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Receiving COVID-19 vaccine, hospitalization, and outcomes of patients with COVID-19: A prospective study

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Abstract

Despite Iraq having started the COVID-19 vaccine in January 2020, there is no official data on vaccination and hospitalization across the country. We aimed to explore the role of the COVID-19 vaccine on the hospitalization and outcomes of patients with COVID-19 in Iraqi Kurdistan. In this prospective study, patients who were admitted to two COVID-19 hospitals in Iraqi Kurdistan in 2021 were followed-up by the discharge time between August and November 2021. The mean age of the patients was 57.6 (27-98 years) of both genders. Most of the patients were illiterate (69.3%) or had a lower level of education (20.5%). A small percentage of patients had previous thrombotic disorders (4.7%) and close to half of the patients had chronic diseases (44.9%). The patients had mild to moderate (44.9%), moderate-severe (36.2%), and critical (18.9%) status. The median hospitalization day was 9 days (1-45 days). The study found that 91.3% of the COVID-19 hospitalized patients did not receive the vaccine and 26.8% of patients died. We did not find a significant association between receiving vaccination and patients' outcomes or disease severity. No patients with previous thrombotic disorders received the COVID-19 vaccine. The male patients were more likely to receive the COVID-19 vaccine compared to female patients; 14.55% *vs* 4.17%, p=0.0394. This study showed that most patients with COVID-19 who were admitted to the hospitals have not received the COVID-19 vaccine. A high percentage of the COVID-19 hospitalized patients died of the disease in this region.

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Introduction

The outbreak of coronavirus disease 2019 (COVID-19) has spread dramatically since its onset in December 2019 in China. The virus has been spread to several countries across the world, including Iraqi Kurdistan. Despite the Kurdistan Regional Government applying several preventive measures, curfew, and complete lockdowns, the virus is endemic currently [1]. Globally, by 11 November 2021, 251,266,207 persons were diagnosed with COVID-19. Of them, 5,070,244 patients died of the COVID-19 disease. In addition, a total of 7,160,396,495 vaccine doses have been administered across the world. In Iraq since starting the COVID-19 vaccination on 3 January 2020 till 11 November 2021, the number of confirmed cases of COVID-19 and deaths were 2,066,042 and 23,415, respectively. By 2 November 2021, 9,632,835 persons have received the COVID-19 vaccine [2].

Three COVID-19 vaccines have been provided by the Ministry of Health in Iraq and Iraqi Kurdistan - PfizerBioNTech BNT162b2 mRNA, Oxford-AstraZeneca ChAdOx1 nCoV-19, and SinoPharm. The COVID-19 vaccines are highly effective against the SARS-CoV-2 virus; including 95% for BNT162b2 mRNA, 94.1% for mRNA-1273, and 70.4% for ChAdOx1 nCoV-19 [3-5].

Patients with COVID-19 can progress to more severe diseases when they are hospitalized. The SARS-CoV-2 infection in vaccinated persons is exposed to trigger memory antibody and cellular responses due to previous vaccination. The immune responses may alleviate disease progression, including life-threatening organ failure and death [6,7]. Nevertheless, still, the link between prior vaccination and disease progression has not been sufficiently understood. Despite Iraq having started the COVID-19 vaccine in January 2020, there is no official data on the role of vaccination on COVID-19 hospitalization and mortality across the country until 12 November 2021. Although COVID-19 mortality is high and vaccination should reduce the disease progression, the COVID-19 vaccine hesitancy is still high in this region [8]. In light of this, more information on the COVID-19 vaccine would assist to strengthen the health education strategies to the public and, in this regard, the results of this report could be useful to encourage the public to receive the COVID-19 vaccine.

The primary aim of the study was to identify the percentage of vaccinated patients in a cohort of patients with SARS-CoV-2 infection, admitted to two COVID hospitals in Iraqi Kurdistan. Secondary objectives were to investigate the outcomes of hospitalized COVID-19 patients with and without previous COVID-19 vaccination.

Methods and patients

In this prospective cohort study, COVID-19 patients who were admitted to two main COVID-19 hospitals in Duhok governorate in Iraqi Kurdistan between August and November 2021 were included in this study. The patients were followed-up by the second author in one hospital and another coordinator in another hospital. The patients were followed-up by the earliest outcome (recovered and discharged from the hospital or death with COVID-19).

The required information of this study was collected by two persons, one of the researchers and one trained nurse. The formal permission was obtained from the hospitals' administrations and verbal consent of patients or their facilities. The hospitals' administrations were given a guarantee to protect the confidentiality of the patients' information of the patients according to the modified Declaration of Helsinki.

Study setting

The patients diagnosed with COVID-19 disease with mild symptoms are managed in a private clinic and receive care at home as required [9]. The patients with moderate-severe and critical medical conditions are admitted to one of the COIVD-19 hospitals in this region. The patients receive the care under the direct supervision of internists, infections, anesthesiologists, and appropriate nursing care. Until the data collection time, there were three COVID-19 hospitals in Duhok governorates. The cases who were admitted to two of these hospitals (Lalav COVID-19 hospital and Azadi Teaching Hospital) were included in this study. The cases of the third hospital were not included in this study owing to technical issues. The third hospital is called burns and plastic surgery hospital. That hospital has been converted to the COVID-19 to present care to the COVID-19 patients in this region. The cases of the burns and plastic surgery hospitals were not included in this study.

Diagnosis and measurement tools

The diagnosis of the patients who were admitted to the mentioned two hospitals was confirmed by RT-PCR test. The following information was collected from the patients. The information was age (years), gender, education (illiterate, under high school, high school, institute, and college graduates), smoking, alcohol consumption, and chronic diseases. The chronic diseases were different from one patient to another one (e.g., cardiovascular, neurological, diabetes mellitus, COPD, asthma).

The thrombotic disorders were collected through a self-reported technique and were documented as yes or no. The disease severity was categorized as mild-moderate, moderate-severe, and critical as documented in the medical records of the patients. The hospitalization duration was determined as the number of days stayed at the hospital.

The following COVID-19 vaccine-related information was collected from the patients, receiving a vaccination (yes/no). The type of the COVID-19 vaccine received by the patients was AstraZeneca, Pfizer, or Sino pharma. Whether the patients received the first or second dose of the COVID-19 vaccine. The outcomes of the patients were determined as dead or recovered from the disease.

Severity of disease

The severity of the disease was determined based on the diagnosis and treatment protocol for novel coronavirus pneumonia (version 7) [10]. Based on this document, the mild cases have no sign of pneumonia on imaging. The moderate cases have a fever and respiratory symptoms with radiological findings of pneumonia. The severe adult cases have the following criteria: i) respiratory distress ($\geqq$30 breaths/min); ii) oxygen saturation $\leq$93% at rest; i) arterial partial pressure of oxygen (PaO_2)/fraction of inspired oxygen (FiO_2) $\leqq$300 mmHg (l mmHg = 0.133 kPa). The critical cases have the following criteria: i) respiratory failure and requiring mechanical ventilation; ii) shock; and iii) other organ failures that require ICU care.

Statistical analyses

The general information of the patients was presented in mean (SD), median (interquartile range), or no (%). The rates of mortality and disease severity were determined in number (%). The association of receiving a COVID-19 vaccine with patients' outcomes, disease severity, and general characteristics was examined in Pearson chi-squared test. The fit model of associated factors to patients' outcomes was examined in a nominal regression model. The significant level of difference was determined in a p-value of less than 0.05. The statistical calculations were performed in JMP Pro 14.3.

Results

The mean age of the patients who were included in this study was 57.6 between 27 and 98 years of different age groups. The patients were males (43.3%) and females (56.7%). The admitted patients had different educational levels. But most of them were illiterate (69.3%) or had had a lower level of education (under high

school: 12.6%; high school: 7.9%). Most of them were non-smokers (89.8%) and non-alcoholics (97.6%). A small percentage of the patients had previous thrombotic disorders (4.7%). However, close to half of the patients had chronic diseases (44.9%) (Table 1). In terms of disease severity, the study found that the patients had different disease severities, including mild to moderate (44.9%), moderate-severe (36.2%), and critical (18.9%). The median hospitalization day was 9 days. The patients stayed at the hospital for between 1 and 45 days. Only 8.7% (n=11) of the patients received the COVID-19 vaccine; including AstraZeneca (n=2), Pfizer (n=6), and Sino pharma (n=3), and only one of them received two doses of the COVID-19 vaccine (AstraZeneca). The study found that 26.8% of the patients died (between 1 and 31 days). The remaining 73.2% were recovered from the disease (Table 2). The patients with older age were more likely to have more severe disease severity and were more likely to die of the disease (Figure 1). We did not find a significant association between receiving vaccination and patients' outcomes or disease severity. But the mortality rate in patients who received the COVID-19 vaccine was slightly lower compared to those who did not receive the vaccine, 26.72% *vs* 27.27%, p=0.9687. In addition, we did not find a significant association between age groups, education level, smoking, chronic disease, and having previous thrombotic disorders. But no patients with previous thrombotic disorders received the COVID-19 vaccine. The study found that the male patients were more likely to receive the COVID-19 vaccine compared to female patients; 14.55% *vs* 4.17%, p=0.0394 (Table 3). The study showed that among unvaccinated COVID-19 patients, the patients with chronic diseases (40.38% *vs* 15.63%; p=0.0027) and those with critical status (54.55% *vs* 17.31% and 23.81%, p=0.0036) were more likely to die compared to those without chronic disease and with lower severity of the disease. A similar pattern was found among vaccinated COVID-19 patients for the disease severity but not for hospitalization duration and chronic disease (Table 4). The fit model of the associated factors to patients' outcomes showed that the more escalated disease severity, having a chronic disease, and lower education were the predictors of more mortality in the studied sample (Table 5).

Discussion

This study showed that most of the patients who did not receive the COVID-19 vaccine were illiterate or have lower levels of education. In addition, most of them have chronic diseases such as diabetes mellitus, cardiac diseases, etc. The patients had different severities and we found that 26.8% of the patients died. We did not find a significant association between vaccination and disease and mortality rate. But, the patients with the critical situation were more likely to die among vaccinated and unvaccinated COVID-19 patients. In the unvaccinated patients with chronic diseases were more likely to die of the disease. The male patients were more likely to receive the COVID-19 vaccine. Only three persons who received the first dose of the COVID-19 vaccine died of the COVID-19 (two patients with critical and one with moderate-severe severity and two of them with chronic diseases).

Our study cannot give a conclusive decision about the role of the COVID-19 vaccine on hospitalization and mortality rate due to the small sample size. Nevertheless, we could show that most of the patients who were admitted to this region have not received the COVID-19 vaccine. A similar study conducted in Spain aimed to find out the association of BNT162b2 vaccination with SARS-CoV-2 infection and hospital admission and mortality with COVID-19 in

Table 1. General information of admitted patients with COVID-19.

Characteristics (n=127)	Frequency distribution	95% confidence interval	
		Lower CI	Upper CI
Age (range 27-98 years)	57.6 (14.8)	55.0 (13.2)	60.2 (16.9)
20-39	13 (10.2)	6.1	16.7
40-59	55 (43.3)	35.0	52.0
60-79	48 (37.8)	29.8	46.5
80-99	11 (8.7)	4.9	14.8
Gender			
Female	72 (56.7)	48.0	65.0
Male	55 (43.3)	35.0	52.0
Education			
Illiterate	88 (69.3)	60.8	76.6
Under high school	16 (12.6)	7.9	19.5
High school	10 (7.9)	4.3	13.9
Institute	6 (4.7)	2.2	9.9
College graduates	7 (5.5)	2.7	10.9
Smoking			
No	114 (89.8)	83.3	93.9
Yes	13 (10.2)	6.1	16.7
Alcohol consumption			
No	124 (97.6)	93.3	99.2
Yes	3 (2.4)	0.8	6.7
Chronic diseases			
No	70 (55.1)	46.4	63.5
Yes	57 (44.9	36.5	53.6
Thrombotic disorders			
No	121 (95.3)	90.1	97.8
Yes	6 (4.7)	2.2	9.9

nursing home residents, nursing home staff, and healthcare workers. They reported that the mortality rate was significantly higher in unvaccinated confirmed cases with COVID-19 compared to those who received the vaccination. They reported that 450 patients died of the COVID-19; 272 among COVID-19 unvaccinated and 145 in one dose vaccination receivers and 33 in two-dose vaccination receivers. The mortality rate of COVID-19 disease was 4.3/10000 person-days in unvaccinated persons compared to 0.5/10000 in COVID-19 receivers (2.2/10,000 in one dose COVID-19 vaccine receivers and 0.1/10,000 in two dose COVID-19 vaccine receivers). The adjusted hazard ratio for hospital admission and mortality following two doses of the COVID-19 vaccine were 0.05 and 0.03, respectively among nursing home residents [11]. Another study reported that unvaccinated patients account for 84.2% of COVID-19 hospitalizations. The hospitalization for COVID-19 disease was substantially related to decreased rate of COVID-19 vaccination; including 15.8% among cases and 54.8% among controls. They added that the hospitalized COVID-19 patients were less likely to receive the mRNA COVID-19 vaccine. In addition, they are more likely to progress to death or mechanical ventilation [12]. Similar findings were reported in a Scottish report as well. They reported a substantial reduction in the rate of hospitalization four weeks after the first dose. The BNT162b2 and ChAdOx1 vaccines decreased the risk of hospital admission by 85% and 94%, respectively. Two doses of BNT162b2 mRNA vaccine provided 85% protection against symptomatic infection among people aged over 80 [13].

The previous studies have shown that chronic diseases are common among patients with COVID-19. These chronic diseases are related to higher severity, admission to intensive care unit (ICU), and higher mortality. A systematic review and meta-analysis reported that hypertension is associated with higher disease severity, mortality, and admission to ICU. Chronic obstructive pulmonary disease (COPD) was found to be the strongest predictor for the severity of the COVID-19 disease, ICU admission, and mortality. In addition, obesity was found to be a higher risk for experiencing severe symptoms of the disease rather than mortality. Also, the patients with the following chronic diseases had a greater likelihood of mortality; cerebrovascular disease, chronic liver disease, chronic renal disease, or cancer [14]. Similar results were confirmed in other systematic reviews as well [15,16]. The COVID-19 patients with pre-existing medical conditions are predisposed to potentially serious COVID-19 infections by common pathophysiological pathways, with chronic systemic inflammation [17].

The health promotion campaigns for enhancing the rate of COVID-19 vaccination are ongoing around the world. However, we have limited knowledge of the effectiveness of COVID-19 vaccines. The Iraqi Kurdistan authorities have not stated the arranged and planned campaigns to increase the vaccination rate in public. Therefore, this report may help the authorities to give more concise information on patients with COVID-19 who were hospitalized in this region.

The findings reported in this report are consistent with those reported in the literature [3,13,18]. Since the literature approves the association of death and invasive mechanical ventilation with a lower likelihood of vaccination, the findings recommend that the COVID-19 mRNA vaccines mitigate disease severity in patients who develop COVID-19 despite vaccination. Also, the total benefits of vaccination exceed those estimated from hospitalization prevention alone [12].

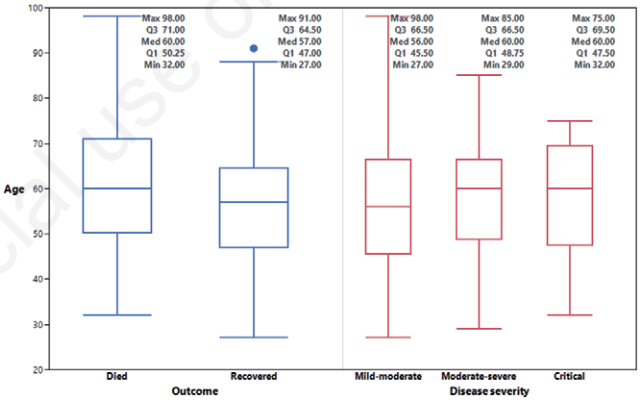

Figure 1. Comparisons of age in patients with different severities and outcomes.

Table 2. Disease severity, vaccination, and outcome of admitted patients with COVID-19.

Characteristics (n=127)	Frequency distribution	95% confidence interval	
		Lower CI	Upper CI
Disease severity			
Mild-moderate	57 (44.9)	36.5	53.6
Moderate-severe	46 (36.2)	28.4	44.9
Critical	24 (18.9)	13.0	26.6
Hospitalization day			
Range: 1-45 days	Median: 9.0	Interquartile range: 12	
Received COVID-19 vaccine			
No	116 (91.3)	85.2	95.1
Yes	11 (8.7)	4.9	14.8
Type of COVID-19 vaccine			
AstraZeneca	2 (18.2)	5.1	47.7
Pfizer	6 (54.5)	28.0	78.7
SinoPharm	3 (27.3)	9.7	56.6
Vaccine dose			
One dose	10 (90.9)	62.3	98.4
Two doses	1 (9.1)	1.6	37.7
Patients' outcome			
Died	34 (26.8)	19.8	35.1
Recovered	93 (73.2)	64.9	80.2

Table 3. Contingency analysis of received vaccination by outcome and disease severity and socio-demographic characteristics. Pearson Chi-squared test was performed for statistical analyses.

Characteristics (n=127)	Received vaccination		p-value (two-sided)
	No	Yes	
Age groups			
20-39	13 (100)	0 (0.00)	
40-59	49 (89.09)	6 (10.91)	0.6610
60-79	44 (91.67)	4 (8.33)	
80-99	10 (90.91)	1 (9.09)	
Education			
Illiterate	82 (93.18)	6 (6.82)	
Under high school	15 (93.75)	1 (6.25)	
High school	7 (70.00)	3 (30.00)	
Institute	6 (100)	0 (0.00)	
College graduates	6 (85.71)	1 (14.29)	0.1307
Gender			
Female	69 (95.83)	3 (4.17)	0.0394*
Male	47 (85.45)	8 (14.55)	
Smoking			
No	104 (91.23)	10 (8.77)	0.8957
Yes	12 (92.31)	1 (7.69)	
Chronic diseases			
No	64 (91.43)	6 (8.57)	0.9681
Yes	52 (91.23)	5 (8.77)	
Thrombotic disorders			
No	110 (90.91)	11 (9.09)	0.4397
Yes	6 (100)	0 (0.00)	
Patients' outcome			
Died	31 (26.72)	3 (27.27)	0.9687
Recovered	85 (73.28)	8 (72.73)	
Disease severity			
Mild-moderate	52 (44.83)	5 (45.45)	
Moderate-severe	42 (36.21)	4 (36.36)	0.9979
Critical	22 (18.97)	2 (18.18)	

Table 4. Analysis of outcomes of vaccinated and unvaccinated COVID-19 patients by chronic disease, disease severity, and hospitalization duration. Pearson Chi-squared test was performed for statistical analyses.

Characteristics (n=127)	Outcome in unvaccinated COVID-19 patients		p-value
	Died	Recovered	
Chronic disease			
No	10 (15.63)	54 (84.38)	0.0027
Yes	21 (40.38)	31 (59.62)	
Disease severity			
Mild-moderate	9 (17.31)	43 (82.69)	
Moderate-severe	10 (23.81)	32 (76.19)	0.0036
Critical	12 (54.55)	10 (45.45)	
Hospital duration			
Week 1	13 (25.00)	39 (75.00)	0.7048
Weeks 2-7	18 (28.13)	46 (71.88)	
Characteristics (n=127)	**Outcome in vaccinated COVID-19 patients**		**p-value**
	Died	**Recovered**	
Chronic disease			
No	2 (33.33)	4 (66.67)	0.6210
Yes	1 (20.00)	4 (80.00)	
Disease severity			
Mild-moderate	0 (0.00)	5 (100.00)	
Moderate-severe	1 (25.00)	3 (75.00)	0.0271
Critical	2 (100)	0 (0.00)	
Hospital duration			
Week 1	2 (40.00)	3 (60.00)	0.3869
Weeks 2-7	1 (16.67)	5 (83.33)	

Table 5. Fit model of associated factors to patients' outcomes. Nominal logistic regression was performed for statistical analyses.

Source	Patients' outcomes: Death	OR (95% CI)	p-value
Disease severity			0.00001
Critical/mild-moderate		21.8 (5.0-94.5)	<0.0001
Critical/moderate-severe		13.4 (3.0-59.1)	0.0006
Chronic disease		9.0 (2.4-34.4)	0.00024
Yes/no			0.0013
Education			
Illiterate/college		0.1 (0.01-1.00)	0.04212
Graduates			0.0487
Smoking			0.08918
Gender			0.26071
Age			0.37020
Alcohol			0.41599
Thrombotic disorders			0.63163
Received vaccination			0.90915

The strong association between vaccination and risk reduction in COVID-19 hospitalization in immunocompetent individuals reported in the literature suggests that the high efficacy reported in mRNA clinical trials translates into beneficial influences in the community settings [19-21].

We found that the male hospitalized patients were more likely to receive the COVID-19 vaccine compared to the female hospitalized patients. Possibly the females have more fear of the COVID-19 vaccine compared to the males as reported in this region [22] despite both genders in this region have fear towards the COVID-19 disease [23].

Limitations of the study

The findings reported in this study must be analyzed with caution since the sample size of this study was not large to make the conclusive decision on the role of receiving COVID-19 vaccine on disease severity and mortality. In addition, we had no information about the time of hospitalization after receiving the vaccination. Also, we do have not any information about the virus variation in this region owing to technical and laboratory challenges. The complications of the COVID-19 disease were not reported in this study as well. We could not include the retrospective cases in this study, as the medical records of the patients had not sufficient and useful information about vaccination and hospitalization. In addition, too much information about the hospitalized patients was missing in the medical records of the patients.

Recommendations

We suggest that the health authorities establish the appropriate health promotion campaigns to increase the rate of COVID-19 vaccination among the public in this region. The previous studies conducted in this region about the COVID-19 vaccine have shown that the public is hesitant to receive the vaccine [8] and has a fear of the COVID-19 vaccine [22].

Conclusions

This study showed that among hospitalized patients, the majority are unvaccinated and many of them have a low socioeconomic status and comorbidities. A high percentage of the COVID-19 hospitalized patients died of the disease.

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