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Original article

Evaluating the COVID-19 Vaccines Effectiveness in Patients Hospitalized with Severe Acute Respiratory Infections

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Abstract

The pandemic of the COVID-19 coronavirus infection, which is caused by a new strain of coronavirus – SARS-CoV-2, has caused a rapid increase in the number of cases and high mortality worldwide. Comorbid patients are the most vulnerable group with a particularly high risk of adverse outcomes. The widespread introduction of vaccination helps to reduce the severity of the course and complications of a new coronavirus infection.

The purpose of this research is to conduct a comparative analysis of the effectiveness of vaccines against COVID-19 in patients hospitalized with a comorbid background and a severe course of the disease.

Methods. Analysis and analysis of previously published studies by foreign and domestic authors, statistical analysis of medical records of 212 patients undergoing inpatient treatment with SARI.

Results. In the course of the conducted analysis in the group of vaccinated patients, despite the fact that initially all were comparable with each other in terms of the severity of lung tissue damage, as well as the presence of concomitant pathology, the severe course of the disease and deaths amounted to 7%. They were discharged for further observation at the outpatient stage with an improvement of 93% of patients. Whereas in unvaccinated patients the mortality rate was 16.1%, 83.9% of patients were discharged with improvement. The duration of hospitalization in vaccinated patients was much shorter, averaging 7 days, whereas in non-vaccinated patients hospitalization lasted 12 days.

Conclusions. According to the conducted research, the Russian Sputnik-V showed a statistical advantage. A negative trend of severe disease course was revealed among unvaccinated patients with a comorbid background. The results obtained allow us to assess the high importance of vaccination to reduce the lethal outcomes of COVID-19.

Keywords: COVID-19, Sputnik V, vaccination, coexisting disease, acute respiratory infections.

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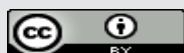
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Introduction

According to the World Health Organization (WHO), the emergence of viral diseases poses a serious threat to public health. Over the past two decades, several epidemics caused by viruses such as severe acute respiratory syndrome coronavirus (SARS-CoV) from 2002 to 2003, H1N1 influenza in 2009 and Middle East respiratory syndrome coronavirus (MERS-CoV) in 2012 have been described as cases that have had a significant impact on global health [1-3].

Since WHO announced the global SARS-CoV-2 pandemic, the virus responsible for COVID-19 has spread to 223 countries with more than 281 million cases and more than 5.4 million deaths worldwide. The United States has the highest number of SARS-CoV-2 infections and COVID-19-related deaths, followed by Brazil and India. In fact, COVID-19 was the third leading cause of death in the United States in 2020 after heart disease and cancer: about 375,000 deaths were reported. The current WHO estimate of global mortality from COVID-19 is 2.2%. However, the mortality rate is influenced by factors such as age, concomitant pre-existing conditions and the severity of the disease, and it varies significantly between countries [4].

People of all ages are at risk of contracting this infection and severe illness. However, patients aged ≥ 60 years and patients with concomitant diseases (obesity, cardiovascular diseases, chronic kidney disease, diabetes, chronic lung disease, smoking, cancer, patients with whole organ transplantation or hematopoietic stem cells) have an increased risk of developing severe COVID-19 infection [5-8]. According to a study conducted by Huang C, the percentage of COVID-19 patients requiring hospitalization was six times higher among patients with pre-existing diseases than among patients without medical indications (45.4% vs. 7.6%), confirmed cases reported to the CDC between January 22 and May 30, 2020 [1].

In the studies of Chinese scientists, among 44,672 confirmed cases of infection, the highest mortality was observed in concomitant diseases of the cardiovascular system (10.5%), diabetes mellitus (7.3%) [7]. At the beginning of the pandemic, in April 2020, data from an American study were published, almost 90% of patients admitted with COVID-19 had concomitant diseases [8]. Cardiovascular disease was the most common concomitant disease (49.7%), followed by obesity (48.3%) and diabetes mellitus (28.3%) [9].

Material and methods

A retrospective analysis of 212 medical records of patients with severe coronavirus infection who received inpatient treatment at the Infectious diseases center of the Regional Clinical Hospital of the city of Karaganda was carried out. Of these, 100 patients were vaccinated with vaccines available in the Karaganda region, both full and incomplete vaccination cycles. In all cases, polymerase chain reaction (PCR) was positive for the detection of SARS CoV-2. These patients were included in the first (main group). The comparison group (group 2) included 112 patients over the age of 18 who were not vaccinated, but with comparable lung tissue damage according to computed tomography and a positive PCR result for COVID-19, which were selected in a randomized manner during the same follow-up period (Figure 1).

- Inclusion criteria: confirmed diagnoses of Sars-Cov-2 by PCR, occurring with complications; age 18 years and older.

Diabetes mellitus is a factor of the greatest risk of rapid progression and a negative prognosis of COVID-19. One of the important mechanisms of this phenomenon is chronic inflammation, which can contribute to the cytokine storm, which causes severe cases of pneumonia in COVID-19 and leads to the death of patients [10,11].

According to 24 retrospective cohort studies conducted in China from January to May 2020, 5 scientific databases showed that COVID-19 coronavirus infection was more severe in obese patients and 40% of them needed ventilation, especially with a high BMI [7,12]. Already in early studies on COVID-19, obesity was mentioned as a factor aggravating the course of coronavirus infection. It has also been reported that obesity can serve as a clinical predictor of adverse outcomes, and BMI should be included as a prognostic factor [8,13].

According to research, vaccination prevents the severe course of COVID-19: coagulopathy, inflammatory syndrome and the development of thrombotic complications. Thus, from the point of view of the authors of the article, the widespread introduction of vaccination against COVID-19 will help reduce the severity of the course and complications of the new coronavirus infection [14-16].

The effectiveness of vaccination against infection caused by SARS-CoV-2 may differ depending on a number of factors: the type of vaccine and the number of doses, the age of people, the characteristics of the state of health at the time of vaccination, profession, geographical region and the incidence rate [17].

Thus, by studying the characteristics of COVID-19 vaccines used in mass immunization in the Republic of Kazakhstan, it is possible to draw conclusions about their high effectiveness. According to the presented data of the literature review, it has been proven that vaccination helps to reduce the number of deaths from COVID-19, reduces the risks of severe disease, and helps to limit the rapid spread of the disease.

The purpose of the study: to conduct a comparative analysis of the effectiveness of vaccines against COVID-19 in patients hospitalized with a comorbid background and severe course of the disease.

- Exclusion criteria: patients without a confirmed diagnosis of Sars-Cov-2 by PCR, age less than 18 and pregnant women.

For the analysis of qualitative variables, the following were used: the Fisher exact test, the criterion of the likelihood ratio. Since the distributions of quantitative data differed from the normal one (Kolmogorov-Smirnov criterion, $p < 0.05$). Median values were used for the description and the values of the first and third quartiles were given. The Mann-Whitney U-test was used to assess the differences. The results of $p < 0.05$ were considered statistically significant.

Statistical processing was performed using Statistica 10 and Excel for Windows 10.

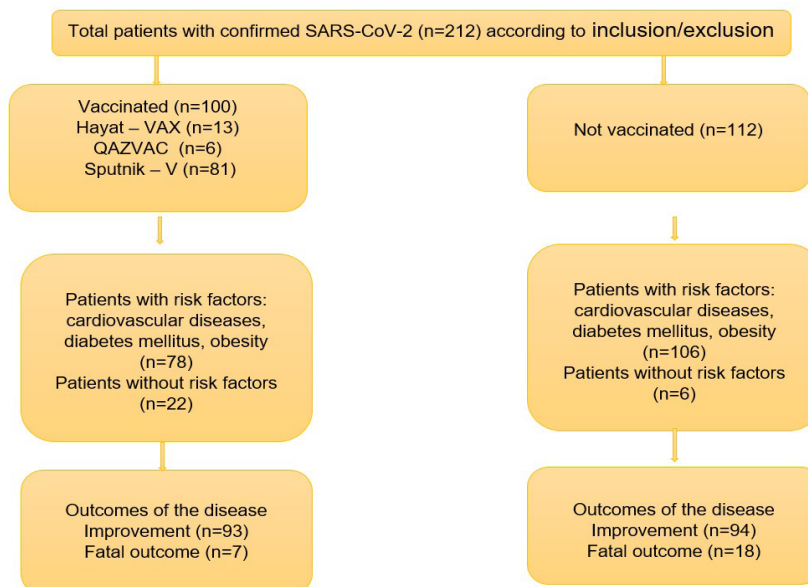


Figure 1 - The sample structure of patients and disease outcomes in the study of the effectiveness of COVID-19 vaccines

Results

The age distribution of patients was as follows: at the age of 25-45, there were only unvaccinated patients – 5.2%, there were no vaccinated patients in this age category, at the age of 46-65, 19.3% were vaccinated, 21.3% were not vaccinated, at the age of 66-75, 18.9% were vaccinated, while not 14.6% were vaccinated, and 8.9% of people over 76 years of age were vaccinated, 11.8% of unvaccinated patients.

Coronavirus infection was more often reported in patients over the age of 65, both vaccinated and unvaccinated. It should be noted that among patients aged 25-45 years, severe severity of the disease was not registered in patients receiving inpatient treatment, this is due to the fact that active vaccination of people of this age was initiated and in this category of patients the severity of the disease was mild.

Among vaccinated patients, 53 (53%) women and 47 (47%) men, 64 (57.1%) women and 42.9% men, respectively, among unvaccinated patients. Women prevailed among vaccinated and non-vaccinated patients in the compared groups.

The result of the study showed that Sputnik-V was the most common type of vaccine (Table 1). After receiving two components, 97 patients fell ill with COVID-19, which was 97%, 3 patients fell ill after receiving the first component of the vaccine. The median value between the introduction of the vaccine and hospitalization was 66 days (23.0-98.8), which indicates that the level of formed immunity does not allow to completely prevent the disease, therefore, in this study we studied the outcomes of COVID-19 disease in vaccinated patients.

Table 1 - Percentage of vaccines

Vaccine name	n	%
Hayat – VAX	13	13.0%
QAZVAC	6	6.0%
Sputnik – V	81	81.0%

The percentage of lung tissue damage according to the results of computed tomography in patients ranged from 45% (CT-2) to 95% of the lesion (CT-4). A high percentage of CT-3 and CT-4 lesions was observed in

unvaccinated patients, which was 35.7% and 64.3%, respectively, which is 1.8 times higher, which indicates that the unvaccinated have rapid progression of lung lesions.

Table 2 - Coexisting diseases during hospitalization with COVID-19

Coexisting disease	Vaccination status				p
	Unvaccinated		Vaccinated		
	n	%	n	%	
Absent	6	5.4%	22	22.0%	0.003
Obesity	26	23.2%	13	13.0%	
Diabetes mellitus	35	31.3%	28	28.0%	
Cardiovascular diseases	45	40.2%	37	37.0%	

It should be noted that the presence of concomitant pathology was one of the strongest risk factors for severe course and high mortality in infected patients (Table 2). Among patients with fatal outcome among vaccinated patients, 42.8% were CVD diseases, compared to 55.5% in unvaccinated patients, diabetes mellitus 28.5% and 27.8%, respectively, with obesity

28.5% and 16.7%, respectively, in unvaccinated patients. The proportion of people without concomitant diseases prevailed among the vaccinated (22.0% vs. 5.4% among the unvaccinated), obesity was more common among the unvaccinated (23.2% vs. 13.0% among the vaccinated), the differences were statistically significant ($p=0.003$).

Table 3 - Use of ALV, NIVs, and humidified oxygen in hospitalized patients with COVID-19

Indicant		Vaccination status				p
		Unvaccinated		Vaccinated		
		n	%	n	%	
Types of respiratory support	Without oxygen	0	0.0%	26	26.0%	<0.001
	ALV	18	16.1%	3	3.0%	
	Concentrator	0	0.0%	44	44.0%	
	NIV	27	24.1%	4	4.0%	
	Humidified oxygen	67	59.8%	23	23.0%	

An important criterion in determining the severity of the disease is the need for oxygen support (Table 3). Thus, 100% of unvaccinated patients received various types of respiratory support, while 18 patients (16.1%) were on a ventilator, 27 patients (24.1%) were on a ventilator, 67 patients (59.8%) were on humidified oxygen. At that time, 74 patients among those vaccinated needed

respiratory support, which is 1.4 times lower. 3 patients (3%) were transferred to a ventilator, 44 patients (44%) to an oxygen concentrator, 24 (24%) to humidified oxygen and 26 patients (26%) without oxygen (Table 3).

Thus, ventilator, ventilator and humidified oxygen were used statistically significantly more often ($p<0.001$).

Discussion

According to numerous studies, vaccination, even with an incomplete cycle, prevents the severe course of the disease [18-20].

In our study, the Russian Sputnik-V showed a statistical advantage, since most of the vaccinated received its components. Those vaccinated with Sputnik-V were more likely to go without oxygen (26% vs. 0%), or used a concentrator (44.0%), while those who were not vaccinated at all were statistically significantly more likely to use ventilation, NIVL and moistened oxygen (likelihood ratio criterion, $p<0.001$).

Thus, the duration of treatment in unvaccinated patients is 1.5 times longer, due to the high percentage of acute respiratory distress syndrome with the progression of the inflammatory process in the lungs. Vaccinated patients were discharged on the 8th day after hospitalization with improvement and further recommendations for the outpatient stage.

The analysis of fatal cases showed that among unvaccinated patients, the mortality rate was 2.3 times higher compared to vaccinated patients and amounted to 16.1% and 7.0%, respectively. It was found that mortality was significantly higher in males (OR=2.09; 95% CI 1.2-3.9; $p=0.022$) and patients with diseases of the cardiovascular system (OR=2.77; 95% CI 1.45-5.02;

$p=0.002$). Mortality was significantly lower in vaccinated patients, which was 7.0% (OR=0.34; 95% CI 0.18-0.67; $p=0.001$).

It should be noted that the presence of concomitant pathology was one of the strongest risk factors for severe course and high mortality of infected patients. Among patients with fatal outcome among vaccinated patients, 42.8% were diseases of the cardiovascular system, against 55.5% in unvaccinated patients, diabetes mellitus 28.5% and 27.8%, respectively, with obesity 28.5% and 16.7%, respectively, in unvaccinated patients.

In this study, we found that vaccination helps reduce the number of deaths from COVID-19, reduces the risks of severe disease, and helps limit the rapid spread of the disease in patients over 65 years of age who either have concomitant diseases (obesity, hypertension, diabetes mellitus).

Limitations:

- considering that at the time of the study, the Sputnik – V vaccine was mainly used, it was not possible to adequately assess the effectiveness of vaccination with other vaccines;

- a small sample of patients.

Conclusions

Based on the above, the following brief conclusions can be drawn:

1. Vaccination helps to reduce the number of deaths from COVID-19, reduces the risk of severe disease, helps to limit the rapid spread of the disease. Vaccination, even with an incomplete cycle, prevents the severe course of the disease.

2. The analysis revealed a negative trend in the severe course of the disease among unvaccinated patients. This cohort of patients were more often

transferred to the intensive care unit, they needed much more time to stabilize their condition than vaccinated patients.

3. Despite the fact that initially all patients were comparable to each other in terms of the severity of lung tissue damage, as well as the presence of concomitant pathology, severe disease and fatal outcomes were more often recorded among unvaccinated patients 16.1%, in vaccinated patients the mortality rate was 7%.

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Conflict of interest. No conflict of interest has been declared. This material has not been previously submitted for publication in other publications and is not under consideration by other publishers.

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Ауыр жедел респираторлық инфекциялармен ауруханаға жатқызылған науқастарда COVID-19 вакцинасының тиімділігін бағалау

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Түйіндіме

Коронавирустың жаңа штаммы - SARS-CoV-2 тудыратын COVID-19 пандемиясы бүкіл әлемде өлім-жітімнің өсуіне себеп болды. Коморбидті науқастар ең осал топ болып табылады және оларда аурудың салдарынан жағымсыз нәтижелердің даму қаупі жоғары. Вакцинациялау шаралары жаңа коронавирустық инфекцияның ауырлығы мен асқинуларының төмендеуіне ықпал ете бастады.

Зерттеудің мақсаты: ауыр ағымдағы және коморбидті фоны бар жедел респираторлық инфекциямен стационарға түскен науқастарда COVID-19-ға қарсы егілген вакцинаның тиімділігіне салыстырмалы талдау жүргізу.

Әдістері. Шетелдік және отандық авторлардың бұрын жарияланған зерттеулерін талдау және талдау, ауыр ағымдағы жедел респираторлық инфекциямен стационарға емделген 212 науқастың медициналық жазбаларына статистикалық талдау.

Нәтижелер. Вакцинацияланған науқастар тобында жүргізілген талдау барысында, барлығы бастапқыда аурудың ағысы, өкпе тінінің зақымдануының ауырлығы, сондай-ақ қатар жүретін патологияның болуы бойынша бір-бірімен салыстырмалы түрде ұқсас болды. Бұл топта өлім-жітім 7% құрады. Науқастардың 93%-ының жағдайы жақсарып, амбулаториялық кезеңге одан әрі бақылауға жазылды. Вакцинацияланбаған науқастарда өлім-жітім 16,1%-ды құраса, олардың 83,9%-ының жағдайы жақсарды. Вакцинацияланған науқастарда ауруханада жату ұзақтығы орташа есеппен 7 күнді құраса, ал вакцинацияланбаған науқастарда ауруханада жатқан күндері 12 күнге созылды.

Қорытынды. Зерттеу деректері бойынша статистикалық артықшылықты ресейлік "Спутник-V" көрсетті. Коморбидті фоны бар вакцинацияланбаған науқастар арасында аурудың ауыр ағымының теріс үрдісі анықталды. Нәтижелер COVID-19 салдарынан болатын өлім-жітімді азайту үшін вакцинацияның жоғары маңыздылығын бағалауға мүмкіндік береді.

Түйін сөздер: COVID-19, Спутник V, вакцинация, ілеспе ауру, жедел респираторлық инфекциялар.

Оценка эффективности вакцины против COVID-19 у пациентов, госпитализированных с тяжелыми острыми респираторными инфекциями

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Резюме

Пандемия коронавирусной инфекции COVID-19, которую вызывает новый штамм коронавируса – SARS-CoV-2, явилась причиной стремительного роста числа заболевших и высокой смертности во всем мире. Коморбидные пациенты являются наиболее уязвимой группой, у которой риск неблагоприятных исходов особенно высок. Широкое внедрение вакцинации способствует уменьшению тяжести течения и осложнений новой коронавирусной инфекции.

Цель исследования: провести сравнительный анализ эффективности вакцин против COVID-19 у пациентов, госпитализированных с коморбидным фоном и тяжелым течением заболевания.

Методы. Разбор и анализ ранее опубликованных исследований зарубежных и отечественных авторов, статистический анализ медицинских карт 212 пациентов, находящихся на стационарном лечении с тяжелыми острыми респираторными инфекциями.

Результаты. В ходе проведенного анализа в группе вакцинированных пациентов, несмотря на то, что первично все, были сопоставимы друг с другом по выраженности поражения легочной ткани, а также наличию сопутствующей патологии, тяжелое течение заболевания и летальные исходы составили 7%. Выписаны на дальнейшее наблюдение на амбулаторный этап с улучшением 93% пациентов. Тогда как у не вакцинированных пациентов летальность составила 16,1%, с улучшением было выписано 83,9% пациентов. Продолжительность госпитализации у вакцинированных пациентов гораздо меньше в среднем составила 7 дней, тогда как у не вакцинированных пациентов госпитализация продолжалась 12 суток.

Выводы. По данным проведенного исследования статистическое преимущество показал российский «Спутник-V». Выявлена негативная тенденция тяжелого течения заболевания среди не вакцинированных пациентов с коморбидным фоном. Полученные результаты позволяют оценить высокую значимость проведения вакцинации для снижения летальных исходов COVID-19.

Ключевые слова: COVID-19, Спутник V, вакцинация, сопутствующее заболевание, острые респираторные инфекции.