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RELATIONSHIP BETWEEN VACCINATION STATUS, CLINICAL MANIFESTATIONS AND OUTCOME IN CRITICAL COVID-19 PATIENTS: A RETROSPECTIVE STUDY

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ABSTRACT: ***Background:*** *The resurgence of COVID-19 cases has led to the administration of repeated vaccine doses. Our study aims to investigate the association between the vaccination status and clinical presentation, amount of oxygen support needed and outcome among patients admitted in ICU for critical SARS-CoV-2 infection.* ***Methods:*** *A retrospective study was conducted from 01 January 2021 to 30 August 2022. Patients admitted for severe/critical SARS-CoV-2 infection were divided into four groups according to their vaccination status: unvaccinated, receiving one dose, two doses and three doses or more. Data were compared according to the vaccination status.* ***Results:*** *Two hundred and thirty-seven (237) patients were included. Age > 60 years and most co-morbidities were more reported among vaccinated patients with 3 doses or more. Arterial oxygen partial pressure/fractional inspired oxygen ratio was correlated to the dose received ($p<10^{-3}$). Severe ARDS ($p<10^{-3}$), mechanical ventilation ($p=0.003$) and mortality ($p=0.04$) were lower among patients receiving 3 doses or more.* ***Conclusion:*** *Vaccination with 3 doses or more was associated with less severe symptoms, biological disorders, CT scan lesions extent, critical forms and need for mechanical ventilation.*

KEYWORDS: SARS-CoV-2-Vaccination Status; Critical care; Respiratory failure; Ventilation; Outcome.

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INTRODUCTION

Several waves of COVID-19 have occurred, since 2019 in Wuhan, China causing damage worldwide and the World Health Organization (WHO) characterised the coronavirus disease (COVID-19) as a pandemic on March 2020 (Adil et al., 2021). Since June 2021, the world has recognised a new wave, the fourth, causing severe acute respiratory syndrome (Adil et al., 2021).

The causal agent, severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), has several known variants and the most concerning are known as variants of concern (VOC). Among them, the Delta B.1.167 (VOC), because of its high transmission, is the most incriminated in these fatal cases (Aleem et al., 2023). It has eight mutations in its protein spike (Aleem et al., 2023).

In Tunisia, as worldwide, first cases were mainly imported. Consequently, many political decisions were made to minimise the spread of SARS-CoV-2: global lockdown, early detection of imported cases, quarantining of confirmed or even suspected cases, borders closure. Firstly, the spread of the virus was slowed down by these drastic decisions reaching zero between June 4 and 12, 2020 (WHO, 2023). Later, three waves have occurred to achieve the fourth one, reaching a peak of 10,334 cases in July 2021 and 873 admissions to ICU for critical forms (Dhaouadi et al., 2022).

LITERATURE/THEORETICAL UNDERPINNING

In order to circumvent this wave, vaccination has taken a primordial place. Starting in March 2021, it initially concerned healthcare workers and later spread to the entire population. The major target of serum neutralizing activity in vaccinated hosts is the Receptor Binding Protein (RBP) (Aslam et al., 2022). Immune selection pressure in infected patients is associated with antigenic drift (Alsam et al., 2022). As a result, various mutations can occur especially in RBP of Spike Proteins (Aslam et al., 2022). This may cause exposure to the emergence of new variants and ultimately to vaccination failure, especially as severe forms that required ICU admission were observed even in vaccinated patients (Aslam et al., 2022). Thus, the durability of vaccination against SARS-CoV-2 was massively raised (Aslam et al., 2022). Hence, it is undoubtedly useful to study the relationship between the vaccination status and the clinical presentation as well as outcome of ICU patients admitted in ICU for critical SARS-CoV-2 infection. This is the aim of this work.

METHODOLOGY

Study Design

It was a retrospective, observational study conducted from 01January 2021 to 30 August 2022 carried out in the medical ICU of the University Hospital Center of la Rabta. During this period, our unit was dedicated exclusively to COVID-19 outbreak. The local ethics committee approved the study and because of its retrospective and descriptive nature, the consent was waived.

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Patients

We included all adult patients (>18 years) admitted for critical SARS-CoV-2 pneumonia, confirmed with positive nasopharyngeal/tracheal aspirate real-time polymerase chain reaction (PCR) or typical ground glass lesions on chest computed tomography (CT). Patients admitted before the beginning of the national vaccination company and those with unknown delay between symptoms and last vaccination dose were excluded. Three hundred and ninety-six (396) patients were admitted for critical SARS-CoV-2 pneumonia and 237 patients were included and divided into four groups according to their vaccination status: no vaccination received, receiving one dose, two doses, three doses or more.

Assessed Data

For each patient, the following data were recorded: demographics, co-morbidities, immune status, clinical features, laboratory findings (mainly inflammation markers and lymphocytes level), Computed Tomography (CT) lesions extension (minor/moderate versus severe/critical), acute respiratory distress syndrome (ARDS) severity, ventilatory support needed: Non Invasive Ventilation (NIV), high flow nasal cannula (HFNC) and mechanical ventilation (MV) in addition to outcome. All these parameters were analysed and compared according to the above-defined vaccination schedule. Data were entered into the computerized database for further analysis.

Definitions

Severe illness was defined by the presence of dyspnea, respiratory rate >30/min, and/or oxygen saturation <93% while breathing ambient air. Critical COVID-19 disease included any of the following parameters: presence of shock, sepsis or severe organ failure requiring ICU admission, respiratory failure requiring ventilatory support (non invasive ventilation, invasive ventilation).

Depending on vaccination status, participants were divided into four groups: unvaccinated, vaccinated with one dose, vaccinated with two doses and with three doses or more. At least ten days between the last vaccine dose and the diagnosis of SARS-CoV-2 infection was required to define a vaccinated patient (Bar-On et al., 2021).

During the study period, a variety of vaccine types were available: Sino Pharm vaccine and Sinovac CoronaVac were both categorized as inactivated virus vaccines, Moderna and Pfizer BioNTech as mRNA vaccines, and AstraZeneca and Sputnik as adenovirus vector based types. It is mentioned that we only had the number of doses received.

Immunocompromised patients were those receiving immunosuppressive drugs or suffering from active malignancy.

Management

Oxygen therapy modalities for COVID-19 patients included nasal cannula, facial mask or reservoir mask to ensure an oxygen saturation>94%. For patients with a severe form, ventilatory support was needed (invasive or non invasive). Standard care was associated to prone position, steroids (Dexamethasone 8 mg daily up to 10 days), anticoagulation and vitamin therapy. Regarding anticoagulation, we used unfractionated heparin or low molecular

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weight heparin. It depended on curative or prophylactic indication, creatinine clearance and the body mass index (BMI) of the patient.

Statistical Analyses

Data were analyzed with IBM SPSS statistics ver. 20. The significance threshold was set at 0.05. Continuous variables were expressed as mean and standard deviation or median [interquartile range: IQR 25^{th}–75^{th} percentile] depending on the variables distribution (Gaussian or non Gaussian respectively). Categorical variables were expressed as counts and percentages. Parametric or non parametric Chi-Square and ANOVA tests were used, as appropriate for comparisons between the study groups (not-vaccinated, receiving one dose, receiving 2 doses, receiving 3 doses or more). Pearson test was used to correlate the number of doses received and other quantitative variables. The logistic regression model was used to predict the independent factors associated with death.

RESULTS/FINDINGS

Flow Chart

Three hundred and ninety-six (396) patients were admitted for severe/critical SARS-CoV-2 pneumonia and 237 patients were included and allocated into the four study groups as shown in (Fig 1).

Clinical Characteristics

Male gender was predominant (sex ratio: 1.5) and the mean age was 62 years ± 15. The most prevalent co-morbidities were hypertension (42.4%) and diabetes mellitus (40%). Mostly, patients were obese (32.5%) and six (1.5%) were immunocompromised.

Between groups: Patients vaccinated with 3 doses or more were older. Hypertension (p=0.001), chronic heart failure (p=0.034), chronic respiratory failure (p=0.011) and chronic kidney disease (p=0.013) were significantly more reported among vaccinated patients with 3 or more doses (Table 1).

As for severity scores, the lowest were found among patients who received more than three doses but without reaching statistical significance (Table 1).

Dyspnea was observed in 73% of cases (N=173) without statistical difference between groups (p=0.54). Fever was more present among non vaccinated patients ($p<10^{-3}$) (Table 1).

The respiratory rate was significantly higher among unvaccinated patients and the lowest value was showed among those vaccinated with 3 doses or more (p=0.004) (Table 1).

Laboratory and CT Scan Findings

Lymphopenia was more pronounced among unvaccinated patients (p=0.003). CRP level and white blood cells count was similar between the different groups (Table 2).

Arterial oxygen partial pressure (PaO_2)/Fractional inspired oxygen (FiO_2) ratio was significantly correlated to the dose received ($p<10^{-3}$) (Fig 2).

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A CT scan was performed for 55 patients (23%). For patients receiving more than 3 doses, no one had severe (extent between 50% and 75%) to critical (extent >75%) CT scan lesions related to SARS-CoV-2, whereas, these lesions were found among unvaccinated patients (Fig 3).

Outcome

Disease outcomes are presented in Table 3. Unvaccinated patients exhibited more critical ARDS ($p<10^{-3}$). In addition, the maximal oxygen support needed was higher among unvaccinated patients. This concerned the HFNC ($p<10^{-3}$), NIV ($p<10^{-3}$) and mechanical ventilation. Among 126 unvaccinated patients, 57% required intubation whereas 36%, 28.5% and 13% required mechanical ventilation respectively among those receiving 1 dose, 2 doses and 3 doses or more (p=0.003) (Table 3).

Furthermore, all-cause mortality was significantly different between the groups, higher among unvaccinated patients (57%). In contrast, it concerned 42% of patients receiving one dose, 42% of patients receiving 2 doses and only 26% of patients receiving 3 doses or more (p=0.04) (Table 3).

In a further analysis of independent risk factors associated with death, variables found to be associated with high mortality in the multivariate analysis were aged >60 years (OR=4,1; 95% CI,1,7-9,6; p=0.001) and Severe ARDS (OR=14,7; 95% CI,4,9-44,6; p=0.001) .

DISCUSSION

Herein, we assessed clinical features, laboratory findings, CT scan lesions extension, ARDS severity, ventilatory support and outcome according to vaccination status among ICU patients admitted for critical SARS-CoV2 infection. Between groups, co-morbidities and older age were significantly more reported among vaccinated patients with 3 doses or more. Lymphopenia was deeper among unvaccinated patients and PaO_2/FiO_2 ratio was significantly correlated to the dose received. Severe to critical CT scan lesions, Severe ARDS, mechanical ventilation and all cause mortality were lower among vaccinated patients with 3 doses or more.

COVID-19 pandemic had affected the entire world with individual and social consequences. Furthermore, physical and psychological burnout among healthcare workers made the situation more dramatic reaching the edge of hypothetical insufficiency of the healthcare system. Governments had taken drastic measures to face this pandemic. But, finally, the generalization and legislation of vaccination, according to a vaccination, schedule was the best guarantee of effective and protective immunity.

In our population of study, vaccinated patients were older with more co-morbidities. This finding was in accordance with studies from previous COVID-19 waves. In fact, studies comparing vaccinated versus non-vaccinated patients showed younger age with less co morbidities among non-vaccinated patients (Cummings et al., 2020). In another study comparing pulmonary involvement on high-resolution computed tomography between vaccinated and non-vaccinated COVID-19 patients, non-vaccinated patients were younger with a mean age of 42.4±15.4 years (Verma et al., 2022). In Pakistan, 884 patients were

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included in a study comparing vaccinated to non-vaccinated patients in the fourth wave. Age was nearly similar between the two groups but co-morbidities including diabetes mellitus (41% vs. 39%), ischemic heart disease (9 vs. 4%), bronchial asthma (4% vs. 3%), and malignancy (6% vs. 1%) were more frequent among vaccinated patients (Khan et al., 2022). In a Mexican study comparing unvaccinated to partially and fully vaccinated patients, The presence of at least 3 co-morbidities was more observed among vaccinated patients with $p<0.001$ (Freund et al., 2022).

Co-morbidities in our study seemed to be higher among the patients who were vaccinated with 3 doses or more. This could be the consequence of a massive awareness and a defensive attitude of this particularly vulnerable population towards the virus by vaccination at a first time and consolidation at a second time in order to ensure a long-lasting immunity.

We found that clinical features, biological findings, radiological involvement and outcomes related to SARS-CoV-2 vary according to vaccination status.

In order to compare partially completely vaccinated and non-vaccinated patients in an ICU department in Mexico, demographic and clinical characteristics were collected in addition to viral variants from 1,014 individuals with a documented SARS-COV-2 infection. Full vaccination status was found to be the most protective factor against in-hospital death (Hernández-Terán et al., 2022). In this study, fever was more present among unvaccinated patients compared to fully vaccinated patients (71,5% vs. 54% $p<0.001$) which joins our findings. As for general signs including cough, diarrhea, myalgia and arthralgia, no statistical difference was found between the different groups (Hernández-Terán et al., 2022).

In a recent study comparing characteristics and outcomes of COVID-19 severe patients according to the vaccine status, vaccinated patients were less likely to develop critical disease, used lower level of oxygen support and had a lower rate of mortality (Freund et al., 2022).This was more reported among fully vaccinated patients (Hernández-Terán et al., 2022) .

In a retrospective multicenter cohort study including centres that were registered in an open data repository for COVID-19 between June and August 2021, patients were divided into three groups according to their vaccination status. Then, differences between clinical and imaging features were analyzed. Full vaccination status was associated with a lower risk of supplemental oxygen (OR=0.24, 95% CI [0.09–0.64], p=0.005]) and ICU admission (OR=0.08, 95% CI [0.09,0.78], p =0.02) compared to partially vaccinated and non-vaccinated patients (Lee et al., 2022). This joins our findings.

In a prospective multicenter cohort study including 1,199 patients with documented COVID-19 infection in US, recent vaccination with 2 or 3 mRNA vaccine doses before infection with delta or omicron variants was associated with attenuated symptoms, duration of illness and viral load (Heroes et al., 2022).Furthermore, across 13 US jurisdictions, incidence rate ratios for hospitalizations and death among these patients changed relatively little after the SARS-CoV-2 delta variant reached predominance suggesting high continued vaccine effectiveness against severe COVID-19 (HEROES-RECOVER Network et al., 2022).

In a case control study conducted in 21 hospitals across US including 5,728 patients with documented SARS-CoV-2 infection, the effectiveness of mRNA vaccine to prevent COVID-

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19 hospital admissions and severe forms was 85% for 2 vaccine doses against the delta variant and reached 94% when receiving 3 doses (Lauring et al., 2022).

In another study conducted in Italy, vaccination seemed not to be a protective factor since many people developed a symptomatic infection with need of hospitalization in ICU especially with the variant delta despite receiving the whole vaccination dose (Loconsole et al., 2021).

Furthermore, vaccine effectiveness after 6 months of receiving 2 doses was analyzed. This latter waned from 89% (82 to 93%; $p<0.001$) at 15–30 days to 64% (44 to 77%; $p<0.001$) from day 121 onwards (Loconsole et al., 2021).

We suggest that repeated vaccination doses can guarantee the protective effect of vaccine against severe forms over time.

IMPLICATION TO RESEARCH AND PRACTICE

The results of our study contribute to a measurable understanding of the protective effect of vaccination against SARS-CoV-2 infections especially with repeated doses. This concerned mainly clinical presentation, amount of oxygen needed and mortality in ICU.

CONCLUSION

Our study describes the association between vaccination status and clinical presentation, biological features, amount of oxygen support needed and outcome among patients admitted in ICU for severe/critical SARS-CoV-2 infection. Vaccination was found to be a protective factor since vaccinated patients (regardless of the type of vaccine) presented moderate symptoms, less biological disorders and less CT scan lesions extent. The maximal oxygen support needed and in-hospital mortality were higher among unvaccinated patients. This protective effect was more pronounced among patients receiving 3 vaccine doses or more.

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FIGURES

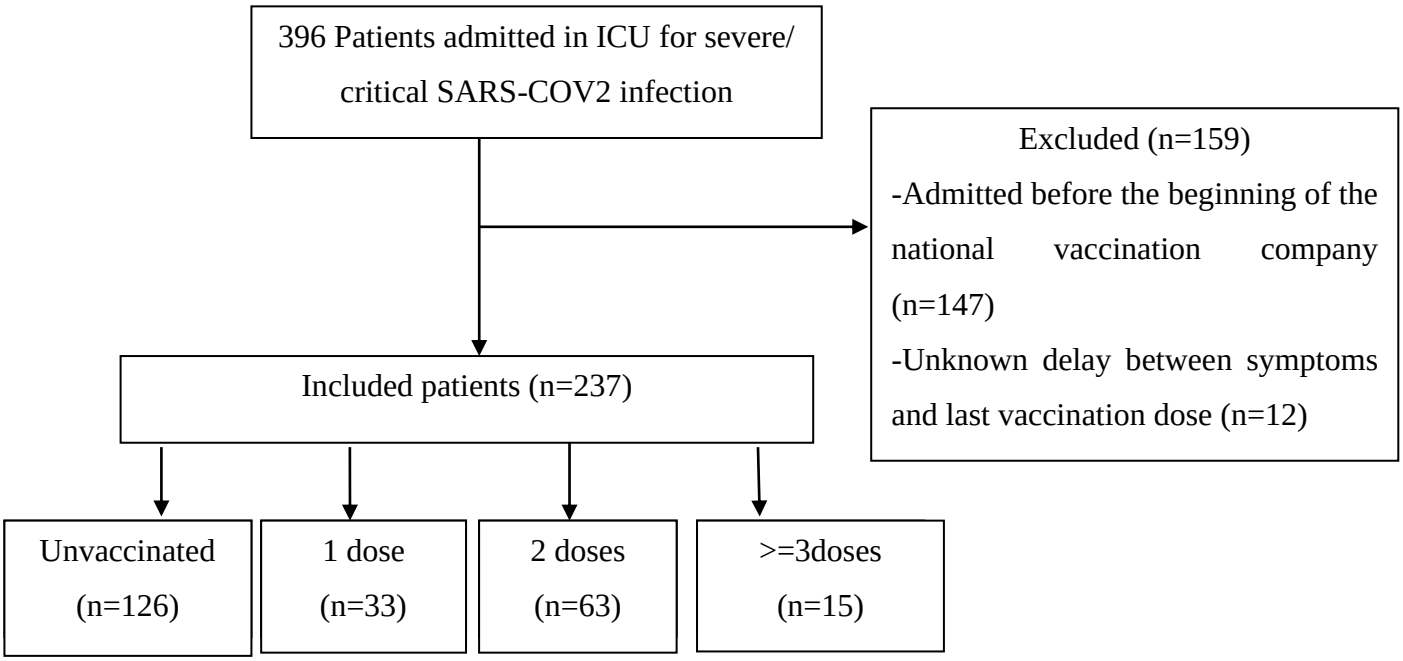

Figure 1: Patients flowchart

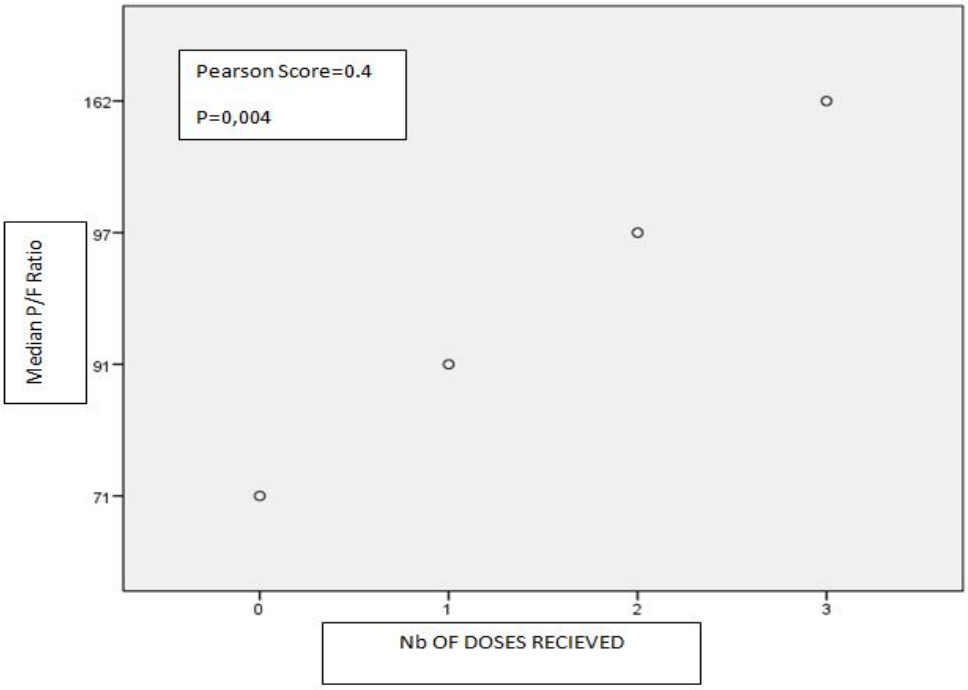

Figure 2: Correlation between arterial oxygen partial pressure (PaO_2) / Fractional inspired oxygen (FiO_2) ratio and vaccine doses number

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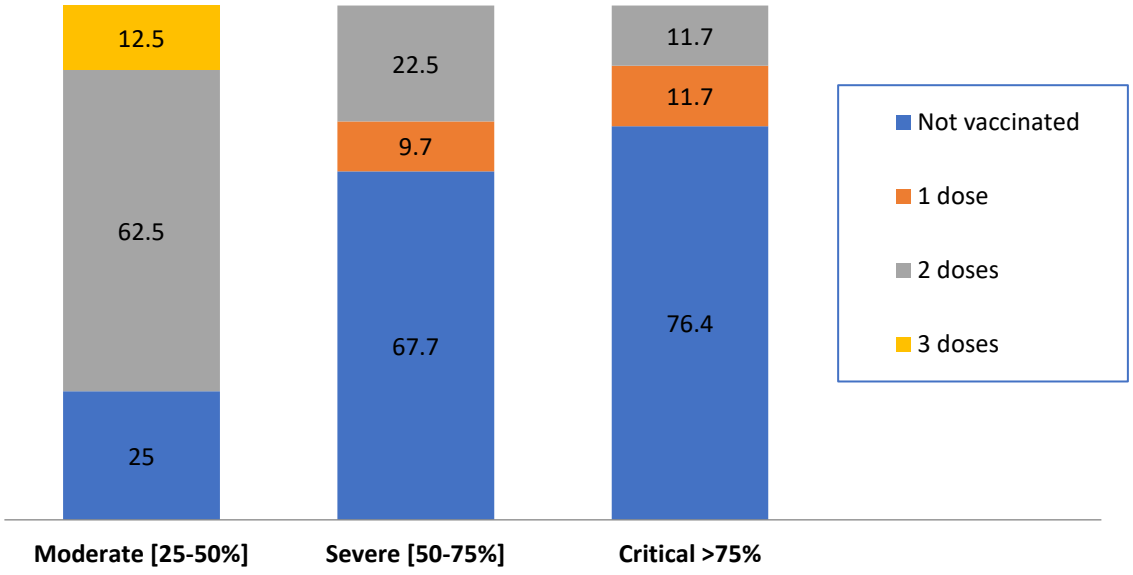

Figure 3: CT scan lesions extent according to the vaccination status

TABLES

Table 1: Demographic and clinical data according to the vaccination status

	Total (n=237)	Unvaccinated (n=126)	1 dose (n=33)	2 doses (n=63)	≥ 3 doses (n=15)	p
Age Mean ±SD	62±15	58±15	60±17	64±17	71±7	0.004
Age > 60 years (%)	139 (59)	63(50)	19(57)	44(70)	13(87)	0.007
Co- morbidities						
Obesity (BMI>30kg/m^2) (%)	76(32)	48 (38)	7(21,2)	17(27)	4(27)	NS
Hypertension (%)	98 (41)	38 (30)	16(48,4)	33(52)	11(73)	10^{-3}
DM (%)	96(40)	43(34)	14(42,4)	30(48)	9 (60)	NS
CHF (%)	20(8,4)	5(4)	3(9)	9(14,2)	3(20)	0.034
CRF (%)	24(10)	6(5)	3(9)	12(19)	3(20)	0.011
CKD (%)	33(14)	12(9,5)	2(6)	15(24)	4(27)	0.013
Immunodeficiency (%)	6(2,5)	2(1,5)	0(0)	2(3)	2(13)	0.037
Severity scores						
IGSII Med [IQR]	27[21-35]	28[24-32]	30[20-38]	26[14-40]	24[19-33]	NS
APACHII Med	12[7-17]	13[8-17]	12[6-18]	11[7-17]	8[5-14]	NS

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[IQR]						
SOFA Mean ± SD	3,8±2,3	3,94±2.7	3,91±2.9	3,9±2.5	2,7±2.1	NS
Clinical Parameters						
Dyspnea (%)	173 (73)	90 (71,4)	22 (67)	50 (80)	11(73)	NS
Fever (%)	155(65,4)	104 (82,5)	21(64)	29(46)	1(7)	$<10^{-3}$
Anosmia (%)	6(2,5)	2(1,5)	0(0)	2(3)	2(13)	0.038
Diarrhea (%)	9(3,8)	4(3)	0(0)	5(8)	0(0)	NS
RR(breaths/min) Mean ± SD	28,25±7	29,6±7	25,7±6	27±7	24,7±5	0.004
DM: diabetes mellitus, CHF: chronic heart failure, CRF: chronic respiratory failure CKD: chronic kidney disease, RR: respiratory rate, NS: not significant						

Table 2: The main biological data according to the vaccination status

	Total (n=237)	Unvaccinated (n=126)	1 dose (n=33)	2 doses (n=63)	≥3 doses (n=15)	p
LCT ($*10^3/mm^3$) Med [IQR]	0,7[0,5-1]	0,65[0,4-0,8]	1[0,4-1,8]	0,9[0,6-1,3]	0,8[0,42-1,3]	**0.003**
CRP (mg/L) Med [IQR]	134±92	125[79-201]	117±84	124±98	140±122	**NS**
WBC ($*10^3/mm^3$) Med [IQR]	9[7-12]	8[7-12]	9[8-13]	9[8-13]	9[7-13]	**NS**
CRP: C - reactive protein, WBC: white blood cells count , LCT: lymphocytes, NS: not significant						

Table 3: Outcome parameters according to the vaccination status

	Total (N=237)	Unvaccinated (N=126)	1 dose (N=33)	2 doses (N=63)	≥3 doses (N=15)	p
Severe/Critical ARDS N (%)	114(48)	77 (61)	9 (27)	24 (38)	4 (26)	$<10^{-3}$
HFNC N (%)	132(56)	97(77)	12(36)	19(30)	4(27)	$<10^{-3}$
NIV N (%)	118(50)	82(65)	14(43)	20(32)	2(13)	$<10^{-3}$
Cannula/Mask N (%)	80(34)	16(13)	15(45)	37(59)	12(80)	$<10^{-3}$
MV N (%)	96 (40)	64 (51)	12 (36)	18(28)	2 (13)	0.003
Mortality (%)	117(49)	72(57)	14 (42)	27 (42)	4(26)	0.04
ARDS: acute respiratory distress syndrome, HFNC: high flow nasal cannula, NIV: non invasive ventilation, MV: mechanical ventilation, ICU: intensive care unit						

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