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Hospital Consequences of COVID-19 Vaccinated and Unvaccinated Patients Among the Iranian Adult Population

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A B S T R A C T

Introduction: Coronavirus disease 2019 is an emerging respiratory infectious disease caused by a strain of the coronavirus family. Vaccination is one of the main ways to control this disease. This study was conducted to investigate the severity of pulmonary involvement and some clinical outcomes in vaccinated and unvaccinated COVID-19 patients.

Materials and Methods: This retrospective study was conducted between December 2021 and May 2022 with 200 patients in two groups. Sampling was done as available, and patients with COVID-19 admitted to the hospital were investigated. Data analysis was performed using SPSS V.16, applying Mann-Whitney U, and chi-square tests were used at a 5% significance level.

Results: The average age of the studied patients was 59.2 (±17) years; the most common pattern of lung involvement in this study was the GGO pattern. According to the report in the documents, 45 people in the vaccinated group and 9 people in the unvaccinated group did not have any lung involvement in CT, and the observed difference was statistically significant (P = 0.001). In the oxygen saturation percentage, the lowest level (75%) was observed in the unvaccinated group. Also, the difference in average hospitalization days between the two groups was statistically significant (P = 0.050).

Conclusion: The results of this study showed that the COVID-19 vaccine can effectively reduce the extent and severity of lung involvement and the need for supplemental oxygen in vaccinated patients.

Keywords: COVID-19, Vaccine, Unvaccinated, Outcome

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Introduction

Coronavirus disease 2019 (COVID-19) is an emerging respiratory infectious disease caused by a strain of the coronavirus family called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (1). The first cases were observed in the Chinese city of Wuhan in late December 2019, and from there it quickly spread to almost the entire world (1).

It was officially declared a pandemic by the World Health Organization (WHO) on March 11, 2020 (2). The quick global expansion of this agent has had a huge social, economic, and health burden and has made the take of stupendous limited social effort inevitable to prevent its spread and damage to health infrastructure (2). The COVID-19 infection has been proven to be transmitted through contact with droplets of upper respiratory tract discharge from people infected with the virus (3). Symptoms of infection usually appear within 14 days after exposure, and in most cases within 4-5 days (3). By the end of 2023, the number of established cases of COVID-19 worldwide exceeded 700 million, and the death toll overreach six million (4). At the end of 2023, 71% of people in the whole world have received at least one dose of vaccine, and this figure is 79% in Iran (4). In most cases, SARS-CoV-2 infection is asymptomatic (5). Clinically, this infection cannot be completely differentiated from other viral respiratory infections because the signs and symptoms of COVID-19 are non-specific (5). In scientific literature and research, asymptomatic patients report approximately 30-40% (6). In symptomatic patients, COVID-19 usually presents with systemic and/or respiratory manifestations, although findings have also indicated the occurrence of gastrointestinal, cardiovascular, and dermatological symptoms (7). To detect SARS-CoV-2, the standard test, reverse transcription polymerase chain reaction (RT-PCR), is performed on a secretion taken from nasopharyngeal or respiratory secretions (8). The review studies conclude that RT-PCR is a specific test, but its sensitivity can vary from 60% to 97%, and false negatives are always a major medical challenge, especially in the initial stages of viral infection (8). The sensitivity of the test depends on the time interval between being infected with the SARS-CoV-2 virus. The probability of a false negative is almost 100% on the first day after being infected with the virus, then it decreases to 38% on the day of the onset of clinical manifestations and to 20% on the next day (9). Imaging tests are a consequential tool in the diagnosis and direction of these patients, which are used to conduct diagnosis, determine the severity of involvement, help for treatment, and evaluate response to treatment (8). Most researchers and doctors agree that a CT scan of the chest is a suitable tool for diagnosing COVID-19 due to its high resolution, fast availability, and diagnostic sensitivity of about 97%. Also, the chest CT scan findings may occur earlier than the positive RT-PCR test (10).

The first step for imaging in patients with acute respiratory syndrome is chest radiography, and in the next step, lung CT is used to image the lungs of these patients (11). Even though it does not have a very high diagnostic feature, as a diagnostic tool, it has a high sensitivity for diagnosing COVID-19 (11). It is always emphasized that it should be used as a diagnostic tool in patients with specific clinical symptoms, neither for screening nor in the first line of diagnosis (11). Generic findings from early stage to advanced disease: ground-glass opacities (GGO), consolidation, peripheral reticulation, and crazy-paving pattern (3). Other less common signs: reversed-halo sign, pleural/subpleural dissonance, fibrotic changes, etc. (3). COVID-19 has been typically explained to present with multifocal GGOs with a basal, peripheral, and posterior distribution (12). According to the findings of a systematic review, the GGO pattern of involvement has been suggested as the most common CT finding in COVID-19 (85%) (13). Few studies have compared the complications and consequences of vaccines against COVID-19 (14, 15). Also, scattered studies in different countries have been conducted to investigate the clinical consequences or CT scan findings of COVID-19 among vaccinated patients compared to non-vaccinated patients (16, 17). However, these studies are few, and almost every study has examined two or more outcomes.

Therefore, it is necessary to conduct a study to compare the results between the groups that received the vaccine and those that did not receive the vaccine, at least to provide information and knowledge about the effects of the vaccines provided in each country and its respective climate. The purpose of this study was to evaluate the severity of pulmonary involvement, days of hospital stay, and ICU admission rate in vaccinated and non-vaccinated COVID-19 patients.

Materials and Methods

Setting and Sample

This case-control study was conducted between "22nd December 2021 to 21st May 2022" with 200 patients. Sampling was done as available, and patients with COVID-19 hospitalized in Qom's Kamkar Hospital were examined at the same time as the peak of the Omicron strain of COVID-19 in Iran.

Sample Size

The sample size was calculated using the formula for comparison of lung involvement in the mean and standard deviation of CT scan score in two groups of patients (17); for a 95% confidence interval and a power of 90%, the minimum number of samples required in each group was 45, which is 200 in total, entered the study.

Outcomes

The collection of patients' information continued until an equal sample size was achieved between the two groups. The demographic variables of age, gender, and underlying diseases were investigated between the two groups. The severity of lung involvement in the CT scan was graded as follows from the radiologist's report: Score 1: <20%, Score 2: 20< 40%, Score 3: 40< 60%, Score 4: 60< 80%, Score 5: 80≤.

All enrolled participants had positive reverse transcription polymerase chain reaction (RT-PCR) and were over 18 years old. All cases underwent high-resolution computed tomography (HRCT) on the chest from the 4th to the 7th day after the onset of the manifestation. Patients were divided into two groups: group 1 unvaccinated patients and group 2 vaccinated patients (patients whose interval between the appearance of the first clinical symptom and the date of receiving the second dose of vaccine is more than 15 days and less than three months). Those who received a single dose of the vaccine, individuals with discrepancies in their medical records, expectant mothers, and those who underwent a CT scan beyond 4-7 days following the onset of symptoms were all included. The study's outcomes include the type of pulmonary involvement, the severity of lung involvement, the number of hospital days, blood oxygen saturation (O2Sat), and the rate of hospitalization in the intensive care unit (ICU).

Ethical Consideration

Ethical considerations consisted of obtaining the ethics code (IR.MUQ.REC.1401.228), honesty in library collection and data reporting, written informed consent from all samples according to the Declaration of Helsinki's announcement, and interventional human principles.

Statistical and Data Analysis

This research employed several statistical tests to analyze the data. Chi-square and independent t-tests were utilized to assess differences in demographic characteristics among groups. Mann-Whitney U tests were conducted to compare score differences between groups. Additionally, the Kolmogorov-Smirnov test was employed to assess the normal distribution of data. A significance threshold of 0.05 was adopted for all statistical analyses. Data analysis was performed using SPSS version 16 software.

Results

Table 1 displays the demographic characteristics of the study participants, accompanied by the results of chi-square and independent t-tests. These tests examine the demographic differences between the two study groups, revealing that 35% of patients in the unvaccinated group were male and 65% were female, while the majority of patients in the vaccinated group were male. In the evaluation of demographic conditions, including age, sex, and underlying diseases, a statistically significant difference was observed between the two study groups. The average age of the patients in this study was 59.2 (±17) years, and the oldest patient in the hospital was 96 years old in the vaccinated group. In terms of comorbidities, diabetes mellitus was the most common disease overall, following the same pattern as the unvaccinated group. In the vaccinated group, high blood pressure was the most common disease.

Table 1. Demographic characteristics of all patients and according to the studied groups

Characteristics	All of patients N (%)	Unvaccinated N (%)	vaccinated N (%)	P-value
	200	100	100	
Age (in years) Mean (± SD)	59.2 (±17.6)	56 (±19.5)	62.3 (±15)	P= 0.011[d]
Min	22	22	27	
Max	96	90	96	
Gender Male	91 (46)	35	56	P= 0.004[b]
Female	109 (54)	65	44	

Co-morbid conditions				P= 0.001[b]
Diabetes Mellitus	51 (25)	32	19	
Hypertension	42 (21)	14	28	
Pulmonary Diseases	8 (4)	6	2	
Hypertension and Diabetes (positive)	7 (3)	0	7	
Other	15 (7)	11	4	
No co-morbidities	76 (38)	36	40	
[d]: Independent t-test [b]: Chi-Square test				

Table 2 shows the CT findings and distribution of lung involvement based on scoring in both groups. In this study, the GGO pattern and consolidation were the most frequently observed patterns. In the vaccinated group, the largest number of patients did not have any specific pattern of lung involvement. InThere was a significant difference in lung involvement severity scores 2, 3, and 5, but this difference was not statistically significant (P = 0.085, P = 0.316, P = 0.151). cording to the report in the documents, 45 people in the vaccinated group and 9 people in the unvaccinated group did not have any lung involvement in CT, and the observed difference was statistically significant (P = 0.001).

The most severe scores were in the non-vaccine group, and 91% of patients in this group had some degree of pulmonary involvement. In contrast, the vaccine group only had involvement in 55% of their lungs. The severe pulmonary complications (scores 4 and 5), which led to long hospitalization and ICU admission, were in the non-vaccines group. The vaccinated group met the same criteria: only 7% of the patients in the group were admitted to the ICU. The average length of stay in the hospital was higher in the unvaccinated patients, and the longest hospitalization day (20 days) was related to this group. Additionally, this group had the lowest oxygen saturation percentage at 75%.

Table 2. Distribution and comparison of CT findings in both groups

	Group 1. Unvaccinated N=100	**Group 2. Vaccinated N=100**	**95% CI**	**P-value (Chi-Square test)**
Pattern				
Consolidation	30	12	7.01 - 28.90	P= 0.041
GGO	46	31	1.87 – 28.13	P= 0.510
Fibroses	7	1	0.65 – 11.35	P= 0.023
Plural Effusion	8	0	3.07 – 12.93	P= 0.053
none	9	56	(-56.41) – (-45.04)	P= 0.001
Lung involvement				
Score 1	28	23	(-7.01) – 17.12	P= 0.710
Score2	26	15	(-.07) – 22	P= 0.085
Score3	18	10	(-1.54) – 17.62	P= 0.316
Score4	13	5	0.16 – 15.8	P= 0.001
Score5	6	2	(-1.29) – 9.30	P= 0.151

Based on the comparisons made in terms of the mean days of hospitalization and the O2Sat between the two study groups, the observed difference was statistically significant (Table 3). This study also investigated ICU admission after hospitalization. Out of the 200 investigated patients, 24 were admitted to the ICU, of which 22 (about 92%) were from the unvaccinated group, and only two cases, about 8%, were from the vaccinated group. Unvaccinated patients had lower oxygen levels at admission, and their response to treatment was low, which ultimately resulted in more hospitalization days and more ICU admissions.

Table 3. Differences in clinical outcomes and hospital stay between unvaccinated and vaccinated groups

Variable	No. of Patients (200)	Unvaccinated (100)	Vaccinated (100)	95% CI	P-value
Hospital stay (days)				1.09 – 3.08 (Mean Difference=2)	P= 0.001[a]
Mean (± SD)	7.39 (±3.7)	8.39 (±4)	6.3 (±3.1)		
Min	1	3	1		
Max	20	20	15		
O2 sat (%)				(-3.17) – 0.23 (Mean Difference= -1.7)	P= 0.050[a]
Mean (± SD)	89.3 (±5.4)	88.4 (±6)	90.1 (±4.5)		
Min	75	75	79		
Max	98	98	98		
ICU admission	24	22	2	11.58 – 28.42	P= 0.001[b]

[a]: U Mann Whitney
[b]: Chi-Square test

Discussion

This study divided hospitalized COVID-19 patients into two groups, vaccinated and non-vaccinated, and evaluated their hospitalization outcomes. The findings of this study showed the low rate of admission to the ICU and the length of hospitalization in vaccinated patients.

For better diagnosis and management of COVID-19 patients, it is necessary to know the common and uncommon findings in chest X-rays and CT scans, because it enables health professionals to make a rapid and reliable diagnosis. Among the frequent findings in chest CT of patients with COVID-19 are GGO, consolidation, Halo sign, and bronchial wall thickening, while pleural thickening is a relatively rare finding, which is consistent with the findings of this study(11).The vaccinated group showed a significant difference in the severity of pulmonary involvement across all scores, from mild to very severe, confirming Dasgupta et al.'s finding that non-vaccinated individuals experience more severe complications when they contract COVID-19 (18). According to the report of Serag et al., the average CT score in the moderate and severe classification in the unvaccinated group was 53 and 26, while in the vaccinated group, these averages were 39 and 0. In the present study, the moderate, severe, and very severe scores of the unvaccinated (Scores 3, 4, 5) were 18, 13, and 6, respectively, and in the vaccinated group, these numbers were 10, 5, and 2 (17). The current study shows similar results. In the statistical comparison, the Score 4 (pulmonary involvement 60–80%) is also significant. The findings of this study were similar to the Modi et al. study in terms of lung involvement in CT (16). It can be inferred that every non-vaccinated COVID-19 patient will be involved with some degree of lung involvement, while most vaccinated patients do not have lung involvement, and if they do, it will be very limited. In this study, the mean length of stay (LOS) in the hospital was significantly different between the unvaccinated and vaccinated groups; these results were consistent with the Havers et al. study (19), but did not match the findings of the Fatima et al., though shorter LOS among vaccinated patients was reported in their study. (20). Shorter length of stay (LOS) is associated with better treatment response, fewer serious complications, and ultimately, lower healthcare costs. The survival rate of unvaccinated people can be due to more or longer complications of COVID-19 disease; one of these complications is the high probability of hospitalization in the ICU. In the present study, the percentage of people admitted to the ICU in the unvaccinated group was much higher than in the vaccinated group; these findings were contrary to the findings of Havers et al. According to their report, the rate of admission to the ICU was not significant between the vaccinated and unvaccinated groups (19).

According to the Bernal et al. study, vaccination was 60% effective in preventing hospitalization in those who received even just one dose of the vaccine and resulted in fewer hospitalizations compared to the unvaccinated group (21). The findings of this study were consistent with their results, and it was estimated that the injection of the vaccine greatly reduces the hospitalization of patients in the ICU; accordingly, it is cost-effective to inject the vaccine in communities that have limited hospital beds and ICU units. The findings of this study were similar to the findings of Ruiz et al.; they found that the O2sat level was lower in the non-

vaccinated patients, and as a result, the rate of supplemental oxygen needed in the non-vaccinated group was higher than in the vaccinated group; their findings were not statistically significant (22). Comparing the demographic characteristics between two groups of patients showed statistically significant differences; therefore, it can be concluded that receiving the vaccine will not lead to the same disease for all members of society, so that in those who were vaccinated, disease often occurred in older age ranges and in people with underlying diseases. In addition, considering the predominance of male gender among vaccinated patients, it can be said that vaccination provides more protection along with social distancing, but men will be more exposed and infected due to their employment; most are outside. Abnormal patterns in this study were relatively high, which did not match the usual patterns of pulmonary infections. It could be due to the difference in performing CT scans at different intervals from the onset of the disease that it is better to use a CT scan and RT PCR test simultaneously. One of the ways to control the outbreak of respiratory diseases is vaccination, and comparing the outcomes of the disease in vaccinated and non-vaccinated people seems to be a logical way to make people and healthcare providers more aware to continue vaccination.

The limited sample size and conducting the study in a single-center hospital with relatively severe COVID-19 patients are the limitations of the present study. As this was a retrospective study, the study findings (such as clinical characteristics) depended solely on the clinical skills of the physicians who treated the patients at the time and may have inadvertently introduced bias, particularly in the reporting of radiographs and CT scans. Also, the current study population only examines the effect of vaccinations given in Iran on the Iranian population, which can impair generalizability to other parts of the world.

Conclusion

This study concludes that vaccinated patients with a severe and critical COVID-19 infection experience fewer average hospital days, require less ventilatory support, and stay in the ICU compared to the unvaccinated population. Therefore, it is recommended that conducting studies to vaccinate as many people as possible and evaluating the need for booster doses.

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Conflict of interest

There are no conflicts of interest.

Authors' contributions

Conceptualization, Methodology, Validation, Formal Analysis, Writing– Review & Editing, Visualization, Supervision, Project Administration: FM
Investigation: MS, Resources, Data Curation, Writing– Original Draft Preparation: FM, MS, Funding Acquisition: No fund.

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