Evaluation of lateral flow and ELISA techniques for detecting IgG and IgM antibodies in COVID-19 cases in Türkiye

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Abstract

Background: Antibody testing can complement molecular assays for detecting COVID-19.

Aims: We evaluated the concurrence between lateral flow assay and enzyme-linked immunosorbent assay (ELISA) for the detection of antibodies in severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2).

Methods: The study was conducted at Kocaeli University, Türkiye. We used a lateral flow assay and ELISA to test serum samples from COVID-19 cases, confirmed by polymerase chain reaction assays (study group) and pre-pandemic stored serum samples (control group). We used Deming regression to evaluate the antibody measurements.

Results: The study group included 100 COVID-19 cases, and the control group included pre-pandemic samples from 156 individuals. The lateral flow assay detected immunoglobulin M (IgM) and G (IgG) antibodies in 35 and 37 study group samples. ELISA detected IgM nucleocapsid (N) antibodies in 18 samples, and IgG (N) and IgG spike 1 (S1) antibodies in 31 and 29 samples, respectively. None of the techniques detected antibodies in the control samples. Strong correlations were found between lateral flow IgG (N+ receptor-binding domain + S1) and ELISA IgG (S) ($r = 0.93$, $P < 0.01$) and ELISA IgG (N) ($r = 0.81$, $P < 0.01$). Weaker correlations were seen between ELISA IgG S and IgG N ($r = 0.79$, $P < 0.01$) and lateral flow assay and ELISA IgM (N) ($r = 0.70$, $P < 0.01$).

Conclusion: Lateral flow assay and ELISA techniques gave consistent results for IgG/IgM antibody measurements towards spike and nucleocapsid proteins, suggesting that both methods can be used to detect COVID-19 where access to molecular test kits is difficult.

Keywords: COVID-19, SARS-CoV-2, lateral flow assay, enzyme-linked immunosorbent assay, antibody.

Introduction

The recently identified severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) causes coronavirus disease 2019 (COVID-19), which was declared a pandemic on 11 March 2020, because of its rapid spread around the world. SARS-CoV-2 has affected all countries leading to more than 430 million confirmed COVID-19 cases and almost 6 million deaths globally. The number of people affected by the COVID-19 pandemic continues to rise *(1)*. Governments have taken measures to reduce the spread of COVID-19 since the first cases were reported in Wuhan, China, on 29 December 2019. Many countries introduced lockdowns, physical distancing, quarantine, and restrictions on travel to control the further spread *(2)*. As a result of these measures, the world economy has been significantly affected *(3)*. Thus, it was essential to develop diagnostic assays that provide reliable and rapid results for SARS-CoV-2 infection and the immune response in the host to prevent future infections, enhance the cure rate, prevent deaths and allow life to return to normal. Diagnostic test manufacturers worldwide worked to develop and produce these assays.

COVID-19 can be diagnosed by detection of RNA gene targets (e.g. spike protein (S), an envelope protein (E), nucleocapsid protein (N), RNA-dependent RNA polymerase enzyme, and *ORF1* gene) *(4–6)* either by nucleic acid amplification testing or detection of virus-specific proteins by antigen testing *(7,8)*. Nucleic acid amplification testing (including reverse transcriptase polymerase chain reaction [RT-PCR]) is empathetic and confirms the presence of SARS-CoV-2; however, previous infections with SARS-CoV-2 cannot be detected *(9,10)*. Therefore, antibody testing, complementing PCR testing for follow-up of recovered patients and identification of asymptomatic individuals, is a valuable tool in the fight against COVID-19. Detection of viral-specific antibodies enables a more accurate and precise diagnosis and to monitor the progression of infection and treatment responses against COVID-19 *(11,12)*. Moreover, antibody testing is commonly used to measure the immune response after infection and vaccination, predict the duration of the body's immunoglobulin M (IgM), immunoglobulin A (IgA), and immunoglobulin (IgG) responses, and provide a retrospective assessment of the infected population for epidemiological surveillance *(6,8,12,13)*. Recent studies have shown high and robust

specificity with serological diagnostic assays that could support a complementary approach to nucleic acid amplification testing to diagnose COVID-19 (14,15).

Various antigen targets – including recombinant full S and N proteins or peptides of the N and S1, S2, and receptor-binding domain (RBD) of S protein – are used in different SARS-CoV-2 serological tests. S and N proteins are the most immunogenic ones, triggering the highest immune responses (16). Recently, the United States Food and Drug Administration approved several anti-SARS-CoV-2 systems for emergency use to detect antibodies against the virus (17). Lateral flow assays, enzyme-linked immunosorbent assays (ELISA), chemiluminescence immunoassays, chemiluminescence microparticle immunoassays, enzyme-linked fluorescent assays, photonic ring immunoassays, fluorescent immunoassays, and fluorescent multiplex bead-based immunoassays have received emergency use authorization for the detection of viral-specific antibodies. These antibodies generally develop several days after the first exposure to the virus (11,12,18).

In this study, we aimed to evaluate the agreement rate of two serological techniques – immunochromatographic lateral flow assays and ELISA – targeting S and N proteins to detect SARS-CoV-2 antibodies in COVID-19 cases. We compared the antibody response with symptoms in hospitalized and recovered patients to better decide the most appropriate technique to manage the COVID-19 pandemic.

Methods

Study group

The study was performed in the PCR Unit at Kocaeli University, Türkiye. We tested 256 samples using a lateral flow assay and an ELISA for IgG and IgM against SARS-CoV-2. Our study group was 100 COVID-19 cases from whom serum samples were confirmed positive for SARS-CoV-2 by RT-PCR. Our control group included 156 individuals from whom samples were taken before the COVID-19 pandemic (negative control). Blood samples from the cases were taken 7–14 days after the first positive SARS-CoV-2 PCR test and were tested using a lateral flow assay and an ELISA.

Symptoms associated with COVID-19 experienced by the cases were recorded, such as high fever, sore throat, cough, shortness of breath, and loss of sense of taste. Other non-specific symptoms were recorded, such as weakness, anorexia, nausea, and muscle and joint pain (19). Demographic and clinical characteristics, including age, sex, symptoms, and clinical outcomes for inpatients, were recorded for each patient. These data were obtained from hospital records.

Lateral flow assay and ELISA

We used lateral flow assay and ELISA techniques targeting S and N proteins to detect IgG and IgM antibodies to SARS-CoV-2. These assays were manufactured by RTA

Laboratories Inc., Istanbul, Türkiye (MaxSure COVID-19 IgG/IgM antibody kit) and Euroimmun, Luebeck, Germany (anti-SARS-CoV-2 ELISA IgM/IgG). The Euroimmun ELISA has been authorized for emergency use by the United States Food and Drug Administration (17). According to the manufacturers' information, the viral protein labelled were the N + RBD + spike 1 (S1) in the MaxSure lateral flow assay, and only N or S proteins for IgG and only N protein for IgM in the Euroimmun ELISA.

Interpretation of the results was based on the manufacturers' recommendations. Test results were evaluated and ranged between 1 and 10 (weak to strong) according to the strength of the positivity. The diagnostic sensitivity and the specificity of the qualitative test results are given as 94.39% and 94.18%, respectively, for the MaxSure lateral flow assay (20). The Euroimmun test results were classified as negative < 0.8, positive ≥ 1.1, and borderline ≥ 0.8–≥ 1.1, with 90% sensitivity (95% confidence interval (CI): 74.4–95%) and 100% specificity (95% CI: 95.4–100%) for IgG (17).

Statistical analysis

All correlation coefficients (r) were calculated using either Pearson or Deming correlations. Correlations between the measurements were assessed using Deming regression analysis for antibody measurements, including 95% CI. Deming regression is preferred when both variables are independent and prone to errors. In our case, both techniques were used independently and thus flat to separate mistakes. The Pearson correlation was used to assess the correlation between a given symptom and an immune response or another symptom. The Pearson correlation was calculated by assigning 1 for the presence and 0 for the absence of the symptoms. The calculations were done through an in-house python script. Observed correlation coefficients were interpreted as follows: < 0.10 = little or negative correlation; 0.10–0.39 weak correlation; 0.40–0.68 moderate correlation; 0.70–0.89 strong correlation; and 0.90–1.00 robust correlation (21).

Ethical approval

Near East University Institutional Review Board approved the study (no. NEU/2021/88-1285). Informed consent forms were not used because the analysis was retrospectively performed.

Results

Of the 100 samples in the study group, 74 were from hospitalized patients (Darica State Hospital), and 26 were from recovered patients (Kocaeli University Hospital) (Table 1). Of the 156 serum samples in the control group, 35 were from individuals with human immunodeficiency virus (HIV) infection, and 57 were from individuals with hepatitis B virus infection, diagnosed in 2017. The remaining 64 samples were from individuals free of COVID-19 infection between 19 October 2019 and 20 February 2020 (Table 1).

Table 1 Characteristics of the COVID-19 patients and type of control sample

Characteristic	No. (%)
Study group (*n* = 100)	
Type of COVID-19 patient	
Hospitalized	74 (74)
Recovered	26 (26)
Sex	
Male	58 (58)
Female	42 (42)
Age, in years; mean (SD)	37 (14.4)
Site	
Darica State Hospital	74 (74)
Kocaeli University Hospital	26 (26)
Symptoms	
Fever	25 (34)
Fatigue	22 (30)
Sore throat	10 (14)
Headache	13 (18)
Cough	13 (18)
Joint pain	9 (12)
Nausea	6 (8)
Shortness of breath	6 (8)
General pain	5 (7)
Diarrhoea	3 (4)
Back pain	3 (4)
Lack of appetite	2 (3)
Asymptomatic	10 (14)
Other[a]	13 (18)
Control group (*n* = 156)	
Type of serum sample	
HIV-1 positive	35 (22)
Hepatitis B positive	57 (37)
Pre-pandemic	64 (41)

COVID-19= coronavirus disease 2019; SD= standard deviation; HIV= human immunodeficiency virus.
[a] *Dizziness, throat squeak, cold sweat, runny nose, chest pain, eye problems, vomiting, abdominal pain, high fever, flu, flank pain, and loss of sense of taste (all 1.3%).*

Of the study patients, 59 were males, and 41 were females, with a mean age of 37 years (standard deviation 14.4) and a range of 4–81 years (Table 1). The symptoms most commonly reported were high temperature (33.7%) and fatigue (29.7%). No correlation was found between these symptoms. We only saw a correlation between loss of taste and lack of appetite ($r = 0.70$, $P < 0.01$). The interpretation of the correlation of the symptoms with each other, age, and an immune response is given in Table 2.

Thirty-five (35%) and 37 (37%), respectively, of the samples were positive for IgM and IgG with the lateral flow assay. Of the lateral flow assay IgM positive samples, 82% were considered weakly positive, while most lateral flow assay IgG positive samples were considered

strongly positive. Using ELISA, IgM (N) antibodies were detected in 18 (18%) samples. Of these 18 samples, 4 (22%) were weakly positive. Moreover, ELISA detected IgG (N) and IgG (S1) antibodies in 31 (31%) and 29 (29%) samples, respectively. Of IgG (N) positive samples, 3 (9.7%) were considered weakly positive with ELISA, while 6 (20.6%) IgG (S1) positive samples were considered weakly positive. No positive results were found in any control sample with either technique.

The strongest (Deming) correlation between measurements was observed between lateral flow assay IgG (N+RBD+S1) and ELISA IgG (spike): $r = 0.93$, $P < 0.01$ (Figure 1E). The Deming analysis gave a correlation curve with a slope close to 0.5, which passed through the origin. A strong correlation was also seen for the N protein. The lateral flow assay IgG (N+RBD+S1) and ELISA IgG (N) showed a strong correlation: $r = 0.81$, $P < 0.01$ (Figure 1 C). The correlation between ELISA IgG (S) and ELISA IgG (N) was also strong: $r = 0.79$, $P < 0.01$ (Figure 1 G). In the case of IgM, lateral flow assay IgM (N+RBD+S1) and ELISA IgM (N) showed a correlation of $r = 0.70$, $P < 0.01$ (Figure 1B), where both shared N-protein as a target. A lower correlation was detected between the different types of immunoglobulins, IgG and IgM. The Deming analysis also showed a correlation between the lateral flow assay IgM (N+RBD+S1) and ELISA IgG (N): $r = 0.72$, $P < 0.01$ (Figure 1D). In comparison, lateral flow assay IgM (N+RBD+S1) and ELISA IgG (S) (Figure 1F), or IgG (N+RBD+S1) and ELISA IgM (N) (Figure 1A) correlations were significantly lower ($r = 0.47$, $P < 0.01$ and $r = 0.42$, $P < 0.01$, respectively).

Discussion

Lateral flow assays and ELISA techniques are serological methods used to detect the presence of antibodies in the blood. We compared the lateral flow assay with ELISA for testing antibodies to SARS-CoV-2 because ELISA is one of the most used serological detection techniques, and lateral flow assay has good commercial value. Since we are in the pandemic, we aimed to investigate the diagnostic benefit of lateral flow assays (13).
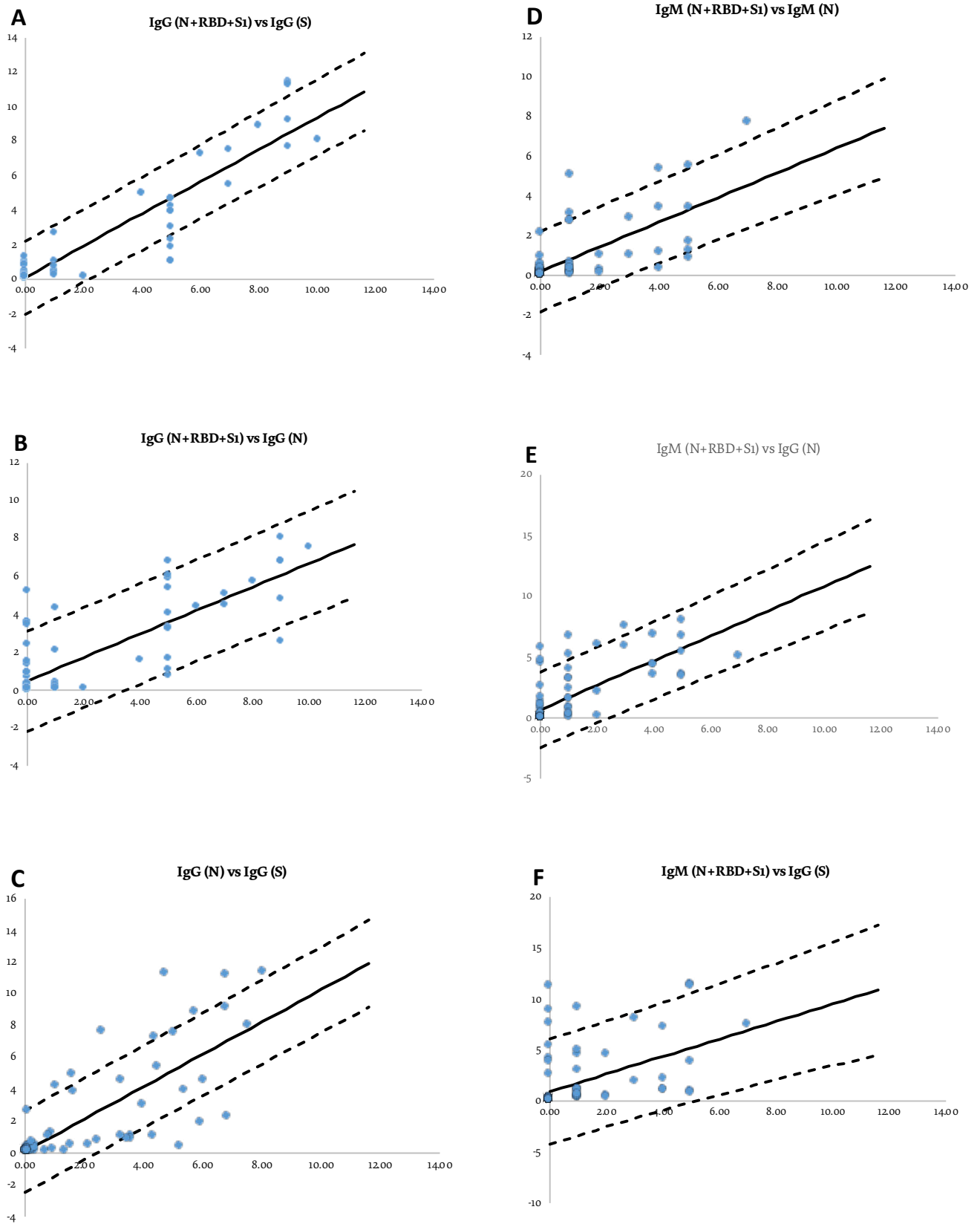
We demonstrated a robust correlation between lateral flow assay IgG (N+RBD+S1) and ELISA IgG (S), $r = 0.93$) since the spike is an important target and is widely used in immunoassays (22,23). The Deming regression analysis gave a correlation curve with a slope close to 0.5, which passed through the starting point, indicating that both lateral flow IgG assay and ELISA assays are comparable and offer similar diagnostic capacity for the spike protein. This was also observed for the N protein: the lateral flow assay IgG (N+RBD+S1) and ELISA IgG (N) were strongly correlated ($r = 0.81$), although the correlation was not as strong as for the spike protein. This suggests that the S and N proteins develop a similar immune response. This can also be seen in the correlation between ELISA IgG (S) and IgG (N) ($r = 0.79$). The Deming analysis showed that many samples did not trigger an IgG response to the N protein, while a reaction because of the S protein existed.

Table 2 Correlation coefficients and associations between symptoms, age, and immune response in the study patients
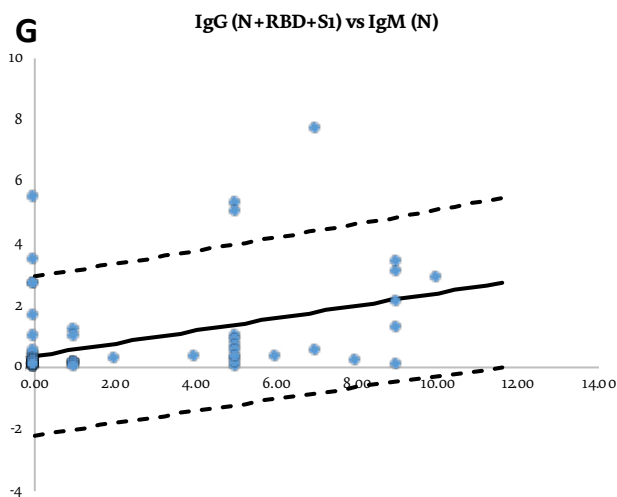
	Fatigue	Sore throat	Headache	Dizziness	Nausea	Shortness of breath	Back pain	Joint pain	Fever	Flank pain	Cough	Sweating	Anorexia	General pain	Diarrhoea	Loss of taste	Throat squeak	Runny nose	Eye problems	Vomiting	Backache	Asymptomatic	Age	IgM (N+RBD+S1)	IgG (N+RBD+S1)	IgM (NCP)	IgG (NCP)	IgG (spike)
IgG (spike)																												1.00
IgG (N)																											1.00	0.79
IgM (N)																										1.00	0.60	0.39
IgG (N+RBD+S1)																									1.00	0.42	0.81	0.93
IgM (N+RBD+S1)																								1.00	0.43	0.70	0.72	0.47
Age																							1.00	0.16	0.29	0.18	0.32	0.26
Asymptomatic																						1.00	-0.16	-0.02	-0.05	-0.06	-0.02	-0.01
Backache																					1.00	-0.03	-0.01	-0.06	-0.03	-0.04	-0.07	-0.05
Vomiting																				1.00	-0.01	-0.03	0.03	-0.06	0.16	-0.01	0.14	0.14
Eye problems																			1.00	-0.01	-0.01	-0.03	0.03	-0.06	0.16	-0.01	0.14	0.14
Runny nose																		1.00	-0.01	-0.01	-0.01	-0.03	0.07	-0.06	-0.06	-0.04	-0.07	-0.06
Throat squeak																	1.00	-0.01	-0.01	-0.01	-0.01	-0.03	0.03	0.20	0.10	0.35	0.26	0.02
Loss of taste																1.00	-0.01	-0.01	-0.01	-0.01	-0.01	-0.03	0.17	-0.06	-0.06	-0.04	-0.06	-0.05
Diarrhoea															1.00	0.57	-0.02	-0.02	0.57	0.57	-0.02	-0.06	0.00	-0.10	0.02	-0.06	0.01	0.02
General pain														1.00	-0.04	-0.02	-0.02	-0.02	-0.02	-0.02	-0.02	-0.08	0.24	-0.04	-0.13	-0.07	0.00	-0.12
Anorexia													1.00	-0.03	0.39	0.70	-0.01	-0.01	-0.01	-0.01	-0.01	-0.05	0.01	0.10	0.05	-0.05	0.06	0.11
Sweating												1.00	-0.02	0.29	-0.03	-0.01	-0.01	-0.01	-0.01	-0.01	-0.01	-0.05	0.12	-0.08	-0.09	-0.07	-0.10	-0.08
Cough											1.00	-0.06	0.16	-0.09	0.11	-0.04	-0.04	0.26	0.26	0.26	-0.04	-0.13	-0.07	0.18	0.08	0.11	0.21	0.06
Flank pain										1.00	-0.04	-0.01	-0.01	-0.02	-0.02	-0.01	-0.01	-0.01	-0.01	-0.01	-0.01	-0.03	0.10	-0.06	-0.06	-0.04	-0.07	-0.06
Fever									1.00	0.17	-0.09	0.25	0.08	-0.03	0.03	-0.06	-0.06	-0.06	-0.06	-0.06	-0.06	-0.19	-0.16	-0.10	-0.21	-0.13	-0.27	-0.19
Joint pain								1.00	0.30	-0.03	-0.12	-0.04	-0.04	-0.07	-0.06	-0.03	-0.03	-0.03	-0.03	-0.03	-0.03	-0.10	-0.09	-0.11	-0.17	-0.07	-0.17	-0.17
Back pain							1.00	-0.06	-0.10	-0.02	-0.07	-0.03	-0.03	-0.04	-0.03	-0.02	-0.02	-0.02	-0.02	-0.02	-0.02	-0.06	0.03	0.24	-0.11	0.31	0.08	-0.06
Shortness of breath						1.00	0.20	-0.08	-0.15	-0.03	0.53	-0.04	-0.04	-0.06	0.20	-0.03	-0.03	-0.03	0.40	0.40	-0.03	-0.08	-0.07	0.07	0.00	0.06	0.11	-0.01
Nausea					1.00	-0.06	0.20	0.07	-0.05	-0.03	-0.10	-0.04	-0.04	-0.06	-0.04	-0.03	-0.03	-0.03	-0.03	-0.03	-0.03	-0.08	0.01	-0.06	-0.09	-0.02	0.01	-0.06
Dizziness				1.00	-0.03	-0.03	-0.02	0.32	0.17	-0.01	-0.04	-0.01	-0.01	-0.02	-0.02	-0.01	-0.01	-0.01	-0.01	-0.01	-0.01	-0.03	0.07	-0.06	-0.06	-0.05	-0.07	-0.06
Headache			1.00	0.26	0.28	-0.10	-0.07	-0.02	0.05	0.26	0.03	-0.06	-0.06	-0.09	-0.07	-0.04	-0.04	-0.04	-0.04	-0.04	-0.04	-0.13	-0.08	-0.12	-0.10	0.01	-0.10	-0.14
Sore throat		1.00	0.07	-0.03	-0.08	0.06	0.14	0.24	0.19	-0.03	-0.03	-0.05	-0.05	-0.08	-0.06	-0.03	-0.03	-0.03	-0.03	-0.03	-0.03	-0.11	-0.19	0.00	-0.12	0.02	-0.14	-0.15
Fatigue	1.00	-0.18	0.30	0.19	0.27	-0.13	0.05	0.00	0.20	0.19	-0.13	0.10	0.10	-0.01	0.05	0.19	-0.05	-0.05	-0.05	-0.05	0.19	-0.18	0.25	-0.04	-0.13	0.06	0.01	-0.07
Clinics	0.31	0.20	0.23	0.06	0.15	0.15	0.10	0.19	0.34	0.06	0.23	0.08	0.08	0.14	0.10	0.06	0.06	0.06	0.06	0.06	0.06	0.20	-0.14	0.00	-0.45	0.04	-0.17	-0.47
Total	22	10	13	1	6	6	3	9	25	1	13	2	2	5	3	1	1	1	1	1	1	10						

IgM= immunoglobulin M; N= nucleocapsid protein; RBD= receptor-binding domain; S= spike protein; IgG= immunoglobulin G.
Note: The green shading indicates positive correlations and the red shading negative correlations. The darker the shade, the stronger the correlation.

Figure 1 Deming regression analysis for antibody measurements

Figure 1 Deming regression analysis for antibody measurements *(concluded)*

The sensitivity of the anti-N response was reported as 73.7% and 82.0% in different tests, while the specificity was reported as 100.0% and 91.7% in the same studies *(23)*. However, the homology of the N protein of SARS-CoV-2 with other coronaviruses and the possibility of false positivity should be considered *(16,24–26)*. Alternate IgM-based measurements targeting different or combined antigens are necessary to reach more definitive conclusions.

We found a positive correlation between lateral flow assay IgM (N+RBD+S1) and ELISA IgG (N), *r = 0.72*. The Deming regression analysis showed that all samples exceeding the 95% CI occurred because of a high IgM signal. This may be attributed to patients in the early stages of infection who develop strong IgM response before an IgG response.

As individuals of different ages may have the infection with other clinical characteristics, we also evaluated the association between the patients' age and symptoms or immune response. Fever (33.7%) and fatigue (29.7%) were the predominant symptoms. Generally, fever, dry cough, and fatigue are the most common clinical observations in patients infected with SARS-CoV-2 *(26–28)*. Notably, no significant correlation was detected between the symptoms except the loss of taste and lack of appetite (*r = 0.70*), which are understandably connected. These findings indicate that the age of the patients did not show any significant association with any symptoms or immune responses, suggesting that the virus-dependent symptoms are independent of age.

Thus, the S protein is preferable to the N protein for diagnosing IgG levels. However, another study reported that detecting N protein against SARS-CoV-2 could be a better choice for diagnosing SARS-CoV-2 infection because anti-N antibodies were detected in most of the samples *(24)*. Similarly, other studies have reported earlier detection of anti-N antibodies than anti-S antibodies *(16)*. Unlike these studies, a recent survey said that IgG antibodies of N and S proteins were detected at about the same time *(25)*.

We found that lateral flow assays and ELISAs correlated positively with antibody responses to S and N proteins. In this context, IgG antibodies can be screened with N-based measurements; however, S-based sizes may be the first option because of a higher positive correlation with the S protein. Our findings suggest potential techniques and antigen targets for monitoring the persistence of SARS-CoV-2 antibodies developed after infection.

We found a correlation between lateral flow assay IgM (N+RBD+S1) and ELISA IgM (N) (*r = 0.70*), where both share N-protein as a target. A relatively higher number of samples exceeded the 95% CI due to a more elevated IgM (N+RBD+S1) signal, which may indicate that the IgM response may occur unevenly because of the different components of the IgM (N+RBD+S1). The anti-N response has been shown to occur earlier than or at the same time as the anti-S response, and it is the preferred measure to use.

The combination of RT-PCR with the SARS-CoV-2 IgM antibody testing can be done for rapid and enhanced diagnosis of COVID-19 cases and for monitoring the progression of infection, therapeutic responses, and immune response to COVID-19 vaccines. As the antibody test is widely used to measure the immune response after infection and vaccination, it allows the evaluation of the persistence of the immune responses that occur and the retrospective evaluation of the infection rate in the population *(29–31)*.

A limitation of our study is that the SARS-CoV-2 variants were not detected, so the variants were not captured. As a result, the effects of the variants on immune response could not be evaluated.

The availability of fast access to reliable, high-quality serological tests to complement RT-PCR would greatly help the fight against COVID-19.

Évaluation du flux latéral et des méthodes ELISA pour la détection des anticorps IgG et IgM parmi les cas de COVID-19 en Türkiye

Résumé

Contexte : Le dépistage des anticorps peut compléter les tests de diagnostic moléculaire pour détecter la COVID-19.

Objectifs : Nous avons évalué la concordance entre un test à flux latéral et un test immuno-enzymatique (ELISA) pour la détection d'anticorps contre le coronavirus-2 du syndrome respiratoire aigu sévère (SARS-CoV-2).

Méthodes : L'étude a été menée à l'Université de Kocaeli en Türkiye. Nous avons utilisé un test à flux latéral et un test ELISA pour analyser des échantillons de sérum provenant des cas de COVID-19, confirmés par des tests d'amplification en chaîne par polymérase (groupe d'étude) et des échantillons de sérum stockés avant la pandémie (groupe témoin). Nous avons eu recours à la régression de Deming pour évaluer les mesures des anticorps.

Résultats : Le groupe d'étude comprenait 100 cas de COVID-19 et le groupe témoin incluait des échantillons prélevés avant la pandémie provenant de 156 personnes. Le test à flux latéral a permis de détecter des anticorps anti-immunoglobulines M (IgM) et G (IgG) dans 35 et 37 échantillons des groupes respectivement. Le test ELISA a permis de détecter des anticorps IgM dirigés contre la protéine de la nucléocapside (N) dans 18 échantillons et des anticorps IgG (N) et IgG dirigés contre la protéine Spike 1 (S1) dans 31 et 29 échantillons respectivement. Aucune des deux méthodes n'a permis de détecter la présence d'anticorps dans les échantillons témoins. De fortes corrélations ont été observées entre les IgG détectés par le test à flux latéral (N + domaine de liaison au récepteur + S1) et les IgG ciblant la protéine S détectés par le test ELISA N (*r* = 0,93, *p* < 0,01) et les IgG ciblant la protéine N détectés par le test ELISA *N* (*r* = 0,81, *p* < 0,01). Des corrélations plus faibles ont été constatées entre les IgG S et N détectés par le test ELISA N (*r* = 0,79, *p* < 0,01) et les IgM N détectés par le test à flux latéral et le test ELISA N (r = 0,70, p < 0,01).

Conclusion : Le test à flux latéral et les méthodes ELISA ont donné des résultats cohérents pour ce qui concerne les mesures des anticorps IgG/IgM dirigés contre les protéines de nucléocapside et Spike. Ceci indique que les deux méthodes peuvent être utilisées, principalement lorsqu'il est difficile d'accéder aux kits de dépistage moléculaire pour détecter la COVID-19.

تقييم استخدام طريقتَي التدفق الجانبي والمُمتز المناعي المرتبط بالإنزيم للكشف عن الأجسام المضادة من مجموعة الجلوبيولين المناعي IgG ومجموعة الجلوبيولين المناعي IgM في حالات الإصابة بكوفيد-19 في تركيا

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الخلاصة

الخلفية: يمكن أن تكون اختبارات الأجسام المضادة مُكمِّلة للمقايسات الجزيئية للكشف عن كوفيد-19.

الأهداف: هدفت هذه الدراسة الى تقييم التوافق بين مقايسة التدفق الجانبي ومقايسة المُمتز المناعي المرتبط بالإنزيم للكشف عن الأجسام المضادة في حالات الإصابة بفيروس كورونا 2 المسبِّب للمتلازمة التنفسية الحادة الوخيمة (فيروس كورونا-سارس-2).

طرق البحث: أُجريت الدراسة في جامعة كوجائلي في تركيا، لاختبار عينات مصلية من حالات مصابة بكوفيد-19 جرى تأكيدها عن طريق مقايسة "تفاعل البوليميراز المتسلسل" (مجموعة دراسة) وعينات مصلية مخزنة سابقة للجائحة (مجموعة مرجعية). واستخدمنا انحدار ديمنج لتقييم قياسات الأجسام المضادة.

النتائج: شملت مجموعة الدراسة 100 حالة إصابة بكوفيد-19، وتضمنت المجموعة المرجعية عينات سابقة للجائحة من 156 شخصًا. وكشفت مقايسة التدفق الجانبي عن وجود أجسام مضادة من مجموعة الجلوبيولين المناعي IgM في 35 عينة وأجسام مضادة من مجموعة الجلوبيولين المناعي IgG في 37 عينة من مجموعة الدراسة. وكشفت مقايسة الممتز المناعي المرتبط بالإنزيم عن وجود أجسام مضادة من مجموعة الجلوبيولين المناعي IgM المضادة للقفيصة النووية (N) في 18 عينة، وأجسام مضادة من مجموعة الجلوبيولين المناعي IgG المضادة للقفيصة النووية (N) في 31 عينة، وأجسام مضادة من مجموعة الجلوبيولين المناعي IgG المضادة للوحدة الفرعية 1 من البروتين الفيروسي الشوكي (S1) في 29 عينة. ولم تكشف أي من الطريقتين عن أجسام مضادة في العينات المرجعية. ووجدنا أوجه ارتباط قوية بين مقايسة التدفق الجانبي للكشف عن الأجسام المضادة من مجموعة الجلوبيولين المناعي IgG (القفيصة النووية + منطقة ارتباط المستقبلات + الوحدة الفرعية 1 من البروتين الشوكي) ومقايسة الممتز المناعي المرتبط بالإنزيم للكشف عن مجموعة الجلوبيولين المناعي IgG المضادة للبروتين الشوكي (S)(معامل الارتباط = 0.93، القيمة الاحتمالية > 0.01) ومقايسة الممتز المناعي المرتبط بالإنزيم للكشف عن الأجسام المضادة من مجموعة الجلوبيولين المناعي IgG المضادة للقفيصة النووية (معامل الارتباط = 0.81، القيمة الاحتمالية > 0.01). ولوحظ ضعف أوجه الارتباط بين مقايسة الممتز المناعي المرتبط بالإنزيم للكشف عن الأجسام المضادة من مجموعة الجلوبيولين المناعي IgG المضادة للبروتين الشوكي (S) ومجموعة الجلوبيولين المناعي IgG المضادة للقفيصة النووية

(N) (معامل الارتباط = 0.79، القيمة الاحتمالية > 0.01) ومقايسة التدفق الجانبي ومقايسة الممتز المناعي المرتبط بالإنزيم للكشف عن الأجسام المضادة من مجموعة الجلوبيولين المناعي IgM المضادة للقفيصة النووية (N) (معامل الارتباط = 0.70، القيمة الاحتمالية > 0.01).

الاستنتاجات: حققت مقايسة التدفق الجانبي ومقايسة الممتز المناعي المرتبط بالإنزيم نتائج متسقة بشأن قياسات الأجسام المضادة من مجموعة الجلوبيولين المناعي IgG والأجسام المضادة من مجموعة الجلوبيولين المناعي IgM، فيما يتعلق بالبروتين الشوكي وبروتين القفيصة النووية، وهو ما يشير إلى إمكانية استخدام كلتا الطريقتين للكشف عن كوفيد-19، في حالة صعوبة توفُّر مجموعات أدوات الاختبارات الجزيئية.

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