

Risk Stratification of COVID-19 Patients based on Proposed Simple Clinical Parameters Score: A Retrospective Observational Study

NIKET RAI¹, SATISH CHANDEL², MANU KUMAR SHETTY³, GEETA KATHEIT RAI⁴, SHRESHTH KHANNA⁵, KUNAL JAIN⁶

ABSTRACT

Introduction: India has impacted severely by multiple waves of Coronavirus Disease-2019 (COVID-19) and still struggling with limitation of resources to cater such a huge population. Available triage methods to treat COVID-19 are either too complex to use or time-consuming. A triage score, that should be independent of any laboratory investigations and exclusively based on clinical parameters was required, so that the healthcare provider at the first contact can segregate patients on the basis of intensity of care required to save, as many lives as, possible. Simple Clinical Parameters (SCIP) score may be a useful tool for fast triage of patients at the point of care and can help to screen patients, who will benefit from early hospitalisation, from those, who can be managed as outpatients.

Aim: To validate the usefulness of SCIP score in triage of COVID-19.

Materials and Methods: This single-centre, retrospective, observational study was conducted at a Tertiary Care Hospital. The duration of the study was six months, from November 2021 to May 2022. A total of 945 patients were involved in the present study. SCIP score was formulated using basic clinical parameters like Pulse Rate (PR), Respiratory Rate (RR), and arterial oxygen saturation at room air (SpO₂). The risk score ranges from 1 to 10. The lower the score, more severe the disease and hence,

more intense care is warranted. All the parameters required for calculating the SCIP score are continuous variables, expressed in mean±Standard Deviation (SD) and categorical data of patients in specific levels of care are represented as proportions. Data was collected and analysed using Microsoft Excel 2007 and the Python statistics module.

Results: The mean age of the study participants was 49.7±16.5 years. A total 945 patients were included in the study, out of which 552 (58.4%) were males and 393 (41.6%) were females. In more than half patients, the Level of Care (LOC) predicted by the proposed SCIP score, matched the actual LOC received. The mean scores were within the proposed score ranges. SCIP score was 97% sensitive in detecting the patients, who can be managed at Outpatient Department (OPD) and 99% specific in detecting those, who did not require intensive treatment at Intensive Care Unit (ICU). SCIP score showed the need for ICU with 92% accuracy and the patients, who can be treated at OPD, without requiring hospitalisation with 90% accuracy.

Conclusion: SCIP scoring system based on routine clinical parameters, is helpful in early detection of severity of the disease and in making a fast decision to predict the LOC required. A score based on clinical parameters ensures the availability of a fast and simple triage method to ensure optimal utilisation of available resources and help healthcare provider to make quick decisions.

Keywords: Coronavirus disease-2019, Pulse rate, Respiratory rate, Triage

INTRODUCTION

A severe healthcare system crisis occurred as a result of the COVID-19. It was a global health emergency that flooded Emergency Departments, with a huge number of patients and caused the system to collapse. By May 2022, World Health Organisation (WHO) reported 519,729,804 cumulative cases of COVID-19, globally and 43,125,370 cumulative cases in India. Cumulative deaths reported are 6,268,281 globally and 524,260 in India [1]. Private healthcare is expensive and unavailable for many poor households in India, which leaves public healthcare facilities as the only available option for them. Due to the large number of cases, that India was dealing with, a shortage of hospital beds, oxygen supply, intensive care facilities, and medical and paramedical staff became evident [2]. Limited resources have added more misery and despair to already diseased state of patients. Further, diagnostic and treatment delays resulted from massive influx of patients in laboratories for blood tests and radiological investigations. Hence, it was necessary to develop a triage method, which can give fast result to take quick decisions. A triage score, that should be independent of any laboratory investigations and exclusively based on clinical parameters was required so that, the healthcare provider at the first contact can segregate patients, on the basis of intensity of care required to save, as many lives as, possible.

Keeping this in mind, the authors have proposed SCIP score. A formula to calculate the score was developed using patient variables like PR, RR and SpO₂ since fever, cough and dyspnoea are very common symptoms observed in COVID-19 patients [3]. It is not dependent on any laboratory investigation and is very easy to use for severity assessment of COVID-19 patients. This scoring method may be a useful tool for fast triage of patients at the point of care and can help to screen patients, who will benefit from early hospitalisation from those, who can be managed as outpatients. The results of a preliminary observation of SCIP scoring criteria based on 10 patients, who presented to a private clinic in second week of April 2021, were encouraging [4]. However, validation of this scoring system in large number of patients needs to be established.

Thus, the present study has been planned to determine the utility of SCIP scoring system, for severity assessment and to correlate it with the LOC advised to the patients at the time of their first clinical contact.

MATERIALS AND METHODS

This single-centre, retrospective, observational study was conducted at a Tertiary Care Hospital. The duration of the study was six months, from Nov 2021 to May 2022. The study was started after obtaining approval from the Institutional Ethics Committee (F.1/IEC/MAMC/86/04/2021/No.503, dated 01/11/2021). Permission to access medical records from medical record department was taken.

Inclusion criteria: Patients of age above 12 years, who were confirmed positive for COVID-19, diagnosed either by Rapid Antigen Test (RAT) or by Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) test on nasal and pharyngeal swab specimens were included in the study.

Exclusion criteria: Patients of age 12 years or below and with underlying medical emergency conditions (malignant hypertension, liver cirrhosis, acute pancreatitis, cardiovascular disease, cerebrovascular disease, peripheral vascular disease) requiring immediate hospitalisation. Patients requiring hospitalisation for surgical intervention. Pregnant females and the patients with incomplete data were excluded from the study.

Sample size calculation: Simple Clinical Parameter score (SCIP) formula [4]:

SCIP score was formulated using clinical parameters like PR, RR and SpO₂ on room air, measured using pulse oximeter.

SCIP score = SpO₂ × 100 / PR × RR

A minimum of 1000 patients' record was evaluated. It was a convenience sample size based on earlier studies [5-10].

Study Procedure

The case file and the investigation reports of the COVID-19 patients admitted to the hospital from the period of March 2020 to January 2022 were evaluated, retrospectively. The study was planned and executed, including data analysis and interpretation. The severity of infection was judged by calculating the SCIP score. The score ranges from 1 to 10. Lower the score, more severe the disease and hence, more intense care is warranted. According to the scoring criteria, patients may be classified under different levels of care i.e., requiring hospitalisation either in the ICU or in the Critical Care Unit (CCU) for close monitoring or in the ward under medical supervision and outpatient management of low risk patients under home isolation [Table/Fig-1].

SCIP score proposed range	The predicted LOC	LOC defined
1 to 2.99	ICU	Critically ill, altered sensorium, poor GC, required invasive ventilation
3 to 4.99	CCU	Sick, critically ill, multiorgan failure, required inotropes, HFNO, NIV
5 to 6.99	Ward	Moderate or severe, vitals stable, requiring O ₂ NRBM/NIV not sick not critical
7 to 10	OPD	Asymptomatic or mild symptoms, vitals stable, SpO ₂ > 94%, RR <24, PR 60-100 beats/minute

[Table/Fig-1]: SCIP score proposed ranges to predict levels of care.

GC: General condition; HFNO: High flow nasal oxygen; NIV: Non invasive ventilation; NRBM: Non rebreather mask; ICU: Intensive care unit; CCU: Critical care unit; OPD: Outpatient department; LOC: Level of care

A performa was used to record gender, clinical features (symptoms, fever, PR, RR and peripheral oxygen saturation) and the actual LOC given to the patients. SCIP score was calculated using the formula and matched with the proposed range to predict the LOC. The predicted LOC, was then correlated with the LOC actually given to the patients.

STATISTICAL ANALYSIS

All the parameters required for calculating the SCIP score were continuous variables, expressed in mean±Standard Deviation (SD) and categorical data of patients in a specific LOC were represented as proportions. These tests were analysed using Microsoft office excel worksheet 2007 and Python (version 3.7) statistics modules. The sensitivity, specificity and accuracy of SCIP score were calculated using a performance matrix. True positive, false positive, true negative and false negative values were calculated using confusion matrix.

RESULTS

A total of 1108 patient's data were extracted from the case file and discharge summary. Out of which, 132 were incomplete as per study requirements. A total of 31 cases were excluded as per exclusion criteria laid down in the protocol. Finally, data of 945 patients were analysed, out of these 552 (58.4%) patients were males and 393 (41.6%) were females. The mean age of the patients was 49.7±16.5 years.

Clinical parameter analysis: The clinical parameters used to formulate SCIP scores were analysed individually from each LOC and presented as mean±SD. The mean SpO₂ level was observed to be higher in patients, whom less intense care was required while, the mean PR and RR of the patients were higher in levels, where more intense care was required [Table/Fig-2].

LOC/clinical parameters	OPD (n=38)	Ward (n=681)	CCU (n=61)	ICU (n=165)
SpO ₂	98±1	92±8	86±9.66	71±7.11
PR	78.47±9	94.14±16	96.03±22.22	102±18.18
RR	16±2	18.79±3	20.06±3.58	27±6.72

[Table/Fig-2]: Analysis of clinical parameters used to formulate SCIP score in respective Level Of Care (LOC).

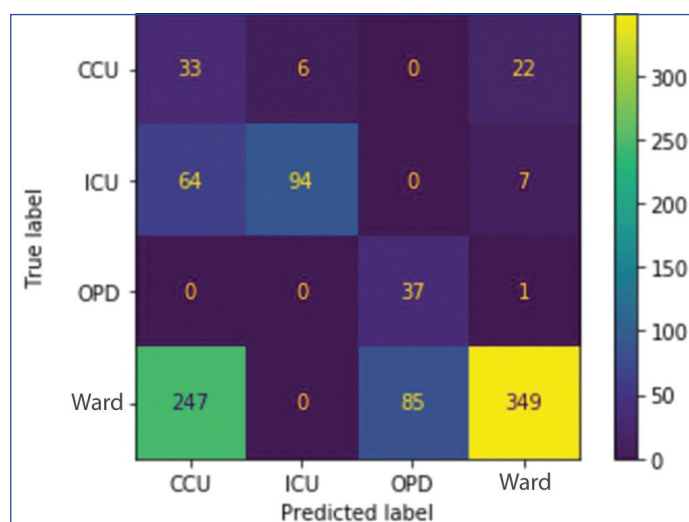
Data expressed in mean±Standard Deviation (SD). n: Number of patients. SpO₂, Arterial oxygen at room air; PR: Pulse rate; RR: Respiratory rate; OPD: Outpatient department; CCU: Critical care unit; ICU: Intensive care unit

Mean SCIP Score and Actual Level of Care (LOC): Out of 945 patients, 681 were admitted to the ward, 61 required CCU support, 165 were on invasive ventilation in ICU, and 38 were managed in OPD. In more than half of the patients, the LOC predicted by the proposed SCIP score matched with the actual LOC, received by these patients. This was observed to be the highest in OPD patients (97%) [Table/Fig-3,4].

Actual LOC	Number of patients, n=945	Within proposed range n (%)	Mean score±SD
OPD	38	37 (97)	7.94±0.75
Ward	681	349 (51.25)	5.54±1.47
CCU	61	33 (54)	4.85±1.64
ICU	165	94 (56.97)	2.91±0.95

[Table/Fig-3]: Patients within the proposed score range.

n: Number of patients; %: Percentage of patients; SD: Standard deviation; OPD: Outpatient department; CCU: Critical care unit; ICU: Intensive care unit; LOC: Level of care

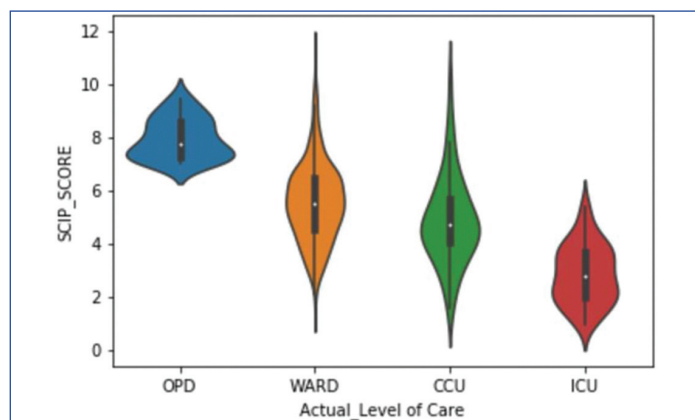


[Table/Fig-4]: [Confusion matrix] X-axis determines the true number of the patients in ward, OPD, CCU and ICU. Y-axis determines the number of patients predicted to be in ward, OPD, CCU and ICU. Right hand-side colour bar indicates the patients' number.

OPD: Outpatient department; CCU: Critical care unit; ICU: Intensive care unit

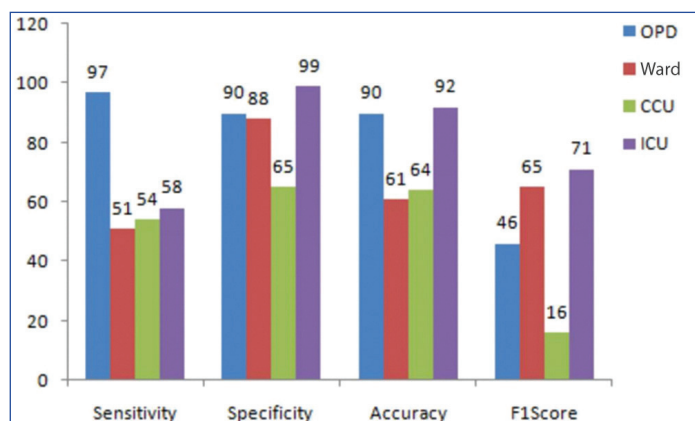
In each LOC there were patients, whose SCIP score was outside the proposed range. It was observed that, the SCIP score of 1 (3%) patient, who attended OPD was in the range of 5-6.99 which

corresponds to the ward level. Similarly, the score for around 332 (49%) patients admitted to the ward was outside the proposed range 247 (36%) patients had a score corresponded to CCU care and remaining had a score in the proposed range for OPD level. Likewise, the score for around 28 (46%) patients admitted to the CCU was outside the proposed range, out of which 6 (10%) had a score corresponds to the ICU, LOC and remaining to the ward level. Also, the score of 71 (43%) patients receiving ICU LOC was outside the proposed range with 64 (39%) corresponds to the CCU and rest to the ward LOC [Table/Fig-4]. It was observed that, the mean score of the patients receiving OPD LOC was 7.94, which was within the proposed score range of 7 to 10. Similarly, the mean score of patients admitted in the ward (5.45), CCU (4.85), and ICU (2.91) was within the proposed score range of 5 to 6.99, 3 to 4.99 and 1 to 2.99 respectively [Table/Fig-3-5].



[Table/Fig-5]: Violin plot to determine mean score in each LOC. X-axis showing mean of SCIP score, Y-axis showing LOC violin plot depicts the results of SCIP score for four groups (ward, ICU, OPD, and CCU). In the middle of each density curve is a small box plot, with the rectangle showing the ends of the first and third quartiles (interquartile range) and central dot is the median. The thin black line represents the rest of the distribution.
OPD: Outpatient department; CCU: Critical care unit; ICU: Intensive care unit

SCIP Score model performance: The performance of the SCIP score model was assessed by comparing multiple performance metrics: sensitivity, specificity and accuracy of the model. Sensitivity is the probability of identifying the true positives (the score correctly predicted the patients treated at particular LOC). Specificity, on the other hand, is the probability of correctly identifying the patients, who will not require a particular LOC (important for higher levels of care like CCU and ICU). Using confusion matrix [Table/Fig-4], True Positive (TP), True Negative (TN), False Positive (FP) and False Negative (FN) were calculated. SCIP score was 97% sensitive in detecting the patients, who can be managed at OPD and 99% specific in detecting those, who did not require intensive treatment at ICU. SCIP score detected the need for ICU with 92% accuracy and the patients, who can be treated at OPD without requiring hospitalisation with 90% accuracy [Table/Fig-6].



[Table/Fig-6]: Bar diagram showing the performance matrix of the SCIP score to predict LOC. X-axis is in percentage, Y-axis performance matrix.
OPD: Outpatient department; CCU: Critical care unit; ICU: Intensive care unit

DISCUSSION

During the pandemic, most of the hospitals were dedicated to treat the COVID-19, exclusively. Number of patients was huge and resources were limited. Optimal utilisation of available resources was the biggest challenge. Therefore, a fast track triage method was required at the point of care to screen patients at high risk, who could benefit from early hospitalisation and segregate them from those at low risk who could be managed as outpatients. Keeping this in view, the authors developed a model purely based on clinical parameters like arterial blood oxygen saturation on room air, RR and PR. The prime objective of the present study was to evaluate the proposed scoring method in predicting the LOC required by the patient. It was observed that, the number of male patients receiving treatment was higher than that of female patients. This suggests that, the propensity of getting infection was more in males, which can be explained on the basis of more work related exposure. The clinical parameters (SpO₂, RR, and PR) used to formulate SCIP score are directly related to severity of disease and intensity of care. Fall in SpO₂ and increased PR and RR corresponds to deterioration of disease. On analysing clinical parameters individually from each LOC, it was clear that, more intense care was required when SpO₂ value was less while PR and RR were more. Therefore, in SCIP score formula SpO₂ was taken in the numerator while PR and RR were taken in the denominator. So, lower the score more severe the disease and warrants more intense treatment. A preliminary observation of SCIP scoring criteria on 10 patients eight males and two females with a mean age of 42.1±11.9 years, who presented to a private clinic in second week of April 2021 showed that, the LOC given to them as per the clinical guidelines for COVID-19 management [11] was in correspondence with the score obtained by the SCIP formula [4]. Hence, use of these parameters to formulate the SCIP score was validated.

In all the LOCs, more than half of patients were getting the treatment as predicted by the proposed scoring method. The patients who were outside the proposed range were mainly due to overlapping of care given at various levels. Mostly, overlapping was observed between the ward and CCU patients and also, between CCU and ICU patients. This may be because of borderline range or overlapping of LOC given in these facilities. Many times, due to overcrowding the higher LOC was not available, either the patients were treated in lower level until they could shift to next level, depending on the availability of beds or the care given at lower level was enhanced. The authors have observed that, during pandemic because of mismatched demand and supply the LOC played interchangeable role to meet the unmet needs. This might be the reason for mismatching of actual LOC with predicted LOC using the proposed SCIP score. The results of the study were encouraging as the mean score in all levels of care was within the proposed range. This suggests that, the ranges proposed to predict levels of care were matched with actual scenario. These ranges can be used to allocate different levels of care at the point of first contact and can help in optimal use of resources.

The score was highly sensitive in predicting the patients, who can be treated at OPD. It is thus, very helpful in prioritising the need for hospitalisation amongst all the patients coming to the healthcare facility. Also, the score was highly specific in predicting the patients, who do not need intensive care at ICU. This helps the doctor to keep the ICU available for those patients, whose lives can be saved by invasive ventilation. The score is highly accurate in determining the requirement of ICU and also, accurate in determining non requirement of hospitalisation. In both cases, the score was helpful in managing the patients as per their requirements. This will reduce the burden on healthcare system, as the patients, who need ICU can be segregated from those, who do not need hospitalisation. This will be helpful in optimal utilisation of resources with best outcome. Even the best of the healthcare systems across the globe were overwhelmed by COVID-19 pandemic due to the mismatch

between demand and supply of the resources. The panic was such that, the available resources were wasted because of lack of preparedness. Many methods for effective triage of COVID-19 patients have been proposed [5-10,12-14]. The score proposed by Lopez-Pais J et al., used four variables: sex, SpO₂, diabetes, and age for fast track triage of COVID-19 patients [8]. However, it did not predict the LOC required as per the severity of disease and also, its usefulness was limited to the patients having comorbidity like diabetes. Levenfus I et al., proposed AIFELL method using parameters like altered smell/taste, inflammation, infiltrate, elevated Lactate dehydrogenase (LDH) and lymphocytopenia as a triage tool [6]. Similarly, some other methods were also developed using several variables like epidemiology, history, demographics, medical history, clinical feature, routine blood test, radiographic imaging findings, and co-morbidities for the effective triage of COVID-19 menace [9,13,15]. Although, the involvement of multiple components made these methods complex and time consuming. Moreover, laboratory dependent components like blood tests and radiological investigations slow down decision-making due to the exhaustion of resources amidst high demand. Soltan AAS, et al., developed artificial intelligence based screening tools for rapid triage of COVID-19 patients [7]. Nevertheless, the methods using artificial intelligence were optimistic but need expertise. Therefore, a quick, less complex and laboratory independent triage method was essential for optimal utilisation of healthcare resources.

The main advantage of the SCIP score is its simplicity, with parameters that can be assessed immediately and precisely at the first point of contact. Other triage models explored had better validation parameters, but included variables which are dependent on laboratory and radiological investigations with less immediate and less precise availability [6,13]. SCIP score can be calculated in few minutes by using a pulse oximeter. The SCIP score can serve as a useful tool for healthcare workers to decide whether or not a patient needs to be admitted to a particular LOC depending on the severity of disease and intensity of treatment required. Public policies could implement this score to reduce hospital burden. Healthcare systems in most of the nations even the developed ones have collapsed due to significant stress, triage models like this score may be useful to avoid that happening again in future waves of infection.

Limitation(s)

The present study was a single centre study, done on limited number of patients. Due to its retrospective nature, some values were not obtained from all patients. The present study extracted data at a single point of time. A strict follow-up of all the patients could have thrown better light on the movement of patient from admission to discharge. This triage score, like any other, should not be considered in patients in an obvious critical situation, in which immediate active measures are mandatory. As the score is totally based on clinical parameters, chances of error are high depending

on the clinical skills of the scorer. The LOC for patients with any co-existing disease may vary and cannot be predicted by using this score.

CONCLUSION(S)

This research showed that, the SCIP scoring system based on routine clinical parameters is helpful in early detection of severity of the disease and in taking fast decision to predict the LOC required. Amidst pandemic with limited resources where laboratory for blood and radiological investigations are either not available or overwhelmed, triage of patients is a real challenge. Hence, a SCIP score is needed to ensure optimal distribution of scarcely available resources to cater to the huge demand without wasting time.

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PARTICULARS OF CONTRIBUTORS:

1. Associate Professor, Department of Pharmacology, Maulana Azad Medical College, New Delhi, India.
2. Assistant Professor, Department of Pharmacology, Government Medical College, Khandwa, Madhya Pradesh, India.
3. Associate Professor, Department of Pharmacology, Maulana Azad Medical College, New Delhi, India.
4. Assistant Professor, Department of Obstetrics and Gynaecology, School of Medical Sciences and Research, Sharda University, Greater Noida, Uttar Pradesh, India.
5. Assistant Professor, Department of Pharmacology, Hamdard Institute of Medical Sciences and Research, Jamia Hamdard, New Delhi, India.
6. Research Fellow, Department of Pharmacology, Maulana Azad Medical College, New Delhi, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Geeta Kathait Rai,
Room No. 155, Department of Pharmacology, MAMC,
Bahadur Shah Zafar Marg, New Delhi-110002, India.
E-mail: geetakathait.06@gmail.com

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