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Research article

Effect of vaccination on COVID-19 mortality during omicron wave among highly marginalized mexican population

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2. ABSTRACT

Background: Social determinants have played a role in COVID-19 outcomes and vaccination has improved these and impacted on inflammatory response, we therefore sought to investigate the association between vaccination and inflammatory response with COVID-19 mortality in a Mexican population with high marginalization during the Omicron wave.
Methods: Prospective, longitudinal, single-center study in a setting of high marginalization conducted during the Omicron wave, from January to November 2022. Clinical and laboratory data were collected during admission and patients were followed until discharge or death. Patients were grouped according to outcome (survival and non-survival), and by complete (2 or more doses) and incomplete vaccination status for comparison.
Results: 118 patients were included, 54% (64/118) male, with a median age 63 years and 86% (102/118) with self-reported comorbidities. Mortality was 42%. 58% (68/118) had complete vaccination. There was a 64% risk reduction for all-cause in-hospital mortality of having complete vaccination, hazard ratio 0.36, (95% CI 0.18–0.71, $p = 0.004$) in the proportional hazards Cox regression test. Survivor group arrived earlier to medical care and had higher SpO2 on admission, and for inflammatory response, had lower levels of Neutrophil-to-lymphocyte ratio, C-reactive protein, and D-dimer at admission. In the longitudinal measurement, only D-dimer showed significant differences between groups according to survival.
Conclusion: In a highly marginalized Mexican population, complete vaccination has a protective effect against COVID-19 all-cause in-hospital mortality compared with incomplete or no vaccination. However, mortality in this population during the Omicron wave is high. Socio-economic inequalities may play an important role in COVID-19 outcomes.

1. Introduction

Throughout the coronavirus disease 2019 (COVID-19) pandemic, Mexico has had one of the highest case-fatality rates (CFR) in the

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List of abbreviations

CFR	case-fatality ratio
COVID-19	coronavirus disease 2019
MoH	Ministry of Health
CONEVAL:	National Council for the Evaluation of Social Development Policy
IMSS	Mexican Institute of Social Security
HIV	Human immunodeficiency virus
SARS-COV-2	severe acute respiratory syndrome coronavirus 2
OW	Omicron wave
OV	Omicron Variant
PCR	polymerase chain reaction
qSOFA	quick Sequential Organ Failure Assessment
SpO2	saturation of Oxygen
FiO2	Fraction of Inspired Oxygen
CRP	C-reactive protein
CBC	complete blood count
COPD	Chronic Obstructive Pulmonary Disease
NLR	Neutrophil-to-lymphocyte ratio
SD	standard deviation
SRC	self-reported comorbidities
PHEIC	public health emergency of international concern
IQR	interquartile range
WHO	World Health Organization
LDH	Lactate dehydrogenase
FDA	Food and Drug Administration
CDC	Centers for Disease Control and Prevention

world, with reports ranging from 38% to 50%, prior to the start of vaccination [1–3]. Accelerated development and access to vaccination contributed to declines in COVID-19 mortality, particularly during the Omicron wave (OW) [4]. Evidence generated from large databases from the Mexican Institute of Social Security (IMSS) [3], and national dataset [5] which includes every subsystem of health services in Mexico, have shown lower mortality from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection during the OW with a complete vaccination (defined by 2 or more doses), correlating with evidence from developed countries [4]. However, this may not be the same for every population group as social determinants have played a role in the pre-Omicron period. For example, a recent report involving patients with severe COVID-19 hospitalized in a private institution reported a mortality rate three times lower than any other public health institutions in Mexico [6]. Among possible explanations for these significant differences in Mexican population, it has been found that having a lower income [7] and belonging to indigenous groups, have a higher risk of hospitalization and mortality [8].

Approximately half of the Mexican population does not have access to social security, this is considered as an indicator of poverty by to the National Council for the Evaluation of Social Development Policy (CONEVAL) [9]. These patients receive medical care in hospitals and clinics surveilled by the Mexican Ministry of Health (MoH) and includes population with the highest levels of marginalization [10]. Mexico is a country with a large indigenous population and therefore at risk of marginalization [8] and our region of the country contributes about one third [11], of which 49.5% lives in poverty [12].

Previous studies in our population support the use of routine laboratory biomarkers as predictors of mortality in hospitalized patients in previous waves of COVID-19 [2]. Likewise, vaccination has been shown to modify the inflammatory response in COVID-19 patients. In patients with 2 or more doses of vaccination, regardless of type, inflammatory markers were significantly lower than in non-vaccinated patients, whose response was similar to that of previous COVID-19 waves [4]. However, very few studies have examined differences in laboratory markers in vaccinated or Omicron-infected cohorts.

Given the differences in CFR between different types of populations within Mexico, as well as the evidence suggesting the influence of socioeconomic variables on outcomes in COVID-19, we aimed to investigate the association of vaccination status and the inflammatory response with all-cause in-hospital mortality among hospitalized patients with severe COVID-19 during the OW in a highly marginalized population, with the hypothesis that having a complete vaccination is associated with lower risk of all-cause in-hospital mortality.

2. Methods

2.1. Study setting

This study was conducted in Yucatan, southeast of Mexico, classified in 2020 by the National Population Council (CONAPO) as a

state with a high index of marginalization [13] where 41.6% of the population received medical care in a center surveilled by MoH [12, 14]. The hospital is a third level COVID-19 reference center, MoH dependent, with 97% of attending patients classified in the lowest levels of socio-economic strata.

2.2. Study design

We conducted an observational, prospective single-center study. Data from hospitalized COVID-19 patients consecutively admitted from January 1st to November 30th, 2022, was analyzed. This period corresponded to the 4th and 5th COVID-19 waves in Mexico [3] with predominance of the Omicron variant (OV), representing 99% of the sequenced samples in our region by the end of January 2022 [15]. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline [16].

This study was approved by the Ethics Committee of the Regional High Specialty Hospital of the Yucatán Peninsula (protocol number: 2023-012), and it was conducted in accordance with the Declaration of Helsinki.

2.3. Study population

Patients aged 18 years or older, hospitalized, and with a polymerase chain reaction (PCR) confirmed SARS-CoV-2 infection were included.

2.4. Data collection: clinical characteristics, vaccination status, blood sample collection and biomarkers

Data were collected during hospital admission, including demographic and clinical characteristics (oxygen saturation, qSOFA scale, and SpO2/FiO2 index). To collect patients' comorbidities, self-reported comorbidities (SRC) were used given the feasibility, cost-effectiveness, and validity in comparison to hospital patients' records [17,18]. PCR sample was taken within 48 h of admission. Vaccination status was obtained from the National Epidemiological Surveillance System (SINAVE, for its acronym in Spanish) database, which contains up-to-date information regarding COVID-19 in Mexico [19]. The participants were considered to have a complete vaccination if they had 2 or more doses, regardless of vaccine type. Patients were followed until discharge or in-hospital death. Biomarkers such as CRP, complete blood count (CBC), and D-dimer were also included. Briefly, blood samples were individually collected at admission and every 72 h in pyrogen-free, K2 EDTA and sodium citrate tubes (Vacutainer; BD Diagnostics) for CRP, CBC, and D-dimer, respectively. The parameters were processed as follows: in vitro immunoturbidimetric test for the quantitative de-termination of CRP (CRPL3®), automated latex-enhanced immunoassay for the quantitative determination of D-dimer (Hemosil® D-dimer HS 500) and in vitro automatic flow cytometry using a semiconductor laser for leukocyte count analysis (XT-2000i®). Neutrophil-to-lymphocyte ratio (NLR) was calculated by dividing total neutrophils by total lymphocyte counts. Patients were grouped according to outcome status (survival and non-survival) as well as complete versus incomplete vaccination status for comparison.

2.5. Statistical analysis

Continuous variables are presented as mean with standard deviation (SD) or the median and interquartile range (IQR, Q3-Q1). Categorical variables are reported as number and percentages. Between groups differences (survivors vs non-survivors) were analyzed as follows: continuous variables using two sample *t*-test or Wilcoxon rank sum test and categorical variables using Chi-square test or fisher's exact test. The survival analysis was conducted using the Kaplan-Meier survival function curve to assess the statistical significance between individuals with complete vaccination status versus those with either one dose or no vaccination.

The results were computed using the hazard ratio (HR) along with the corresponding 95% confidence intervals (CI) and assessed using the Tarone-Ware test for univariate estimates and the Cox proportional hazard model for multivariate estimates. In all cases, the proportional hazard/risk assumption was evaluated through residual or beta analysis against time. Furthermore, to examine potential differences in biomarkers over time during the hospital stay, comparisons were performed using Mixed ANOVA. The comparison factors considered were the group of non-survivors versus the group of survivors, as well as the vaccination status (complete vaccination versus incomplete/no vaccination). Due to in-complete data for some cases resulting from discharge or death, there were small sample sizes in the final measurements. Therefore, variables that exhibited approaching significance were identified, and a second analysis was conducted using a non-parametric analysis based on the rank-transformation of variables [20].

In all analyses, a significance level of $p < 0.05$ was applied. The handling of missing data

involved the listwise exclusion technique, which entails performing the analyses only on cases with complete data for the variables used in the analysis [21]. All analyses were carried out using SPSS version 25.

3. Results

3.1. Patient characteristics

A total of 169 patients were hospitalized for suspected COVID-19 during the period of January 1st to November 30th, 2022. 51 patients were excluded due to missing data or having an alternative diagnosis (Supplementary Fig. 1). Final data are from 118 patients. The median age was 63 years (IQR 27), 54% (64/118) were male and 86% (102/118) of patients had SRC, the most frequent being

hypertension (40%), obesity (37%), and diabetes (31%). The median follow-up duration was 4 ± 5 days. 58% (68/118) patients had a complete vaccination. All-cause in-hospital mortality rate was 42% during the OW. All patient characteristics are presented in Table 1.

3.2. Comparisons according to vaccination status

Survival time was compared according to vaccination status. The null hypothesis assessed stated that risks were proportional over time ($\chi^2 = 3.31$; df = 1; p = 00.07) (Supplementary Fig. 2). Results from the Schoenfeld residuals analysis indicate that the assumption of proportional hazards was met for all predictors (Supplementary Fig. 3). The hazard ratio for having complete vaccination was 0.36, (95% CI 0.18–0.71, p = 0.004) in the proportional hazards Cox regression test, which translates to a 64% reduction in all-cause in-hospital mortality risk in patients with complete vaccination (Fig. 1). Patients with complete vaccination were less classified, according to OMS criteria, as critical disease (27 (40%) vs 30 (60%), p = 0.029) and had lower mortality (23 (34%) vs 26 (52%), p = 0.048) compared to incomplete or non-vaccinated patients (1 or 0 doses). No differences were observed in age, sex, SRC, SpO2 or SpO2/FiO2 index, need for IMV or routine biomarkers (CBC, CRP, and D-dimer), on admission (Supplementary Table 1).

3.3. Comparisons according to survival status

Patients in the survivor group arrived earlier to medical care (5.4 vs 7.1 days, p = 0.022), had higher SpO2 on admission (92% (85–97) vs 86% (75–92), p < 0.001), higher SpO2/FiO2 index (375 (156–449) vs 184 (97–381), p = 0.004), lower need for IMV during hospitalization (3 (4%) vs 26 (53%), p < 0.001) and were less classified as critically ill during hospitalization (13 (19%) vs 44 (90%), p < 0.001) in comparison to patients in non-survivor group. Regarding biomarkers at admission, lower levels of NLR (9.1 (5.2–18.1) vs 12.1 (9.0–27.7), p = 0.013), CRP (83.2 mg/L (30.8–191.9) vs 148.7 mg/L (80.2–241), p = 0.009) and D-dimer (1640 ng/mL (891–2540) vs 2546 ng/mL (1353–5078), p = 0.004) were observed among the survivor group in comparison to patients in the non-survivor group.

No differences were observed in age, sex, SRC, follow-up duration, absolute levels of leucocytes, eosinophils, and platelets. All differences between survivor and non-survivor patients are presented in Table 1.

3.4. Comparisons of routine biomarkers over time

The routine laboratory biomarkers were evaluated as far as 10 days and higher levels of neutrophils, NLR, CRP and D-dimer were

Table 1
Overall and between group comparisons of clinical characteristics and routine biomarkers according to survival status.

Variable	Overall n = 118	Survivor n = 69	Non-survivor n = 49	p value
Age (years)	63 (27)	61 (25)	65 (29)	0.081
Male sex	64 (54%)	39 (56%)	25 (51%)	0.554
Self-reported comorbidities	102 (86%)	60 (87%)	42 (86%)	0.846
Hypertension	47 (40%)	28 (41%)	19 (39%)	0.844
Type 2 diabetes	37 (31%)	19 (28%)	18 (37%)	0.289
Cardiovascular disease	19 (16%)	12 (17%)	7 (14%)	0.651
COPD	9 (8%)	6 (9%)	3 (6%)	0.604
Obesity	43 (37%)	22 (32%)	21 (43%)	0.222
Chronic liver disease	6 (5%)	3 (4%)	3 (6%)	0.665
Chronic kidney disease	12 (10%)	7 (10%)	5 (10%)	0.992
HIV infection	3 (3%)	1 (1.5%)	2 (4%)	0.371
On-admission SpO2 (%)	89 (16)	92 (12)	86 (17)	**<0.001**
On-admission SpO2/FiO2 Index	331 (295)	375 (293)	184 (284)	**0.004**
In hospital need of IMV	29 (25%)	3 (4%)	26 (53%)	**<0.001**
On admission q-SOFA	1 (1)	1 (2)	2 (1)	**0.012**
Critically ill	57 (48%)	13 (19%)	44 (90%)	**<0.001**
Follow-up duration (days)	4 (5)	4 (4)	4 (7)	0.662
Time from onset to medical care (days)	6.1 (SD 4.0)	5.4 (SD 3.7)	7.1 (SD 4.3)	**0.022**
Vaccination status				**0.048**
0–1 doses	50 (42%)	24 (35%)	26 (53%)	
2 or more doses	68 (58%)	45 (65%)	23 (47%)	
Routine biomarkers at admission				
Leucocytes (cell x 10^3/mcL)	10.9 (7.2)	10.7 (6.9)	11.3 (6.4)	0.056
NLR	11.2 (14.3)	9.1 (12.9)	12.1 (18.7)	**0.013**
Eosinophils (cell x 10^3/mcL)	0.01 (0.09)	0.02 (0.09)	0.01 (0.09)	0.899
Platelets (cell x 10^3/mcL)	252 (181)	252 (160)	259 (199)	0.764
CRP (mg/L)	108.2 (162.6)	83.2 (161.1)	148.7 (160.8)	**0.009**
D-dimer (ng/mL)	1915 (2382)	1640 (1649)	2546 (3725)	**0.004**

Data are n (%), and median (interquartile range, IQR), unless otherwise specified. All results were considered statistically significant at p < 0.05. Boldened values signify p < 0.05. COPD: Chronic Obstructive Pulmonary Disease, HIV: Human Immunodeficiency Virus, IMV: invasive mechanical ventilation, qSOFA: quick Sequential Organ Failure Assessment, SD: Standard deviation, NLR: Neutrophil-to-lymphocyte ratio, CRP: C-reactive protein.

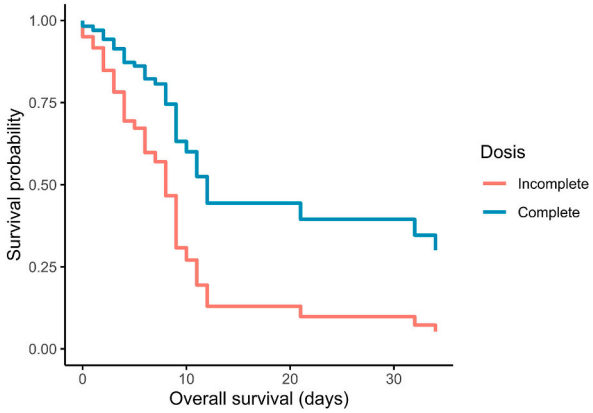

Fig. 1. Kaplan-Meier survival estimates according to vaccination status.
The hazard ratio of having complete vaccination was 0.36, (95% CI 0.18–0.71, p = 0.004).

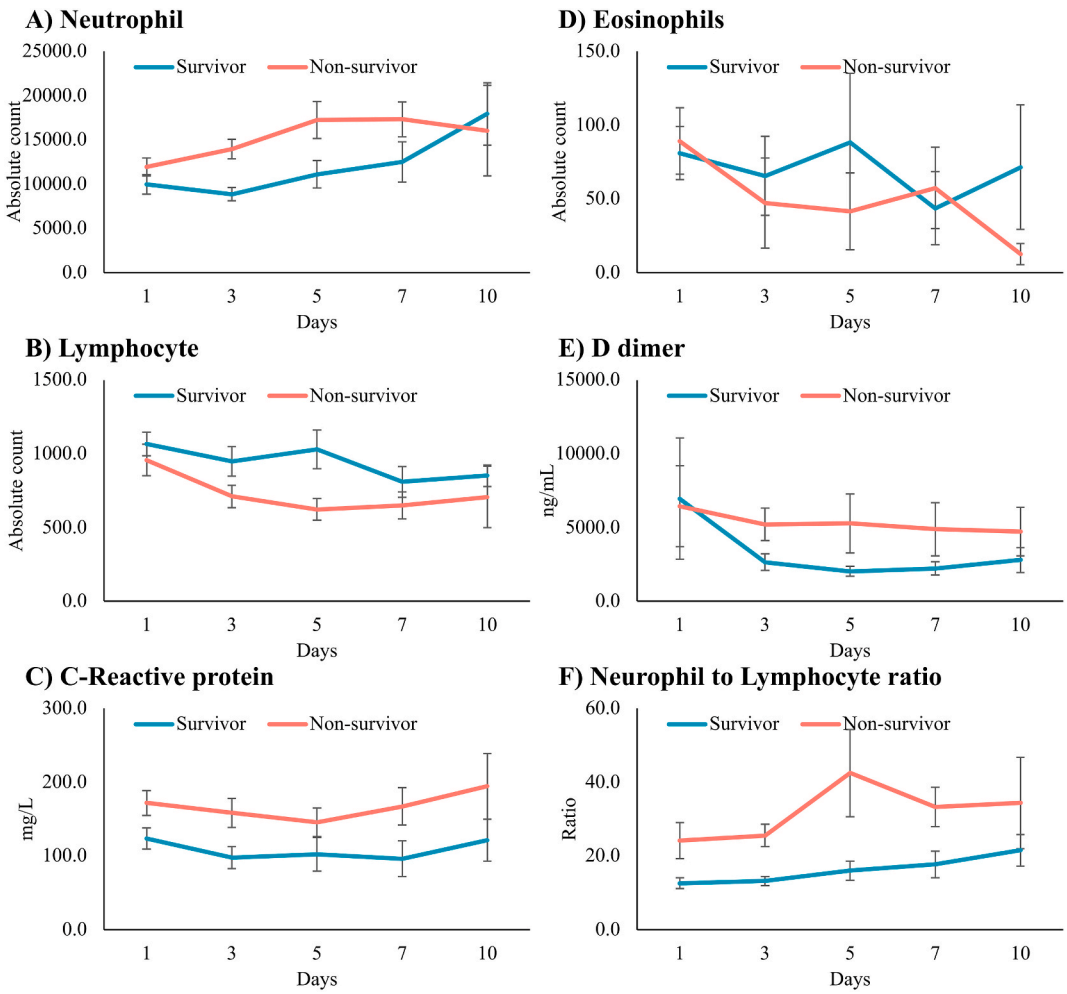

Fig. 2. Dynamical changes according to survival status in the levels of inflammatory biomarkers in severe COVID-19 patients during hospitalization. A) Neutrophils, B) Lymphocyte, C) C-reactive protein, D) Eosinophils, E) D dimer, F) Neutrophil to Lymphocyte ratio in patients within 10 days from admission. The patients were stratified into a non-survival group and a survival group. Data represents mean ± SD. Statistically significant differences are marked with a *.

registered in the non-survivor group (Fig. 2 A, C, E, F) as well as lower levels of lymphocytes and eosinophils (Fig. 2 B, D). Mixed ANOVA analysis showed no statistically significant differences in routine biomarkers over time according to survival status, although the values of absolute lymphocyte count and D-dimer close to statistical significance (**Table 2**). Conover's rank transformation analysis of these variables showed that only the value of D-dimer for survival status was statistically significant in their longitudinal measurements ($F_{1,13} = 4.92$; $p = 0.045$; $\eta^2 = 0.11$).

4. Discussion

To the best of our knowledge, this is the first study to demonstrate the impact of complete vaccination for COVID-19 in a highly marginalized Mexican population. This is of great relevance because Mexico comprises a mosaic of micro-regional circumstances where people face different social opportunities [13] and therefore different health outcomes. In addition, we documented the following findings: a) 58% of this population had a complete vaccination; b) a high all-cause in-hospital mortality rate persists in OW in this population; c) 86% of patients had SRC with no differences in mortality; d) routine biomarkers on admission (NLR, CRP and D-dimer) continue to be strong predictors of outcome at admission and only D-dimer differentiates adverse outcomes throughout hospitalization.

With the introduction of vaccination, a worldwide decrease in the rate of hospital admissions and death from COVID-19 was observed [5]. Our data has confirmed the effectiveness of vaccination during the OW, particularly in a highly marginalized population, finding a 64% reduction in the risk of COVID-19 all-cause in-hospital mortality in subjects with 2 or more doses. The effectiveness is similar to what is reported from countries with lower marginalization indexes, as well as from ethnicities other than our population (non-Hispanic whites) [22]. In sum, our results strengthen the evidence on the effectiveness of vaccination and allow for the promotion of vaccination-focused strategies that include highly marginalized populations. This is in line with the position taken by the Food and Drug administration (FDA), which recommends annual revaccination [23].

On the other hand, our results contrast markedly with those reported in the Mexican population with health insurance (people with IMSS affiliation), where only a 15% reduction in mortality with the beginning of vaccination was observed [3]. One possible explanation is the heterogeneity of the sample used in the aforementioned report, given that Ascencio-Montiel et al. did not segment the data based on COVID-19 severity, nor did they analyze based on socio-economic stratum or population with high marginalization.

Since the beginning of the pandemic, several risk factors for death from COVID-19 have been identified and replicated across all SARS-CoV-2 variants and ethnic groups, including older age, SRC such as type 2 diabetes, hypertension, obesity, chronic obstructive pulmonary disease (COPD) or cardiovascular disease [4]. However, despite the high prevalence of SRC in our population (86%), these did not represent a risk factor for adverse outcomes. This finding is in line with studies in our population in waves prior to vaccination. During the first wave of COVID-19, the survivor group had 73% comorbidities compared to the non-survivor group with 70%, with no significant statistical difference ($p = 0.557$) [1]. This was once again confirmed in our population during the second wave, where SRC also failed to demonstrate a predictive role in the survival of individuals with severe COVID-19 [1,2]. In contrast, it has been reported in the Mexican population before the first vaccine application, that SRC integrated into a prediction model report the risk of severity rather than mortality from COVID-19 [24]. Additionally, the population with high marginalization have poorer health behaviors, such as tobacco consumption and physical activity [25], as well as a generally less healthy diet [26], which together are strong promoters of comorbidities [27].

Overall, the Centers for Disease Control and Prevention (CDC) has reported a 47% decrease in mortality from COVID-19 in 2022 compared to 2021 [28]; developed countries, such as Australia and the United States, have reported mortality rates as low as 5.9% and 7%, respectively [4,22]. Certainly, vaccination has been the most important factor in reducing mortality. However, the data contrasts with the mortality rate obtained in our study (42%). Among the possible explanations for these significant differences, several factors have been identified, including lower income [7], and belonging to an indigenous group, which represent more marginalized populations [8], such as the one included in the present study. It has been hypothesized that these populations delay seeking medical care [7] and therefore have more severe disease at admission and our results seem to support this given that patients who did not survive arrived later compared to those who did survive; likewise they had lower SpO2 and elevated biomarkers of inflammation and coagulation disorders (NLR, CRP, D dimer) at admission, which have been observed as predictors of disease severity and mortality [2].

Table 2
Mixed ANOVA model for non-survivor vs survivor and routine biomarkers.

Variable	Non-survivor vs survivors	
	F	p-value
Neutrophil absolute count	0.172	0.685
Lymphocyte absolute count	4.60	0.051
CRP (mg/L)	0.454	0.514
Eosinophils absolute count	0.239	0.633
D-dimer (ng/mL)	4.28	0.059
NLR	1.01	0.332
Platelet count	0.722	0.411

All results were considered statistically significant at $p < 0.05$. NLR: Neutrophil-to-lymphocyte ratio, CRP: C-reactive protein.

Moreover, during OW, D-dimer persists as a strong biomarker of mortality, remaining as the only biomarker that showed significant differences in its longitudinal measurement, as consistently reported in previous studies [29]. Further exploration should strengthen the hypothesis between delay in medical care and risk of adverse outcomes. In addition to the delay in care, coverage of complete vaccination in our population was 58%. This finding resembles with reports from Brazil, where indigenous populations have lower vaccination coverage [30], in contrast to 80.2% coverage in countries with greater resources for health care such as Australia [4].

We are aware of the limitations of our study. First, this is a single-center study, however, our hospital was designated exclusively for COVID-19 care, in addition to being a center surveilled by MoH and receiving a highly marginalized population based on the socio-economic level of our region, which contributes to the representativeness of these populations, strengthening external validity to other highly marginalized populations. We acknowledge the small sample size compared to retrospective studies generated with large population-based databases, however, the conclusions drawn from our study are based on prospectively captured data. Comorbidities were recorded as SRC; however, they have shown feasibility, cost-effectiveness, and validity in comparison to hospital patients' records; also, we were not able to capture current tobacco use or smoking history. We measured all-cause in-hospital mortality rather than mortality attributable to COVID-19 to define mortality in our study, as we were not able to collect the specific cause of death of the participants. Despite the World Health Organization (WHO) declared that the SARS-CoV-2 pandemic no longer constitutes a public health emergency of international concern (PHEIC) [31], our data confirm a higher impact of COVID-19 to populations with high marginalization and contribute to its classification as a syndemic [32]. Further exploration should seek to understand the causes of this poorer outcome in populations with high marginalization, and our results call for a re-evaluation of vaccination policies and an expansion of vaccination distribution to areas of high marginalization.

5. Conclusion

In a Mexican population with high marginalization, complete vaccination (2 or more doses) has a protective effect against all-cause in-hospital mortality during COVID-19 OW in comparison to patients that have incomplete or no vaccination at all. However, even in the context of effective vaccination schemes and a theoretically milder variant of the virus, such as the OV, in-hospital mortality among this population is still as high as the first wave from the ancestorial variant, and higher than the OW in populations with lower marginalization. Therefore, socio-economic inequalities may play a major role in COVID-19 outcomes and a vaccine centered approach must be followed in managing the syndemic.

Declarations

5.1. Ethics

This study was reviewed and approved by Ethics Committee of the Regional High Specialty Hospital of the Yucatán Peninsula, with the approval number: 2023-012.

All participants/patients (or their proxies/legal guardians) provided informed consent to participate in the study.

Competing interests

The authors declare that they have no competing interests.

5.3. Authors' contributions

AC-T and VA-S designed the study and wrote the manuscript. AC-T, VA-S, and MS-P performed the experiments. AC-T analyzed the data. AC-T, VA-S, MS-P, and GB-B were involved in the revision and editing of tables and figures. All authors read and approved the final manuscript.

5.5. Funding

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5.6. Data availability statement

Has data associated with your study been deposited into a publicly available repository? No. Data will be made available on request.

CRediT authorship contribution statement

Víctor Aarón Álvarez-Sánchez: Writing – original draft, Visualization, Data curation, Conceptualization. **María Alejandra Salcedo-Parra:** Resources, Investigation. **Gustavo Bonnabel-Becerra:** Resources, Investigation, Data curation. **Arturo Cortes-Telles:** Writing – review & editing, Supervision, Project administration, Methodology, Funding acquisition, Formal analysis,

Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e28781.

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