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Evaluation of two SARS-CoV-2 lateral flow antibody kits for serological diagnosis of COVID-19

COVID-19 serolojik tanısında iki SARS-CoV-2 lateral flow antikor kitinin değerlendirilmesi

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ABSTRACT

Objective: The emergence of new SARS-CoV-2 has prompted the development of new serological tests that could be complementary to RT-PCR. Serological tests can also be used for purposes such as demonstrating the presence of antibodies in individuals who have had the disease, contact screening, screening of healthcare professionals, monitoring of vaccine responses, detection of antibody levels of plasma donors, and determination of seroprevalence in risky groups. For this purpose, different methods such as ELISA, CLIA or rapid antibody detection tests are used. LFIA tests are fast, easy to apply, do not require experience, and are cheap tests that give a result in as little as 10 minutes. However, the clinical performance of existing serological tests used in diagnosis needs to be evaluated. The aim of this study was to assess the performance of two immunological tests for the detection of SARS-CoV-2 antibodies.

Methods: As a positive serum panel, 101 serum samples from patients confirmed by SARS-CoV-2 RT-PCR test and also found antibody positive by ELISA test were included in the study. As the negative serum panel, 30 serum samples were determined, including 11 serum

ÖZET

Amaç: Yeni SARS-CoV-2 virüsünün ortaya çıkışı, RT-PCR'ı tamamlayıcı olabilecek yeni serolojik testlerin geliştirilmesini teşvik etmiştir. Serolojik testler ayrıca hastalığı geçirmiş olan bireylerde antikor varlığının gösterilmesi, temaslı kişilerin taranması, sağlık çalışanlarının taranması, aşı yanıtlarının takibi, plazma verici kişilerin antikor düzeylerinin tespiti ve riskli gruplardaki bireylerde seroprevalansın belirlenmesi gibi amaçlarla kullanılabilmektedir. Bu amaçla ELISA, CLIA veya hızlı antikor tespit testleri gibi farklı yöntemler kullanılmaktadır. LFIA testleri 10 dakika gibi kısa sürede sonuçlanan, hızlı, uygulaması kolay, tecrübe gerektirmeyen ve ucuz testlerdir. Bununla birlikte, tanıda kullanılan mevcut serolojik testlerin klinik performanslarının değerlendirilmesi gerekmektedir. Bu çalışmanın amacı, SARS-CoV-2 antikorlarının tespiti için iki immünolojik testin performansını değerlendirmektir.

Yöntem: Çalışmaya pozitif serum paneli olarak SARS-CoV-2 RT-PCR testi ile doğrulanan hastalardan alınan ve ELISA testi ile antikor pozitif saptanan 101 serum örneği dahil edilmiştir. Negatif serum paneli olarak da SARS-CoV-2 dışındaki diğer virüslere karşı antikor saptanmış 11 serum

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samples with antibodies against viruses other than SARS-CoV-2, and 19 serum samples from healthy donors in 2019. First, SARS-CoV-2 antibodies were tested by ELISA (Wantai, China) and than these serum samples were tested simultaneously with the SureScreen COVID-19 IgG/IgM Rapid Test Cassette and YHLO Gline 2019 nCov IgG/IgM kits.

Results: The SureScreen and YHLO Gline kits showed an overall sensitivity of 86.1% and 75.3%, for detecting IgG and/or IgM, respectively. Specificity was 100% in both rapid antibody tests. The kappa value for IgG of the two rapid antibody tests was 0.816, while it was 0.695 for IgM.

Conclusion: Our study shows that SureScreen and YHLO Gline are reliable kits for use as point-of-care tests for rapid antibody detection. According to Cohen's kappa statistics the 91% (κ=0.816) agreement between SureScreen IgG and YHLO Gline IgG, "Almost Perfect", and 85% agreement (κ=0.695) between SureScreen IgM and YHLO Gline IgM, "Substantial", indicate a good correlation between the performance of the LFIAs used in the study. Total antibody conformity was determined as 92% (κ=0.822), "Almost Perfect". Agreement between IgM tests was lower than that between IgG tests.

Key Words: SARS-CoV-2, COVID-19, serology, antibody

örneği ve 2019 yılına ait sağlıklı donörlerden alınmış 19 serum örneği olmak üzere 30 serum örneği belirlenmiştir. Serum örnekleri ilk olarak SARS-CoV-2 Ab ELISA, (Wantai, China) kiti ile test edildi ve daha sonra SureScreen COVID-19 IgG/IgM Rapid Test Cassette ve YHLO Gline 2019 nCov IgG/IgM kitleri ile eş zamanlı test edildi.

Bulgular: SureScreen ve YHLO Gline kitleri, IgG ve/veya IgM'yi saptamak için sırasıyla %86,1 ve %75,3'lük bir genel duyarlılık gösterdi. Spesifite ise her iki hızlı antikor testinde de %100,0 olarak hesaplandı. İki hızlı antikor testinin IgG için kappa değeri 0.816 iken IgM için 0.695 idi.

Sonuç: Çalışmamız, SureScreen ve Gline'in hızlı antikor tespiti için hasta başı testleri olarak kullanım için güvenilir kitler olduğunu göstermektedir. Cohen'in kappa istatistiğine göre, SureScreen IgG ve YHLO Gline IgG arasında %91 (κ=0.816) uyum, "Neredeyse Mükemmel" ve SureScreen IgM ile YHLO Gline IgM arasında %85 (κ=0.695) uyum, "Önemli" olarak bulundu. Bu sonuçlar bu çalışmada kullanılan LFIA'ların performansı arasında iyi bir korelasyon olduğunu gösterdi. Toplam antikor uygunluğu %92 (κ=0.822), "Neredeyse Mükemmel" olarak belirlendi. IgM testleri arasındaki uyum, IgG testleri arasındakinden daha düşüktü.

Anahtar Kelimeler: SARS-CoV-2, COVID-19, seroloji, antikor

INTRODUCTION

A new coronavirus emerged from the Wuhan region in China in December 2019, causing a new acute respiratory syndrome named coronavirus disease 2019 (COVID-19). This infection, caused by a new Sarbecovirus, is called as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), rapidly turned to be a pandemic and became a common cause of mortality and morbidity around the world (1,2). Detection of viral RNA by real-time reverse transcriptase polymerase chain reaction (RT-PCR) in respiratory tract samples in the early phase of infection is considered the gold standard method for screening and diagnosis. However, the sensitivity of the RT-PCR test can vary depending on sample types, sampling technique, anatomical site, time of infection, and viral load (3,4). Computed tomography (CT) complementary to RT-PCR may be helpful for diagnosis, but is not specific (5). Serological tests have been used as complementary tests, especially in the period after the first week, in cases where RT-PCR

tests are negative. It can also be used for purposes such as showing antibody development in patients with the disease, close contact screening, health care worker screening, monitoring of vaccine responses, detection of antibody levels in plasma donors and determining seroprevalence in high-risk groups. Serological tests are also important in demonstrating the presence of antibodies in immune plasma collected from patients with the disease. For this purpose, different methods such as enzyme-linked immunosorbent assay (ELISA), chemiluminescence enzyme immunoassay (CLIA), or rapid antibody detection tests are used (6). Lateral flow immunoassay (LFIA) tests appear to be suitable for large seroprevalence studies. These tests can be easily used as bedside tests or in small laboratories that do not have ELISA capabilities (7,8). LFIA tests are fast, easy to apply, do not require experience, and are cheap tests that give a result in as little as 10 minutes. In addition, they enable IgM and IgG to be evaluated separately at the same time. The most important disadvantage in serological tests is that antibody formation takes a certain time following infection (9,10). Another disadvantage is the invasive sampling technique such as blood collection. Moreover, the clinical performance of serological tests varies according to the assay method, the application process, the production quality of the target antigen, or the selected target site. Therefore, antibody (Ab) tests with high sensitivity and specificity are needed. Despite the increasing number of commercial test kits, studies are still insufficient to determine the performance of these kits (13-19).

The aim of the present study was to evaluate the performance of two CE-marked immunological tests used in the detection of SARS-CoV-2 antibodies.

MATERIAL and METHOD

Patients and serum samples

During the initial period of the COVID-19 pandemic, consecutive, routine samples from patients over the age of 18 who were hospitalized and whose COVID-19 PCR positivity were confirmed were included in the study. A total of 131 samples, 101 serum samples obtained from patients confirmed by the SARS-CoV-2 RT-PCR test (Bio-Speedy® COVID-19 RT-qPCR Detection Kit, Bioeksen R&D Ltd., Turkey) and positive by ELISA test, and 30 serum samples as a negative serum panel, were included in the study. All samples were tested with the same PCR kit. The negative serum panel was composed of 11 sera with antibodies detected against viruses other than SARS-CoV-2 and 19 serum samples from healthy donors in 2019.

Serum samples were heat inactivated at 56 °C for 60 minutes and stored at 4 °C until the day of the study. Before the study, all samples were brought to room temperature and vortexed for a short time.

Serological assays

ELISA assay

All patient and control serum samples were tested with the WANTAI SARS-CoV-2 Ab ELISA (Beijing Wantai Biological Pharmacy Enterprise, China) kit according to the manufacturer's instructions. Total antibodies against SARS-CoV-2 spike protein were detected by ELISA. WANTAI SARS-COV-2 Ab ELISA is a double antigen sandwich immunoassay for the qualitative detection of antibodies against the RBD domain of the S1 protein. Optical densities were read at 450 nm with an ELISA reader. Samples with an index value higher than 1.1 were considered positive. All serum samples were tested with the same ELISA kit.

Lateral flow immunoassays

The SureScreen Covid-19 IgG/IgM Antibody Test (SureScreen, UK) and Shenzhen YHLO Biotech - Gline 2019-nCoV IgG/IgM Antibody Test (colloidal gold) (Avioq, Bio-Tech, Shandong, China) were used. These are immunochromatographic systems used for the qualitative detection of IgM and IgG antibodies against SARS-CoV-2 in human whole blood, serum, or plasma samples. LFIA tests were performed simultaneously with SureScreen and YHLO Gline with 10 µL of serum, according to the manufacturers' instructions.

According to the manufacturers' instructions, all results should be evaluated within 10-15 minutes. The results were read and interpreted in 10 minutes. The LFIA results were easily interpreted as light and dark pink IgG and IgM lines. In some sera, the IgM line was very difficult to read in both LFIA tests. The results of such samples were considered "Positive". Color density was not evaluated. The sensitivity and specificity of the rapid antibody kits were calculated according to the ELISA results.

Statistical analyses

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for each serological test. The kappa index was calculated for agreement between all analyzed assays. For the interpretation of kappa statistics, the intervals suggested by Landis and Koch were used. Here, if the Kappa value is 0, it is interpreted as "intra/interobserver harmony depends only on chance, and in other cases there is no harmony". If the kappa value is 1, it is interpreted as "the measurements within/between observers completely match each other". If Kappa value is <0.00, it is interpreted as Poor, between 0.00-0.20 as Slight, between 0.21-0.40 as Fair, between 0.41-0.60 as Moderate, between 0.61-0.80 as Substantial and between 0.81-1.00 as Almost Perfect (11,12). In our study, sample size calculations were made with the G*Power 3.1.9.7 program. The power is calculated as 0.6224. Since the samples were obtained in the first months of the pandemic and during the period when the seroprevalence was very low, the study was carried out with the existing number of samples.

Ethical Approval

This retrospective study was conducted at National Virology Reference Laboratory after the approval of the Head of the Ethics Committee of Clinical Research No:2 of Ankara City Hospital, Ministry of Health (Number: E2-21-837 and Date: 20.09.2021).

All procedures performed in the present study were made in accordance with the ethical standards of the Helsinki Declaration (2008).

For this study, the necessary permits were obtained from the Scientific Research Studies platform on COVID-19 of the Ministry of Health with the application number 2021-09-02T15_17_25.

RESULTS

The results for the rapid antibody test kits are summarized in Table 1. The LFIA tests SureScreen and YHLO Gline showed sensitivities of 86.1% and 75.3%, respectively. Specificity was 100.0% in both rapid antibody tests. In the negative serum panel, no false positive results were observed for the parameters of the rapid antibody tests. In the present study, all the samples had a reactive control line and valid results were obtained in all tests performed. Because our sample number is limited, further studies with larger sample numbers will contribute to such studies.

Agreement between serological tests

When the agreement between SureScreen IgG and YHLO Gline IgG was examined according to Cohen's kappa statistics, 91% (kappa value = 0.816), "Almost Perfect", was observed. The agreement between SureScreen IgM and YHLO Gline IgM was 85% (kappa value = 0.695), "Substantial". When overall antibody compatibility was evaluated, it was 92% (kappa value = 0.822), indicating a value as "Almost Perfect".

DISCUSSION

Serological tests, especially rapid antibody tests, are complementary tests in the diagnosis of COVID-19, and in the later stages of the pandemic they play a strategic role in epidemiological studies and determining vaccine efficacy. Some studies on the diagnosis of COVID-19 emphasized the complementary role of serological tests to RT-qPCR, especially in critical patients with negative RT-qPCR.

Table 1. The analytical sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for SARS-CoV-2 antibody detection for LFIAs

	SureScreen	YHLO Biotech
Sensitivity (95% CI)	86.14% (77.84 - 92.21)	75.25% (65.67 - 83.30)
Specificity (95% CI)	100% (88.43 - 100)	100% (88.43 - 100)
Positive predictive value* (95% CI)	100.00%	100.00%
Negative predictive value* (95% CI)	68.18% (56.86 - 77.7)	54.55% (46.07 - 62.77)
Accuracy* (95% CI)	89.31% (82.72 - 94.03)	80.92% (73.13 - 87.25)

(*) These values are dependent on disease prevalence.

Zhao et al. found 28.6% positivity in the 1-3-day period and 53.6% positivity in the 4-7-day period with the ELISA total antibody test in patients with negative RT-PCR result. Diagnosis rates of 67.1%, based on RT-PCR alone increased to 99.4% when antibody results were also considered (13). Guo et al. reported that 51.9% of the diagnoses were made with a single RT-qPCR test in the first 5.5 days, and when the IgM ELISA test was combined with RT-PCR, the positive detection rate reached to 98.6% (14). There are many different serological tests on the market, and it is clear that we are currently facing difficulties regarding the many factors involved in evaluating the accuracy of these tests. LFIA tests allow the qualitative determination of antibodies against SARS-CoV-2. Recently, many commercial rapid antibody kits have been developed with the CE label. In our study, when the SureScreen and YHLO Gline kits were evaluated in terms of IgM and/or IgG antibodies, they revealed a sensitivity of 86.1% and 75.3%, respectively. Specificity was 100.0% in both rapid antibody tests. The performance of the Wantai ELISA kit, which is used to calculate sensitivity and specificity, has been found to be quite high in previous studies. Zhao et al. determined that with the Wantai ELISA kit the antibody positivity rates also increased as the days from the onset of symptoms increased and reached to 100% between 15 and 39 days (13). Marlet et al. found that the sensitivity of the Wantai ELISA kit was 97.8% and the specificity was 100.0% in serum samples taken on day 14 after the onset of symptoms (15). Because the ELISA kit we used has high sensitivity and specificity, the sensitivity and specificity of the LFIA kits were calculated according to this kit. With the combined LFIA kit designed by Jiangsu Medomics Medical Technologies in China, 88.6% sensitivity and 90.6% specificity were obtained in a study conducted with 397 RT-PCR-positive COVID-19 patients and 128 control samples obtained from eight different centers (16). Montesinos et al. used 128 SARS-CoV-2 positive and 72 negative control serum samples in their study investigating the serological response with one ELISA, one CLIA, and three LFIAs. In three different LFIA studies, when IgM and/or IgG positivity were evaluated together, they found sensitivity of 68.8%, 71.1%, and 71.9% and specificity of 95.8%, 100.0%, and 100.0%, respectively. When IgM and/or IgG positivity were evaluated together for the CLIA test, they found 64.3% sensitivity and 100.0% specificity. The ELISA test that they used gave 84.4% sensitivity and 100.0% specificity when IgA and/or IgG positivity were evaluated together. However, since 28 of the 128 positive samples were taken between days 0 and 7, this may have led to a low sensitivity (17). Since we did not have the data for the sample

collection time, the specificity and sensitivity could not be calculated in detail according to the times and were stated as a total. However, specificity and sensitivity were found in similar ranges with the studies in the literature. Charlton et al. compared six EIA and six POCT kits and found the sensitivity of the EIA tests ranging between 64-95% and the sensitivity of the POCT tests 64-83 %; specificity being more than 98% in all kits (18). In our study, the sensitivity of the LFIA kits was similarly lower than that of the ELISA tests. Flower et al., tested 11 LFIA kits and obtained sensitivity between 48% and 93% and specificity between 97.2% and 99.8%. They also found 88% sensitivity and 99.8% specificity for SureScreen, one of the LFIA kits tested in our study (19). The results were similar to the SureScreen results in our study. In our study, we aimed to measure SARS-CoV-2 total antibodies with ELISA and LFIA. In the classical antibody response, IgM is usually produced first and then IgG develops. However, studies on SARS-CoV suggested that IgM and IgG may develop between 2 and 4 days apart or at the same time (20,21). For this reason, total antibodies were determined with ELISA. IgG and IgM positivity was evaluated as a IgM and/or IgG with LFIA. Van Elslande et al. evaluated seven different LFIA kits and the overall sensitivities were 65.4-79.1 % and the specificities 85.4-99.0 %. When their performances for IgM and IgG were evaluated separately, the sensitivities were 32-72.5 % for IgM and 55.6-71.2 % for IgG. Moreover, specificity was reported for IgM and IgG as 91.3-100 % and 90.3-99 %, respectively (22). In cases where the performance of LFIAs is evaluated independently from the onset of symptoms, it is obvious that overall evaluation of IgG and IgM positivity is a correct approach. In our study, although positivity was expected in at least one of the IgG or IgM antibodies with rapid antibody tests in sera obtained from patients with infection and with positive ELISA total antibody test, approximately 14% false negative results were obtained with the SureScreen kit and 25% with the YHLO Gline kit. In ELISA tests, the color change due to the reaction of the patient samples in the virus antigen-coated wells is read spectrophotometrically in the ELISA reader. Since the absorbance values obtained are determined as optical density, the results are clearly perceived and a numerical value emerges. Since there are positive sera with a low OD value with ELISA in the positive serum panel, it was thought that these low positivity levels may not have been detected by card tests. In card tests, band formation is evaluated visually. In cases where there is insufficient band formation to be seen by the naked eye, there may be erroneous negative evaluations depending on subjective evaluations. Ong et al. detected 3 out of 128 negative samples as false positives with the Wantai total antibody kit and they calculated specificity of 98% (23). Therefore, the specificity of ELISA kits may not be 100% and false positive results may occur. For this reason, it is useful to verify the samples by testing them with different ELISA kits. We found lower sensitivity in our study than the manufacturers reported possibly because the patient groups belonging to the samples tested may have had clinical, age, sex, sample collection time, and population differences such as immune competence status. According to Cohen's kappa statistics the 91% (kappa value = 0.816) agreement between SureScreen IgG and YHLO Gline IgG, "Almost Perfect", and 85% agreement (kappa value = 0.695) between SureScreen IgM and YHLO Gline IgM, "Substantial", indicate a good correlation between the performance of the LFIAs used in the study. Total antibody conformity was determined as 92% (kappa value = 0.822), "Almost Perfect". Agreement between IgM tests was lower than that between IgG tests. Studies generally show similar results. When Van Elslande et al. evaluated the compatibility of seven different LFIAs with each other using 153 samples taken from 94 COVID-19 patients, they observed the IgM compatibility to be 58.2-96.1 % and the IgG compatibility to be 78.4-98 %. While a general agreement of 70% was found between IgM LFIAs, an average of 89% agreement was found between IgG LFIAs (22). Charpentier et

al. reported that 82.8% (kappa: 0.643), "Substantial" agreement was observed in IgM and 96.9% (kappa: 0.937), "Perfect conformity", was observed between the two rapid tests.

There are some limitations of our study. First, the number of samples tested for cross-reaction in the control group was low and serum samples positive for measles, Crimean-Congo hemorrhagic fever and hantavirus serology were used, and it would be more effective to use patient samples with respiratory tract infection for this purpose. A second limitation is the small number of samples used to assess specificity. A third limitation is that no information was available regarding the severity of the disease in the patients from whom the samples were taken. A further limitation of the present study is the lack of data regarding the time of sample collection since the onset of symptoms of the patient samples tested. Another limitation is that the neutralization test could not be used. One of the strengths of this study, however, is that it investigated the value of IgM as well as IgG with LFIAs. The debate about whether IgM/IgG LFIAs should be used in emergency departments has allowed support for the intended use of IgM/IgG LFIAs for the detection of antibodies against SARS-CoV-2.

CONCLUSION

It was observed that the two different LFIA tests exhibited high sensitivity and specificity when evaluated according to the ELISA test results. The LFIA kits were also found to have good compatibility with each other.

It is thought that rapid antibody tests, whose results are comparable to those of ELISA tests, can be used to evaluate immune status in seroepidemiological studies with their fast and economical use, especially in cases where laboratory conditions cannot be achieved.

ETHICS COMITTEE APPROVAL

* The study was approved by the Ankara City Hospital Clinic Research Ethics Committee No:2 (Date: 20.09.2021 and Number: E2-21-837).

CONFLICT OF INTEREST

The authors declare no conflict of interest.

KAYNAKLAR

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