

SAPS 3, SOFA, QSOFA, PORT and 4C Mortality Score as Predictors of Mortality in Patients with COVID 19 in Mexico

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Abstract

Introduction: At the end of 2019, a new coronavirus (2019-nCoV) was identified as the cause of pneumonia in the city of Wuhan, in the province of Hubei, China. In February 2020, the WHO designated this disease as COVID 19 (Coronavirus Disease 2019) and its etiological agent was named as SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus-2). In Mexico until June 23, 2021 there were 2,487,172 confirmed cases, 434,533 suspected cases, with 231,184 deaths. Regarding the confirmed cases, 18.51% required hospitalization and 81.29% only isolation at home. In the city of Piedras Negras, Coahuila, 6,701 confirmed cases were reported with 424 deaths and 43 active cases; of these, 10.87% required hospitalization and 89.13% only isolation at home. The markers that have been related to an increase in disease severity and mortality are Pro-B natriuretic peptide, high sensitivity troponin I, creatine phosphokinase MB fraction, interleukin-6, D dimer, C-reactive protein, sequential organ failure assessment (SOFA), lactate dehydrogenase, alanine-amino transferase, aspartate-amino transferase, hypoalbuminemia, leukocytosis, neutrophilia, lymphopenia, procalcitonin.

Objective of the Study: Evaluate the ability to predict mortality, in COVID 19 patients treated at the Respiratory Unit at Clinica México, of the SAPS 3, SOFA, qSOFA, PORT and 4C Mortality Score.

Methods: Prospective, observational, longitudinal study from April 8, 2020 to May 21, 2021, patients with COVID 19. Severity scales and demographic data were recorded in the first 24 hours of admission. The statistical analysis was correlation and calculation of AUC for mortality with $p < 0.05$. Informed consent was obtained.

Results: 58 patients were admitted to the study, age 51.05 years, male 74.1%. Hospital mortality was 20.7%. The cause of admission was classified as Threat of organic failure 53.45%, Invasive Mechanical Ventilation and/or non-invasive since admission 43.10%. The average days of stay was 11.12, the average hours of invasive mechanical ventilation were 141.39, the average hours of non-invasive mechanical ventilation were 50.79. The predictive capacity for mortality was statistically significant for the four scales SAPS3 AUC = 0.84, SOFA AUC = 0.99, qSOFA AUC = 0.89, PORT AUC = 0.73 and 4C Mortality Score AUC = 0.81.

Conclusion: The scales SAPS 3, SOFA, qSOFA, PORT and 4C Mortality Score are useful as tools for predicting mortality in Mexican COVID 19 patients. The use of these tools can improve the profiling of patients to better distribute care resources, which are limited in most centers in our country. It is necessary to evaluate these results in a larger cohort and in other units with different characteristics from ours.

Keywords: COVID19; Mexico; Mortality; Mechanical Ventilation; Pneumonia; Prognosis

Introduction

Coronaviruses are important pathogens for animals and humans [1]. Human coronaviruses (hCoV) are globally endemic and cause 10 - 30% of acute respiratory infections in adults [2]. hCoV infections are generally considered mild, until the SARS (Severe Acute Respiratory Syndrome) epidemics in 2002 and MERS (Middle East Respiratory Syndrome) in 2012 caused high mortality in the affected countries [3]. In 2017 the World Health Organization (WHO) placed them on the list of priority pathogens [3]. At the end of 2019, a new coronavirus (2019-nCoV) was identified as causing pneumonia in the city of Wuhan, Hubei province, China [4]. In February 2020, the WHO designated this disease as COVID-19 (Coronavirus Disease 2019) and its etiological agent was named SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) [4].

The geographical distribution is global, on March 11, 2020 it was declared a pandemic, the most affected countries are the United States, Spain, and Italy [5]. In Mexico, as of June 23, 2021, there were 2,487,172 confirmed cases, 434,533 suspected cases, with 231,184 deaths [6]. Regarding confirmed cases, 18.51% required hospitalization and 81.29% only home isolation [6]. In the city of Piedras Negras, Coahuila, 6,701 cases are reported or confirmed with 424 deaths and 43 active cases; Of these, 10.87% required hospitalization and 89.13% only home isolation [6].

The operational definition for COVID-19 surveillance is [7,8]:

- Suspected case: Person of any age who in the last 7 days has presented at least two of the following signs and symptoms: cough, fever or headache. Accompanied by at least one of the following signs or symptoms: dyspnea (severity data), arthralgias, myalgias,odynophagia/pharyngeal pain, rhinorrhea, conjunctivitis, chest pain.
- Confirmed case: Person who meets the operational definition of a suspected case and who has a diagnosis confirmed by the National Network of Public Health Laboratories recognized by the InDRE.

Most reported cases are in adults; In a retrospective study in China of 44,672 patients, 86.6% of patients were in the range of 30 - 79 years of age [9]. In Mexico the range is 25-54 years [6].

The risk factors associated with infection are:

- Close contact with people suspected, possible or confirmed to have the disease, this includes: family members, romantic partners, health personnel who did not use personal protective equipment, people in contact within 2 meters without personal protective equipment in a prolonged period of time.
- Travel to places where there is reported community transmission [9,10].

SARS-CoV-2 is a beta-coronavirus related to the species that causes severe respiratory distress syndrome (SARS) [11]. Initial transmission is suspected from animal to human in the Wuhan animal market, China; person-to-person transmission in close contact, distance less than 2 meters, due to aerosol production when coughing or sneezing [12]. Contact with fomites is possible, but it is not the main route of transmission, the viability of SARS-CoV-2 on surfaces is: 6.8 hours on plastic, 5.6 hours on steel, 3.5 hours on cardboard, 1.1 hours in aerosol and 0.8 hours in copper [12]. There is transmission from asymptomatic carriers [12].

COVID-19 has an average incubation period of 5.2 days with a range of 4.1 to 7 days [13], each carrier person has the capacity to infect 2.2 people [13]. The prodromal period with contagion capacity is 2.3 days with a peak of 0.7 days [14].

The pathogenesis of COVID-19 is largely unknown, however some studies suggest that the angiotensin-converting enzyme 2-related carboxypeptidase (ACE2) receptor is used by the virus to enter cells. (fifteen). This receptor is present in heart, lung and hematopoietic tissue.

*In children under five years of age, irritability can replace headache.

**The updated list of laboratories validated by InDRE will be published and each update will be disseminated by CONAVE.

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According to the WHO and the CDC, sampling for diagnosis should be prioritized in patients who are hospitalized, symptomatic health workers, patients in nursing homes, adults over 65 years of age with symptoms, and patients with chronic-degenerative diseases [16,17].

The hospital mortality reported in patients with COVID 19 is 10% and 34% in those who were admitted to the Intensive Care Unit [18,19], the age range of the patients is 38 - 69 years with a predominance of men (56.4%), the mortality of patients who require invasive mechanical ventilation and develop Severe Respiratory Failure Syndrome is 83% and 75% respectively [20].

In 29 first world countries, an excess mortality of 979,000 patients was reported. The countries with the highest excess mortality were the United States, Italy, England, Spain and Poland [21,22].

The markers that have been related to increased disease severity and mortality are Pro-B Natriuretic peptide, High-sensitivity Troponin I, Creatine phosphokinase fraction MB [22], Interleukin-6, D-dimer [23], C-reactive protein, Sequential Organ Failure Assessment (SOFA) [24], lactate dehydrogenase, alanine-amino transferase, aspartate-amino transferase, hypoalbuminemia [25], leukocytosis, neutrophilia, lymphopenia, procalcitonin [26].

Due to the impact of COVID 19, various tools have been developed to predict mortality, evolution and risks of complications. The QCOVID risk scale was derived from a cohort of 6,083,102 adult patients in England, with a mean age of 50 years. The model was validated by obtaining data such as age, body mass index, Townsend scale, ethnicity and co-morbidities; and a significant utility for predicting mortality was reported (concordance 0.92 men and 0.93 women) [27].

The COVID-19 SEIMC scale was derived from a cohort of 4,035 patients in Spain, with a mean age of 70 years. The model was validated with 6 factors: age, neutrophil index/lymphocyte, glomerular filtration rate calculated by the KDIGO equation, sex, presence of dyspnea and SPO₂; reporting an agreement with the mortality prediction of 0.84 [28].

The SOFA is a scale that was originally designed as a scale to evaluate the degree of organ damage in patients with sepsis, the model was derived from a cohort of 1449 patients from 16 intensive care units in 40 countries [29]. Because organ failure is very common in critically ill patients, it has been used to predict mortality in patients due to causes other than sepsis such as acute and chronic liver failure, cancer, and cardiac surgery [30]. Evaluates the following parameters: Respiratory (blood pressure ratio of oxygen/inspired fraction of oxygen), cardiovascular (amount of vasopressor to avoid hypotension), renal (uresis and creatinine), hematological (number of platelets), hepatic (concentration total bilirubin), neurological (Glasgow scale).

The qSOFA (quickSOFA) is a scale proposed by the Society Critical Care Medicine and the European Society of Intensive Care Medicine as a tool to improve the diagnosis of sepsis. The model uses 3 easily measurable variables at the patient's bedside respiratory rate > 22, altered mental status, systolic blood pressure < 100 mmHG; two points or more are associated with a prognosis in patients with sepsis [31].

The SAPS (Simplified Acute Physiologic Score) in its three versions (1,2,3), the model uses 20 variables, some dichotomous others numerical that are introduced into a mathematical formula which results in a numerical value of severity and a percentage of mortality [32]. The SAPS3 (latest version) was designed and validated in a cohort of 20,000 patients, in 300 Intensive Care Units in 35 countries.

The 4C mortality Score scale is derived from a cohort of 35,463 patients in the United Kingdom, who required hospitalization > 4 weeks with an average age of 73 years, validation was carried out in a cohort of 22,361 patients. It uses 8 factors that were significantly associated with in-hospital mortality, the score is from 0 to 21 points. The factors that increase the score are male sex, age, number of comorbidities, respiratory rate, urea levels, c-reactive protein levels, low SPO₂, Glasgow Coma Scale [33].

The PSI (Pneumonia Severity Index) or PORT (Pneumonia Patient Outcomes Research Team) scale derived from a prospective cohort with the objective of identifying patients with community-acquired pneumonia who had a low risk of mortality to decide the need for hospitalization. The variables evaluated are gender, age, nursing home resident, comorbidities, physical, laboratory and imaging findings.

According to the joint ATS/IDSA (American Thoracic Society/Infectious Diseases Society of America) recommendations, they are classified as class I-II (< 70 points) = outpatient treatment, class III (71 - 90 points) = treatment in an observation unit and/or hospitalization and class IV (> 90 points) = in-hospital treatment [3,4].

In Piedras Negras Coahuila, information was published on patients who required admission to the ICU, the mortality prediction capacity in Intensive and Hospital Therapy of the SAPS3, qSOFA and SOFA in a cohort of 211 patients; Finding a good predictive capacity of the three scales, SAPS 3 hospital mortality AUC 0.85 95% CI 0.79 - 0.90, SOFA hospital mortality AUC 0.84 95% CI 0.78 - 0.91 and qSOFA 0.77 95% CI 0.69 - 0.85 [35].

Objective of the Study

The objective of our study was to evaluate the mortality prediction capacity, in COVID19 patients treated in the Respiratory Unit of Clínica México, of the SAPS 3, SOFA, qSOFA, PORT and 4c Mortality Score scales.

Methods

A prospective, observational, longitudinal study was carried out from April 8, 2020 to May 21, 2021 of all patients admitted to the Respiratory Unit of the Clínica México. The inclusion criteria were patients with clinical data and simple chest tomography compatible with COVID 19. A nasal swab for PCR-SARS-Co2 was performed in the first 24 hours of admission (laboratory certified by the Secretary of Health of the State of Coahuila N. Official letter JURVI/CRFS/RSS/00366/2020), without this last result being a criterion for elimination from the study. All patients admitted in this period of time were reported in the unit's database (BASCOVID), which collected demographic data, diagnoses, prognostic scales, mortality, days of stay, hours of mechanical ventilation, complications and evolution of the patients.

The SAPS 3, SOFA, qSOFA, PORT and 4C Mortality Score scales were calculated in the first 24 hours of hospitalization, reporting their severity value, percentage probability of mortality (on the scales that applied).

The statistical analysis was performed with Wizard Pro software ver 1.9.4.4 © 2014-2016, John McNamara <jmcmamara@cpan.org> All rights reserved. The quantitative variables were described in means and standard deviation (SD), the qualitative variables in frequency and percentage, the distribution of the quantitative variables was evaluated with the Kolmogorov-Smirnov test, the qualitative variables with z-score and chi-square, both for a statistical significance $p < 0.05$. The relationship of all variables with mortality was carried out through covariance analysis with chi-square for quantitative variables and z-score for qualitative variables. The variables that were statistically significant were analyzed with Pearson correlation. To evaluate the mortality prediction capacity of the studied scales (SAPS3, SOFA, qSOFA, PORT and 4C Mortality Score), the odds ratio and COR (Receiver Operating Characteristics) curve were determined for statistical significance $p < 0.05$.

The research was not carried out in a vulnerable population and the risk of side effects is zero because it was an observational study and was carried out in accordance with good clinical practices, in accordance with the provisions of the General Health Law on Health Research. Declaration of Helsinki and International Council of Harmonization.

A letter of informed consent was requested from the patients included in the study, the personal identification data of the patients was protected and only the data required for the statistical analysis and reporting of results was obtained. The research was authorized by the Medical Research and Education Committee of the México Clinic.

Results

During the study period April 2020 to May 2021, 62 patients were admitted to the Respiratory Unit, of which 58 gave their authorization to participate in this study. PCR for SARS-COV-2 was performed, resulting in Negative results in 12 (20.69%) $p < 0.001$. The main characteristics were: Age 51.05 years SD + 4.3 $p < 0.001$, male sex 74.1% $p < 0.001$, health status prior to admission to the unit was classified as functional (no chronic-degenerative history) 51.7% $p < 0.001$, symptomatic (1 or more chronic-degenerative history but without limitation for work and/or recreational activities) 37.9% $p < 0.001$ and Inbed < 50% (with chronic-degenerative history,

limitation of daily activities and requires assistance for some basic needs) 10.3% $p < 0.001$. The administrative category (derived from the payment method) was medical expenses insurance 74.1% $p < 0.001$ and private 25.9% $p < 0.001$.

The cause of admission was classified as threat of organ failure 53.45%, invasive and/or non-invasive mechanical ventilation since admission 43.10%, post-operative elective surgery 1.72% and state of shock 1.72% (all $p < 0.001$). The average number of days of stay was 11.12 days $SD \pm 2.55$ $p < 0.001$, the average hours of invasive mechanical ventilation were 141.39 $SD \pm 65.04$ $p < 0.001$, the average hours of non-invasive mechanical ventilation were 50.79 $SD \pm 19.85$ $p < 0.001$; 17 patients (29.31%) $p < 0.001$ were assisted with both types of mechanical ventilation during their stay.

The main complications reported were: Neuromuscular weakness associated with critical condition 13.8% $p < 0.001$, bronchoaspiration 1.7% $p < 0.001$, Reintubation < 24 hrs 6.9% $p < 0.001$, Reintubation > 24 hrs 3.4% $p < 0.001$, Unexpected cardiorespiratory arrest 5.2% $p < 0.001$, Pneumothorax 2.4% $p < 0.001$, Accidental extubation 5.2% $p < 0.001$, Serum or capillary glucose > 150 mg/dL 36.2% $p = 0.03$. Treatment with Insulin for hyperglycemia 36.2% $p = 0.03$, ventilation associated pneumonia 22.4% $p < 0.001$. The mortality was 20.7% $p < 0.001$.

Regarding the severity scales, the results reported are in the table 1.

Scale	Result median (SD)	p
SOFA	6.65 (+1.65)	<0.001
Respiratory SOFA	2.31 (+0.36)	<0.001
Cardiovascular SOFA	1.60 (+0.50)	<0.001
Renal SOFA	0.96 (+0.34)	<0.001
Hepatic SOFA	0.45 (+0.21)	<0.001
Hematological SOFA	0.29 (+0.18)	<0.001
Neurological SOFA	1.02 (+0.36)	<0.001
SAPS 3	54.43 (+4.85)	<0.001
Mortality predicted by SAPS 3	27.41% (+6.89)	<0.001
qSOFA	1.94 (+0.23)	<0.001
PORT	108.71 (+17.81)	<0.001
Mortality predicted by PORT	10.05% (+3.19)	<0.001
4C Mortality Score	9.31 (+1.14)	0.19
Mortality predicted by 4C Mortality Score	25.39% (+5.91)	<0.001
Risk classification derived from 4C Mortality Score		
Low risk; n (%)	5 (8.6%)	<0.001
Intermediate Risk; n (%)	24 (41.4%)	<0.001
High risk; n (%)	23 (39.7%)	<0.001
Very High Risk; n (%)	6 (10.3%)	<0.001

Table 1: Severity scales and mortality prediction in COVID 19 patients treated in the respiratory unit of Clinica Mexico.

Abbreviations: SOFA: Sequential Organ Failure Assessment; SAPS3: Simplified Acute Physiologic Score 3; qSOFA: quickSOFA; PORT: Pneumonia Patient Outcomes Research Team; SD: Standard Deviation.

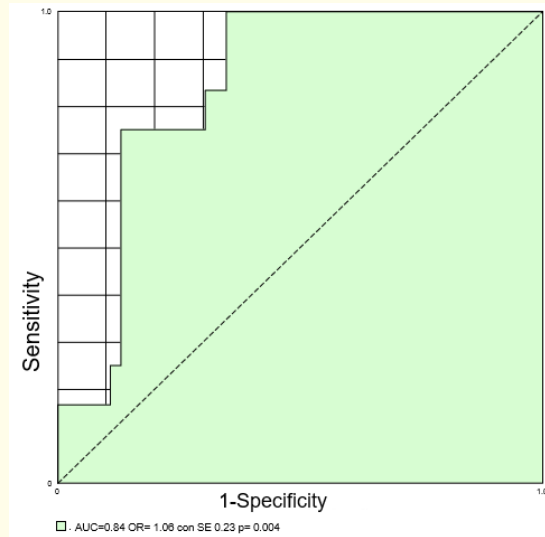
Age, sex, functional status prior to admission, mechanical ventilation at admission, total number of hours of non-invasive mechanical ventilation, pneumonia associated with mechanical ventilation, accidental extubation, percentage of mortality predicted by PORT and the high and low risk categories calculated by 4C mortality score; They did not have a statistically significant correlation with mortality; on the contrary, the variables with statistical correlation are described in table 2.

Variable	Correlation	R2	Covariance	p
Vasopressor upon admission	0.25	0.067	0.014	0.04
MVI hours	0.47	0.22	48.23	<0.001
Severe ARDS	0.44	0.19	0.07	<0.001
Days of hospital stay	0.29	0.087	1.16	0.02
Use of arterial catheter	0.42	0.18	0.08	<0.001
Use of central venous catheter	0.58	0.35	0.14	<0.001
Glucose >150 mg/dL	0.32	0.10	0.06	0.01
Insulin treatment	0.32	0.10	0.06	0.01
Pneumothorax	0.37	0.13	0.02	0.004
Unexpected cardiorespiratory arrest	0.45	0.20	0.04	<0.001
PORT scale	0.31	0.09	8.46	0.02
SOFA	0.78	0.60	1.98	<0.001
SOFA Renal	0.56	0.31	0.32	<0.001
SOFA Renal	0.61	0.37	0.32	<0.001
SOFA Hepatic	0.89	0.79	0.29	<0.001
SOFA Cardiovascular	0.58	0.34	0.45	<0.001
SOFA Hematologic	0.85	0.73	0.23	<0.001
SOFA Neurologic	0.65	0.42	0.37	<0.001
SAPS 3	0.47	0.22	3.54	<0.001
Mortality SAPS 3	0.46	0.21	0.05	<0.001
qSOFA	0.55	0.30	0.20	<0.001
4C Mortality Score	0.40	0.16	0.72	0.002
4C Mortality Score Intermediate Risk	-0.34	0.11	-0.07	0.008
4C Mortality Score Very High Risk	0.39	0.15	0.05	0.003
Mortality percentage due to 4C Mortality Score	0.31	0.09	0.03	0.01

Table 2: Pearson correlation analysis for association with mortality in patients with COVID 19 treated in the respiratory unit of Clinica México.

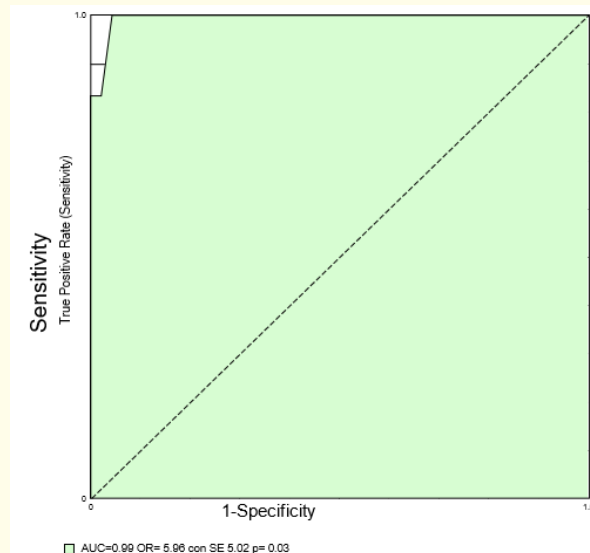
Abbreviations: VMI: Invasive Mechanical Ventilation; ARDS: Acute Respiratory Failure Syndrome; SOFA: Sequential Organ Failure Assessment; SAPS3: Simplified Acute Physiologic Score 3; qSOFA: quickSOFA. PORT: Pneumonia Patient Outcomes Research Team.

The mortality prediction capacity of the SAPS 3, SOFA, qSOFA, PORT and 4C Mortality Score scales was evaluated with COR curves and calculation of MR (odds ratio) (Graphs 1-5).



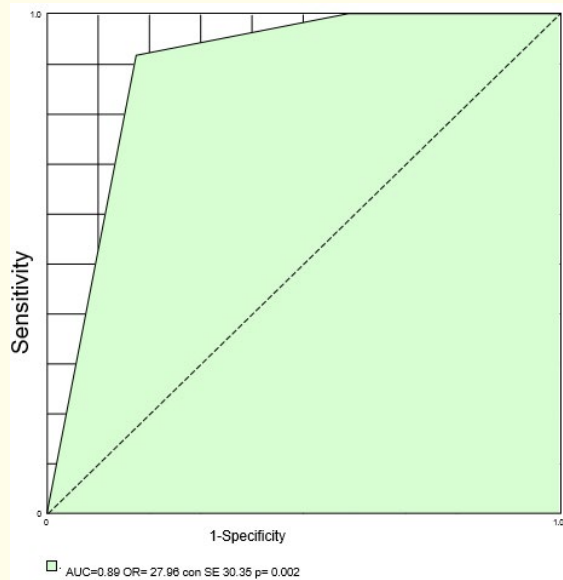
Graph 1: ROC SAPS 3.

Abbreviations: ROC: Receiver Operator Curve; SAPS 3: Simplified Acute Physiologic Score 3; OR: Odds Ratio; SE: Standard Error; AUC: Area Under the Curve.



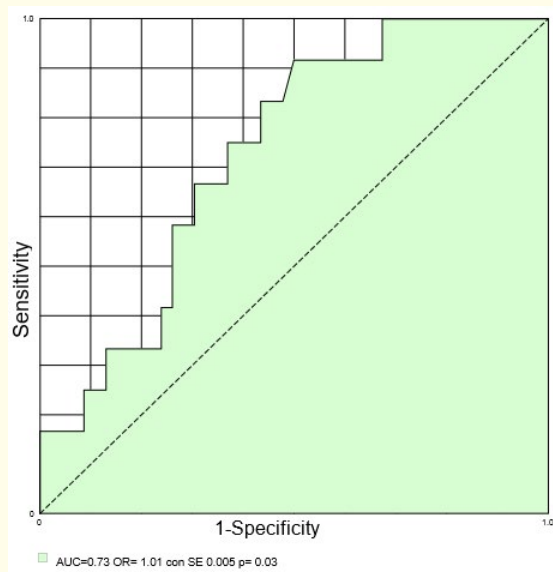
Graph 2: ROC SOFA.

Abbreviations: ROC: Receiver Operating Characteristics; SOFA: Sequential Organ Failure Assessment; OR: Odds Ratio; SE: Standard Error; AUC: Area Under the Curve.



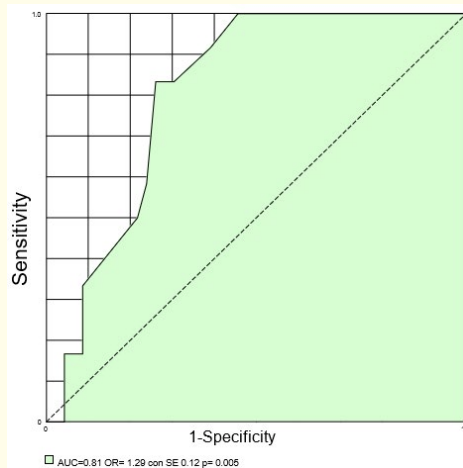
Graph 3: ROC qSOFA.

Abbreviations: ROC: Receiver Operating Characteristics; SOFA: Sequential Organ Failure Assessment; OR: Odds Ratio; SE: Standard Error; AUC: Area Under the Curve.



Graph 4: ROC PORT.

Abbreviations: ROC: Receiver Operating Characteristics; SOFA: Sequential Organ Failure Assessment; OR: Odds Ratio; SE: Standard Error; AUC: Area Under the Curve.



Graph 5: ROC 4C mortality score.

Abbreviations: ROC: Receiver Operating Characteristics; SOFA: Sequential Organ Failure Assessment; OR: Odds Ratio; SE: Standard Error; AUC: Area Under the Curve.

Discussion

In our prospective study of mortality prediction with the SAPS 3, SOFA, qSOFA, PORT and 4C Mortality Score scales in patients with COVID19, a total of 58 patients were recruited with a mean age of 51.05 years and a predominance of males with 74.1%, this is similar to what was reported by Galicia C and collaborators [36] in Mexican patients with COVID 19 with a mean age of 58.45 years, male sex in 58.4% and Montalvo, M and collaborators [37] with 56.1% over 50 years, male sex 64.1%. Regarding the international literature, Artero, A and collaborators [38] in Spain reported a mean age of 66 years and male sex of 57.9%. Kurtz, P. and collaborators [39] in Brazil reported an age of 55 years.

The mortality that our cohort presented was 20.7%, this is a little lower than that reported in the international literature; In the United Kingdom it was reported 32.2% [33], Spain 20.9% [38]. In Mexico, 25% [36] to 47.4% [37] have been reported. The variables prior to patients' admission to the unit (age, sex, previous health status) did not have a statistically significant correlation with mortality, this is different from what was reported in the literature. In China [40] the factors associated with higher mortality were age over 80 years, elevated biomarkers (LDH, CRP, procalcitonin, D-Dimer, Troponin), SOFA, previous history such as diabetes mellitus, hypertension and COPD.

Regarding the severity scales that we analyzed, the usefulness of these tools for predicting mortality was demonstrated, obtaining AUC greater than 0.70 in the four scales (all $p < 0.05$), with SOFA being superior with AUC 0.99 $p=0.03$. This is similar to what is reported in the international literature with AUC of PORT, SOFA, qSOFA and SAPS 3 of 0.83, 0.86, 0.72 and 0.83 respectively [38,40].

The 4C Mortality Score had AUC 0.81, this result was higher than that reported in the literature with AUC 0.79 [33].

The PORT, SOFA and qSOFA scales were not created specifically for mortality, however over the years they have demonstrated their usefulness in this area in various publications [38]. The SOFA demonstrated to have the best predictive capacity for mortality, this may be due to the fact that all the 6 parameters that evaluate this scale had a statistically significant correlation with mortality, in comparison with the SAPS3, PORT and 4 C Mortality Score scales that They have a greater number of parameters. The qSOFA scale had a lower mortality prediction capacity (AUC 0.89) compared to SOFA, however it was superior to the other scales. It also has the strength of being

practical, being able to be performed at the patient's bedside and not requiring laboratory results. The PORT scale, although it obtained a lower predictive capacity value for mortality in this cohort (AUC 0.73), is useful in this group of patients, in addition to being one of the recommended scales for the stratification and prognosis of community-acquired pneumonia [3,4].

The 4C Mortality Score is the only scale designed specifically for mortality in COVID19 [33], the parameters used between clinical and laboratory are simple and accessible to most hospitals. This scale demonstrated that all the parameters obtained in its calculation (numerical value of severity, risk group categorization and percentage of predicted mortality) had a statistically significant correlation with mortality; These results may explain its better mortality prediction capacity in this cohort vs. the original creation group (0.81vs. 0.79) [33].

This study has several limitations: the sample size and the conduct in a single care center may increase bias and decrease the power of our data. The strengths derive from its prospective characteristic, a very low patient exclusion rate was reported (2 patients) and so far it is the only study in the Mexican population that reports the predictive capacity for mortality of these 4 scales in patients with COVID 19.

Conclusion

The SAPS 3, SOFA, qSOFA, PORT and 4C mortality score scales are useful as tools for predicting mortality in Mexican COVID 19 patients. The use of these tools can improve patient profiling to better distribute care resources, which are limited in most centers in the country. It is necessary to evaluate these results in a larger cohort and in other units with characteristics different from ours.

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