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Prognostic nomogram on admission predicting progression for patients with nonsevere COVID-19

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\begin{table}[h]
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\textbf{Keywords:} & \textbf{Keywords:} & \\
COVID-19 & Severe disease & Progression \\
Nomogram & Risk factor & \\
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\end{table}

\begin{abstract}
The present study aimed to establish a prognostic nomogram to stratify high-risk patients with Coronavirus Disease 2019 (COVID-19) who progressed from the nonsevere condition on admission to severe during hospitalization. This multicenter retrospective study included patients with nonsevere COVID-19 on admission from Jan 10, 2020 to Feb 7, 2020. In the training cohort, independent risk factors associated with disease progression were identified by univariate and multivariate analyses. The prognostic nomogram was established and then validated externally using C-index. The study included 351 patients (293 and 58 in the training and validation cohorts, respectively), with 27 (9.2%) and 5 (8.6%) patients progressed, respectively. In the training cohort, older age (OR 1.036, 95% CI 1.000–1.073), more lobes involved on chest CT (OR 1.841, 95% CI 1.117–3.035), comorbidity present (OR 2.478, 95% CI 1.020–6.018), and lower lymphocyte count (OR 0.081, 95% CI 0.019–0.349) were identified as independent risk factors. The prognostic nomogram was established in the training cohort with satisfied external prognostic performance (C-index 0.906, 95% CI 0.806–1.000). In conclusion, older age, comorbidity present, more lobes involved on chest CT, and lower lymphocyte count are independent risk factors associated with disease progression during hospitalization for patients with nonsevere COVID-19.
\end{abstract}

\section{Introduction}
In December 2019, a cluster of cases with viral pneumonia of unknown origin were confirmed to contract a novel coronavirus, previously known as 2019 novel coronavirus (2019-nCoV). The pathogen has subsequently been renamed severe acute respiratory syndrome (SARS) coronavirus 2 (SARS-CoV-2) and is a member of the subgenus Sarbecovirus (Beta-CoV lineage B) closely related to severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) [1, 2]. Clinical features of the first confirmed cases were characterized in Feb 2020 [3]. As of Dec 1, 2020, a total of 65,872,391 confirmed coronavirus disease 2019 (COVID-19) cases including 1523,656 deaths have been reported globally, resulting in a fatality rate about 2.3% [4].

Previous reports indicated that 26–33% of patients in Wuhan required intensive care and 4–15% died [2, 3, 5]. Afterwards, the largest case series of 72,314 cases published by the Chinese Center for Disease Control and Prevention (China CDC) has further elaborated severe and critical disease in 18.5% of cases and an overall case-fatality rate (CFR) of 2.3% [6]. Notably, the case fatality in severe (8.1% vs 0.1%) or critical cases (49.0% vs 0.0%) is far beyond that in nonsevere cases [6, 7]. Therefore, it is important to distinguish several possible hallmarks of progression at the early stage to guide clinical decision-making as well as infection management. An early study elaborated that ICU patients

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had higher plasma levels of cytokines compared with non-ICU patients [3]. Moreover, it was reported that COVID-19 more likely affected older males with comorbidities [8] and patients who required ICU care were significantly older and more likely to have underlying comorbidities, such as hypertension, diabetes, cardiovascular disease and cerebrovascular disease [5].

Herein, we aimed to further elucidate the potential risk factors for disease progression and to establish a prognostic nomogram among hospitalized patients with COVID-19. To our knowledge, this prediction model is the first nomogram, which combined demographic, clinical, laboratory and radiologic characteristics solely on admission and was validated externally, for calculating risk of progression in patients with COVID-19.

2. Materials and methods

2.1. Patient criteria

This multicenter retrospective study was approved by the institutional review boards of the relevant centers. The need for written informed consent was waived due to the retrospective nature of the study. The study was performed in accordance with the Declaration of Helsinki. Patients admitted to hospital with laboratory-confirmed COVID-19 in 16 designated tertiary hospitals outside Hubei Province (13, 2, and 1 hospitals in Jiangsu, Zhejiang, and Anhui Provinces, respectively) from Jan 10, 2020 to Feb 7, 2020 were screened and included in the study. The cutoff date of follow-up and data collection for the study was Mar 17, 2020. The diagnosis of COVID-19 was based on the WHO interim guidance with a positive result on high-throughput sequencing or real-time reverse-transcriptase-polymerase-chain-reaction (RT-PCR) assay of nasal and pharyngeal swab specimens [9]. The illness severity of COVID-19 was defined according to the Chinese management guideline for COVID-19 (version 6.0) [10]. Mild was characterized by mild symptoms without imaging findings. Moderate was characterized by fever and/or respiratory symptom as well as imaging findings. Severe was characterized by dyspnea, respiratory frequency ≥ 30/min, blood oxygen saturation ≤93%, PaO₂/FIO₂ ratio <300, and/or lung infiltrates >50% within 24–48 h. Critical cases were those that exhibited respiratory failure, septic shock, and/or multiple organ dysfunction/failure. Based on this, we classify mild/moderate disease as “nonsevere” and severe/critical diseases as “severe” in this study. Progression was defined as one patient was categorized as “severe” at any time during hospitalization. Patients admitted to designated hospitals in Jiangsu Province were included in the training cohort to establish the prognostic nomogram and those from Zhejiang and Anhui Provinces were included in the validation cohort to validate the nomogram externally.

The inclusion criteria of the study were as follows: 1) laboratory-confirmed diagnosis of COVID-19 during the first hospital admission as mentioned above; 2) classified as nonsevere condition on admission; and 3) chest computed tomography (CT) and laboratory tests performed within 24 h after admission. The major exclusion criterion was patients in the severe condition on admission.

2.2. Data sources and collection

Laboratory confirmation with RT-PCR, laboratory tests (mainly including a complete blood count, serum biochemistry, and coagulation test), and chest CT were conducted on admission and repeated according to the clinical care needs of the patient. Most patients received antiviral treatment mainly with interferon alpha inhalation, lopinavir, and ritonavir. Baseline characteristics, recent exposure history, clinical signs and symptoms, and laboratory results on admission were extracted from electronic medical records of the participating hospitals. CT images on admission were re-reviewed by HD and YGL, with more than 15 years’ experience in diagnostic radiology. Major disagreement between these two radiologists was resolved by the third radiologist, QZX., with more than 25 years’ experience in diagnostic radiology. Image interpretation including ground-glass opacity, consolidation, bilateral lung involved and number of involved lobes was recorded. Any ground-glass opacity or consolidation was considered as abnormalities on chest CT. All medical records were copied and collected under the coordination of the corresponding authors of the study. Re-collection was requested from the participating hospitals if core data was missing.

2.3. Study outcomes and definitions

The endpoint of the study was the progression of COVID-19 severity from nonsevere to severe. The progression was defined based on the criteria presented in Table 1. Fever was defined as axillary temperature of at least 37.3 °C. The definitions of lymphopenia and thrombocytopenia were made based on a previous study with the largest COVID-19 cohort reported [7]. Comorbidity is defined as hypertension, diabetes and cardiovascular disease.

2.4. Establishment and validation of the prognostic nomogram

The prognostic nomogram was established based on the identified independent risk factors associated with the primary endpoint in the training cohort. The performance on prognostic discrimination about the nomogram was validated externally using the concordance c statistic (C-index) in the validation cohort.

2.5. Statistical analysis

Patients were classified into two groups: with progression of COVID-19 severity from nonsevere to severe (study group) and without progression of COVID-19 severity from nonsevere to severe (control group). Variables with P ≤ 0.10 in the univariate logistic analysis were considered strong risk factors associated with prognosis and were then put into the multivariate logistic analysis with forward selection. Variables remaining in the multivariable logistic analysis results were considered independent risk factors associated with prognosis. Continuous variables were presented as mean (SD) or median (IQR), and categorical variables as frequency (%). Statistical analyses were performed using SPSS version 22.0 software for Windows (IBM Corporation, Somers, New York, USA), and the nomogram was created and validated through the regression modeling strategies package in R language version 3.4.3 software for Windows (R Package for Statistical Computing; www.r-project.org).

3. Results

3.1. Patient characteristics

Of 374 patients with laboratory-confirmed COVID-19 cases, a total of 351 patients were included in the study, with 293 and 58 in the training and validation cohort, respectively (Fig 1). Among them, 27 (9.2%) patients progressed from nonsevere on admission to severe during hospitalization in the training cohort, while 5 (8.6%) patients progressed in the validation cohort. None and 1 (1.7%) patients died in the training and validation cohorts, respectively. All of the remaining patients were discharged after successful treatment in both cohorts. Detailed demographic, clinical, laboratory and radiologic characteristics of the included patients are listed and compared between patients with or without progression in Table 1. The mean age of the patients in the entire cohort was 45.1 years (SD 15.2), and more than a half (198 [56.0%]) were men. The median period from symptom onset to first hospital admission was 4 days.

Ninety-seven (27.6%) patients had underlying comorbidities, including hypertension (82 [23.4%]), diabetes (47 [13.4%]) and cardiovascular disease (22 [6.3%]). The most common symptoms were fever (256 [72.9%]), cough (213 [60.7%]), and fatigue (67 [19.1%]). Regarding radiologic and laboratory findings on admission, 332 (94.6%) chest CT images were considered abnormal.
Fig. 1. Study flow diagram.

Table 1
Baseline characteristics of included patients in training and validation cohorts.

| Characteristics | Training cohort | Validation cohort | p value |
|-----------------|-----------------|-------------------|---------|
|                 | All patients (n = 293) | Non-progression (n = 266) | Progression (n = 27) |          | All patients (n = 58) | Non-progression (n = 53) | Progression (n = 5) | p value |
| Age, yr, mean (SD) | 44.9 (15.3) | 43.9 (15.2) | 54.6 (12.1) | -0.001 | 46.4 (15.3) | 45.4 (15.0) | 56.6 (16.0) | 0.118 |
| >50 | 112 (38.2%) | 94 (35.3%) | 18 (66.7%) | 0.001 | 23 (39.7%) | 19 (35.8%) | 4 (80.0%) | 0.147 |
| ≤50 | 181 (61.8%) | 172 (64.7%) | 9 (33.3%) | - | 35 (60.3%) | 34 (64.2%) | 1 (20.0%) | - |
| Sex, n (%) |          |          |          |         |          |          |          |         |
| Female | 129 (44.0%) | 121 (45.5%) | 8 (29.6%) | 0.114 | 24 (41.4%) | 22 (41.5%) | 2 (40.0%) | 1.000 |
| Male | 164 (56.0%) | 145 (54.5%) | 19 (70.4%) | - | 34 (58.6%) | 31 (58.5%) | 3 (60.0%) | - |
| Travel history to Hubei Province, n (%) | 138 (47.1%) | 121 (45.5%) | 17 (63.0%) | 0.083 | 34 (58.6%) | 32 (60.4%) | 2 (40.0%) | 0.682 |
| Onset to admission time, days, median (IQR) | 4 (2–7) | 4 (2–7) | 5 (3–9) | 0.196 | 4 (2–7) | 4 (2–7) | 4 (2–6) | 0.635 |
| Comorbidity (%) |          |          |          |         |          |          |          |         |
| Hypertension | 66 (22.5%) | 55 (20.7%) | 11 (40.7%) | 0.017 | 16 (27.6%) | 12 (22.6%) | 4 (80.0%) | 0.026 |
| Diabetes | 38 (13.0%) | 30 (11.3%) | 8 (29.6%) | 0.007 | 9 (15.5%) | 6 (11.3%) | 3 (60.0%) | 0.023 |
| Cardiovascular disease | 14 (4.8%) | 10 (3.8%) | 4 (14.8%) | 0.010 | 8 (13.8%) | 5 (9.4%) | 3 (60.0%) | 0.016 |
| Radiologic findings, n (%) |          |          |          |         |          |          |          |         |
| Abnormalities on chest CT | 279 (95.2%) | 252 (94.7%) | 27 (100.0%) | 0.454 | 54 (93.1%) | 49 (92.5%) | 5 (100.0%) | 1.000 |
| Ground-glass opacity | 273 (93.2%) | 246 (92.6%) | 27 (100.0%) | 0.282 | 35 (60.3%) | 30 (56.6%) | 5 (100.0%) | 0.156 |
| Consolidation | 171 (58.4%) | 148 (55.6%) | 23 (85.2%) | 0.003 | 39 (67.2%) | 34 (64.2%) | 5 (100.0%) | 0.257 |
| Bilateral lung involved | 229 (78.2%) | 202 (75.9%) | 27 (100.0%) | 0.004 | 41 (70.7%) | 36 (67.9%) | 5 (100.0%) | 0.321 |
| Number of involved lobes, median (IQR) | 4 (2–5) | 4 (2–3) | 5 (4–5) | <0.001 | 3 (1–4) | 3 (1–4) | 5 (3–5) | 0.050 |
| Laboratory findings, mean (SD) |          |          |          |         |          |          |          |         |
| Leukocyte count, x10^9/L | 5.2 (2.1) | 5.1 (1.9) | 5.9 (3.2) | 0.177 | 5.4 (1.5) | 5.4 (1.5) | 5.5 (1.7) | 0.883 |
| Lymphocyte count, x10^9/L | 1.3 (0.6) | 1.3 (0.6) | 0.8 (0.3) | <0.001 | 1.2 (0.5) | 1.2 (0.7) | 0.5 (0.1) | <0.001 |
| Platelet count, x10^9/L | 183.3 (60.9) | 184.0 (71.1) | 176.7 (58.2) | 0.612 | 194.7 (63.2) | 196.1 (62.5) | 180.6 (76.2) | 0.505 |
| C-reactive protein, mg/L | 18.1 (31.4) | 14.3 (20.5) | 54.9 (72.5) | 0.009 | 16.2 (15.6) | 15.3 (15.1) | 23.2 (20.3) | 0.347 |

Abbreviations: SD, standard deviation; IQR, interquartile range. p values comparing non-progressors and progressors are from t-test, χ² test, Fisher’s exact test, or Mann-Whitney U test.
scans showed abnormalities including ground-glass opacity or consolidation. Leukopenia and lymphocytopenia was detected in 99 (28.2%) and 248 (70.7%) patients, respectively.

3.2. Independent risk factors associated with progression in the training cohort

In the training cohort, patients with progression were older (43.9 [SD 15.2] vs 54.6 [12.1], p<0.001), more likely to have chronic disease (63 (23.7%) patients vs 14 (51.9%) patients, p = 0.002), have more lobes involved on baseline CT (4 [IQR 2–5] vs 5 [IQR 4–5], p<0.001) and less lymphocyte count (1.3 × 10⁹/L [SD 0.6], vs 0.8 × 10⁹/L [SD 0.3], p<0.001) (Table 1). Six variables, namely, older age, comorbidity present, more lobes involved on chest CT, lesions consolidation on chest CT, lower lymphocyte count, and elevated C-reactive protein (CRP), were identified as strong risk factors after univariate analysis (Table 2). After multivariate analysis, older age, comorbidity present, more lobes involved on chest CT, and lower lymphocyte count were identified as independent risk factors associated with severity progression (Fig. 2).

3.3. Establishment and validation of the prognostic nomogram

Based on the above-mentioned independent risk factors, the prognostic nomogram was then established in the training cohort (Fig. 3). Through the nomograms, each patient received an individualized point, which was the sum of the points from the four independent risk factors, to predict the probability of severity progression from the nonsevere to severe condition during hospitalization. We present the following specific scenario to show how to use the nomogram: A nonsevere COVID-19 patient aged 50 (20 points) with comorbidity present (10 points) showed 5 lobes involvement on chest CT (35 points), and the lymphocyte count was 0.5 × 10⁹/mL (85 points). The patient had 150 points on the nomogram. The estimated probability of this patient progressing to the severe condition during hospitalization was 50%. In another patient aged 40 (15 points) without comorbidity (0 point) showed a 2 lobes involvement on chest CT (15 points), and the lymphocyte count was 1 × 10⁹/mL (70 points). The patient had 100 points on the nomogram. The estimated probability of this patient progressing to the severe condition was around 1%. The prognostic performance of the nomogram was then validated externally in the validation cohort. A C-index of 0.849 (95% CI 0.782–0.917) in the training cohort and 0.906 (95% CI 0.806–1.000) in the validation cohort was generated, demonstrating a high accuracy and good performance of the nomogram. The Calibration curve shows good agreement with the actual state of progression (Fig. 4).

4. Discussion

For patients with COVID-19 in the nonsevere condition on admission, a simple prognostic nomogram, which included older age, comorbidity present, more lobes involved on chest CT, and lower lymphocyte count, was established for severity progression from nonsevere on admission to severe during hospitalization. In addition, the nomogram showed high accuracy after external validation. Through the nomogram, probability of disease progression from nonsevere on admission to severe during hospitalization could be predicted individually and accurately. Hence, early detection and intervention could be applied exactly to prevent disease progression.

In this study, 27 (9.2%) and 5 (8.6%) patients in the training and validation cohorts experienced disease progression from nonsevere on admission to severe during hospitalization. The rates were lower than two previous studies with large sample sizes from China, mainly due to the difference in inclusion criteria and sample sizes [6, 7]. The rates were much lower when compared to a cohort from Wuhan, with 41.8% developed acute respiratory distress syndrome during hospitalization [11], attributed to the relative mild condition in other areas.

Many studies have so far observed reduced absolute values of lymphocytes in most patients [3, 5, 7, 8, 12], suggesting that SARS-CoV-2...
might mainly act on lymphocytes, especially on T lymphocytes. In addition, cytokine storm is thought to play an important role in disease severity [13], followed by several immune responses causing lymphocyte decrease. Considering that older patients are associated with declined immune competence, it is reasonable to be a potential risk factor associated with disease progression. In line with previous studies, we identified that lower lymphocyte count and older age were independent risk factors associated with disease progression [3, 5, 7, 8, 11, 12, 14].

Previous studies showed that more patients with hypertension, diabetes, or cardiovascular disease were observed in severe patients compared to that for nonsevere ones [5, 7, 14]. Human pathogenic coronaviruses including SARS-CoV-2 bind to their target cells through angiotensin-converting enzyme 2 (ACE2) [15]. Therefore, patients with hypertension, diabetes, and cardiovascular disease, who often experience upregulation of ACE2 with certain medications, are at higher risk for SARS-CoV-2 infection and disease progression [16].

With its non-invasive modality, high accuracy and speed, chest CT plays an important role in diagnosis and severity assessment for COVID-19 [17–19]. Previous studies demonstrated that chest CT has a high sensitivity for diagnosing COVID-19 when compared to RT-PCR [20]. Chest CT abnormalities occurred in most patients with COVID-19 even in asymptomatic patients [21]. It developed rapidly from focal unilateral to diffuse bilateral ground-glass opacities that progressed to or co-existed with consolidations within 1–3 weeks [21]. In addition, previous studies found that incidence of diffuse lesions and more lobes involved was higher and associated with disease severity [22]. A perspective from China indicated that in severe COVID-19, CT scan often presented with bilateral multiple lobular and subsegmental involvement [19]. In this study, we demonstrated that more lobes involvement on chest CT scan on admission was an independent risk factor associated with disease progression, indicating that advanced progression presented on chest CT might occur earlier than that for clinical symptom [21-23].

The prognostic nomogram reflected the real characteristics in clinical setting because it was established and validated based on the patients with COVID-19 during the outbreak in China. All variables in the nomogram are easy to obtain from clinical practice and all related examinations are regarded as necessary measures to be taken upon hospital admission. For this reason, the nomogram should have potential to act as an effective and easy tool to assess the probability of COVID-19 progression from the nonsevere to severe condition.

Several notable limitations of this study should be acknowledged. First, incomplete documentation of the laboratory testing made it difficult to fully analyze the potential risk factors such as d-dimer and lactate dehydrogenase, which have been mentioned previously. Such limitation therefore can affect the accuracy of the nomogram. Urgent timeline for data collection and extraction was to blame for this challenge. Second, the sample size was relatively small for a prognostic nomogram. A larger cohort study is warranted to validate the accuracy and application of the nomogram.

5. Conclusion

In conclusion, older age, comorbidity present, more lobes involved on chest CT, and lower lymphocyte count are the key risk factors for patients with nonsevere COVID-19 on admission to progress to the severe condition during hospitalization. The nomogram based on these factors has a strong and accurate predictive ability for disease progression. It is able to accurately stratify high-risk patients and assist clinicians in making appropriate decisions for nonsevere COVID-19 patients.

Declaration of Competing Interest

The authors declare that they have no conflict of interest

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