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Risk factors associated with mortality among vaccinated COVID-19 patients: A retrospective study

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ABSTRACT

Objective: To explore the underlying causes of death among vaccinated COVID-19 patients.

Methods: The medical record of COVID-19 patients admitted to the main COVID-19 referral center in southeast Iran from January to March 2022 was investigated. Then, risk factors for mortality were statistically assessed.

Results: 92 patients were included, with 50 in infectious disease ward and 42 in ICU ward. In total, 37% of patients succumbed to COVID-19. The median age of those who died was 69.9 years. Dementia and genitourinary system-related diseases was associated with an increased risk of death [6.00 (95% CI: 1.14-31.66) and 4.93 (95% CI: 1.80-13.52)]. Furthermore, the elevated levels of white blood cells, neutrophils, lactate dehydrogenase, blood urea nitrogen, and creatinine were associated with an increased risk of death by 4.93 (95% CI: 1.82-13.36), 16.57 (95% CI: 2.10-131.31), 3.23 (95% CI: 1.15-9.03), 4.48 (95% CI: 1.78-11.31), and 4.27 (95% CI: 1.49-12.22), respectively.

Conclusions: Despite receiving the SARS-CoV-2 vaccine, individuals who suffer from dementia and genitourinary system-related diseases are at risk of death with new strains of SARS-CoV-2 infection. Furthermore, the increase of white blood cell, neutrophils, lactate dehydrogenase, blood urea nitrogen,

and creatinine in patients' blood can be considered as warning indicators of disease progression and death.

KEYWORDS: COVID-19; Mortality; Risk factors; Comorbidities; Laboratory parameters

Significance

This retrospective study identified the most important risk factors of mortality among patients with COVID-19. Although most patients had been vaccinated against SARS-CoV-2, elderly individuals and patients with specific underlying diseases, particularly those with dementia and genitourinary system disorders were at increased risks of death from infection with new strains of SARS-CoV-2.

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1. Introduction

During recent two decades, the coronaviruses mutated and emerged as serious respiratory pathogens for human beings[1]. In 2019, SARS-CoV-2 speedily spread worldwide and became a serious threat to public health[2]. Although SARS-CoV-2 causes mild to moderate self-limiting respiratory disease, severe manifestations including pneumonia, severe acute respiratory syndrome, and even death were observed in some others[3]. As of 19 November 2023, the WHO data recorded a total of 772 million confirmed cases of COVID-19 and over six million deaths[4]. Much research has been done to determine the risk factors that increase the death rate in COVID-19 patients[5-7]. Some studies reported an increase in COVID-19-related deaths in elderly people and males[8,9]. Furthermore, pre-existing comorbidities, including cardiovascular disease, hypertension, diabetes, respiratory disease, and cancers, were considered risk factors related to COVID-19 mortality in some research[10,11]. After the pandemic, despite vaccination against SARS-CoV-2, some patients developed severe symptoms and succumbed to COVID-19[12,13]. Fortunately, the outbreak of SARS-CoV-2 has dramatically reduced in most countries. However, the emergence of new species belonging to this family is not far-fetched. To manage this challenge in the future, this study evaluated the probable risk factors that affect the fatality rate in COVID-19 patients despite they were vaccinated against SARS-CoV-2.

2. Patients and methods

2.1. Study setting

This retrospective study was performed on COVID-19 patients hospitalized at the main COVID-19 referral centers in southeast Iran from January to March 2022, the period after the first pandemic peak, when nearly all people got vaccinated against SARS-CoV-2 in Iran. All patients included in this study were vaccinated at least two shots against COVID-19. The COVID-19 infection of subjects was confirmed with real-time polymerase-chain reaction. The study flowchart was presented in Figure 1.

2.2. Ethical consideration

The ethical committee of Kerman University of Medical Sciences with code of IR.KMU.AH.REC.1401.128 (Grant No. 401000292). approved this research. Each study participant signed written informed consent. All methods were performed in accordance with the guidelines and regulations of the ethics committee.

2.3. Data collecting

To estimate the most effective risk factors in the rate of COVID-19 patients' deaths, common demographic and clinical information was collected from the Corona Information Registration System. The outcome of the disease, the patients' death, and the patients' recovery have been also recorded in the system. Regarding clinical The outcome of the disease, the patient's death, and the patient's symptoms and comorbidities, the features were classified according to the International Classification of Diseases 11th[14]. Disease severity was classified according to the hospitalization ward of patients in the infectious and ICU ward. Severe cases with oxygen saturation lower than 94.0 were hospitalized in the ICU ward, whereas patients with moderate symptoms and evidence of lower respiratory disease on the imaging systems were admitted to the infectious ward. In the following, the impact of different features on the mortality rate of COVID-19 patients was explored in two groups of cases based on the outcome of the disease.

2.4. Statistical analysis

Data extracted from patients' medical records was analyzed using the Statistical Package of Social Sciences version 22 (IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.). Categorical variables were represented as frequencies (percentages and 95% *CI*), whereas mean±standard deviation was calculated for continuous variables. To examine the features which contribute to the death occurring in the hospital, logistic regression analysis was utilized. For logistic regression, entry was set at 0.05 and removal at 0.005 using backward wald. Odds ratios and adjusted *OR* with a 95% confidence interval (*CI*) were also estimated. Checking for collinearity was carried out using tolerance and variance inflation factors. *P* value of <0.05 was considered statistically significant. The reference range for laboratory tests was based on the protocol kits used in COVID-19 referral centers in southeast Iran.

3. Results

3.1. Demographics and clinical characteristics of patients

In the present study, the information of ninety-two COVID-19 patients was comprehensively surveyed. In total, fifty-five (59.7%) males with an average age of 65.1 years and forty-eight (45.0%) females with an average age of 63.2 years participated in this study. Regarding the hospitalization ward, 45.0% and 55.0% of subjects were hospitalized in the ICU and infectious ward respectively (Figure 1). As Table 1 shows the most frequently reported symptoms among COVID-19 patients were disorders in the respiratory system

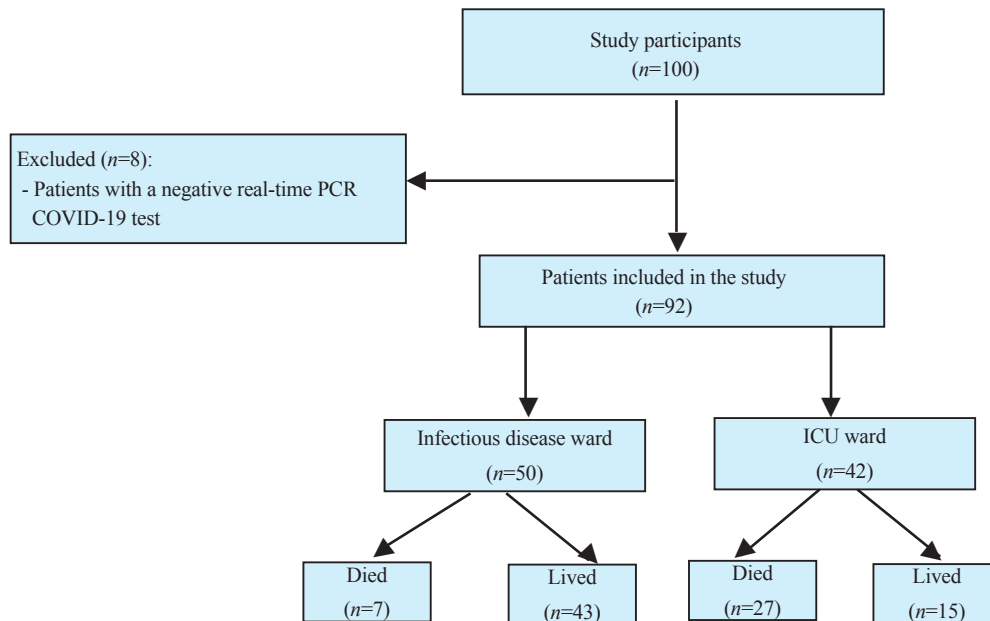


Figure 1. The study flowchart. PCR: polymerase chain reaction.

Table 1. Demographics and clinical characteristics of the patients. *

Variables	Non-survivor group (n=34)	Survivor group (n=58)	P
Sex, n, %			
Male	21 (61.8)	33 (56.9)	0.647
Female	13 (38.2)	25 (43.1)	
Age, median, Q1, Q3	69 (49, 79)	61 (41, 81)	0.028
Ward unit			
Infectious disease wards	7 (20.6)	43 (74.1)	0.000
ICU wards	27 (79.4)	15 (25.9)	
Clinical systems by systems, n, % †			
Respiratory system disorder	28 (82.3)	48 (82.7)	0.960
General symptoms	24 (70.5)	49 (84.4)	0.112
Musculoskeletal system diseases	19 (55.8)	34 (58.6)	0.798
Digestive system or abdomen disorder	16 (47.0)	20 (34.4)	0.233
Mental or behavioral problems	11 (32.0)	7 (12.0)	0.018
Nervous system disorder	4 (11.7)	12 (20.6)	0.276
Genitourinary system disorder	5 (14.7)	5 (8.6)	0.365
Skin disorder	2 (5.8)	7 (12.0)	0.335
Circulatory system disorder	3 (8.8)	2 (3.4)	0.272
Speech or voice disorder	0 (0.0)	1 (1.7)	0.441
Visual system disorder	1 (2.9)	0 (0.0)	0.189
Ear or mastoid process disorder	1 (2.9)	0 (0.0)	0.189
Laboratory parameters			
WBC, 10 ³ /mm ³	12.51	9.12	0.022
RBC, 10 ⁶ /mm ³	3.78	4.30	0.039
Neutrophil, %	67.10	75.64	0.000
Lymphocyte, %	8.28	15.46	0.000
Platelet, 10 ³ /mL	164.14	218.98	0.023

Table 1. Continued.

Variables	Non-survivor group (n=34)	Survivor group (n=58)	P
ALT, IU/mL	37.00	33.51	0.155
AST, IU/mL	59.88	33.22	0.014
LDH, IU/mL	797.51	465.34	0.000
Bilirubin total, mg/dL	2.71	1.10	0.026
Plasma glucose, mg/dL	164.12	156.29	0.582
CRP, mg/L	82.83	44.86	0.059
ESR, %	57.31	47.21	0.340
BUN, mg/dL	85.59	46.21	0.000
Creatinine, mg/dL	1.62	1.22	0.065
Comorbidities by systems, n, % †			
Circulatory system diseases	19 (55.9)	28 (48.3)	0.481
Metabolic disorders	13 (38.2)	33 (56.9)	0.084
Respiratory system diseases	16 (47.1)	22 (37.9)	0.391
Genitourinary system diseases	15 (44.1)	8 (13.8)	0.001
Nervous system disorders	5 (14.7)	8 (13.8)	0.903
Digestive system diseases	8 (23.5)	5 (8.6)	0.048
Cancer	7 (20.6)	5 (8.6)	0.100
Infectious disease	4 (11.8)	4 (6.9)	0.424
Mental disorders	6 (17.6)	2 (3.4)	0.020
Immune system disorders	1 (2.9)	3 (5.2)	0.612
Blood disorders	1 (2.9)	2 (3.4)	0.895
Skin disorders	0 (0.0)	3 (5.2)	0.178
Musculoskeletal system diseases	0 (0.0)	1 (1.7)	0.441

* Data are expressed as frequency (%) or mean±SD, and percentage may be greater than 100% due to rounding.

† According to the International Classification of Disease 11th.

WBC: white blood cell; RBC: red blood cell; ALT: alanine aminotransferase; AST: aspartate aminotransferase; LDH: lactate dehydrogenase; CRP: C reactive protein; ESR: erythrocyte sedimentation rate; BUN: blood urea nitrogen.

(82.6%) followed by general symptoms (79.3%), musculoskeletal system diseases (57.6%), and digestive diseases (39.1%). The most common Comorbidities among included patients were circulatory system diseases (51.1%), metabolic disorders (50%), respiratory system diseases (41.3%), and genitourinary system disorders (25%). In total, 34% of patients in this study were dead due to COVID-19. Further clinical details including the average of laboratory tests are illustrated in Table 1.

3.2. Clinical symptoms and hospitalization ward

The only clinical manifestations, that affected the death, were mental symptoms particularly loss of consciousness. The frequency of these signs in patients who died was more than those who recovered (Table 1). Moreover, the risk of death among cases with mental symptoms was estimated at 3.4 times more than those who did not show these signs (Table 3). Regarding the Hospitalization

ward, 79.4% of patients who needed intensive care succumbed to COVID-19 (Table 1). The logistic regression analysis showed the mortality rate of these patients was 11 times more than those who were hospitalized in the infectious ward.

3.3. Comorbidities, age and sex

The most prevalent diseases among dead patients were genitourinary, digestive, and mental disorders (Table 1). The association of comorbidities with mortality is presented in Table 3. Digestive and genitourinary system-related diseases were associated with 3.2 and 4.9-fold increase in the risk of mortality. Furthermore, mental disorders including dementia and anxiety showed the highest risk of death with 6 times more than those without these disorders. The average age of those who passed away was 69.9 years compared with 61.0 years for survivors. However, age and sex had no significant effect on the increase of death rate (Tables 1 and 3).

Table 2. Laboratory parameters among COVID-19 patients survivors and non-survivors groups (n, %).

Laboratory parameters	Reference	Non-survivor group (n=34)	Survivor group (n=58)	P
WBC				
<4.5	4.5-11.0×10 ³ /mm ³	6 (17.6)	8 (13.8)	0.005
4.5-11		9 (26.5)	35 (60.3)	
>11.0		19 (55.9)	15 (25.9)	
RBC				
<4.2	4.2-5.4×10 ⁶ /mm ³	22 (64.7)	31 (53.4)	0.179
4.2-5.4		12/34 (35.3)	22 (37.9)	
>5.4		0 (0.0)	5 (8.6)	
Neutrophil				
<45	45-75%	0 (0.0)	2 (3.5)	0.002
45-75		1 (3.3)	20 (35.1)	
>75		29 (96.7)	35 (61.4)	
Lymphocyte				
<16	16-46%	31 (91.2)	33 (57.9)	0.001
16-46		3 (8.8)	24 (42.1)	
Platelet				
<130	130-400×10 ³ /mL	16 (47.1)	13 (22.4)	0.023
130-400		18 (52.9)	41 (70.7)	
>400		0 (0.0)	4 (6.9)	
ALT				
Normal	M<4, F<31 IU/mL	23 (67.6)	46 (79.3)	0.212
High		11 (32.4)	12 (20.7)	
AST				
Normal	M<37, F<31 IU/mL	20 (58.8)	43 (74.1)	0.127
High		14 (41.2)	15 (25.9)	
LDH				
Normal	F<580, M<746 IU/mL	17 (58.6)	41 (82.0)	0.023
High		12 (41.4)	9 (18.0)	
Bilirubin total				
0.1-1.2	0.1-1.2 mg/dL	21 (63.6)	39 (70.9)	0.478
>1.2		12 (36.4)	16 (29.1)	
Plasma glucose				
<140	<140 mg/dL	21 (61.8)	34 (58.6)	0.512
140-199		3 (8.8)	10 (17.2)	
≥200		10 (29.4)	14 (24.1)	
CRP				
≤6	≤6 mg/L	5 (16.7)	11 (20.4)	0.679
>6		25 (83.3)	43 (79.6)	
ESR				
Normal	M≤12, F≤22	7 (24.1)	16 (28.6)	0.663
High		22 (75.9)	40 (71.4)	
BUN				
<15	15-45 mg/dL	1 (2.9)	2 (3.4)	0.005
15-45		10 (29.4)	37 (63.8)	
>45		23 (67.6)	19 (32.8)	
Creatinine				
<0.6	0.6-1.4 mg/dL	5 (14.7)	8 (13.8)	0.020
0.6-1.4		16 (47.1)	42 (72.4)	
>1.4		13 (38.2)	8 (13.8)	

Data are expressed as frequency (%).

Table 3. Logistic regression analysis of risks of mortality of patients with SARS-CoV-2 infection.

Variables	OR (95% CI)	P
Demographic features		
Sex (male vs. female)	1.03 (1.003-1.056)	0.028
Age (<60 vs. ≥60)	0.842 (0.395-1.996)	0.696
Hospitalization ward (ICU vs. infectious disease ward)	11.057 (3.995-30.605)	0.000
Clinical symptoms by systems (yes vs. no)		
Speech or voice disorder	-	-
Mental or behavioral problems	3.484 (1.198-10.137)	0.022
Nervous system disorder	0.511 (0.151-1.734)	0.282
Visual system disorder	-	-
Ear or mastoid process disorder	-	-
Circulatory system disorder	2.710 (0.429-17.099)	0.289
Respiratory system disorder	0.972 (0.319-2.963)	0.960
Digestive system or abdomen disorder	1.689 (0.712-4.008)	0.235
Skin disorder	0.455 (0.089-2.330)	0.345
Musculoskeletal system diseases	0.894 (0.380-2.103)	0.798
Genitourinary system disorder	1.828 (0.488-6.839)	0.370
General symptoms	0.441 (0.158-1.228)	0.117
Comorbidities by systems (yes vs. no)		
Infectious disease	1.800 (0.420-7.720)	0.429
Cancer	2.748 (0.797-9.474)	0.109
Blood disorders	0.848 (0.074-9.722)	0.895
Immune system disorders	0.556 (0.055-5.563)	0.617
Metabolic disorders	0.469 (0.197-1.114)	0.086
Mental disorders	6.000 (1.137-31.662)	0.035
Nervous system disorders	1.078 (0.322-3.604)	0.903
Circulatory system diseases	1.357 (0.580-3.177)	0.482
Respiratory system diseases	1.455 (0.617-3.428)	0.392
Digestive system diseases	3.262 (0.971-10.958)	0.056
Genitourinary system diseases	4.934 (1.801-13.515)	0.002

Table 4. Logistic regression analysis of risks of mortality of patients with SARS-CoV-2 infection based on laboratory parameters.

Laboratory parameters	OR (95% CI)	P
WBC, $10^3/\text{mm}^3$		
<4.5	2.917 (0.805-10.567)	0.103
4.5-11	Ref	
>11.0	4.926 (1.817-13.356)	0.002
Neutrophil, %		
45-75	Ref	
>75	16.571 (2.096-131.306)	0.008
Lymphocyte, %		
<16	7.515 (2.055-27.479)	0.002
16-46	Ref	
Platelet, $10^3/\text{mL}$		
<130	2.803 (1.119-7.020)	0.028
130-400	Ref	
LDH, IU/mL		
Normal	Ref	
High	3.216 (1.145-9.032)	0.027
BUN, mg/dL		
<15	1.850 (0.152-22.538)	0.630
15-45	Ref	
>45	4.479 (1.775-11.305)	0.002
Creatinine, mg/dL		
<0.6	1.641 (0.467-5.767)	0.440
0.6-1.4	Ref	
>1.4	4.266 (1.489-12.217)	0.007

3.4. Laboratory data

The analysis of laboratory factors exhibits elevated levels of white blood cells (WBC) ($>11.0 \times 10^3/\text{mm}^3$), neutrophils ($>75\%$), lactate dehydrogenase ($>746 \text{ IU/mL}$), blood urea nitrogen (BUN) ($>45 \text{ mg/dL}$), and creatinine ($>1.4 \text{ mg/dL}$) in patients' blood increase the risk of death by 4.9, 16.6, 3.2, 4.5 and 4.3, respectively. In contrast, the decline of lymphocytes ($<16\%$) and platelets ($<130 \times 10^3/\text{mm}^3$) can raise the rate of mortality by 7.5 and 2.8. (Table 2 and 4).

4. Discussion

The major predictors of death among COVID-19 patients hospitalized in the southeast of Iran from January to March 2022 were discussed in this study. In total, 34% of patients died due to COVID-19 and this finding was notable. The possible cause of the high percentage of death among patients might be due to their older age as the mean age of passed-away patients was 69.9 years. Moreover, the majority of patients suffered from one or two comorbidities. In the current survey, the most prevalent underlying diseases in COVID-19 cases were circulatory system diseases, metabolic disorders, respiratory system, and genitourinary system diseases, respectively. However, the risk of death significantly rose among patients with dementia, digestive disorders including hepatic cirrhosis, and gastrointestinal bleeding, and those with genitourinary system-related diseases. Consistent with our finding, other research also showed that the cooccurrence of SARS-CoV-2 infection with dementia, chronic kidney diseases, and digestive illnesses associated with the poor prognosis of COVID-19[15-22]. It seems the presence of the main cellular receptor of SARS-CoV-2, angiotensin-converting enzyme 2, on the central nervous system, kidney, gastrointestinal tract, and liver, makes them a potential target for SARS-CoV-2[23,24]. Consequently, SARS-CoV-2 attacks those organs and directly causes severe manifestations in vulnerable patients. Furthermore, cytokine storm as an aggressive condition in COVID-19 infection[24,25] can exacerbate systemic inflammation reactions in individuals affected by dementia, digestive and kidney diseases.

Among laboratory parameters, WBC count, neutrophil count, lymphocyte, and platelet count were remarkably associated with mortality. As results show, the high number of WBC ($>11.0 \times 10^3/\text{mm}^3$) and neutrophils ($>75\%$), increase the rate of mortality to 4.9 and 16 times in COVID-19 patients. The abnormality in these hematologic parameters reflects the hyperinflammatory and cytokine storm state in patients[25,26] which can predict mortality. In contrast, the severe decline of lymphocyte and platelets to lower 16% and $130 \times 10^3/\text{mm}^3$ showed 7.5 and 2.8-fold increase in mortality rate. Thrombocytopenia and particularly lymphopenia are observed in patients with severe COVID-19[27,28]. It seems SARS-CoV-2 can indirectly suppress lymphocyte and platelet proliferation through inflammatory cytokines[27,29]. Besides hematological factors, a high concentration of lactate dehydrogenase, BUN, and creatinine was observed among patients who succumbed to SARS-CoV-2. The mechanism involved in the increase of BUN and creatinine levels might be due to the potential attack of SARS-CoV-2 on renal epithelial cells. In the case of individuals with

preexisting renal impairment, COVID-19 infection is more likely to worsen their condition.

To conclude, our results highlight the importance of special protective measures and treatment options for elderly individuals with comorbidities particularly those with dementia, renal and digestive diseases. Remarkably, the baseline renal parameters and hematological markers can serve as warning signs for mortality in COVID-19 patients. Thus, it is critically important to monitor these parameters in patients who would be infected with new strains of SARS-CoV-2.

Conflict of interest statement

The authors report no conflict of interest.

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There was no extramural funding received for conducting this study.

Data availability statement

The data supporting the findings of this study are available from the corresponding authors upon request.

Authors' contributions

LH, AN, FM and ME performed experiments, collected the data, and wrote the manuscript; ME is the supervisor; LH, R-NH, HE, ES and ME analyzed the data, evaluated and interpreted the results; All authors approved the current version of the manuscript.

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