Comparison of Rapid Antibody Test and Thorax Computed Tomography Results in Patients who Underwent RT-PCR with the Pre-Diagnosis of COVID-19

İlker Kızıloglu[1], Aslı Şener[2], and Neslihan Siliv[3]

[1]Dr. Suat Seren Göğüs Hastalıkları ve Cerrahisi Eğitim ve Araştırma Hastanesi
[2]Bakırçay Üniversitesi Çiğli Eğitim ve Araştırma Hastanesi
[3]Bakircay Universitesi Cigli Egitim ve Arastirma Hastanesi

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Abstract

Introduction: In this study, it is planned to compare the RT-PCR test, which is the gold standard in the diagnosis of COVID-19, with Thorax computed tomography (CT) and rapid antibody test results. Methods: Patients who were admitted to the emergency service of İzmir Çiğli Training and Research Hospital between 01.04.2020 and 31.05.2020 and who were suspected of having COVID-19 infection were included in the study. The medical records of the patients were retrospectively analyzed through the hospital data processing database. Age, gender, hospitalization, status of home quarantine, real-time reverse transcription-polymerase chain reaction (RT-PCR), thorax CT and rapid antibody test results of the patients were examined. The relationship between RT-PCR, thorax CT and rapid antibody test results were compared statistically. Results: A total of 181 patients, 115 (63.5%) male and 66 (36.5%) female, with an average age of 56.4 ± 18.06 years were included in the study. The nasopharyngeal swab PCR result obtained at the first admission of the patients to the emergency department was positive in 71 (39.2%) patients. Thorax CT was performed in 173 (95.6%) patients who applied to the emergency department, and 112 (64.7%) of them had findings that could be compatible with COVID-19. According to the thorax CT findings in patients, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for detecting COVID-19 infection were respectively; 76.1%, 43.1%, 48.2% and 72.1% (: 0.176, p <0.001). In our study, the mortality rate for COVID-19 was found to be 2.8%. Conclusion: Rapid antibody test and thorax CT examinations were found to have low diagnostic value in patients who admitted to the emergency department of our hospital and whose first RT-PCR SARS-CoV-2 test was positive. Studies involving larger patient groups are needed for their use alone in diagnosis and screening.

INTRODUCTION

In December 2019, a series of 41 severe viral pneumonia cases were reported in Wuhan city, Hubei Province, China, whose cause could not be identified (1). Subsequent full genome sequencing and phylogenic analysis showed that SARS-CoV-2 belongs to the betacoronavirus 2b lineage, which belongs to the same group as Severe Acute Respiratory Syndrome coronavirus (SARS CoV), a highly virulent pathogen in humans (2,3). SARS-CoV-2 infection (COVID-19) was reported as a global public health emergency by the World Health Organization (WHO) in January 2020 and was declared a pandemic on March 11 (4,5).

The disease is transmitted by inhalation or contact with infected droplets, and the incubation period varies between 2-14 days. Symptoms are usually fever, cough, sore throat, dyspnoea. Symptoms are mild in most of the asymptomatic cases. However, in some patients (usually the elderly and those with comorbidities), it can progress to pneumonia, acute respiratory distress syndrome, and multiple organ dysfunction. It is estimated that the case mortality rate varies between 2-3% (6). However, most people infected with SARS-CoV-2 do

not have symptoms (7,8). The potential for patients with no symptoms to spread COVID-19; It confirms the importance of early diagnosis, monitoring and isolation.

Accurate and rapid diagnosis of COVID-19 infection is very important to provide appropriate medical support to patients and to prevent disease spread by quarantine. The current recommendation for the diagnosis of active infection is to detect viral RNA from respiratory tract samples by real-time reverse transcription-polymerase chain reaction (RT-PCR). (9–12). RT-PCR test for COVID-19 is thought to have high specificity, but its sensitivity has been reported to be as low as 59-71% (13,14).

Alternative protocols with similar sensitivity were needed in SARS-CoV-2 screening due to the increasing rapidity of the COVID-19 pandemic, the difficulty of detecting asymptomatic cases, low sensitivity and time-consuming results of the RT-PCR test, and the inability of thorax CT (15-17). Recently, test methods have been developed for the rapid detection of combined SARS-CoV-2 IgG and IgM antibodies in human serum / plasma (19). In our study, we aimed to evaluate the results of simultaneous thorax CT and ELISA-based IgM / IgG tests in COVID-19 patients diagnosed with RT-PCR in our emergency department and to demonstrate the value of serological tests in the diagnosis of COVID-19.

MATERIAL AND METHODS

Among the patients aged 18 and over who applied to the emergency department with suspicion of COVID-19 between 01.04.2020 and 31.05.2020, the patients whose COVID-19 diagnostic code (U07.3) was entered according to the ICD-10 classification were included in the study. The medical records of the patients were retrospectively examined through the hospital data processing database. Patients younger than 18 years old, patients for whom the COVID-19 diagnosis code was not entered, and those whose any of RT-PCR, thorax CT or rapid antibody tests were absent were excluded from the study.

A verified COVID-19 case was identified based on Coronavirus Pandemic Outbreak Management Guide published by the Republic of Turkey Ministry of Health the Science Board National Healthcare Commission. According to this guideline, the gold standard in the diagnosis of COVID-19 was considered to be RT-PCR positivity in nasopharyngeal swab (NS), sputum or endotracheal aspirates. Disease onset date, clinical classification, RT-PCR test results during the hospitalization period and personal demographic information were obtained from the clinical records.

This study was reviewed and approved by the Bakırçay University Medical Ethics Committee. Written and verbal consents were obtained from all participants in the study.

RT-PCR

RT-PCR analysis was performed on materials obtained by NS from patients admitted to the emergency department. A 1-step real-time RT-PCR test targeting the nucleocapsid gene and the open reading frame 1 ab gene was performed with 5 µL of a total nucleic acid according to the manufacturer's instructions.

Rapid antibody test

The rapid antibody test (Bioeasy COVID-19 Coronavirus IgG / IgM GICA Rapid Test Kit ©) used for evaluation gives a qualitative IgG / IgM result to reveal a current or past SARS-CoV-2 infection (20). This test has been approved by the Ministry of Health for use in detecting antibody formation in risk groups in the community, healthcare workers and recovered patients. There are rapid antibody tests used for COVID-19 and produced by different companies. In head-to-head studies conducted with these tests, Bioeasy kits have been reported to have 91-95% sensitivity levels (: 0.8, p <0.001) (20). The rapid antibody test gives results in as little as 30 minutes. The serum sample taken for the test is dropped onto the cassette of the rapid test kit and the presence of antibody is qualitatively shown in 15 minutes.

Thorax CT protocol

CT imaging was performed in the supine position with raised arms, and at the end of inspiration.Two radiologists experienced in the field of thorax CT reviewed the thin-section and thick-section CT images

respectively and the decision was made. Radiologists have identified the dominant appearances on CT images: ground glass density, crazy-paving pattern, consolidation, and other findings.

All thorax CT images were classified as normal, non-COVID lung findings, compatible with low probability COVID-19, intermediate probability COVID-19, high probability-definite COVID-19 as previously defined (13,21).

Statistical Method

SPSS 26.0 (IBM Corporation, Armonk, New York, United States) program was used in the analysis of variables. The compliance of nonparametric variables to normal distribution was evaluated using the Shapiro-Wilk francia test. Mann-Whitney U test was used together with Monte Carlo simulation results in comparing the two independent groups according to quantitative data. In the comparison of categorical variables, Pearson Chi-Square test, Fisher exact test and Monte Carlo Simulation technique were tested and column ratios were compared and expressed according to Benjamini-Hochberg corrected p-value results. Odds ratio was used with 95% confidence intervals to show how many times more risky those with a risk factor were compared to those who did not. Sensitivity and specificity ratios for the relationship between the classification separated by the cut-off value calculated according to the variables of the groups and the actual classification were expressed by ROC (Receiver Operating Curve) analysis. Kappa statistics were used to evaluate the correlation between PCR and rapid antibody test and CT methods. Quantitative variables were expressed as mean ± SD (standard deviation) and Median (Minimum / Maximum) in the tables, while categorical variables were shown as n (%). Variables were examined at a 95% confidence level, and a p-value of less than 0.05 was considered significant.

RESULTS

A total of 181 patients, 115 (63.5%) male and 66 (36.5%) female, with a mean age of 56.4 ± 18.06 years were included in our study, and 71 (39.2%) of the patients were diagnosed with COVID-19 confirmed by positive PCR. The demographic findings of the patients are summarized in Table 1.

Chest CT was performed in 173 (95.6%) of the patients, and findings that may be compatible with COVID-19 were found in 112 (64.7%). Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) in the diagnosis of COVID-19 infection based on thorax CT findings were 76.1%, 43.1%, 48.2% and 72.1%, respectively (kappa coefficient: 0.176, p <0.001). In addition, in patients aged [?]57, sensitivity, specificity, PPV and NPV values of thorax CT positivity in detecting PCR positivity were 69.6%, 71.1%, 74.4% and 65.9%, respectively [kappa () coefficient: 0.403, p <0.001] (Table 2).

The rapid antibody test performed during hospital admission was positive in 57 (31.5%) patients. The COVID-19 PCR positivity status of the patients was compared with the rapid antibody test findings. According to the rapid antibody test results, the sensitivity, specificity, PPV and NPV in detecting COVID-19 infection were 57.5%, 85.5%, 71.9% and 75.8%, respectively (: 0.448, p <0.001) (Table 3).

While the rate of hospitalization of patients with positive COVID-19 PCR was higher, the rate of intensive care admission was lower than other patients. However, 4 (5.6%) of the patients with positive PCR were followed up as intubated in the intensive care unit. In our study, the mortality rate for COVID-19 was found to be 2.8%.

DISCUSSION

Two main conclusions have been reached in our study. The sensitivity and specificity levels of rapid antibody tests in detecting COVID-19 cases confirmed by RT-PCR in the emergency department are 57.5% and 85.5%, respectively. In addition, thorax CT sensitivity and specificity were determined as 76.1% and 43.1%, respectively.

Regardless of whether people with COVID-19 infection are symptomatic or asymptomatic, early and accurate diagnosis is important for treating patients and reducing the rate of disease spread. Molecular and serological tests were previously compared during the SARS-CoV-1 epidemic and demonstrated that molecular tests

have high sensitivity and specificity. The current gold standard for SARS-CoV-2 detection is the SARS-CoV 2-specific quantitative RT-PCR test from a nasal and/or pharyngeal swab, sputum, or bronchoalveolar lavage (1,9,22–24). However, if the amount of viral genome in the sample is insufficient or if the correct window period of viral replication is missed, it may give false-negative results (25). This situation may result in false-negative results due to technical problems in sampling, laboratory practice standards, complex technical procedures and lack of experienced staff. As a result of a systematic review of COVID-19 test accuracy, false-negative rates ranging from 2-29% were reported based on the results of patients whose first RT-PCR result was negative and repeat tests were positive (26).

Due to the low sensitivity of the PCR test in the diagnosis and treatment algorithm of the disease, it is aimed to support the diagnosis and to prevent possible false negativities with thorax CT examination. In a study performed on 1,014 patients who underwent thorax CT and RT-PCR tests, the sensitivity of CT was found to be 97% in positive RT-PCR patients (14). It is thought that CT scanning can help distinguish COVID-19 positive and negative patients in the emergency room (27–29). Based on this, guidelines were prepared by the WHO for the combined use of thorax CT and RT-PCR in the diagnosis of COVID-19 (27).

Due to the lack of diagnostic reagents, some patients can be clinically diagnosed with thorax CT imaging (21). Some typical radiological images can be detected by CT in patients with COVID-19 pneumonia. Prominent CT findings of COVID-19 infection are the appearance of prominent ground glass density in bilateral, peripheral, and basal regions (30,31). To date, many descriptive studies and case reports have focused on the CT findings of COVID-19 (1,32–35). However, clinical and laboratory findings of COVID-19 infection are indistinguishable from pneumonia caused by some common respiratory pathogens such as influenza virus, Streptococcus pneumoniae and Mycoplasma pneumoniae (36).

Chung et al. (34) reported that thorax CT may be negative for viral pneumonia of COVID-19 at the first admission of patients (3/21 patients). Xi et al. (37) reported 5/167 (3%) patients with negative RT PCR for COVID-19 at first admission, despite the thorax CT findings specific to viral pneumonia. In our study, PPV and NPV values of thorax CT in detecting COVID-19 patients were found at low levels such as 48.2% and 72.1%. This situation was thought to be related to the normal tomography images of patients who presented especially in the early period of the disease. Today, with the gradual recognition of the radiological findings of COVID-19 pneumonia, guidelines are prepared for prompt and accurate diagnosis (38).

Successful management of disease spread will require serological detection of past infection to determine immunity (39). Antibodies specific to SARS-CoV-2 are usually detected within just more than a week after the onset of symptoms, limiting the role of serology in identifying acute infection (40). As stated in the literature, it has been shown that IgM and IgG levels can be measured in patients with SARS-CoV-2 infection from the first week of the disease or generally from the second week (41-43). These findings were found to be parallel to the antibody development characteristics of MERS-CoV infection (44). This situation restricts the use of antibody tests for screening purposes during the COVID-19 pandemic (43,45,46).

These limitations have led to the development of different serological microplate ELISA tests (45,47). Some authors stated that the combination of molecular and serological techniques can reach a sensitivity of 97% in the diagnosis of SARS-CoV-2 infection (43,45). However, these time-consuming tests based on ELISA are generally not as suitable for clinical use as rapid tests and are difficult to incorporate into management algorithms in emergency departments (43,45,48,49). Testing IgM and IgG production in response to viral infection can be a simple method to increase the sensitivity and accuracy of the molecular test (45). Additionally, it can be used for screening purposes to evaluate antibody profiles in a large population. Large-scale screening programs using the antibody test are currently carried out by different governments to reveal the percentage of population immunity.

In our study, the sensitivity of the rapid antibody test performed at the first admission of the patients was evaluated. According to our preliminary findings, despite the low sensitivity (57.5%), our having high specificity (85.5%) levels in rapid antibody tests suggests that the use of rapid antibody test combining with RT-PCR and thorax CT may prevent false-negative results in our society, which population immunity is still

low.

There are some limitations in our study. First of all, the selection of patients among the patients who applied to the emergency department made it difficult to evaluate asymptomatic SARS-CoV-2 carriers. It was thought that taking the single NS RT-PCR tests taken at the time of admission as an index caused the false-negative patients to be excluded due to the low sensitivity of the PCR test. In addition, rapid antibody tests evaluated in the emergency department was thought to affect the test results as they could not reach sufficient levels as a result of not allowing the window time required for antibody development.

In conclusion, rapid antibody test and thorax CT examinations were found to have low diagnostic value in patients who applied to the emergency department of our hospital and had a positive first RT-PCR SARS-CoV-2 test. Studies involving larger patient groups are needed for their use alone in diagnosis and screening.

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TABLES

Table 1. Demographic characteristics and clinical findings of the patients

Age	**Age**
Gender	**Gend**
	Female
	Male
PCR	**PCR**
	Negati
	Positiv
Rapid antibody test	**Rapid**
	Negati
	Positiv
Thorax CT	**Thora**
	No
	Yes
CT Finding	**CT F**
	Anoth
	COVI
	Norma
Need for MV	**Need**
	No
	Yes
Clinical management and follow-up	**Clinic**
	Home
	Exitus
	Hospit
Comorbidity	**Como**
	Absent
	Presen
SD. Standard Deviation, Min.:Minimum, Max.:Maximum, CT: Computed tomography, MV: Mechanical ventilator	SD. St

Table 2.Sensitivity levels of Thorax CT findings in patients with positive PCR results

Clinical management

Mechanical ventilator	
Total	

Kappa Statisticial Test (Monte Carlo), **k**: Kappa Coefficient, [ss:] Sensitivity, [sp:] Specificity, [ppv:] Positive predictive value, [npv

Table 3. Sensitivity levels of rapid antibody test in patients with positive PCR results.

Clinical management	
Mechanical ventilator	
Total	

Kappa Statisticial Test (Monte Carlo), **k**: Kappa Coefficient, [ss:] Sensitivity, [sp:] Specificity, [ppv:] Pozitive predictive value, [npv

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rapid-antibody-test-and-thorax-computed-tomography-results-in-patients-who-underwent-rt-pcr-with-the-pre-diagnosis-of-covid-19