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Predictive Factors for the Diagnosis of Coronavirus Disease 2019

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ABSTRACT

Objective : We evaluated patients suspected or confirmed to have coronavirus disease 2019 (COVID-19) to determine predictive factors for the diagnosis of COVID-19.

Methods : We conducted a retrospective cohort study at The Jikei University Hospital, Tokyo, Japan. This study included adult patients who underwent medical examination for suspected or confirmed COVID-19 in April and May 2020. We analyzed the clinical characteristics, blood test results, and findings of computed tomography of the chest from the medical record system of the hospital.

Results : Of the 267 patients included in this study, 27 were found to be positive for COVID-19 on reverse transcription polymerase chain reaction testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Of the patients, 128 (47.9%) were men, and the median age was 47 years (interquartile range, 34.5-65). Twenty-two (8.2%) patients had a history of close contact with a COVID-19 patient. The most common symptoms were fever, general malaise, and cough. Multivariate analysis with the logistic regression model revealed that close contact, fever for 4 or more days, dysgeusia, and dysosmia were independent predictive factors for reverse transcription polymerase chain reaction test results being positive for SARS-CoV-2.

Conclusion : Patients who have had close contact with a COVID-19 patient, fever for 4 days or more, dysgeusia, or dysosmia should undergo diagnostic testing for SARS-CoV-2.

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Key words : coronavirus disease 2019, persistent fever, close contact, dysgeusia, dysosmia, predictive factor

INTRODUCTION

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was first reported in Wuhan, China, in December 2019 and then spread worldwide[1]. In Japan, the first case of COVID-19 was reported in January 2020, after which the number of COVID-19 patients increased. Because SARS-

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CoV-2 is mainly transmitted by droplets and contact infection, widely recommended to prevent infection have been social distancing, universal use of masks, and hand hygiene. Healthcare workers are recommended to wear respirators or surgical masks, eye protection, gloves, and gowns when in contact with patients suspected of having or diagnosed with COVID-19[2]. Furthermore, to prevent the spread of COVID-19, patients with COVID-19 should be quickly diagnosed to ensure proper treatment and isolation. However, distinguishing COVID-19 from other infectious diseases, especially respiratory infection, has been difficult without diagnostic testing for SARS-CoV-2 because COVID-19 patients present with common symptoms, such as fever, cough, dyspnea, and headache[3].

Independent risk factors for the diagnosis of COVID-19 have been reported to include exposure histories, weakness, and bilateral pneumonia[4]. However, an evaluation of 262 patients with influenza-like symptoms has shown that olfactory and gustatory impairment are significantly associated with COVID-19[5]. Thus, several studies have shown predictive factors for COVID-19, but few have included Japanese patients. Therefore, to determine predictive factors for the diagnosis of COVID-19 in Japanese patients, in the present study we evaluated patients suspected or confirmed to have COVID-19.

Materials and Methods

Study design

This retrospective cohort study was conducted at The Jikei University Hospital, a 1,075-bed hospital in Tokyo, Japan. The study included adult patients who had undergone medical examination for suspected or confirmed COVID-19 at our hospital in April and May 2020. Patients who visited our outpatient clinic several times were included as a single patient. To determine the predictive factors for the diagnosis of COVID-19, the following characteristics were collected from the medical record system and analyzed : age, sex, underlying disease, signs, symptoms, blood test results, and abnormal shadows on computed tomography (CT) of the chest when they visited our hospital.

Definitions

Cases of COVID-19 were diagnosed via reverse transcription polymerase chain reaction (RT-PCR) testing for SARS-CoV-2, with specimens from the nasopharynx or lower respiratory tract. On the basis of the results of this test, patients were determined to be positive or negative for COVID-19. Nonpositive patients included patients with negative results of SARS-CoV-2 RT-PCR test and those who were not tested, because none of these patients were later diagnosed with COVID-19. Close contact was defined as any contact with a COVID-19 patient without sufficient personal protective equipment within 2 weeks before undergoing RT-PCR testing for SARS-CoV-2. Leukocytopenia and thrombocytopenia were defined as absolute leukocyte and platelet counts of < 4000 cells and $<150{,}000$ cells per cubic millimeter[6].

Statistical Analyses

To compare categorical variables, the $\chi 2$ test or Fisher's exact test was used. To compare continuous variables, Student's *t*-test and the Mann-Whitney *U* test were used. The factors with $p < 0.1$ in the univariate analysis were included in the multivariate analysis. Logistic regression analysis was used to determine independent predictive factors for COVID-19. These results were demonstrated as adjusted odds ratios with a 95% confidence interval and the 2-tailed statistical significance set at $p < 0.05$. Statistical analyses were performed with the program IBM SPSS Statistics, version 25.0 (IBM Japan, Ltd., Tokyo, Japan).

Ethical Considerations

This study was approved (approval no. 32-180(10261)) by the institutional ethics committee of The Jikei University Hospital.

Results

Clinical characteristics of patients with suspected to have or diagnosed with COVID-19

The subjects of this study were 267 adult patients who were suspected of having or diagnosed with COVID-19 and underwent a medical examination at The Jikei University Hospital from April 6 to May 31, 2020 (Table 1). Of these patients, 47.9% were men, and the median age was 47 years. The most common underlying diseases for all patients were hypertension (13.9%) and chronic respiratory diseases (12.7%), but 37.8% of patients had no underlying disease. Of all patients, 83.1% underwent RT-PCR testing

Table 1. Clinical characteristics of patients suspected to have or diagnosed with COVID-19

	All	SARS-CoV-2 PCR		*P* value	Nonpositive	*P* value
		Positive	Negative			
	n = 267	*n* = 27	*n* = 195		*n* = 240	
Median age(IQR)	47 (34.5, 65)	36 (26.5, 48)	47 (35, 66)	0.001	48 (35, 66.25)	0.001
Male, *n* (%)	128 (47.9)	12 (44.4)	94 (48.2)	0.838	116 (48.3)	0.839
Underlying disease						
No medical history, *n* (%)	101 (37.8)	15 (55.6)	73 (37.4)	0.093	86 (35.8)	0.059
Hypertension, *n* (%)	37 (13.9)	4 (14.8)	23 (11.8)	0.752	33 (13.8)	0.775
Chronic respiratory diseases, *n* (%)	34 (12.7)	3 (11.1)	23 (11.8)	1.000	31 (12.9)	1.000
Diabetes mellitus, *n* (%)	21 (7.9)	3 (11.1)	17 (8.7)	0.718	18 (7.5)	0.456
Solid tumor, *n* (%)	26 (9.7)	0 (0)	22 (11.3)	0.840	26 (10.8)	0.088
Leukemia or malignant lymphoma, *n* (%)	8 (3.0)	0 (0)	8 (4.1)	0.600	8 (3.3)	0.600
Collagen disease, *n* (%)	11 (4.1)	0 (0)	10 (5.1)	0.614	11 (4.6)	0.610
Inflammatory bowel disease, *n* (%)	5 (1.9)	1 (3.7)	2 (1.0)	0.324	4 (1.7)	0.416
Closed contact, *n* (%)	22 (8.2)	15 (55.6)	7 (3.6)	<0.0001	7 (2.9)	<0.0001

IQR : interquartile range ; PCR : polymerase chain reaction

for SARS-CoV-2 ; 12.2% of them (27 patients) received positive results and were diagnosed with COVID-19. The median age of patients diagnosed with COVID-19 was significantly lower than those of negative or nonpositive patients ($p = 0.001$). However, sex and underlying disease did not differ significantly between positive and negative patients. Close contact with a COVID-19 patient had been had by 22 (8.2%) of the 267 patients and had occurred at home (8 patients) or with healthcare workers at our hospital or another hospital (11 patients). Having had close contact with a COVID-19 patient was significantly more common for positive patients (55.6%) than for nonpositive patients (2.9%, $p < 0.0001$).

Symptoms at the time of medical examination

Of the symptoms at the time of medical examination, the most common were fever (77.2%), general malaise (28.8%), and cough (22.1%) (Table 2). In addition, 9.0% of patients complained of dysgeusia or dysosmia. The fever had been present for 2 or more days in 61.8% of patients with fever and for 4 or more days in 33.7%. A fever lasting 4 or more days was significantly more common among positive patients than among nonpositive patients. In addition, the presence of dysgeusia or dysosmia was significantly more common in positive patients than in other patients.

Analyses of predictive factors in logistic regression analysis

The results of univariate analysis revealed that age, close contact with a COVID-19 patient, persistent fever for 4 days or more, and dysgeusia or dysosmia were significantly associated with positive RT-PCR results for SARS-CoV-2. In addition to these variables, we included the factors with $p < 0.1$ in the univariate analysis for multivariate analysis. Using logistic regression model, it was found that persistent fever for 4 days or more, dysgeusia or dysosmia, and close contact were independent predictive factors for positive RT-PCR results for SARS-CoV-2 : close contact (AOR = 103.314 ; 95% CI = 22.639-471.470 ; $p < 0.0001$), persistent fever for 4 days or more (AOR = 5.256 ; 95% CI = 1.465-18.857 ; p = 0.011) and dysgeusia or dysosmia (AOR = 20.347 ; 95% CI = 5.363-77.201 ; $p < 0.0001$) (Table 3-1). Further, these factors were also independent predictive factors among all patients : close contact (AOR= 127.463 ; 95% CI = 28.014-579.959 ; $p < 0.0001$), persistent fever for 4 days or more (AOR = 5.439 ; 95% CI = 1.519-19.469 ; $p= 0.009$), and dysgeusia or dysosmia (AOR = 24.719 ; 95% CI = 6.510-93.862 ; $p < 0.0001$) (Table 3-2). These results indicate that diagnostic testing for SARS-CoV-2 is strongly recommended for patients with close contact with COVID-19 patients or those suffering from dysgeusia, dysosmia, or persistent fever for 4 days or more.

Blood examination results in patients suspected to have or diagnosed with COVID-19

Of all patients, 46.1% underwent blood examinations

Table 2. Symptoms at the time of medical examination at our hospital

	All	SARS-CoV-2 PCR		*P* value	Nonpositive	*P* value
		Positive	Negative			
	n=267 (%)	*n*=27 (%)	*n*=195 (%)		*n*=240 (%)	
Fever, *n* (%)	206 (77.2)	23 (85.2)	148 (75.9)	0.338	183 (76.3)	0.345
Fever for 2 or more days, *n* (%)	165 (61.8)	21 (77.8)	121 (62.1)	0.136	144 (60.0)	0.094
Fever for 4 or more days, *n* (%)	90 (33.7)	15 (55.6)	64 (32.8)	0.031	75 (31.3)	0.017
General malaise, *n* (%)	77 (28.8)	10 (37.0)	58 (29.7)	0.505	67 (27.9)	0.371
Cough, *n* (%)	59 (22.1)	9 (33.3)	44 (22.6)	0.232	50 (20.8)	0.146
Sore throat, *n* (%)	48 (18.0)	5 (18.5)	37 (19.0)	1.000	43 (17.9)	1.000
Dysgeusia or dysosmia, *n* (%)	24 (9.0)	11 (40.7)	13 (6.7)	<0.0001	13 (5.4)	<0.0001
Diarrhea, *n* (%)	14 (5.2)	2 (7.4)	9 (4.6)	0.628	12 (5.0)	0.640

Table 3-1. Predictive factors identified via logistic regression analysis in patients with positive results of polymerase chain reaction testing for SARS-CoV-2

	Adjusted odds ratio	95% confidence interval	*P* value
Closed contact	103.314	22.639-471.470	<0.0001
Fever for 4 or more days	5.256	1.465-18.857	0.011
Dysgeusia or dysosmia	20.347	5.363-77.201	<0.0001

Table 3-2. Predictive factors identified via logistic regression analysis in all patients

	Adjusted odds ratio	95% confidence interval	*P* value
Closed contact	127.463	28.014-579.959	<0.0001
Fever for 4 or more days	5.439	1.519-19.469	0.009
Dysgeusia or dysosmia	24.719	6.510-93.862	<0.0001

Table 4. Blood investigation results at the time of medical examination

	All	SARS-CoV-2 PCR		*P* value	Nonpositive	*P* value
		Positive	Negative			
	n = 123 (%)	*n* = 12 (%)	*n* = 91 (%)		*n* = 111 (%)	
White blood cells < 4,000/mL	19 (15.4)	5 (41.7)	10 (11.0)	0.014	14 (12.6)	0.02
Lymphocytes < 1,000/mL	41 (33.3)	5 (41.7)	34 (37.4)	0.762	36 (32.4)	0.532
Platelets < 150,000/mL	17 (13.8)	1 (8.3)	13 (14.3)	1.000	16 (14.4)	1.000
AST > 30 U/L	39 (31.7)	6 (50.0)	29 (31.9)	0.33	33 (29.7)	0.193
ALT > 42 U/L	20 (16.3)	2 (16.7)	15 (16.5)	1.000	18 (16.2)	1.000
CRP > 1.0 mg/dL	67 (54.5)	6 (50.0)	53 (58.2)	0.758	61 (55.0)	0.769

AST, aspartate aminotransferase ; ALT, alanine aminotransferase ; CRP, C-reactive protein

after the medical examination at our hospital (Table 4). Findings of blood examinations included leukopenia (15.4% of patients), lymphopenia (33.3%), and thrombocytopenia (13.8%). Elevated serum levels were found for aspartate aminotransferase (31.7% of patients), alanine aminotransferase (16.3%), and C-reactive protein (54.5%). Although the rate of leukocytopenia was higher in positive patients than in negative or nonpositive patients, other blood examination results did not differ significantly among these patient groups.

Pneumonia associated with positive RT-PCR results for SARS-CoV-2

Only 113 patients (49.8% of all patients) underwent

Table 5. Pneumonia diagnosed with computed tomography of the chest at medical examination

	All	SARS-CoV-2 PCR		*P* value	Nonpositive	*P* value
		Positive	Negative			
	$n = 133$	$n = 19$	$n = 99$		$n = 114$	
Pneumonia, *n* (%)	46 (34.6)	12 (63.2)	36 (36.4)	0.041	37 (32.5)	0.019
Bilateral pneumonia, *n* (%)	27 (20.3)	10 (52.6)	17 (17.2)	0.002	17 (14.9)	0.0007

CT of the chest (Table 5). Pneumonia was suspected or diagnosed in 34.6% of patients undergoing CT, 63.2% of positive patients, 36.4%, of negative patients, and 32.5% of nonpositive patients. In addition, bilateral pneumonia was present in 20.3% of patients undergoing CT, 52.6% of positive patients, and 17.2% of negative patients. Thus, the rates of both pneumonia and bilateral pneumonia were significantly higher in positive patients than in negative patients ($p = 0.019$) and nonpositive patients ($p = 0.0007$).

Discussion

Numerous studies have shown that fever is the most common symptom of COVID-19[4,7-10]. However, COVID-19 is difficult to distinguish from other infectious diseases because its symptoms are similar to those of respiratory tract infections. Similarly, we found in the present study that the rate of fever did not differ between patients who were positive for COVID-19 and those who were nonpositive, as shown by RT-PCR testing for SARS-CoV-2 infection, despite fever being the most common symptom. In February 2020, the Japanese government recommended that people with fever for 4 or more days should consult with the consultation center[11]. Therefore, we investigated the relationship between persistent fever and SARS-CoV-2 infection. We found that a fever lasting 4 or more days occurred significantly more often in patients with positive rather than nonpositive RT-PCR test results. This finding suggests that physicians should perform RT-PCR testing for SARS-CoV-2 in patients with a fever for 4 or more days.

Neurological manifestation is an important symptom in patients with COVID-19. Approximately one-third of patients with COVID-19 present with neurological signs and symptoms, such as dizziness, dysgeusia, and nerve pain[9]. The viral neurotropism of SARS-CoV-2 might be related to the distribution of angiotensin converting enzyme 2 receptors, which are the receptors of choice for SARS-CoV-2. However, the mechanism of action remains unclear[9,12]. Dysosmia has been suggested to be an early symptom of COVID-19 because 11.8% of COVID-19 patients have reportedly complained of olfactory dysfunction before other symptoms appear[13]. In the present study, 24 (9.0%) of 267 patients complained of dysgeusia or dysosmia. The frequency of this manifestation was similar to that reported in a previous study[9], whereas several other studies have demonstrated that taste or smell disorders occur in more than half of patients with COVID-19[5,14,15]. Thus, the incidence of dysgeusia or dysosmia has varied among studies. In contrast, a study of 145 COVID-19-positive and 157 COVID-19-negative patients has found that dysgeusia or dysosmia was the strongest predictor of COVID-19[16]. Similarly, we found in the present study that dysgeusia or dysosmia was significantly associated with positive RT-PCR results for SARS-CoV-2. These findings show that patients with dysgeusia or dysosmia should undergo diagnostic testing for SARS-CoV-2.

According to several studies that reviewed blood test results in COVID-19 patients[17,18], a common abnormal finding is lymphopenia, probably due to lymphopoiesis being reduced by an increase in proinflammatory cytokines[19] and to the SARS-CoV-2-associated necrosis or apoptosis of lymphocytes[18]. In the present study, we found that lymphopenia was present in 41.7% of COVID-19 patients, which was similar to percentages in other studies[18]. However, we also found lymphopenia in 32.4% of nonpositive patients; therefore, no significant difference in the rate of lymphopenia was found between SARS-CoV-2-positive and -nonpositive patients. Furthermore, we did not find that levels of thrombocytopenia, aspartate aminotransferase, alanine aminotransferase, and C-reactive protein were independent predictive factors for COVID-19. These findings were consistent with those of previous studies that had assessed hematological variables among COVID-19 patients[6,18,20]. Therefore, these findings suggest that distin-

guishing COVID-19 from other infectious diseases on the basis of blood variables is difficult. Further research is needed to assess whether abnormal findings, such as leukopenia, are predictive factors for COVID-19.

Various abnormal shadows, such as ground glass capacity, consolidation, and crazy-paving pattern, have been observed in patients with COVID-19[21]. Abnormal shadows, including ground glass opacity and consolidation, were found in 134 of 135 patients (99.3%) with COVID-19 who underwent CT on admission[8]. The sensitivity of CT examination of the chest for diagnosing COVID-19 infection has been reported to be 97%[22]. In addition, chest CT has been suggested to be used to screen for COVID-19 in patients suspected to have COVID-19, particularly when the results of RT-PCR tests are negative[23]. Furthermore, bilateral involvement in chest CT has been found to be significantly greater in patients with COVID-19 than in patients with pneumonia due to other pathogens[24]. In the present study we also found that the frequency of pneumonia was higher in COVID-positive patients than in COVID-negative or COVID-nonpositive patients. In contrast, a study has found that no abnormalities were found with chest CT in 56% of patients in the early phase of COVID-19 and that total lung involvement, including bilateral lung involvement, increased over time[25]. Thus, COVID-19 should be suspected in patients with lung involvement, such as ground glass opacity and consolidation, detected with chest CT.

LIMITATIONS

This study was conducted in April and May 2020 because patients with fever or respiratory symptoms have difficulty consulting a clinic or hospital. Also, physicians had to restrict RT-PCR tests for SARS-CoV-2 to a small acceptable number of patients during that time. Consequently, the present study had several limitations. For example, this study was a small, retrospective study conducted in a single hospital with blood investigations and chest CT examinations performed for only half of the patients. Despite these limitations, this study demonstrated predictive factors that would be crucial when considering diagnostic testing for SARS-CoV-2 among patients with certain signs and symptoms. Therefore, physicians should attempt to detect SARS-CoV-2 in patients who have had close contact with COVID patients, fever for 4 or more days, dysgeusia, or dysosmia. In addition, leukopenia and pneumonia on CT examinations might suggest COVID-19.

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Authors' Contribution Statement

All authors examined the patients suspected to have or diagnosed with coronavirus disease 2019 in this study. In addition, Yumiko Hosaka, Tetsuya Horino, Tokio Hoshina, and Kazuhiko Nakaharai contributed to the analysis of the patients' data.

Authors have no conflict of interest.

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