Original Article DOI: https://doi.org/10.18502/fem.v5i3.5891

Seven Criteria of Severe COVID-19 (SCSC): A New Pre-Hospital Prognostic Scoring Tool Suggested for Screening of Probable/Confirmed COVID-19 Patients with Severe Outcomes

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Published online: 2020-01-19

Abstract

Introduction: COVID-19 pandemic led to various consequences in medical care that had been long provided for the patients referred to the hospitals.

Objective: We conducted this study to derive and validate a new scoring system that can accurately differentiate COVID-19 patients who may have a worse outcome from others at the prehospital stage.

Methods: This study was performed on probable/confirmed COVID-19 patients, who were transferred to the hospitals by Tehran emergency medical services (EMS). Occurrence of one of the items including: in-hospital death, intensive care unit (ICU) admission, or hospitalization for more than 20 days was considered to indicate a "severe disease". Univariate and multivariate logistic regression were used for assessment of the relationship between all independent variables and the outcome. In the validity assessment step, area under the receiver operating characteristic (ROC) curve was calculated for a data set independent from the data based on which the model was designed. The sensitivity and specificity were also presented based on the best suggested cut-off point.

Results: In this study, the data of 557 cases were analyzed in the derivation step and 356 cases were assessed in the validation step. The univariate logistic regression showed that age, weakness and fatigue, disease history, systolic blood pressure, SpO2, respiratory rate, and Glasgow coma scale (GCS) were statistically significant in severe disease group. The area under the ROC curve (AUC-ROC) of the tool was 0.808 (95% CI: 0.779, 0.834). The best cut-off point for screening was the score of ≥4, in which the sensitivity and specificity of the tool for the best cut-off point were 71.87% and 78.06%, respectively. In the validation step, the AUC-ROC of the tool was 0.723.

Conclusions: Seven criteria of severe COVID-19 (SCSC) tool could properly differentiate probable/confirmed COVID-19 patients with severe outcomes in the pre-hospital stage.

Key words: Clinical Decision Rules; COVID-19; Emergency Medical Services; Patient Outcome Assessment

Cite this article as: Saberian P, Tavakoli N, Hasani-Sharamin P, Kheyrati L, Younesian S, Rafiemanesh H. Seven Criteria of Severe COVID-19 (SCSC): A New Pre-Hospital Prognostic Scoring Tool Suggested for Screening of Probable/Confirmed COVID-19 Patients with Severe Outcomes. Front Emerg Med. 2021;5(3):e29.

INTRODUCTION

COVID-19 pandemic led to various consequences in medical care that had been long provided for the patients referred to the hospitals (1, 2). It is well-known that the disease can present with a wide range of manifestations from asymptomatic infection to severely morbid disease. Although most patients are affected with a minor illness, but still some are affected with a severe form that necessitates being hospitalized or even admitted to intensive care unit (ICU) (3). The pandemic overwhelmed and increased the workload of medical staff both at the prehospital and hospital stages, as a considerable number of people seek care in dealing with COVID-19. Apparently, most of the patients who call the Emergency Medical Services (EMS) in this regard do not need any specific care but still, some must be transferred to hospitals (4, 5). Therefore, it seems that a scoring

system, which can predict the outcome, would be of great help for the triage of patients in this step. It is expected that such a scoring system can accurately differentiate those who may develop the severe form of the disease from the others (6, 7). There are several prehospital triage scoring systems that have been previously used in dealing with septic patients such as the qSOFA, SOFA, NEWS, and PRESEP (8-10); but we found that none of them have proper efficacy to predict death, ICU admission, and disease severity of COVID-19 patients. Therefore, we conducted this study to derive and validate a new scoring system that can accurately differentiate COVID-19 patients who may have a worse outcome from others at the prehospital stage.

Methods

Study design and setting

This study was performed on patients older than 16 years old who were transferred to the hospitals by Tehran EMS from February 20 until March 19, 2020, and were diagnosed as a probable or confirmed case of COVID-19 (11). Death at the scene, missing data in pre-hospital/hospital records, and unwillingness of the patient or his/her relatives to participate in the study were considered as exclusion criteria. The proposal of the study was approved by the ethics committee of Iran University of Medical Sciences (code: IR.IUMS.REC.1399.225). To adhere to the principles of confidentiality, all information was used anonymously throughout the study.

Study population

In this study, the relationship between 15 independent variables and the outcome was evaluated. Assuming a 20% prevalence of severe outcome (meeting one of the criteria of >20 days of hospitalization, ICU admission, or death) in probable COVID-19 cases, and considering 10 patients per independent variable, we needed 750 patients to examine the relationship between the independent variables and dual state outcome using logistic regression. Also, assuming 15% sample loss in follow-up, the minimum required sample size in this study was 865. Sampling was based on the transferred COVID-19 missions from February 20, 2020 until March 19, 2020), and was performed using simple random sampling. All included patients were followed up within two months after the call (mission) for the intended outcomes of the study.

Data gathering

The information of the patients at the pre-hospital stage was extracted from the data registry of Tehran EMS center using a pre-prepared checklist. The required data included demographic information (age, gender), accompanying symptoms (fever, shortness of breath, weakness, and fatigue), past medical history (diabetes mellitus, cardiovascular disease (CVD), respiratory disease), and vital signs (systolic and diastolic blood pressure, SpO2, respiratory rate, pulse rate, tympanic temperature, and Glasgow coma scale (GCS)).

Outcome assessment

We aimed to derive a scoring system to differentiate patients with severe form of COVID-19 disease from the others. Due to the limited capacity of the ICU beds, it was impossible to admit all patients (despite their need) to the ICU; Therefore, beside in-hospital death and ICU admission, we considered hospitalization for more than 20 days as an indicator of severe disease. The outcome of the patients was assessed through a telephone follow-up.

Data validity

To assess the validity of the proposed tool, the data in the registry database of the Ministry of Health was used to screen the patients. The minimum sample size required for testing the validity of the tool was calculated to be 360, based on assuming 75% sensitivity for the proposed screening tool, 20% prevalence of severe outcome in probable COVID-19 patients, 10% probability of error in estimation of sensitivity, and a type 1 error of 5%. For this purpose, from all probable COVID-19 cases recorded during the period from February 20, 2020, to July 21, 2020, 360 cases were selected, using random sampling, and the patients' outcome was investigated through integrating the data with the hospital data. In evaluating the validity of the proposed tool for screening probable COVID-19 patients at the scene, patients with severe disease were those who had one of the criteria of hospitalization >20 days, ICU admission, or death.

Statistical analysis

After providing descriptive data, the variables were compared in the two groups of patients with severe and non-severe disease. For quantitative variables, the mean difference between the two groups was analyzed using Independent T-test, and for qualitative variables, the frequency distribution difference between the two groups was evaluated using $\chi 2$ test. Using Univariate logistic regression test, the relationship between all variables and the dual state outcome of the study was investigated, and finally, the Multivariate model was applied using the Backward Stepwise (Likelihood Ratio) method. To calculate the cut-off points of the

remaining quantitative variables in the final model of predicting patients' prognosis, J-Youden index and the Clinician's opinion were used. In addition, different cut-off points were assessed and the best cut-off points and the scores of the variables were calculated for screening and the best scenario was selected based on the area under the receiver operating characteristic (ROC) curve (AUC-ROC) index. The best cut-off point for the final screening score of patients at the scene was selected using the J-Youden statistics. In examining the validity, the area under the ROC curve was calculated for a data set independent from the data based on which the model was designed. The sensitivity and specificity were also presented with 95% confidence interval based on the best suggested cut-off point. All analyzes were performed using STATA software version 14.

Results

Basic information

In this study, the data of 821 individuals with probable/confirmed COVID-19 diagnosis were analyzed. In total, 376 (45.8%) were male and the rest were female. The mean age of studied patients was 55.8 years (standard deviation (SD) = 17.8), and patients with severe disease were significantly older than those with non-severe disease (70.9 vs 52.1, P-value<0.001). The prevalence of severe illness was 19.5%.

Of all patients, 104 (12.7%) died, 105 (12.8%) were admitted to the ICU, and 24 (2.9%) were hospitalized for more than 20 days. Also, of all patients, 354 (43.1%) were not hospitalized (did not need to be hospitalized) and 130 (15.8%) were hospitalized for 1-3 days. The overall mean length of hospital stay for the studied patients was 4.4 days (SD = 6.8). Of all patients, 61.9% in the severe group and 49.5% in the non-severe group had symptoms of weakness and fatigue, and this difference was statistically significant (P-value = 0.005). History of diabetes, cardiovascular diseases, or respiratory diseases was significantly more prevalent among patients in severe group (P-value <0.05). The mean percentage of SpO2 for patients with severe disease was 87.2%, which was significantly lower than that of patients with non-severe disease (P-value <0.001). Mean Respiratory Rate was also significantly higher in patients with severe disease (17.7 vs 17.2, p = 0.032). Moreover, 7.5% and 1.5% of patients in severe and non-severe groups had GCS <15, respectively (P <0.001) (Table 1).

The univariate logistic regression showed that age, weakness and fatigue, disease history, systolic blood pressure, SpO2, respiratory rate, and GCS were statistically significant different between the 2 groups. In the multivariate logistic regression model, old age (OR=1.06 per year), weakness and fatigue (OR=4.8), lower SpO2 (OR=19.6), and GCS lower than 15 (OR=2.1) had a significant role in predicting the severity of the disease in probable COVID-19 patients. Also, a positive history of diabetes (OR=1.03), CVD (OR=1.6) and higher respiratory rate (OR=1.1) were important and were kept in the model (Table 2). The Nagelkerke R Square for the multivariate logistic model was 0.338.

Table 1: Demographic and clinical characteristics of the studied patients in the severe and non-severe disease groups

	Non-severe (n=661); n (%) or mean (SD)	Severe (n=160); n (%) or mean (SD)	P-value
Age, year	52.1 (16.6)	70.9 (14.5)	<0.001
Sex, Male	290 (66.4)	86 (72.3)	0.222
Accompanying symptoms			
Fever	269 (40.7)	69 (43.1)	0.575
Shortness of breath	462 (69.9)	118 (73.8)	0.337
Weakness and fatigue	327 (49.5)	99 (61.9)	0.005
Disease history			
Diabetic	74 (11.2)	31 (19.4)	0.005
Cardiovascular disease	61 (13.4)	47 (37.0)	<0.001
Respiratory disease	40 (6.1)	18 (11.3)	0.021
Systolic blood pressure	119.1 (14.5)	123.3 (16.7)	0.004
Diastolic blood pressure	75.6 (8.2)	77.0 (9.3)	0.080
SpO_2	91.5 (5.5)	87.2 (8.1)	<0.001
Respiratory rate	17.2 (1.9)	17.7 (2.8)	0.032
Pulse rate	90.7 (14.2)	91.3 (17.1)	0.661
Temperature	38.1 (0.84)	38.1 (0.83)	0.642
GCS<15	10 (1.5)	12 (7.5)	<0.001
Definitive case of COVID-19	20 (12.7)	132 (22.3)	0.007

SD: Standard deviation; GCS: Glasgow coma scale

Table 3 shows the suggested scoring system. The best screening cut-off points for age and SpO2 were considered 60 and 80 years old, and 93% and 88%, respectively; and 20 breaths/min for respiratory rate. The point given to each of the items of age≥80, SpO2≤88%, and a positive history of CVD was 3, which is higher than other variables.

The Hosmer and Lemeshow goodness-of-fit test gave a P-value of 0.623, thereby showing that the model had a good fitting. The AUC-ROC of the screening tool was 0.808 (95% CI: 0.779, 0.834) (Figure 1). The best cut-off point for screening was a score≥4. The sensitivity and specificity of the tool in the best cut-off point were 71.87% (95% CI: 64.2%, 78.7%) and 78.06% (95% CI: 74.7%, 81.2%), respectively (Table 4).

Validity assessment

In the Validity Analysis stage of the proposed scoring tool, after excluding patients with missing data, the data of 356 individuals were analyzed,

Table 2: Univariate and multivariate logistic regression analyses

	Univariate				Multivariate			
	Wald	**OR**	**95% CI**	**P-Value**	**Wald**	**OR**	**95% CI**	**P-Value**
Age, year	115.5	1.08	1.07, 1.09	<0.001	74.3	1.06	1.05, 1.08	<0.001
Sex, Male	1.5	1.3	0.84, 2.1	0.223				
Accompanying symptoms								
Fever	0.31	1.1	0.78, 1.6	0.575				
Shortness of breath	0.92	1.2	0.82, 1.8	0.337				
Weakness and fatigue	7.8	1.7	1.2, 2.4	0.005	4.8	1.6	1.0, 2.4	0.029
Disease History								
Diabetic	7.5	1.9	1.2, 3.0	0.006	1.03	1.3	0.78, 2.2	0.311
Cardiovascular disease	41.2	4.1	2.7, 6.3	<0.001	3.8	1.6	1.0, 2.7	0.052
Respiratory disease	5.1	2.0	1.1, 3.5	0.023				
Systolic blood pressure	9.8	1.02	1.0, 1.03	0.002				
Diastolic blood pressure	3.6	1.02	0.99, 1.04	0.059				
SpO2	44.7	0.91	0.89, 0.94	<0.001	19.6	0.94	0.91, 0.96	<0.001
Respiratory rate	7.2	1.1	1.0, 1.2	0.007	2.8	1.1	0.99, 1.2	0.096
Pulse rate	0.24	1.0	0.99, 1.0	0.623				
Temperature	0.22	1.1	0.84, 1.3	0.642				
GCS<15	14.4	5.3	2.2, 12.4	<0.001	2.1	2.1	0.77, 5.7	0.148

CI: Confidence interval; OR: Odds ratio; GCS: Glasgow coma scale

Table 3: Variable, cut-off and score of suggested seven criteria of severe COVID-19 (SCSC) screening tool and result of its validity assessment

Variable		**Score**	**Result of validity data**
Age, year	≥80	3	66 (18.5)
	60-79	1	116 (32.6)
	<60	0	174 (48.9)
SpO_2	≤88%	3	102 (29.1)
	89-93%	1	125 (35.6)
	≥94%	0	124 (35.3)
Respiratory rate, breaths per minute	>20	1	22 (6.4)
	12-20	0	321 (93.6)
Diabetic	Positive	1	60 (16.9)
	Negative	0	296 (83.1)
Cardiovascular disease	Positive	3	63 (17.7)
	Negative	0	293 (82.3)
Glasgow coma scale	<15	1	40 (11.2)
	=15	0	316 (88.8)
Weakness and fatigue	Positive	1	207 (58.1)
	Negative	0	149 (41.9)

Table 4: Statistical values for each cut-off point of seven criteria of severe COVID-19 (SCSC) scoring model

Cut-off	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**PLR (95% CI)**	**NLR (95% CI)**
>1	91.25 (85.8, 95.1)	40.09 (36.3, 43.9)	1.52 (1.4, 1.6)	0.22 (0.1, 0.4)
>2	81.87 (75.0, 87.5)	64.90 (61.1, 68.5)	2.33 (2.1, 2.6)	0.28 (0.2, 0.4)
>3	71.87 (64.2, 78.7)	78.06 (74.7, 81.2)	3.28 (2.8, 3.9)	0.36 (0.3, 0.5)
>4	54.37 (46.3, 62.3)	89.26 (86.6, 91.5)	5.06 (3.9, 6.6)	0.51 (0.4, 0.6)
>5	29.37 (22.4, 37.1)	95.92 (94.1, 97.3)	7.19 (4.6, 11.2)	0.74 (0.7, 0.8)

NLR: Negative likelihood ratio; PLR: Positive likelihood ratio; CI: Confidence interval

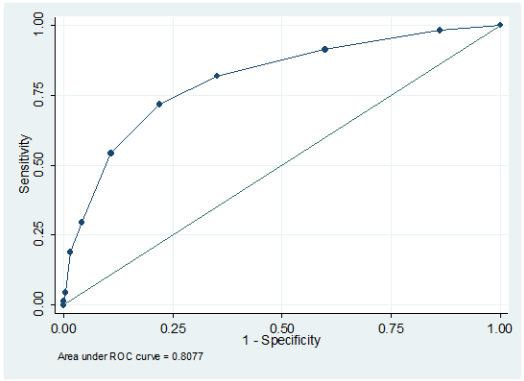

Figure 1: The Receiver operating characteristic (ROC) curve of seven criteria of severe COVID-19 (SCSC) screening tool in the studied patients.

214 (60.1%) of which were male. The mean age of patients was 59.4 years (SD = 19.5). 29.1% of patients had SpO2≤88% and 6.4% had respiratory rate (RR) >20. 16.9% and 17.7% of the total patients reported a history of diabetes and heart disease, respectively (Table 3). The outcome was severe in 81 of the studied patients (22.8%); out of which, 73 patients died in the hospital, and 8 were discharged after more than 20 days of hospitalization. The area under the ROC curve of the proposed instrument was 0.723. Also, at the proposed cut-off point, its sensitivity and specificity in screening of severe patients were 70.4% (95% CI: 59.2, 80.0) and 61.8% (95% CI: 55.8, 67.6), respectively.

Discussion

In this study, we suggested a new model, seven criteria of severe COVID-19 (SCSC), which can screen COVID-19 patients who may later face severe consequences in the prehospital stage; so that they can be prioritized over others who need less care and be transferred to the hospital more rapidly. This model was derived and also validated based on usually obtained information, which is easily available to EMTs when they tend to a patient. This simple tool is a clinical prediction rule that can help in triage of patients in the pre-hospital setting without the need for any paraclinical test. The need for such a tool is undeniable, because the future of COVID-19 pandemic is uncertain and no one can yet imagine its end; and it is commonly known that the disease has multiplied the workload of the emergency services, at both prehospital and hospital stages. In different countries, and after the initial peak of the disease, a relative decline in statistics was observed, but unfortunately, after the weakening of quarantine conditions, it increased again, and in fact, its future is not clear and predictable at all.

Pros and cons

What is obvious is that although this tool is not 100% accurate, it could still properly differentiate those with severe consequences from the others. In its best cut off point, which was statistically calculated as score ≥4, this tool has 71.87% sensitivity and 78.06% specificity. But if policymakers decide to use maximum sensitivity or specificity, other cut-offs must be considered proportionally. It is necessary to design another study with the same tool and objectives to accurately examine the validity of the tool and its power of prediction.

Limitations

The data used in the derivation phase of this study was collected in the first month of the epidemic, at which time, according to the instructions, almost all probable COVID-19 cases were transported to hospitals by the pre-hospital emergency. In fact, at that time, there was no tool for screening severe patients from non-severe ones. Therefore, the studied cases included severe to mild cases of COVID-19, and that is why we had a percentage of non-hospitalized cases in this study population. Also, at this stage, the cases were followed up by telephone two months after their call to the EMS. However, in the data used in the validity assessment phase, the required data was extracted from different populations and the outcome was based on hospital records and did not include possible deaths after discharge. Therefore, the different methods of investigating the outcome in these two study populations may be one of the reasons for the decline in accuracy indicators when examining the validity of the proposed tool.

Conclusions

In this study, we introduced a new prognostic scoring tool, seven criteria of severe COVID-19 (SCSC), which could properly differentiate probable/confirmed COVID-19 patients with severe consequences from others in the pre-hospital stage.

Acknowledgements

We would like to express our gratitude to the Prehospital and Hospital Emergency Research Center affiliated to Tehran University of Medical Sciences.

Authors' contribution

The conception and design of the work by HR, PS and SY; Data acquisition by PHS, NT and LK; Analysis and interpretation of data by HR and SY;

Drafting the work by HR, SY and LK; Revising it critically for important intellectual content by PS, NK and PHS.
All the authors approved the final version to be published; AND agree to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work will be addressed.

CONFLICT OF INTEREST

None declared.

FUNDING

This study was funded by a grant from Tehran EMS Center. The project was commissioned by the organization and the cost was paid to the contractor.

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