Cross-sectional Study

ANNALS OF MEDICINE & SURGERY

OPEN

Predictive performance of SOFA (Sequential Organ Failure Assessment) and qSOFA (quick Sequential Organ Failure Assessment) for in-hospital mortality in ICU patients with COVID-19 of referral center in the north of Iran a retrospective study

Alireza Nikzad Jamnani, MD[a], Afshin Gholipour Baradari, MD[b], Saeed Kargar-soleimanabad, MD, MPH[c], Sepehr Javaheri, MD[d,*]

Introduction: Patients diagnosed with Coronavirus disease 2019 exhibit varied clinical outcomes, with a reported mortality rate exceeding 30% in those requiring admission to the ICU. The objective of this study was to assess the predictive capacity of Sequential Organ Failure Assessment (SOFA) and quick Sequential Organ Failure Assessment (qSOFA) scores in determining mortality risk among severe COVID-19 patients.

Method and materials: This retrospective study was performed by analyzing the data of patients with COVID-19 who were hospitalized in the ICUs. Data collection of the parameters required to calculate the SOFA and qSOFA Scores were extracted from patient's medical records. All data analysis was performed using SPSS V.25. Significance level considered as *P* less than 0.05.

Findings: In this study, 258 patients were included. The results showed that the subjects ranged in age from 21 to 98 years with a mean and SD of 62.7 ± 15.6. Of all patients, 127 (49.2%) were female and the rest were male. The mortality rate was 102 (39.5%). The underlying disease of diabetes mellitus with an odds ratio of 1.81 (CI = 1.02–3.22) had a significant effect on mortality. In addition, a significant correlation was obtained between admission duration and SOFA score (r = 0.147, *P* = 0.018). The SOFA had a very high accuracy of 0.941 and at the cut-off point less than 5 had a sensitivity and specificity of 91.2% and 82.7%. In addition, qSOFA had high accuracy (0.914) and a sensitivity and specificity of 87.3% and 91.7% at the optimal cutting point of greater than 1.

Conclusion: The findings of present study illustrated that deceased COVID-19 patients admitted to the ICU had higher scores on both SOFA and qSOFA scales than surviving patients. Also, both scales have high sensitivity and specificity for anticipating of mortality in these patients. The underlying diabetes mellitus was associated with an increase in patient mortality.

Key words: Covid-19, Intensive Care Unit, Mortality, qSOFA, SOFA

Introduction

The global spread of COVID-19 caused by SARS-COV2 has been rampant since its emergence in Wuhan, China in December 2019, resulting in numerous fatalities worldwide. The causative agent of this disease belongs to the extensive family of coronaviruses, characterized by single-stranded RNA and capable of infecting various living organisms, particularly birds and mammals[1,2].

Numerous studies have been conducted on the epidemiological and clinical characteristics of COVID-19, which primarily presents as pneumonia in patients. The initial symptoms include fever, cough, and shortness of breath, and chest X-rays reveal bilateral infiltration in some cases. Additional symptoms include upper respiratory tract problems, myalgia, diarrhoea, and anosmia or ageusia[3]. A subset of patients exhibits severe manifestations that necessitate hospitalization and intensive care, such as pneumonia, acute respiratory failure, sepsis, septic shock, cardiomyopathy and arrhythmias, and long-term complications like secondary

HIGHLIGHTS

- COVID-19, which is caused by the SARS-COV2.
- This retrospective study was performed by analyzing the data of patients with COVID-19 who were hospitalized in the ICUs of Fatemeh Al-Zahra Hospital in Sari.
- The findings of present study reveals that Both scales have high sensitivity and specificity for anticipating of mortality in these patients.

[a]Department of Anesthesiology and Critical Care, [b]Diabetes Research Center and Orthopedic Research Center, Faculty of Medicine, [c]Student Research Committee, Faculty of Medicine and [d]Medical Research Center, Mazandaran University of Medical Sciences, Sari, Iran

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

*Corresponding author. Address: Medical Research Center, Mazandaran University of Medical Sciences, Sari, Iran Tel.:+983 335 0670; fax:+98 33363754. E-mail: sepehr.javaheri@yahoo.com (S. Javaheri).

Annals of Medicine & Surgery (2023) 85:5414–5419

Received 18 June 2023; Accepted 6 September 2023

Published online 22 September 2023

http://dx.doi.org/10.1097/MS9.0000000000001304

bacterial infections, thromboembolism, gastrointestinal bleeding, polyneuropathy, and myopathy[4]. However, there is limited information on prognostic factors and risk factors associated with mortality. Recent studies indicate that critically ill patients with COVID-19 have a mortality rate ranging from 11 to 61%[5]. Patients with COVID-19 exhibit diverse outcomes, with ~1.3% requiring admission to the ICU, and those admitted to the ICU experiencing a mortality rate exceeding 30%[5]. Accurately predicting the outcome of ICU-admitted patients is crucial, as it can inform treatment decisions, enable performance evaluations and comparisons of ICU facilities, and establish correlations between critical illness and recovery rates[6].

Currently, there is no established method for evaluating the condition and prognosis of COVID-19 patients. However, it is possible to predict the mortality of critically ill patients by utilizing existing scoring criteria[1]. Among the criteria used for predicting patient outcomes are the acute physiology and chronic health evaluation (APACHE), sequential organ failure assessment (SOFA) score, quick sequential organ failure assessment (qSOFA), and others[6] The SOFA scoring method, along with its more recent criterion, qSOFA, can aid physicians in predicting patient prognosis and mortality[5]. The SOFA scoring standard was developed by a group of experts in 1996[7]. The SOFA score is a scoring system that evaluates the performance of several organ systems in the body, including the neurologic, blood, liver, kidney, and blood pressure/hemodynamics systems. Each organ's performance is scored on a scale from 0 to 4, and the total score is expressed as a single score ranging from 0 to 24. A higher score indicates a worse patient condition, with a SOFA score above 15 being associated with more than 90% of patient deaths[8].

The qSOFA score was introduced as a rapid method for assessing patients in the Sepsis-3 consensus definitions for sepsis and septic shock. It consists of three criteria, including systolic blood pressure less than 100 mmHg, tachypnea greater than 22 breaths per minute, and altered mental status, with scores ranging from zero to three. This screening tool has been found to be useful in clinical practice[5]. Despite not being originally intended for mortality prediction, both the SOFA and qSOFA scores have been investigated in numerous diseases to evaluate their predictive capabilities. For instance, a study conducted in 1999 aimed to establish a correlation between patient mortality in the ICU and their SOFA score. The results indicated that patients with a SOFA score exceeding 11 or an average score exceeding 5 upon admission had a mortality rate exceeding 80%[6].

However, no correlation was found between patients' SOFA score and length of hospital stay in the ICU[6]. Therefore, the relationship between SOFA scores and qSOFA score in COVID-19 patients to predict their mortality is controversial and worth considering. The aim of this study is to evaluate the performance of the SOFA and qSOFA criteria in patients with COVID-19.

Materials and methods

Study design

This retrospective, single-centre study was performed by including data from patients with severe COVID-19 who were hospitalized in the ICU between March 2020 and July 2020, Current study is reporting in line with the STROCSS criteria[9].

Participant

Participants included in the study had met the following criteria: (1) severe patients had been admitted to the ICU of Hospital between March 2020 and July 2020 based on positive polymerase chain reaction test for COVID-19 on a nasopharyngeal swab; (2) complete laboratory and clinical data in medical record systems; (3) were over 18 years of age. Patients with missing data, pregnant women, and patients under 18 years of age were excluded.

In this Study Severe disease defines as Individuals who have SpO_2 less than 94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO_2/FiO_2) less than 300 mmHg, a respiratory rate greater than 30 breaths/min, or lung infiltrates greater than 50%.

Cardiovascular: a type of disease that affects the heart or blood vessels.

Before any evaluation or use of data of patients, written informed consent was obtained from all patients.

Data collection

Researchers collected patient demographic, laboratory, and clinical data from the medical record system in April 2020. Data collection was by completing the designed form by the researchers and the parameters required to calculate the SOFA and qSOFA Scores were extracted for each patient at ICU admission. Oxygenation index [blood oxygen tension (PaO2)/fraction of Inspired oxygen (FiO2)], mean arterial pressure, need for vasopressor, Glasgow Coma Scale, creatinine or urine volume, bilirubin, and platelets for respiratory, circulatory, neurological, renal, hepatobiliary, and coagulation systems are needed component to compute SOFA, and systolic blood pressure less than or equal to 100 mmHg, respiratory rate greater than or equal to 22 breaths/min, and altered mental status are three clinical Parameters to calculate qSOFA. The data collection is strictly confidential and the information related to any of the patients has not been provided to the authors in such a way that they can be identified later.

Statistical analysis

Data were accessed for research purposes in May 2020, The characteristics of the subjects were reported in terms of quantitative variables with a mean (SD) and qualitative variables with a number (percentage). Compared to the above characteristics, the deceased and survivors were compared with a *t*-test. Receiver operating characteristic (ROC) curve was used to find the appropriate cut-off point and Youden Index was used to capture the performance of a dichotomous diagnostic test. These include sensitivity, specificity, Positive and Negative predictive values and 95% CIs were calculated. Logistic regression was used to control the effect of other variables (comorbidities). All data analysis was performed using SPSS software version 25. The Significance level is considered P less than 0.05.

Findings

Baseline characteristics

A total of 258 patients diagnosed with COVID-19 admitted to Hospital were included in this study the patients ranged in age from 21 to 98 years with a mean and standard deviation of

62.7 ± 15.6 years. The duration of hospitalization was between 1 and 35 days with a mean and standard deviation of 6.7 ± 7.7 (days). Of all patients, 127 (49.2%) were female and the rest were male. The most frequent comorbidities were diabetes mellitus at 87 (33.7%), hypertension at 121 (46.9%), cardiovascular disease at 92 (35.7%), chronic lung disease at 10 (9.9%), and chronic kidney disease with at 29 (11.2%). In ICU mortality rate of COVID-19 patients admitted to the ICU was 102 (39.5%). (Table 1)

There was no statistically significant difference in the duration of hospitalization, and the sex of patients based on the outcome ($P < 0.05$). This shows that patients in terms of age and sex have a similar distribution between the two groups.

However, a review of the underlying disease history of patients based on the outcome showed that diabetes mellitus in the deceased group was significantly higher than in the surviving group ($P = 0.041$). There were no other statistically significant differences underlying diseases between the two groups ($P < 0.05$).

Patients enroled in the study were evaluated for SOFA and qSOFA scores at the time of admission to the ICU, the median, and IQE of SOFA and qSOFA were 5.0 (3.0–9.0) and 1.0 (1.0–2.0) respectively.

The evaluation of SOFA and qSOFA at the beginning of admission to the ICU based on the outcome showed that the deceased had higher scores in both evaluations, which was statistically significant ($P = 0.000$). Also, a significant correlation was obtained between the length of hospital stay and SOFA score ($r = 0.147$, $P = 0.018$). (Table 2)

To more accurately evaluate the effect of each variable in the study, a logistic regression test was used. No significant relationship was found in other variables ($P < 0.05$).

To determine the sensitivity, specificity, positive and negative predictive value, and the positive and negative likelihood ratios for the SOFA and qSOFA evaluation criteria in COVID-19 patients, the ROC curve was plotted and the optimal cut-off point was found using the Youden Index. (Fig. 1) In the SOFA criterion, the area under the curve, which indicates the accuracy of the test, had a very high accuracy of 0.941, and at the cut-off point less than 5 had a sensitivity and specificity of 91.2% and 82.7%, the positive and negative predictive values were 77.5 and 93.5, respectively. Positive and negative likelihood ratios were 5.3 and 0.11, respectively.

Table 1

Baseline characteristics of the patients.

Variable	Overall	Survivors	Non-survivors
Total	*N* = 258	*N* = 156/60.5%	*N* = 102/39.5%
Sex			
Male	131/50.5%	79/50.6%	52/50.9%
Female	127/49.5%	77/49.3%	50/49.1%
Age			
Median	62.7	58.1	69.8
Comorbidities			
Hypertension	121/46.9%	60/37%	40/39%
cardiovascular	92/35.7%	55/35.2%	37/36.2%
Diabetes	87/33.7%	37/25.6%%	50/47%
CKD	29/11.2%	19/12.1%	10/9.8%%
COPD	10/9.9%	7/4.4%%	3/2.9%%
Length of ICU admission	6.7	8.1	4.5

CKD, Chronic kidney disease; COPD, Chronic obstructive pulmonary disease.

Table 2

SOFA and qSOFA scores at admission to ICU based on final outcome.

Score	Survived Median (IQR)	Deceased Median (IQR)	*P*
qSOFA	1.0 (0.0–1.0)	2.0 (2.0–3.0)	$P < 0.001$
SOFA	4.0 (2.0–5.0)	10.0 (7.0–11.0)	$P < 0.001$

IQR, interquantile range; qSOFA, quick sequential organ failure assessment; SOFA, sequential organ failure assessment.

SOFA and qSOFA associations with mortality and ROC curves

In this study association between SOFA and qSOFA with mortality and ROC curves is the main finding, In the qSOFA evaluation criterion, the accuracy of the test was high (0.914) and at the optimal cut-off point greater than 1 based on Youden Index J, it had a sensitivity and specificity of 87.3% and 91.7%, respectively. The positive and negative predictive values were 87.3% and 91.7%, respectively. Also, the positive and negative likelihood ratios were 10.5 and 0.14, respectively.

Discussion

The ICU is a specialized unit of medical centre that treats critically ill patients[10]. Patient status assessment systems have been developed to predict the outcome of patients, which can be used to predict and determine the death rate of patients[11]. Assessment systems help the medical staff assess the patient's chances of recovery and condition, and know the patient's physiological instability at the time of admission to the ICU by knowing the patient's prognosis. It is necessary in allocating and prioritizing facilities and optimizing care for patients[12].

Previous studies have shown that a higher SOFA score is associated with an increased mortality rate, so in patients who had a score of 0 to 5 at the time of admission, and whose score increased moderately or higher after admission to the ICU, the mortality rate increased by more than 50%[13]. Another study has shown that in the absence of organ failure, the death rate in the ICU is 3.2% and organ failure, increases the rate to 91.3%[14].

This study aimed to determine the predictive power of SOFA in the mortality rate of critically ill patients with COVID-19 disease. The results show that the SOFA score had a very high accuracy (0.941) and at the cut-off point less than 5 had a sensitivity and specificity of 91.2% and 82.7%, the positive and negative predictive values were 77.5% and 93.5%, respectively. Also, the positive and negative likelihood ratios were 5.3 and 0.11, respectively. In the qSOFA score, the accuracy of the test was high (0.914) and at the optimal cut-off point greater than 1 based on Youden Index J, it had a sensitivity and specificity of 87.3% and 91.7%, respectively. Also, the positive and negative predictive values were 87.3% and 91.7%, respectively. In addition, the positive and negative likelihood ratios were 10.5 and 0.14, respectively. SOFA and qSOFA scores at the admission time to the ICU based on the outcome showed that the deceased had

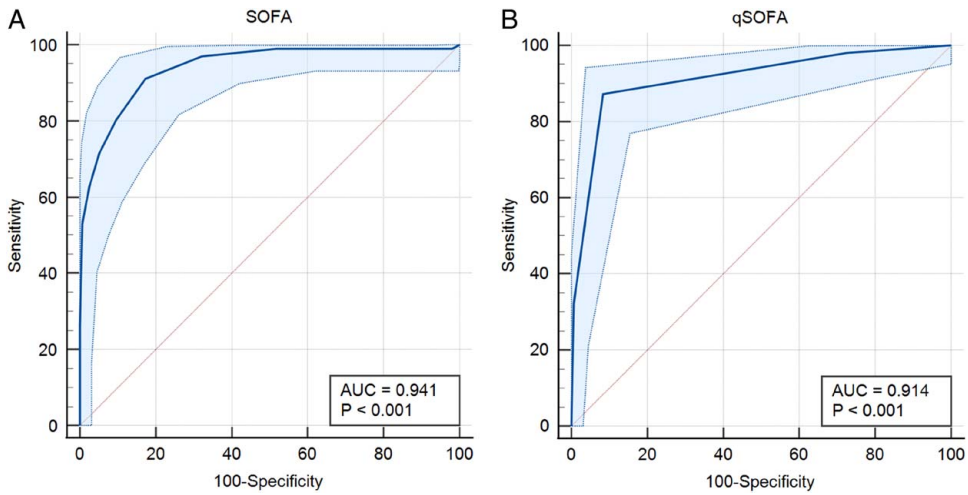

Figure 1. (A) ROC curve for SOFA score based on final outcome in COVID-19 patients. (B) ROC curve for qSOFA score based on final outcome in COVID-19 patients. AUC, area under the curve; qSOFA, quick sequential organ failure assessment; ROC, receiver operating characteristic; SOFA, sequential organ failure assessment.

higher scores in both evaluations, which was statistically significant ($P = 0.000$).

In the study of Hosseini and Ramezani[15] who evaluated the SOFA scoring system in predicting the outcome of 300 patients admitted to the vs., the results show that SOFA scores in the deceased group were significantly higher than the rescued group ($P = 0.001$). In the study of Sawicka *et al.*[16], to evaluate the effectiveness of SOFA in determining the prognosis of patients with haematologic malignancies admitted to the ICU, a higher SOFA score was an independent mortality risk factor. Kellner *et al.*[17] examined the predictive power of SOFA in patients with cardiogenic shock following myocardial infarction, examination of 41 critically ill patients revealed that the mortality rate was 44% and the SOFA score was significantly higher in a deceased group than the survivor group. San *et al.*[18], research on SOFA, qSOFA and, Brescia-COVID Respiratory Severity Scale (BRCSS) in assessing the severity of the disease in COVID-19 patients showed that SOFA score was significantly higher in the deceased than in the survivors so that the median SOFA score in the deceased group was 8. Similarly, in the study by Zhou *et al.*[19], the SOFA score was 5.4 in the deceased group and 1 in the surviving group. In addition, San *et al.*[18] reported excellent test accuracy (0.958), sensitivity, and specificity of 89.1% and 91.6%, respectively. In the study of Wang *et al.*[20] In Wuhan, China, SOFA scores above 4 had a significant relationship with mortality. These findings are consistent with the present study. The discrepancy between the SOFA scores in these studies may be due to the severity of the disease in the studies, so similar to the present study, all studies that examined critically ill patients reported higher scores.

In contrast, in Hosseini and Ramezani's[15] study, the accuracy of SOFA evaluation based on the ROC curve was poor and reported as 63.4%. At the cut-off point of 5.5, sensitivity and specificity were 57.3 and 67%, and positive and negative predictive values were 39.5% and 80.7%, respectively. This difference may be due to the inclusion criteria of all patients admitted to the surgical and ICUs of the two hospitals who had a lower mortality rate of 25% than the present study, while in our study only critically ill patients with COVID-19 were included and the mortality rate is about 39.5%. The mortality rate of hospitalized patients due to COVID-19 in the study of Bhargava *et al.*[21] and Auld *et al.*[22] who examined critically ill patients were more than 30% and in the study of Gupta *et al.*[23] Who studied critically ill patients with COVID-19; the mortality rate has been reported as 35.4%.

The qSOFA scale has been introduced by the Third International Conference on the Definition of Sepsis and Septic Shock (Sepsis-3) and has a more accurate prognosis of inpatient mortality in patients with SIRS and severe sepsis[24]. In the present study, patients with COVID-19 who died had a higher qSOFA score upon admission to the ICU. In the study of Bhargava *et al.*[21] , the mortality rate with increasing qSOFA score has shown a significant increase. The findings of Jang *et al.*[25] show that the scores of the qSOFA scale are significantly higher in critically ill patients than in other patients, which is consistent with the findings of the present study.

San *et al.*[18] reported excellent test accuracy (0.961) for the qSOFA scale scores and a sensitivity and specificity of 97.8% and 88.7% at the optimal cut-off point greater than 1 based on the Youden Index J. Which is in line with the findings of the present study. Halim *et al.*[26] Showed that the use of the qSOFA scale in predicting mortality and length of stay of patients in the ICU is superior to the Apache II scale. Also, the study of Artero *et al.*[27] Shows that in the evaluation of mortality of patients with COVID-19, qSOFA had the highest specificity (95.7%) among other evaluation criteria.

However, in the study of Artero *et al.*[27] , the sensitivity of qSOFA for prognosis of mortality in patients with COVID-19 has been reported to be as low as 26.2%. According to the evaluation of all patients admitted to different wards of the hospital due to COVID-19 and the lower mortality rate in these patients, which was reported to be 20.9%, could be the reason for the discrepancy with the findings of our study, the mortality rate was about twice as high, which was due to study of critically ill COVID-19 patients hospitalized in the ICU.

In the present study, a direct and significant relationship was found between the scores of the SOFA system and the duration of hospitalization, so the higher the SOFA score, the longer the patient was hospitalized in the ICU. Other studies showed that the SOFA scoring system is a good tool for determining the length of stay in the ICU and there is a significant relationship between the SOFA score and the length of stay in patients[28]. Mahjubipour *et al*.[29] evaluated the efficiency of SOFA scoring system in predicting mortality and length of stay of patients in the ICU with 107 patients over 4 months, the SOFA score at admission time had a significant relationship with the length of stay ($P = 0.007$). Milic *et al*.[30] Examination of the correlation between SOFA and length of stay in the cardiac ICU showed that there is a significant relationship between SOFA score and length of stay in the ICU, which is consistent with the findings of the present study.

In our study, the most common underlying diseases were hypertension (46.9%), cardiovascular disease (35.7%), and diabetes mellitus (33.7%), chronic kidney disease (11.2% pain), and chronic lung disease (3.9%). Diabetes mellitus had a significant effect on mortality with an odds ratio of 1.81 (CI 95%: 1.02–3.22). Artero *et al*.[26] , a retrospective and multicenter cohort of 10 238 patients in the evaluation of COVID-19 pneumonia severity, showed that the most frequent underlying diseases were hypertension (49.2%), diabetes mellitus (18.8%) and chronic lung disease (12.8%).after adjusting for comorbidities and age, the predictive value of qSOFA and SOFA mortality scores remains high which reveals the same results as Citu and colleagues study.

Conclusion

The results of the current study illustrated that deceased COVID-19 patients admitted to the ICU had higher scores on both qSOFA and SOFA scales than surviving patients. In addition, both scales have high sensitivity and specificity for predicting mortality in these patients. And, can be used widely in these patients.

Limitations

In this study, the number of participants is not too much, and conducted as a single-centre study; further studies have to perform with more participants and in a multicenter setting.

Ethical approval

The Ethics Committee of University of Medical Sciences and National Ethics Committee approved this study and it was carried out following the principles of the Helsinki Declaration.

Consent

Written informed consent was obtained from the patients for publication and any accompanying images. Copies of the written consent are available for review by the Editor-in-Chief of this journal on request.

Sources of funding

None.

Author contribution

S.J. and A.N. involved in interpretation and collecting of data, and editing the manuscript A.G., S.K., involved in writing, editing and preparing the final version of manuscript. All authors reviewed the paper and approved the final version of the manuscript.

Conflicts of interest disclosure

All the authors declaration they have no conflict of interest.

Research registration unique identifying number (UIN)

Current study registered in: research registry Unique Identifying Number (UIN): researchregistry9105 Hyperlink to our specific registration: https://www.researchregistry.com/browsethe- registry#home/registrationdetails/6478bf3787a4bd0026e3d626/.

Guarantor

Sepehr Javaheri.

Availability of data and materials

Data and materials are available from the corresponding author on reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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