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Research Paper

A retrospective analysis of the clinical characteristics of vaccinated COVID-19 patients admitted to a tertiary hospital, northern Iran

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ABSTRACT

Coronavirus disease 2019 (COVID-19) vaccines have played a critical role in reducing the severity and complications of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. While various vaccine types have been administered globally, the clinical manifestations of COVID-19 among vaccinated individuals may differ based on the number of doses received. This study aimed to evaluate and compare the initial clinical characteristics of vaccinated COVID-19 patients. This retrospective descriptive-analytical study was conducted on 594 adult patients with confirmed COVID-19 who had received at least one dose of a COVID-19 vaccine. Patients were admitted to Razi Hospital in Rasht, Iran, between June 6, 2021 and March 21, 2022. Medical records were reviewed to collect demographic data, vaccination history, and clinical symptoms at admission. Patients were categorized into three groups: one dose, two doses, and three doses (booster). Clinical symptoms and oxygen saturation levels were compared across these groups. Among 594 patients, 30% had received one dose, 55.1% two doses, and 15% three doses of a COVID-19 vaccine. Fever, cough, myalgia, respiratory distress, and anosmia showed significant differences across the groups. The mean oxygen saturation was highest in the two-dose group. No significant differences were observed in comorbidities among the groups. The number of vaccine doses received was associated with differences in several clinical symptoms and oxygen saturation levels among hospitalized patients. These findings suggest a possible dose-related trend in clinical presentation among vaccinated individuals.

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1. Introduction

Vaccines have proven to be the greatest savior of humankind in the global battle against the COVID-19 pandemic, and many vaccine candidates have been established in clinical trials in early 2020 [1,2]. Among adults hospitalized with SARS-CoV-2 infection during the pandemic, COVID-19 vaccination, including a booster dose, was associated with a lower likelihood of intensive care unit admission [3]. The COVID-19 patients have some clinical manifestations such as fever and cough as primary clinical presentations, and shortness of breath and myalgia as the following manifestation [4,5]. Due to the wide spectrum of SARS-CoV-2 symptoms, some patients may have serious and extensive complications such as acute respiratory distress syndrome (ARDS) and cytokine storm, which may result in organ failure and death [6–8]. Unvaccinated patients had less protection from innate immunity than fully vaccinated patients. Also, Unvaccinated cases of SARS-CoV-2 reinfection have statistically longer hospital stays and require non-invasive oxygen supplementation during their stay than breakthrough cases [9].

Various types of vaccines are designed to stimulate the immune system and fight the SARS-CoV-2. Scientists determine the type of vaccine based on the best approaches and techniques available for the production of vaccines. Vaccines come in several categories, including messenger RNA (mRNA), live attenuated, inactivated subunits, and viral vector vaccines [10]. Vaccination experiments have shown that neutralizing antibodies correlate with protection. Following studies of outbreaks on fishing vessels, neutralizing antibodies are now also implicated as a human protection correlation. Nevertheless, it is important to note that natural infections elicit the reaction of both mucosal antibodies (secretory immunoglobulin A (IgA)) and systemic antibodies (IgG) [11–14].Viruses constantly change over mutation and with one or more new mutations and they are represented as variants of the original virus. Some SARS-CoV-2 variants, are more transmissible and can result in more severe complications than the ancient ones [15].

According to some studies, it has been suggested that the antibody level triggered by COVID-19 vaccines is falling [16,17]. Also, most COVID vaccines require two doses that are administered 3 to 12 weeks apart to provide adequate immunity to the individual; nevertheless, many countries geared up to provide a third (second booster) shot of the COVID-19 vaccine [18].

Administration of the third dose of COVID-19 vaccines can potentially elevate the neutralizing antibody titers against SARS-CoV-2 variants, particularly in individuals with immune deficiency or with underlying disease, and individuals who are at an increased risk for COVID-19 exposure and transmission [19]. Since the COVID-19 vaccine was developed and distributed rapidly following a short clinical trial period, any clinical outcomes observed in vaccinated patients can contribute valuable insights into its long-term efficacy. In this context, we aimed to conduct a study to evaluate the clinical symptoms of vaccinated COVID-19 patients in Rasht, Iran.

2. Materials and Methods

2.1 *Study design and setting*

This descriptive-analytical study was conducted on adult patients with confirmed COVID-19 who had received at least one dose of a COVID-19 vaccine. All patients were admitted to Razi Hospital, Rasht, Iran, between 6 June, 2021 and 21 March 2022. A total of 594 patients were selected using a census sampling method. This study design was approved by the Ethics Committee of Guilan University of Medical Sciences (Approval Code: IR.GUMS.REC.1402.025). Patient data were analyzed anonymously. The need for written informed consent was waived by the committee due to the retrospective design of the study.

2.2 *Inclusion and exclusion criteria*

Inclusion criteria consisted of a confirmed diagnosis of COVID-19 by reverse transcription polymerase chain reaction (RT-PCR) based on nasopharyngeal and oropharyngeal swab samples, as documented in medical records. Patients were excluded if their PCR test results were negative or if their medical records lacked essential clinical data.

2.3 *Data collection*

Demographic data (age, gender), substance use history (smoking and opium use), and initial clinical characteristics including fever, cough, myalgia, nausea, vomiting, diarrhea, respiratory distress, peripheral oxygen saturation (SpO_2), and the need for oxygen therapy or intubation were extracted from patient records. Patients were categorized into three groups based on vaccination status: first dose only, second dose, and third dose (booster). Clinical features were compared among these groups.

2.4 *Statistical analysis*

All statistical analyses were performed using SPSS software version 21.0 (IBM Corp., Armonk, NY, USA). Continuous variables such as age and SpO_2 levels were tested for normality using the Shapiro–Wilk test. Due to non-normal distribution, the Kruskal–Wallis test was used to compare continuous variables across the three vaccination groups (one dose, two doses, and three doses). Categorical variables such as sex, clinical symptoms, and comorbidities were presented as

frequencies and percentages, and compared using the Chi-square test. A two-sided p-value less than 0.05 was considered statistically significant.

3. Results

A total of 594 vaccinated patients with confirmed COVID-19 were included, categorized into three groups based on the number of vaccine doses received: one dose (n = 178, 30%), two doses (n = 327, 55.1%), and three doses (n = 89, 15%). Only 3 (0.5%) of patients had a history of previous COVID-19 infection. Based on the results, 291 (49%) patients were male and 303 (51 %) were female. Sex distribution did not differ significantly between groups (p = 0.646). Age differed significantly across groups, with a median increase in age in the three-dose group (mean ± SD: 69.6 ± 12.4) compared to the one-dose (60.4 ± 14) and two-dose (62 ± 15.5) groups (p < 0.001).

Regarding to clinical symptoms, a significant association was observed between the number of vaccine doses and the presence of fever (p < 0.001), cough (p = 0.005), myalgia (p = 0.004), respiratory distress (p = 0.044), and anosmia (p < 0.001). Other symptoms such as ageusia, nausea, vomiting, diarrhea, anorexia, and decreased consciousness showed no significant difference among the groups. The full results of demographic and initial clinical characteristics of vaccinated COVID-19 showed in Table 1.

The SpO_2 also differed significantly among groups: Mean PO_2 was highest in the two-dose group (92.7 ± 5.7), followed by the three-dose (91.3 ± 7) and one-dose (90.7 ± 7.6) groups (p = 0.001). The categorical distribution of PO_2 ≥93 vs. <93 also showed significance (p = 0.034).

There were no statistically significant differences among groups in the prevalence of comorbidities such as diabetes, heart disease, renal disorders, malignancy, liver disease, or addiction (Table 2).

Table 1. Comparison of demographic characteristics and initial clinical manifestations of vaccinated COVID-19

Variable	Group	1st (n = 178) No. (%)	2nd (n = 327) No. (%)	3rd (n = 89) No. (%)	P value
Age	Mean ± SD	60.4 ± 14	62 ± 15.5	69.6 ± 12.4	<0.001
	Min-Max	1-89	20-97	28-99	
Sex	Male	82 (46.1)	164 (50.2)	45 (50.6)	0.646
	Female	96 (53.9)	163 (49.8)	44 (49.4)	
Contact with COVID-19 patients	No	74 (41.6)	97 (29.7)	53 (59.6)	<0.001
	Yes	104 (58.4)	230 (70.3)	36 (40.4)	
Prior COVID-19	No	177 (99.4)	327 (100)	82 (97.8)	0.029
	Yes	1 (0.6)	0	2 (2.2)	
Fever	No	100 (56.2)	250 (76.5)	62 (69.7)	<0.001
	Yes	78 (43.8)	77 (23.5)	27 (30.3)	
Cough	No	53 (29.8)	146 (44.6)	35 (39.3)	0.005
	Yes	125 (70.2)	181 (55.4)	54 (60.7)	
Myalgia	No	69 (38.8)	120 (36.7)	50 (56.2)	0.004
	Yes	109 (61.2)	207 (63.3)	39 (43.8)	
Respiratory distress	No	63 (35.4)	153 (46.8)	40 (44.9)	0.044
	Yes	115 (64)	174 (53.2)	49 (55.1)	
Decreased consciousness	No	164 (92.1)	299 (91.4)	79 (88.8)	0.646
	Yes	14 (7.9)	28 (8.6)	10 (11.2)	
Anosmia	No	164 (92.1)	322 (98.5)	88 (98.9)	<0.001
	Yes	14 (7.9)	5 (1.5)	1 (1.1)	
Ageusia	No	165 (92.7)	317 (96.9)	86 (96.6)	0.074
	Yes	13 (7.3)	10 (3.1)	3 (3.4)	
Seizure	No	177 (99.4)	327 (100)	89 (100)	0.31
	Yes	1 (0.6)	0	0	
Cramp	No	177 (99.4)	326 (99.7)	89 (100)	0.749
	Yes	1 (0.6)	1 (0.3)	0	
Nausea	No	147 (82.6)	283 (86.5)	75 (84.3)	0.481
	Yes	31 (17.4)	44 (13.5)	14 (15.7)	
Vomiting	No	170 (95.5)	307 (93.9)	80 (89.9)	0.2
	Yes	8 (4.5)	20 (6.1)	9 (10.1)	
Diarrhea	No	169 (94.9)	311 (95.1)	87 (97.8)	0.527
	Yes	9 (5.1)	16 (4.9)	2 (2.2)	
Anorexia	No	174 (97.8)	322 (98.5)	86 (96.6)	0.531
	Yes	4 (2.2)	5 (1.5)	3 (3.4)	
Intubation	No	172 (96.6)	320 (97.9)	85 (95.5)	0.442
	Yes	6 (3.4)	7 (2.1)	4 (4.5)	
SpO_2 status	≥93	93 (52.2)	207 (63.3)	48 (53.9)	0.034
	<93	85 (47.8)	120 (36.7)	41 (46.1)	
SpO_2 levels	Mean ± SD	90.7 ± 7.6	92.7 ± 5.7	91.3 ± 7	0.001
	Min-Max	40-98	60-99	60-100	
Body temperature	Mean ± SD	37.03 ± 0.45	37.03 ± 0.42	37.07 ± 0.4	0.536
	Min-Max	33-39	32-39	36-39	

Table 2. Distribution of comorbidities and medical histories among COVID-19 patients

Variable	Group	1st (n = 178) No. (%)	2nd (n = 327) No. (%)	3rd (n = 89) No. (%)	P value
Smoking	No	173 (97.2)	319 (97.6)	84 (94.4)	0.296
	Yes	5 (2.8)	8 (2.4)	5 (5.6)	
Opium addiction	No	170 (95.5)	318 (97.2)	82 (92.1)	0.088
	Yes	8 (4.5)	9 (2.8)	7 (7.9)	
Malignancy	No	174 (97.8)	314 (96)	82 (92.1)	0.089
	Yes	4 (2.2)	13 (4)	7 (7.9)	
Liver diseases	No	175 (98.3)	321 (98.2)	89 (100)	0.443
	Yes	3 (1.7)	6 (1.8)	0	
Hematologic disorders	No	177 (99.4)	327 (100)	88 (98.9)	0.221
	Yes	1 (0.6)	0	1 (1.1)	
Heart diseases	No	172 (96.6)	318 (97.2)	86 (96.6)	0.909
	Yes	6 (3.4)	9 (2.8)	3 (3.4)	
Renal disorders	No	168 (94.4)	301 (92.0)	82 (92.1)	0.608
	Yes	10 (5.6)	26 (8)	7 (7.9)	
Diabetes	No	119 (66.9)	220 (67.3)	57 (64)	0.847
	Yes	59 (33.1)	107 (32.7)	32 (36)	
History of mucormycosis	No	176 (98.9)	326 (99.7)	89 (100)	0.356
	Yes	2 (1.1)	1 (0.3)	0	

4. Discussion

In this retrospective analysis of 594 vaccinated COVID-19 patients, we observed significant differences in age, oxygen saturation, and selected clinical symptoms across groups categorized by vaccine dose. While patients in the two-dose group exhibited the highest average SpO_2, and some symptoms such as fever and myalgia were less frequent in patients with higher vaccine doses, not all clinical outcomes differed significantly. These findings suggest a potential dose-related trend in vaccine efficacy among hospitalized patients, though confounding factors such as age may influence interpretations. A previous study showed almost all symptoms were reported less frequently in infected vaccinated patients than in infected unvaccinated ones, and vaccinated individuals were more likely to be completely asymptomatic, especially if they were 60 years or older [20]. The risk of long COVID-19 is reduced in individuals who have received second dose of vaccine, when additionally considering the already documented reduced risk of infection overall [21–23]. Previous studies also support the protective effect of multiple vaccine doses. For example, Accorsi et al. reported that receipt of three doses of an mRNA COVID-19 vaccine was associated with greater protection against SARS-CoV-2 variants compared to both two doses and no vaccination [24]. Vassallo et al. similarly found that severe cases were less frequent among fully vaccinated individuals, and the majority of hospitalized patients were either unvaccinated or incompletely vaccinated [25]. In a study conducted in Saudi Arabia, it was observed significantly lower mortality among patients who had received two doses of the vaccine compared to those with only one dose ($p < 0.001$) [26]. These findings collectively highlight a dose-dependent benefit of vaccination. It is important to note, however, that not all studies have reported consistent differences. A retrospective study by Zhang et al. found no significant variation in clinical manifestations, laboratory findings, or radiological results between vaccinated and unvaccinated patients [27]. This variability underscores the need for further research that accounts for confounding factors such as age, comorbidities, timing of vaccination, and vaccine type when assessing vaccine effectiveness in real-world settings. This study has several limitations that should be considered when interpreting the findings. First, the retrospective design and lack of a control group of unvaccinated patients limit the ability to draw causal inferences or directly evaluate vaccine effectiveness. Second, although most participants reported receiving the Sinopharm/BBIBP vaccine, many were unaware of the specific vaccine type administered, leading to the exclusion of this potentially influential variable from analysis. Lastly, potential confounding factors such as time since vaccination or immune status were not controlled for, which may have influenced the observed outcomes. This retrospective study of vaccinated COVID-19 patients demonstrated that certain clinical symptoms, including fever, cough, myalgia, respiratory distress, and anosmia, varied significantly with the number of vaccine doses received. Oxygen saturation was highest in the two-dose group, suggesting a possible benefit of completing the primary vaccine series. No significant differences were found in comorbidities across groups. Although vaccine type was not analyzed due to missing data, these findings suggest a dose-related trend in clinical outcomes, warranting further investigation with more controlled variables.

Authors' contributions

Concept, Study design, Methods, Resource: MH, HS, TY. Data collection, Analysis, Article drafting: FA, TY. Critical revisions of article: MH, HS. All authors read and approved the final version of manuscript.

Conflict of interest

No potential conflict of interest was reported by the authors.

Ethical declarations

This study design was approved by the Ethics Committee of Guilan University of Medical Sciences (Approval Code: IR.GUMS.REC.1402.025). Patient data were analyzed anonymously. The need for written informed consent was waived by the committee due to the retrospective design of the study.

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