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Utility of Rapid Antibody Test for Screening COVID-19 Among Healthcare Professionals

Sağlık Çalışanı Taramasında COVİD-19 Hızlı Antikor Testlerinin Kullanımı ve Etkinliğinin Değerlendirilmesi

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ABSTRACT

Objective: This study aims to assess the effectivity of a rapid antibody test on detecting the occupational exposure in healthcare professionals who have been working in a pandemic hospital since the initial cases were seen in our country.

Methods: Prevention of Coronavirus disease 2019 (COVID-19) in our institution was managed according to the Republic of Turkey (T.C.) Ministry of Health recommendations. Between 20.04.2020 and 05.05.2020, 376 high-risk professionals (triage, emergency room, COVID-19 outpatient unit, COVID-19 clinic and intensive care unit) were screened by rapid antibody test for COVID-19. Positive cases were retrospectively examined in terms of COVID-19 diagnosis or potential symptoms of COVID-19 infection (fever, perspiration, debility, cough, myalgia, sour throat, nasal flow, diarrhea, loss of smell/taste sensation).

Results: The mean age was 32.7±8.9 years, 222 patients were female and 154 were male. Positive rapid antibody test was detected in 27 (7.2%) patients: 24 of those had COVID-19 diagnosis or potential symptoms of COVID-19 infection, where 3 patients had no signs or symptoms of the disease.

Conclusion: During pandemic, the reliability of rapid antibody tests has become under question due to validation issues. However, rapid antibody test may be feasible for COVID-19 screening among healthcare professionals in order to assess the precautions and prevent nosocomial infection.

ÖZ

Amaç: Çalışmamızda pandemi sürecinde yüksek riskli alanlarda görev yapan sağlık çalışanlarında hızlı antikor testleriyle Coronavirus hastalığı 2019 (COVİD-19) enfeksiyonuyla maruziyetlerini belirlemeyi ve kitin etkinliği hakkında fikir edinmeyi amaçladık.

Yöntemler: Sağlık çalışanlarında COVİD-19 enfeksiyonundan korunma önerileri Türkiye Cumhuriyeti (T.C.) Sağlık Bakanlığı COVİD-19 Rehberi doğrultusunda gerçekleştirildi. Yüksek riskli alanlarda görev yapan (triyaj alanları, acil servis, COVİD-19 polikliniği, COVİD-19 servisleri, yoğun bakım ünitesi) 376 sağlık çalışanı COVİD-19 ile maruziyetlerinin değerlendirilmesi amacıyla kesitsel olarak 20.04.2020-05.05.2020 tarihleri arasında hızlı antikor kitleri ile tarandı. Taramada antikor pozitif saptananlar geriye dönük olarak son 2 ay içinde kesin COVİD-19 enfeksiyonu tanısı veya başka bir sebeple açıklanmayan olası COVİD-19 semptomları (ateş yüksekliği, terleme, öksürük, nefes darlığı, halsizlik, kas ağrısı, baş ağrısı, boğaz ağrısı, burun akıntısı, ishal, tat ve koku kaybı) açısından sorgulandı ve verileri kaydedildi.

Bulgular: Çalışmamızda 222 kadın, 154 erkek olmak üzere 376 sağlık çalışanı tarandı. Yaş ortalaması 32,7±8,9 idi. Bunlardan 27'sinde (%7,2) hızlı antikor testleri pozitif saptanırken 349 (%92,8) çalışanda COVİD-19 hızlı antikor testleri negatif olarak sonuçlandı. Yirmi yedi sağlık çalışanının 24'ünde kesin COVİD-19 tanısı ya da son 2 ay içinde COVİD-19 enfeksiyonu düşündüren semptomlar olduğu değerlendirildi. Üç çalışan ise bu süreçte herhangi bir semptom tariflemedi.

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Sonuç: Pandemi sürecinde hızlı antikor testleriyle yaşanan validasyon sorunları nedeniyle test sonuçlarına güvenilirlik azalmaktadır. Literatürde benzer bir çalışmaya rastlanmazken COVİD-19 hastalarına hizmet sunan hastanelerde sağlık çalışanı taramalarının enfeksiyon kontrol önlemlerini değerlendirmek ve nozokomiyal bulaşı engellemek için akılcı bir yaklaşım olduğunu düşünmekteyiz.

Anahtar Sözcükler: COVİD-19, sağlık çalışanı, hızlı antikor testi

Introduction

Since the Severe Acute Respiratory Syndrome-Coronavirus-2 (SARS-CoV-2) infection was first reported in the city of China-Wuhan and the date of March 11, 2020 when World Health Organization declared it as a pandemic, its impact has been continuing all over the world. In our country, the disease is tried to be taken under control and the whole process is followed closely in the company of the Coronavirus Disease 2019 (COVID-19) Guide (1), which is updated periodically by the scientific committee established by the Republic of Turkey Ministry of Health. Since March 11, 2020, when the first case was reported in our country, the total number of cases confirmed on June 28, 2020 is 195,883, and the number of those who died is 5,082 (2).

In the last 20 years, global outbreaks have been experienced with SARS and Middle East Respiratory Syndrome (MERS)-CoV-2, which are members of the coronavirus family (3,4). The contagiousness of COVID-19 infection is higher than these infections, but mortality rates are lower (5). Due to the structural similarities with SARS and MERS-CoV-2, evaluations and recommendations regarding the diagnosis, treatment, prognosis and prevention methods of COVID-19 disease have been made, and many studies are ongoing in this area (6).

SARS-CoV-2 is thought to be a zoonotic infection (1). Although its source is not yet clear, the transition from the wholesale fish and livestock market to human was first identified in Wuhan, Hubei state of China, and it was shown to be transmitted from person to person through droplets and close contact (1,5). Therefore, healthcare professionals who have contact with and care for patients are at high risk of contamination. Compliance with hand hygiene while providing services to patients and proper use of personal protective equipment in line with the Republic of Turkey Ministry of Health's COVID-19 Guidelines minimizes this risk (1). Fever, cough, weakness and muscle pain are the most common complaints in the course of infection, while approximately 75% of the patients have a mild clinical course and 25% have a severe course. Mortality rates are evaluated as 2-3%, and the prognosis of the disease is seen to be poor, especially in patients with advanced age and underlying chronic diseases (7).

The gold standard in the diagnosis of the disease is the COVID-19 real-time polymerase chain reaction (RT-PCR) test (8). The sensitivity of the RT-PCR test is evaluated as 50-70%; when the sample is taken, it is seen that the duration of the infection, the technique of taking it and the appropriate transport methods affect this rate (8). In addition to the sensitivity problems experienced in the molecular method, the high cost and the inability to reach results in the early period also created the need for rapid serological tests (9). It is also very important to diagnose suspicious patients in as little as 15 minutes to prevent nosocomial infection and to protect healthcare workers (10). In addition, in epidemiological studies and in cases with negative RT-PCR, rapid antibody tests and enzyme-linked immunosorbent assays are used to confirm the diagnosis (10). In this process, many rapid antibody kits were used without validation, without knowledge of their specificity and sensitivity. This has also raised concerns about the effectiveness of rapid antibody tests. However, it has been shown in studies that the diagnostic efficiency of kits approved by Food and Drug Administration (FDA), Conformité Européenne (CE) and CE-European CE Marking for *In Vitro* Diagnostic (IVD) are high, and new studies are also needed (9-12).

In our study, we aimed to evaluate the exposure of our healthcare professionals working in high-risk units with COVID-19 infection and to evaluate the effectiveness of these tests.

Method

Our study was planned retrospectively using a cross-sectional study method. Recommendations for protection from COVID-19 infection in healthcare workers during the pandemic process in our hospital were provided in line with the Republic of Turkey Ministry of Health COVID-19 Guidelines. Three hundred seventy six healthcare staff working in high-risk areas (triage, emergency service, COVID-19 outpatient clinic, COVID-19 services, intensive care unit) were scanned with the COVID-19 rapid antibody test for evaluating their exposure to COVID-19 virus between April 20, 2020 and May 05, 2020.

For scanning, the COVID-19 immunoglobulin M (IgM)-IgG lateral flow test was used, which was supplied to our hospital as approved by the Ministry of Health. Blood samples were taken from the individuals and studied in the microbiology laboratory, and they were concluded within 15 minutes. The patients who were detected to have only IgM positive, only IgG positive or IgM and IgG positive were questioned about whether they were diagnozed with definite COVID-19 infection and whether they had at least two of non-explained symptoms (fever, sweating, cough, shortness of breath, weakness, muscle pain, headache, sore throat, runny nose, diarrhea, loss of taste and smell) suspected for COVID-19 in the last 2 months and their data were recorded.

Statistical Analysis

Parametric values will be expressed as mean ± standard deviation, categorical data will be expressed as percentages.

Results

In our study, 376 healthcare workers, including 222 women and 154 men, were screened. The mean age was 32.7±8.9 years. Rapid antibody tests were found to be positive in 27 of these (7.2%), while COVID-19 rapid antibody tests were negative in 349 (92.8%) workers.

It was evaluated that 24 of the 27 healthcare staff had at least 2 of the symptoms suggesting COVID-19 infection, which were not explained for any other reason, or diagnozed with COVID-19 in the last 2 months. 3 employees did not describe any symptoms during this period (Figure 1).

Of the 27 people whose rapid antibody tests were positive, only 2 were IgM positive, 4 of them were IgM and IgG positive, and 21 of them were only IgG positive. One of staff with only IgM positive described fever, weakness, and runny nose 10 days before the scan. Another health worker, who was IgM positive, stated that he had no active complaints in the last 2 months. One of the employees who were IgM and IgG positive was diagnosed with COVID-19 one month ago. Three other employees described symptoms suggesting possible COVID-19 infection in the past 2 months. In 21 healthcare workers who were only IgG positive; 3 received treatment within the last 2 months with the definitive diagnosis of COVID-19. One employee was followed up with a definite diagnosis of COVID-19 2 days after the screening test was found to be positive. Fifteen healthcare workers said they had symptoms that were not explained for any other reason during this process, suggesting a possible COVID-19 infection. Two employees had no symptoms (Figure 2).

Discussion

While the severity and effects of the COVID-19 pandemic differ among countries, we see that the isolation of infected individuals is a determinant in epidemic management, because the biggest obstacle in breaking the chain of transmission is that SARS-CoV-2 infection is often passed as asymptomatic or with mild symptoms (13). Those who are admitted to the hospital and hospitalized are generally the patients with severe clinical condition or expected progression. These patients have the most contagious disease and healthcare workers are at great risk worldwide (14). Early and rapid diagnosis of patients is critical to protect healthcare professionals.

At the diagnosis stage of SARS-CoV-2, the molecular method RT-PCR is used in naso-oropharyngeal swab samples and lower respiratory tract samples in people who meet the possible case definition of COVID-19 (10). The medical microbiology laboratory of our hospital also served as a reference laboratory for the COVID-19 RT-PCR test shortly after the announcement of the pandemic. The sensitivity of this method, which is the gold standard in diagnosis, is 50-70% (8). However, problems such as low sensitivity of the test, expensive molecular methods, and inability to obtain results immediately led to the development of serological methods (10). For this purpose, laboratory-based enzyme immunoassays and point-of-care rapid tests are used (10).

Both antigen and antibody presence can be evaluated with serological methods. Among serological methods, antibody tests have important advantages such as evaluating the presence of antibodies in patients who have recovered, detecting individuals who are asymptomatic and showing the prevalence of the disease in the society (10). Rapid antibody tests are performed on whole blood, serum or plasma samples. The methods used are lateral flow immunoassays, time-resolved fluorescence immunoassays, and colloidal gold immunoassays (10). As the COVID-19 pandemic continues, various serological tests have been allowed to be developed and it has been allowed to accelerate their availability regardless of the presence of emergency use authorization from the FDA. (10) However, all antibody tests need to be validated to ensure reliability, accuracy, consistency, and reproducibility (15). For this reason, different kits have been evaluated in many studies, especially in which rapid antibody tests were used, and it has been shown in studies that the diagnostic efficiency of kits approved by FDA, CE and CE-IVD is high (10-12). In the largest study conducted in this area, the sensitivity of

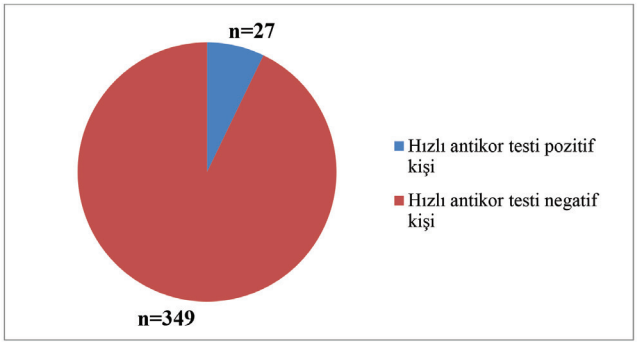

Figure 1. Rapid antibody test results of healthcare workers (n=number)

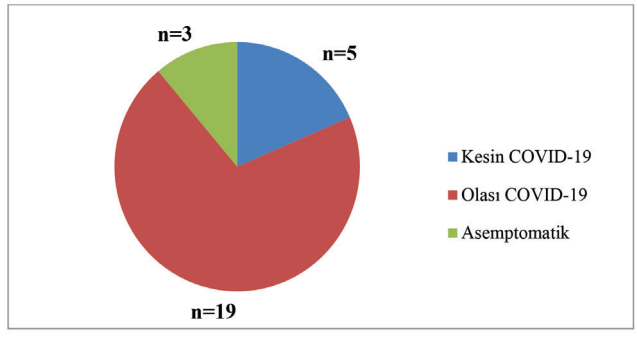

Figure 2. Distribution of healthcare professionals with positive rapid antibody test result (n=number)

BioMedomics IgM-IgG lateral flow rapid antibody tests in the sample including 525 patient was 89% and the specificity was 91% (9). The disadvantages of serological tests are the absence of IgM-IgG positivity in the early period of the disease, and test positivity that is expected at the earliest 3 days after the onset of symptoms and 7-10 days after the infection (16). In addition, it has been reported that there is no antibody response in people with mild COVID-19 infection (10). In another study in which antibody responses were evaluated, it was found that IgM positivity could extend up to 8 weeks, and IgG positivity was still high at the 8th week (17).

In our country, COVID-19 IgM-IgG lateral flow rapid antibody tests approved by the Republic of Turkey Ministry of Health were used for screening in our hospital due to the high risk of transmission in healthcare workers during the pandemic. The test is not approved by FDA, CE, and CE-IVD, which reduces the reliability of the test results. However, in clinical evaluations, it was seen that 89% of those with positive antibody tests were diagnosed with definite COVID-19 or had possible COVID-19 symptoms that could not be explained for any other reason in the last 2 months, only 3 (11%) employees did not describe any symptoms. However, approximately 20-80% of patients with SARS-CoV-2 infection are also thought to be asymptomatic (18). Considering that the pandemic strains are the dominant strain in the circulation, the average age of the screened group is 32.7 years and the COVID-19 infection has a mild course at the rate of 75%, it can be suggested that the results of those with positive antibody results are consistent. Studies have shown that antibody responses and the time when antibodies remain positive in individuals with COVID-19 infection vary (19). Therefore, with the use of validated rapid antibody tests, reliable results will be obtained in screening and evaluating the antibody responses of people who have had COVID-19 infection. Further studies in this area are needed.

Study Limitations

Our study's being single-centered and its cross-sectional and retrospective design are the limitations.

Conclusion

While the pandemic process continues, all healthcare professionals work under high risk. Use of protective equipment and compliance with recommendations for appropriate isolation minimize the possibility of transmission, but do not eliminate it. For this reason, screening of healthcare workers is a rational approach for both evaluating infection control measures and preventing nosocomial transmission, especially in hospitals giving care to COVID-19 patients, and no similar study has been found in the literature.

Ethics

Ethics Committee Approval: Permission was obtained from the Scientific Research Platform of the Ministry of Health.

Informed Consent: Consent was not obtained because the study was planned retrospectively.

Peer-review: İnternally peer reviewed.

Authorship Contributions

Concept: A.B.K., B.S., Design: A.B.K., B.S., M.M.K., Data Collection or Processing: A.B.K., B.S., S.B., G.O., B.D., Y.A., M.M.K., Analysis or Interpretation: A.B.K., B.S., S.B., G.O., B.D., Y.A., M.M.K., Literature Search: A.B.K., Writing: A.B.K.

Conflict of Interest: No conflict of interest was declared by the authors.

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