are increasingly stable and, when they stop changing, the survey is stopped. 4 rounds were conducted.

10 research assistants, doctors of sciences, 7 in the specialty «Obstetrics and Gynecology», 3 in «Neonatology», were involved as experts. Experts were offered a list of candidate indicators for inclusion in the mathematical prediction model with calculated HRs to highlight the most mathematically and clinically significant markers, assign a score to each of them, and determine the threshold value of the sum of points for classifying a specific patient as a high-risk group.

The obtained data were processed by methods of variational statistics accepted in medicine, using the Fisher angular transformation criterion with the calculation of the odds ratio (OR) with a 95% confidence interval (95% CI), the significance level – $p<0.05$.

The study was approved by the Ethics Committee of the Shupyk National Institute of Healthcare of Ukraine. The work is a fragment of the research project «Development of tactics for managing pregnancy after influenza and other acute respiratory viral infections». All studies were conducted after obtaining informed consent from the patient.

Research results and their discussion

Among the indicators of extragenital pathology (Table 1), the highest and statistically significant OR was obtained for diabetes mellitus (OR=3.44; 95% CI: 1.28–9.23, $p<0.05$) and obesity of the II-III degree (OR=3.07; 95% CI: 1.31–7.18, $p<0.05$). OR greater than 2 was also found for the indicators of cardiovascular pathology (OR=2.25) and chronic respiratory diseases (OR=2.04), but they are not statistically significant.

The calculations demonstrated statistical significance in predicting perinatal abnormalities of COVID-19 cha-

Table 3

Results of calculating OR for features of the course of COVID-19 in pregnant women

Candidate indicator	P1	P2	OR	95% CI	
Severe disease	40.0	18.7	2.90	1.44	5.84
Pneumonia	48.0	22.0	3.27	1.66	6.43
Hyperthermia:	58.0	21.3	5.09	2.57	10.09
- more than 5 days	26.0	6.7	4.92	2.00	12.10
Stay in the Intensive Care Unit:	50.0	20.7	3.84	1.94	7.58
- more than 5 days	28.0	11.3	3.04	1.37	6.75
Oxygen saturation less than 93%	52.0	23.3	3.56	1.82	6.97
Respiratory support:	56.0	20.0	5.09	2.56	10.12
- more than 7 days	28.0	6.0	6.09	2.44	15.20
Duration of hospitalization more than 5 days	58.0	26.0	3.93	2.01	7.68

Notes: P1, P2 – frequency of the indicator in the groups O1 and O2; OR – odds ratio, 95% CI – confidence interval; * – OR is statistically significant.

Table 4

Results of calculating OR for laboratory indicators of COVID-19 in pregnant women

Candidate indicator	P1	P2	OR	95% CI	
Anemia	82.0	34.0	8.84	3.99	19.62
Platelet count less than 150 109/l	22.0	5.3	5.01	1.88	13.30
Leukocyte count more than 15 109/l	72.0	45.3	3.10	1.55	6.22
Lymphocyte count less than 15%	18.0	7.3	2.77	1.08	7.15
ALT above normal	84.0	45.3	6.33	2.78	14.40
AST above normal	80.0	44.0	5.09	2.37	10.93
Creatinine level more than 75 µmol/l	16.0	3.3	5.52	1.72	17.78
ADP-induced platelet aggregation index more than 60%	36.0	9.3	5.46	2.46	12.13
Prothrombin index more than 120%	42.0	8.7	7.63	3.43	16.97
D-dimer more than 250 ng/ml	84.0	62.0	3.22	1.41	7.34
Von Willebrand factor more than 1.5 IU/ml	46.0	28.0	2.19	1.13	4.24
Vitamin D deficiency	84.0	68.0	2.47	1.08	5.67
C-reactive protein level more than 11 mg/l:	90.0	68.7	4.11	1.53	11.01
- ≥50	50.0	8.0	11.50	5.12	25.84
Procalcitonin level ≥0.1 ng/ml	50.0	12.7	6.89	3.31	14.37
Interleukin-6 level ≥7 mg/ml:	52.0	15.3	5.98	2.94	12.18
- 50 mg/ml and more	10.0	1.3	8.22	1.54	43.83

Notes: P1, P2 – frequency of the indicator in the groups O1 and O2; OR – odds ratio, 95% CI – confidence interval; * – OR is statistically significant.

racteristics in pregnant women at the time of hospitalization (Table 2). The highest OR was obtained for shortness of breath (OR=6.73; 95% CI: 3.33–13.58, p<0.05) and in order of decreasing OR: 3rd trimester of pregnancy at the time of illness (OR=3.41; 95% CI: 1.59–7.31, p<0.05), fever above 38°C (OR=3.30; 95% CI: 1.64–6.64, p<0.05), duration of symptoms of the disease by the time of hospitalization more than 5 days (OR=3.19; 95% CI: 1.64–6.21, p<0.05).

As for the negative impact of the further course of COVID-19 in the pregnant women (Table 3), the following indicators were statistically most significant: the need for respiratory support (OR=5.09; 95% CI: 2.56–10.12, p<0.05), especially if it lasted more than 5 days (OR=6.09; 95% CI: 2.44–15.20, p<0.05), hyperthermia (OR=5.09; 95% CI 2.57–10.09, p<0.05), duration of hospitalization more than 5 days (OR=3.93; 95% CI: 2.01–7.68, p<0.05).

Table 5

Results of calculating OR for socio-economic indicators of pregnant women with COVID-19

Candidate indicator	P1	P2	OR	CI	
Residence city	44.0	30.7	1.78	0.92	3.43
Higher education	44.0	24.0	2.49*	1.27	4.87
Not in a registered marriage	56.0	29.3	3.07*	1.59	5.93
In an unregistered marriage	30.0	16.7	2.14*	1.02	4.50
Widow, without a partner	26.0	12.7	2.42*	1.09	5.36
Income per family member, UAH:					
- less than 2000	18.0	8.7	2.31	0.92	5.80
- less than 5000	46.0	22.7	2.91*	1.48	5.71
Harmful habits, including:	16.0	9.3	1.85	0.73	4.71
- drinking alcohol	10.0	3.3	3.22	0.89	11.63
- smoking	14.0	7.3	2.06	0.75	5.63
Sedentary lifestyle	44.0	26.0	2.24*	1.15	4.36
Stress:	70.0	43.3	3.05*	1.54	6.06
- in the family	34.0	24.0	1.63	0.81	3.27
- at work	22.0	11.3	2.21	0.95	5.10
- in the family and at work	16.0	7.3	2.41	0.91	6.37

Notes: P1, P2 – frequency of the indicator in the groups O1 and O2; OR – odds ratio, 95% CI – confidence interval; * – OR is statistically significant.

Table 6

Results of calculating OR for anxiety and depression indicators (HADS scale)

Candidate indicator	P1	P2	OR	95% CI	
Anxiety:	90.0	73.3	3.27	1.21	8.83
- clinically severe	30.0	11.3	3.35	1.52	7.37
Depression:	66.0	50.0	1.94	1.00	3.78
- clinically severe	28.0	7.3	4.91	2.06	11.74

Notes: P1, P2 – frequency of the indicator in the groups O1 and O2; OR – odds ratio, 95% CI – confidence interval; * – OR is statistically significant.

High statistical significance in terms of predicting perinatal outcomes was also established for laboratory indicators that reflect the presence and degree of damage to the body associated with COVID-19 in pregnant women (Table 4). The most statistically significant were inflammatory markers: C-reactive protein level more than 50 mg/l (OR=11.50; 95% CI: 5.12–25.84, p<0.05), interleukin-6 level ⩾50 mg/ml (OR=8.22; 95% CI: 1.54–43.83, p<0.05); indicators of prothrombotic changes: prothrombin index more than 120% (OR=7.63; 95% CI: 3.43–16.97, p<0.05), platelet level, adenosine diphosphate induced (ADP-induced) platelet aggregation index more than 60%; anemia (OR=8.84; 95% CI: 3.99–19.62, p<0.05). The level of destructive processes reflects the increase in hepatic transaminases: alanine aminotransferase (ALT) – OR=6.33; 95% CI: 2.98–14.40 (p<0.05) and aspartate aminotransferase (AST) – OR=5.09; 95% CI: 2.37–10.93 (p<0.05).

Among the socio-economic indicators of pregnant women with COVID-19 (Table 5), the following can be distinguished by their negative impact on perinatal outcomes: the presence of stress (OR=3.05; 95% CI: 1.54–7.68, p<0.05) and not being in a registered marriage (OR=3.07; 95% CI: 1.59–5.93, p<0.05).

Mathematical calculations confirmed the negative impact of anxiety and depression (according to the Hospital Anxiety and Depression Scale – HADS) on the course and outcomes of pregnancy with COVID-19 (Table 6). The highest value of the OR was obtained for clinically pronounced depression (OR=4.91; 95% CI: 2.01–7.68, p<0.05).

Thus, among the considered candidate indicators for inclusion in the mathematical model for predict-

Table 7

Mathematical model of the first stage of predicting perinatal complications in pregnant women with COVID-19

Indicator	Score
3rd trimester of pregnancy at the time of illness	2
Difficulty breathing	2
Fever (above 38°C)	2
Obesity of II-III degree	1
Diabetes mellitus	1
Stress	1
Anxiety	1
Clinically expressed depression	1
Duration of symptoms of the disease by the time of hospitalization is more than 5 days	1

Table 8

Mathematical model of the II stage of predicting perinatal complications in pregnant women with COVID-19

Indicator	Score
Hyperthermia:	1
– hyperthermia for more than 5 days	1
Stay in the intensive care unit:	1
– stay in the intensive care unit for more than 5 days	1
Respiratory support:	1
– respiratory support for more than 7 days	1
Duration of hospitalization for more than 5 days	1
Anemia	2
Platelet level less than 150 109/l	2
Leukocyte level more than 15 109/l	2
ALT above normal	2
AST above normal	2
Creatinine level more than 75 μmol/l	2
Prothrombin index more than 120%	2
D-dimer more than 250 ng/ml	2
C-reactive protein level more than 11 mg/l:	2
– ≥ 50 mg/l	3
Procalcitonin level ≥0.1 ng/ml	2
Interleukin-6 level ≥7 mg/ml:	2
– 50 mg/ml and more	3

ing perinatal disorders in pregnant women with COVID-19, the most statistically significant were laboratory indicators associated with COVID-19, indicators of disease severity, stress, the presence of anxiety and depression, and endocrine pathology.

Based on the data obtained, a group of experts developed a two-stage model (scale) for predicting perinatal complications in pregnant women with COVID-19. The experts were offered a list of candidate indicators for inclusion in the mathematical model of prediction with calculated OR to highlight the most mathematically and clinically significant markers, assign a score to each of them, and determine the threshold value of the sum of points for classifying a particular patient as a high-risk group.

For the first stage, which can be used both at the prehospital stage and at the beginning of hospitalization, 9 indicators with an OR more than 3 were selected, and a score was assigned to each (Table 7).

A score of 4 or more indicates a high risk of perinatal complications in pregnant women with COVID-19.

At stage 2 in the dynamics of the course of the disease, if high risk is not identified at the first stage, the scores of indicators detected during hospitalization are added to the resulting score (Table 8). When the threshold of 4 points is reached, there is a high risk of perinatal complications.

The accuracy of the prediction model was tested on a sample of 30 pregnant women with confirmed COVID-19 who were not included in the training samples. Perinatal complications occurred in 8 patients, of which 7 were at high risk according to the model (true positive result), only 1 was predicted to be at low risk (false negative result), out of 22 women without complications, 19 were at low risk according to the model (true negative result) and 3 were at high risk (false positive result). That is, the prediction accuracy was 86.7%, sensitivity – 87.5%, specificity – 86.4%.

Conclusions

The most statistically significant indicators of predicting perinatal disorders in pregnant women with COVID-19 are laboratory indicators associated with COVID-19, indicators of disease severity, stress, the presence of anxiety and depression, and endocrine pathology.

The constructed model (scale) for predicting perinatal disorders in pregnant women with COVID-19 includes 24 indicators and can be used in 2 stages:

1 – at the prehospital stage and/or at the beginning of hospitalization 9 indicators), 2 – in the dynamics of the course of the disease at the hospital stage (15 indicators).

Ease of use (scoring), as well as the established fairly high accuracy (86.7%), sensitivity (87.5%), and specificity (86.4%) of the prediction model, allow us to recommend it for use in clinical practice for the purpose of early detection of patients at high risk of perinatal disorders with COVID-19, their timely hospitalization and treatment.

The authors declare no conflict of interest.

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