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Clinical and laboratory features of COVID-19 in the vaccinated patients and the patients after previous illness

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Abstract: *patients with COVID-19 can have a wide range of clinical manifestations: from generalized intoxication and respiratory symptoms to complaints from other organs and systems. The severity of the disease primarily depends on the age of the patients, the presence of comorbidities, and the susceptibility of the body to a particular variant of the SARS-CoV-2 virus. Vaccination and pre-infection provide a period of immune protection against reinfection. However, it has been reported that patients who have been vaccinated or have had COVID-19 can get sick in the same way as non-immune individuals. The aim of our study was to analyze and compare clinical and laboratory features of the course of coronavirus disease 2019 among hospitalized vaccinated patients who contracted COVID-19 for the first time and hospitalized unvaccinated patients who had previously contracted COVID-19, which was confirmed by laboratory tests. The study included 220 hospitalized patients who were divided into two groups: vaccinated patients who had no history of confirmed COVID-19 (n=129) and unvaccinated patients who had previously contracted COVID-19 (n=91). Results: unvaccinated patients who had history of confirmed COVID-19 had a more pronounced clinical picture of the disease; absolute lymphopenia was significantly more common in patients with severe and critical course in both study groups (p=0,0001); mean C-reactive protein values were statistically significantly different between patients of both groups with moderate, severe and critical course of COVID-19, and were the highest ones in patients with critical course who died (p=0,0001).*

Keywords: COVID-19; C-Reactive Protein; Diagnosis; Disease Progression; Lymphopenia; Pneumonia; Respiratory Insufficiency.

Introduction

Coronavirus disease 2019 is an acute respiratory illness caused by the novel highly contagious coronavirus SARS-CoV-2, which was first detected in late 2019 in the Chinese city of Wuhan. The COVID-19 outbreak in China reached an epidemic peak in February 2020. According to China's National Health Commission, the total number of cases continued to rise sharply in early February, averaging more than 3,000 newly confirmed cases per day. To combat COVID-19, China introduced unprecedentedly strict health measures. However, despite this, the virus quickly spread to other countries, and on March 11, 2020, the WHO officially characterized the global COVID-19 outbreak as a pandemic [1,2].

After three years of fighting the pandemic, on May 4, 2023, the World Health Organization finally announced that COVID-19 is no longer a

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«global health emergency of international concern» [3].

The study of the clinical course of coronavirus disease 2019 remains one of the leading scientific interests of scientists around the world. Thus, according to the accumulated data of numerous studies, it is known that the spectrum of clinical manifestations of infection caused by the SARS-CoV-2 virus can vary from asymptomatic to life-threatening complications of COVID-19 and death. The severity of the disease depends on gender, age, comorbidities, virus variant, and the dose of the pathogen that entered the body [4-6].

The incubation period is usually about 5 days (1 to 14 days). The most common clinical symptoms are fever, dry cough, headache, and fatigue [7-9]. Patients with coronavirus disease 2019 may also experience complaints of sore throat, impaired sense of smell or taste, chest pain, sputum production, shortness of breath, or less common symptoms such as nausea, vomiting, diarrhea, and gastrointestinal complications, making it difficult to make a definitive diagnosis [10-13].

In the vast majority of patients, coronavirus disease 2019 is mild, without the development of clinically significant pneumonia and respiratory insufficiency. Severe disease is associated mainly with the following risk factors: obesity, cardiovascular disease, diabetes mellitus, COPD, malignant tumors, chronic renal failure [14].

The laboratory findings most consistent with COVID-19 are lymphopenia, elevated C-reactive protein (CRP) levels, and an increased erythrocyte sedimentation rate. Procalcitonin can usually be elevated due to bacterial co-infection. Patients with severe COVID-19 may have high levels of cytokines and chemokines in blood, such as interleukin (IL)-7, IL-8, IL-9, IL-10 [1,4,6].

Vaccination and prior infection result in a humoral and cellular immune response. Unvaccinated individuals with a previous infection may have the same level of protection as fully vaccinated individuals without a previous infection [15]. However, with the emergence of new strains of SARS-CoV-2, reinfection after COVID-19 or breakthrough infection in fully vaccinated patients is increasingly reported [16,17].

In summary, it can be noted that for a better understanding of coronavirus disease 2019, there is a need to study the clinical and laboratory features of this disease in patients after primary infection compared to vaccinated patients.

Aim

The aim to analyze and compare clinical and laboratory features of the course of coronavirus disease 2019 among hospitalized vaccinated patients who contracted COVID-19 for the first time and hospitalized unvaccinated patients who had previously contracted COVID-19, which was confirmed by laboratory tests.

Materials and methods

220 case histories of patients with coronavirus disease 2019 who were hospitalized in the Infectious Diseases Department and the Intensive Care Unit for Infectious Diseases at Kyiv City Clinical Hospital No. 9 between December 2021 and January 2023 were included in our study. The diagnosis of COVID-19 was confirmed in the laboratory by PCR or a rapid test for the qualitative determination of viral antigen in all patients. Two study groups were identified: hospitalized vaccinated patients without a history of COVID-19 (group I), and hospitalized unvaccinated patients who had previously had COVID-19, which was confirmed by laboratory tests (group II). Vaccination status and previous COVID-19 disease were checked through the eHealth electronic healthcare system. The hospitalized vaccinated patients had coronavirus disease 2019 for the first time (no laboratory-confirmed case of the disease was previously recorded).

Criteria for severe disease were determined in accordance with the protocol «PROVIDING MEDICAL CARE FOR THE TREATMENT OF CORONAVIRAL DISEASE (COVID-19)» (Order of the Ministry of Health of Ukraine No. 762 of April 02, 2020 (as amended by the Order of the Ministry of Health of Ukraine of May 17, 2023)). Patients were divided into three groups according to their severity: moderate, severe, and critical. All patients in critical condition died.

The collected data included age, gender, symptoms of the disease (fever, cough, catarrhal manifestations), respiratory insufficiency, X-ray

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picture, general, biochemical blood counts, and coagulation.

Depersonalized patient data were used in the processing of medical histories. Statistical analysis was performed using the licensed statistical package Stata 12.1. Descriptive statistics for qualitative parameters are presented through the distribution in absolute values and percentages. For quantitative features, the characteristic of compliance with the normal distribution of data was determined by the Shapiro-Wilk test. According to the results, the median [IQR], arithmetic mean and standard deviation were determined. Comparison of subgroups for qualitative traits was performed by Pearson's Chi-square and Fisher's exact test with the number of observations in subgroups up to 5. Analysis of variance (ANOVA) was used to compare quantitative parameters. The difference between the study groups is considered statistically significant at a significance level of $p<0,05$.

Results

Group I consisted of 129 people with an average age of 66,7±13,7 years, including 74 (57,4%) women with an average age of 63,5±14,2 years and 55 (42,6%) men with an average age of 63,3±13,5 years. Group II consisted of 91 people with an average age of 67,6±14,3 years, including 49 (53,8%) women with an average age of 68,9±15,1 years and 42 (46,2%) men with an average age of 59,9±14,7 years. Tables 1 and 2 show the age statistics in different severity of the COVID-19 in both groups. The difference in the age composition among vaccinated patients (group I) depending on the severity was not statistically significant (p=0,121). The difference in age composition among unvaccinated patients after the disease (group II), depending on the severity, is statistically significant (p=0,0007).

Tables 3 and 4 show the sex distribution in both study groups depending on the severity of the disease. The groups do not differ in terms of gender composition and distribution depending on the severity of the disease (p = 0,092 for group I and 0,906 for group II, respectively).

The main clinical symptoms observed in patients of both groups included fever, dry cough, and catarrhal manifestations (sore throat, runny nose, nasal congestion).

The respiratory insufficiency was determined by a combination of clinical signs (presence of dyspnea, respiratory rate, level of saturation due to pulse oximetry). Patients with moderate severity of the disease in both groups had no respiratory insufficiency, while severe and critical patients in both groups had respiratory insufficiency.

Instrumental diagnostics for the detection of pneumonia included X-ray and/or CT of the chest organs. It should be noted that the sensitivity of

Table 1. Age statistics analysis: vaccinated patients without prior history of COVID-19 (n=129)

COVID-19 severity	N	Age (year)					
		Me (25-75%)	M	SD	Min	Max	95% ДІ
Moderate	101	67 (50-75)	61,9	17,0	18	88	58,5-65,3
Severe	18	69 (58-78)	67,4	11,9	42	85	61,5-73,4
Critical	10	77 (61-79)	71,1	11,6	48	84	62,7-79,4
P		0,121 (ANOVA)					

Table 2. Age statistics analisys: unvaccinated patients who had previously had COVID-19 (n=91)

COVID-19 severity	N	Age (year)					
		Me (25-75%)	M	SD	Min	Max	95% ДІ
Moderate	50	61,5 (45-74)	59,3	17,5	20	88	54,2-64,2
Severe	22	72,5 (55-81)	67,7	15,9	40	92	60,7-74,8
Critical	19	82 (71-84)	75,8	10,9	49	86	70,9-80,7
P		0,0007 (ANOVA)					

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Table 3. Analysis of sex distribution: vaccinated patients without prior history of COVID-19 (n=129)

COVID-19 severity	N	Womem abs, (%)	Men abs, (%)	P (X^2)
Moderate	101	63 (62,4%)	38 (37,6%)	0,092
Severe	18	7 (38,9%)	11 (61,1%)	
Critical	10	4 (40,0%)	6 (60,0%)	
All	129	74 (57,4%)	55 (42,6%)	

Table 4. Analysis of sex distribution: unvaccinated patients who had previously had COVID-19 (n=91)

COVID-19 severity	N	Women abs. (%)	Men abs. (%)	P (X^2)
Moderate	50	26 (52,0%)	24 (48,0%)	0,906
Severe	22	12 (54,6%)	10 (45,4%)	
Critical	19	11 (57,9%)	8 (42,1%)	
All	91	49 (53,9%)	42 (46,1%)	

radiography did not allow detecting pneumonia in some cases. Patients who recovered were discharged without radiographic evidence of pneumonia or with residual effects.

All laboratory methods of examination were evaluated over time. Clinical and laboratory features of the course of coronavirus disease 2019 for both study groups according to the severity of the disease are presented in Tables 5 and 6.

The analysis revealed that in the group of vaccinated patients, pneumonia was diagnosed in 107 (83,0%), and among unvaccinated patients who contracted COVID-19 again, in 77 (84,6%). All patients with severe and critical illness had pneumonia and respiratory failure (p=0,018 and p=0,0001, respectively).

In both study groups, fever was observed in all patients of varying severity without a significant difference between the groups (p=0,999 for group I and p=0,998 for group II). While such clinical signs as cough and catarrhal manifestations did not differ statistically in patients of group I of moderate, severe and critical course (p=0,163, p=0,347, respectively), in group II the presence of these symptoms was significantly more common in patients with severe disease (p=0,001 and p=0,0001, respectively).

Among the main differences in the changes in the complete blood count, it can be noted that in unvaccinated patients with a repeated case of COVID-19 who had a moderate degree of severity, lymphocytosis was more often recorded in the complete blood count (p=0,037), in contrast to vaccinated patients, in whom lymphocytosis was observed without a significant difference between the groups in terms of severity of the disease (p=1,00). In both groups, absolute lymphopenia was significantly more common in patients with severe disease (p=0,0001). The increase in ESR in vaccinated patients was statistically significantly different between patients with moderate, severe and critical disease (p=0,002), but did not differ in patients with previous COVID-19 (p=0,388). Average CRP values increased with increasing severity of COVID-19 in both study groups. Thus, for patients of group I with moderate severity, the CRP value ranged from 23,7±40,2, for severe – 59,2±55,3, for critical – 106±111,4 (difference between groups is statistically significant, p=0,0001). For patients of group II with moderate severity, CRP values ranged from 16,0±24,9, for patients with severe course – 41,7±32,0, and for patients with critical course – 124,1±84,4 (p=0,0001). Changes in blood chemistry and coagulogram were significantly more frequent in patients of both groups with severe and critical course of the disease.

Discussion

In most cases, coronavirus disease 2019 manifests with generalized intoxication and

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Table 5. Clinical and laboratory features of COVID-19 in hospitalized vaccinated patients (n=129)

Name of indicators	ALL n=129	Moderate severity n=101	Severe condition n=18	Critical condition n=10	P (F)
Presence of pneumonia abs, (%)	107 (83,0%)	79 (78,2%)	18 (100%)	10 (100%)	0,018
Presence of respiratory insufficiency abs, (%)	28 (23,1%)	0 (0%)	18 (100%)	10 (100%)	0,0001
Presence of fever abs, (%)	129 (100%)	101 (100%)	18 (100%)	10 (100%)	0,999
Presence of cough abs, (%)	81 (62,8%)	60 (59,4%)	12 (66,7%)	9 (90,0%)	0,163
Presence of catarrhal manifestations abs, (%)	60 (46,5%)	48 (47,5%)	6 (33,3%)	6 (60,0%)	0,347
Normal general blood test abs, (%)	25 (19,4%)	24 (23,8%)	1 (5,6%)	0 (0%)	0,064
Leukocytosis abs, (%)	20 (15,5%)	12 (11,9%)	6 (33,3%)	2 (20,0%)	0,055
Lymphocytosis abs, (%)	5 (3,9%)	5 (5,0%)	0 (0%)	0 (0%)	1,00
Absolute lymphopenia abs, (%)	59 (45,7%)	34 (33,7%)	15 (83,3%)	10 (100%)	0,0001
Increased ESR abs, (%)	87 (67,4%)	63 (62,4%)	18 (100%)	6 (60,0%)	0,002
CRP (average)	35,1±55,8	23,7±40,2	59,2±55,3	106±111,4	0,0001
Increased glucose level abs (%)	40 (31,0%)	22 (21,8%)	10 (55,6%)	8 (80,0%)	0,0001
Increased liver function tests abs, (%)	18 (14,0%)	10 (9,9%)	4 (22,2%)	4 (40,0%)	0,016
Increased levels of renal function tests abs, (%)	5 (3,9%)	0 (0%)	3 (16,7%)	2 (20,0%)	0,0001
Normal coagulogram values abs, (%)	43 (33,3%)	41 (40,6%)	2 (11,1%)	0 (0%)	0,002
Increased prothrombin time abs, (%)	86 (66,7%)	60 (59,4%)	16 (88,9%)	10 (100%)	0,002
Reduced prothrombin index abs, (%)	18 (14,0%)	12 (11,9%)	6 (33,3%)	0 (0%)	0,029

Table 6. Clinical and laboratory features of COVID-19 in hospitalized patients who had previously had COVID-19 (n=91)

Name of indicators	ALL n=91	Moderate severity n=55	Severe condition n=22	Critical condition n=19	P (F)
Presence of pneumonia abs, (%)	77 (84,6%)	36 (72,0%)	22 (100%)	19 (100%)	0,0001
Presence of respiratory insufficiency abs, (%)	41 (45,1%)	0 (0%)	22 (100%)	19 (100%)	0,0001
Presence of fever abs, (%)	90 (98,9%)	49 (98,0%)	22 (100%)	19 (100%)	0,998
Presence of cough abs, (%)	67 (73,6%)	31 (62,0%)	22 (100%)	14 (73,7%)	0,001
Presence of catarrhal manifestations abs, (%)	37 (40,7%)	18 (36,0%)	19 (86,4%)	0 (0%)	0,0001

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Table 6. (continued)

Name of indicators	ALL n=91	Moderate severity n=55	Severe condition n=22	Critical condition n=19	P (F)
Normal general blood test abs, (%)	4 (4,4%)	4 (8,0%)	0 (0%)	0 (0%)	0,402
Leukocytosis abs, (%)	28 (30,8%)	9 (18,0%)	8 (36,4%)	11 (57,9%)	0,005
Lymphocytosis abs, (%)	11 (12,1%)	10 (20,0%)	1 (4,6%)	0 (0%)	0,037
Absolute lymphopenia abs, (%)	37 (40,7%)	11 (22,0%)	15 (68,2%)	11 (57,9%)	0,0001
Increased ESR abs, (%)	77 (84,6%)	40 (80,0%)	19 (86,4%)	18 (94,7%)	0,388
CRP (average)	44,8±61,6	16,0±24,9	41,7±32,0	124,1±84,4	0,0001
Increased glucose level abs (%)	45 (49,5%)	21 (42,0%)	6 (27,3%)	18 (94,7%)	0,0001
Increased liver function tests abs, (%)	4 (4,4%)	0 (0%)	3 (13,6%)	1 (5,3%)	0,023
Increased levels of renal function tests abs, (%)	17 (18,7%)	1 (2,0%)	4 (18,2%)	12 (63,2%)	0,0001
Normal coagulogram values abs, (%)	22 (24,2%)	16 (32,0%)	6 (27,3%)	0 (0%)	0,009
Increased prothrombin time abs, (%)	69 (75,8%)	34 (68,0%)	16 (72,7%)	19 (100%)	0,009
Reduced prothrombin index abs, (%)	26 (28,8%)	9 (18,0%)	7 (31,8%)	10 (52,6%)	0,015

respiratory symptoms, which may generally resemble other respiratory viral infections. The clinical features of COVID-19 can vary from asymptomatic to severe pneumonia and respiratory failure. The most common symptoms of this infection include cough, sore throat, fever, fatigue, and headache [6]. In general, the symptoms of coronavirus disease 2019 are not specific, and laboratory testing is required to confirm the diagnosis. Laboratory monitoring, including complete blood count, C-reactive protein, liver and renal function tests, and coagulation parameters, is an important part of patient management, as laboratory changes often precede deterioration in the clinical course of the disease and allow for the prediction and prevention of complications. Our findings expand the understanding of the clinical course depending on changes in the main laboratory parameters in patients with coronavirus disease 2019 who were hospitalized. Further research in this area involving a larger sample of patients and evaluation of additional laboratory parameters will allow us to more accurately study the features of the clinical and laboratory course of the disease caused by the SARS-CoV-2 virus.

Conclusions

As a result of our analysis and comparison of the clinical and laboratory features of the course of coronavirus disease 2019 in hospitalized patients of varying severity, depending on the vaccination status and history of previous COVID-19 disease, we found that:

1. All the patients enrolled in the study who had severe and critical disease were diagnosed with pneumonia (p=0,018 and p=0,0001 for group I and group II, respectively).
2. Absolute lymphopenia was significantly more common in patients with severe and critical course in both study groups (p=0,0001).
3. The mean CRP values were statistically significantly different between patients in both groups with moderate, severe, and critical course of COVID-19, and were the

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highest in patients with critical course who died (p=0,0001).

4. Clinical features, namely the presence of complaints of fever, cough and catarrhal manifestations, did not differ statistically in patients of group I of moderate, severe and critical course (p=0,999, p=0,163, p=0,347, respectively). Whereas, in patients of the study group II, the presence of cough and catarrhal manifestations was significantly more common in patients with severe disease (p=0,001 and p=0,0001, respectively).

Therefore, it can be concluded that unvaccinated patients who have repeated coronavirus disease 2019 have more severe symptoms and clinical manifestations than vaccinated patients who have not previously had COVID-19. Severe absolute lymphopenia and elevated CRP levels were associated with severe coronavirus disease 2019.

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Conflict of interest

The authors declare no conflicts of interest.

Consent for publication

All authors have read the manuscript and agreed to its publication.

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A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of article.

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Клініко-лабораторні особливості перебігу COVID-19 у вакцинованих пацієнтів та пацієнтів після попередньо перенесеного захворювання

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Анотація: *пацієнти з COVID-19 можуть мати широкий спектр клінічних проявів: від загально-інтоксикаційних та респіраторних симптомів до скарг з боку інших органів та систем. Тяжкість захворювання насамперед залежить від віку пацієнтів, наявності супутньої патології, а також від сприйнятливості організму до того чи іншого варіанту вірусу SARS-CoV-2. Вакцинація та попереднє інфікування забезпечують період імунного захисту від реінфекції. Проте повідомляється про те, що пацієнти, які отримали вакцинацію або перенесли COVID-19, можуть хворіти так само, як і неімунні особи. Метою нашої роботи було проведення аналізу та порівняння клініко-лабораторних особливостей перебігу коронавірусної хвороби 2019 серед госпіталізованих вакцинованих пацієнтів, які захворіли COVID-19 вперше, та госпіталізованих не вакцинованих пацієнтів, які*

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перенесли раніше COVID-19, що був підтверджений лабораторно. Дослідження включало 220 госпіталізованих пацієнтів, які були поділені на дві групи: вакциновані пацієнти, у яких не було в анамнезі підтвердженого COVID-19 (n=129), та невакциновані пацієнти з перенесеним COVID-19 (n=91). Результати: не вакциновані пацієнти, які хворіли на коронавірусну хворобу 2019 повторно, мали більш виражену клінічну картину захворювання; абсолютна лімфопенія достовірно частіше зустрічалась у хворих із тяжким та критичним перебігом в обох групах порівняння (p=0,0001); середні показники С-реактивного білка статистично значимо відрізнялись між пацієнтами обох груп із середнім, тяжким та критичним перебігом COVID-19, та були найвищими для пацієнтів із критичним перебігом, які померли (p=0,0001).

Ключові слова: дихальна недостатність, діагностика, клінічний перебіг, коронавірусна хвороба 2019, лімфопенія, пневмонія, С-реактивний білок.