Received: 11 May 2020 | Accepted: 22 May 2020

DOI: 10.1002/jmv.26060

RESEARCH ARTICLE

JOURNAL OF MEDICAL VIROLOGY WILEY

Diagnostic performance of immunochromatography assay for rapid detection of IgM and IgG in coronavirus disease 2019

Jung-Yoon Choe MD, PhD[1] | Ji-Won Kim MD, PhD[1] | Hyun Hee Kwon MD[2] | Hyo-Lim Hong MD[2] | Chi Young Jung MD, PhD[3] | Chang-Ho Jeon MD, PhD[4] | Eun-Jin Park BS[1] | Seong-Kyu Kim MD, PhD[1]

[1]Division of Rheumatology, Department of Internal Medicine, Catholic University of Daegu School of Medicine, Daegu, Republic of Korea

[2]Division of Infectious Diseases, Department of Internal Medicine, Catholic University of Daegu School of Medicine, Daegu, Republic of Korea

[3]Division of Pulmonology, Department of Internal Medicine, Catholic University of Daegu School of Medicine, Daegu, Republic of Korea

[4]Department of Laboratory Medicine, Catholic University of Daegu School of Medicine, Daegu, Republic of Korea

Correspondence
Seong-Kyu Kim, MD, PhD, Division of Rheumatology, Department of Internal Medicine, Catholic University of Daegu School of Medicine School of Medicine, 33, Duryugongwon-ro 17-gil, Nam-gu, Daegu 42472, Republic of Korea.
Email: kimsk714@cu.ac.kr

Abstract

Serologic assays have been developed to detect infection with coronavirus disease 2019 (COVID-19). This study was conducted to evaluate the diagnostic performance of an immunochromatography-based assay of human serum for COVID-19. The present study enrolled 149 subjects who had been tested by real-time reverse transcription-polymerase chain reaction (RT-PCR) for COVID-19 and were classified into two groups: 70 who were positive for COVID-19 and 79 who were negative for COVID-19 based on RT-PCR. An immunochromatography-based COVID-19 immunoglobulin G (IgG)/immunoglobulin M (IgM) rapid test on the sera of the study population was applied to measure the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and receiver operating characteristic (ROC) curve compared to RT-PCR, with a 95% confidence interval (CI). IgM or IgG antibodies were detected in 65 subjects (92.9%) classified as positive for COVID-19 and in three subjects (3.8%) classified as negative for COVID-19. The sensitivity and specificity percentages for IgM or IgG antibodies were 92.9% (95% CI: 84.1-97.6) and 96.2% (95% CI: 89.3-99.2), respectively, with 95.6% PPV and 93.8% NPV. The PPV rapidly improved with increasing disease prevalence from 19.8% to 96.1% in the presence of either IgM or IgG, while the NPV remained high with a change from 99.9% to 93.1%. The area under the ROC curve was 0.945 (95% CI: 0.903-0.988) for subjects with either IgM or IgG positivity. In conclusion, the immunochromatography-based COVID-19 IgG/IgM rapid test is a useful and practical diagnostic assay for detection of COVID-19, especially in the presence of IgM or IgG antibodies.

KEYWORDS

coronavirus, COVID-19, immunochromatography, real-time polymerase chain reaction

1 | INTRODUCTION

Following the development of sporadic cases of an unknown pneumonia accompanied by respiratory failure in Wuhan, Hubei Province, China, in early December 2019,[1] a new coronavirus was identified in respiratory samples obtained from patients with pneumonia and was named 2019 novel coronavirus (2019-nCoV). The World Health Organization (WHO) officially announced that the coronavirus would be identified as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[2] The disease is also referred to as coronavirus disease 2019 (COVID-19).[3] The global mortality rate of COVID-19 was reported to range from 1.5% to 3.6%.[4]

Currently, the diagnosis of COVID-19 has been confirmed using next-generation sequencing or real-time reverse

transcription-polymerase chain reaction (RT-PCR) to directly detect SARS-CoV-2 in specimens obtained from the upper and lower respiratory tracts of affected patients.[1,2,5,6] However, this process takes a relatively long time (at least 6 hours) to produce the final results regarding COVID-19 infection via detection of the virus itself. Recently, new serologic laboratory diagnostic tests, such as enzyme-linked immunosorbent assay (ELISA) and immunochromatography, have been developed to identify the presence of COVID-19 antibodies in blood or tissue samples following SARS-CoV-2 infection. However, the effectiveness and diagnostic value of these serologic tests, including immunochromatography, have not been sufficiently validated.

Early and rapid diagnosis of COVID-19 infection is necessary to prevent the spread of infection and to reduce the associated morbidity and mortality rates. Therefore, this study evaluated the diagnostic performance of an immunochromatography-based immunoglobulin G (IgG)/immunoglobulin M (IgM) rapid test using serum to detect SARS-CoV-2 infection and compared its results to those of RT-PCR using nasopharyngeal aspirates and sputum.

2 | SUBJECTS AND METHODS

2.1 | Study population

In total, 149 subjects who ranged in age from 26 to 89 years were consecutively enrolled in this study between 20 March and 8 April 2020 in Daegu, Republic of Korea. Participants in this study were divided into two groups: those with positive RT-PCR (n = 70) findings for SARS-CoV-2 and those with negative RT-PCR (n = 79) results for SARS-CoV-2. The positive RT-PCR group comprised patients being treated in the quarantine ward of our hospital after confirming infection with COVID-19. Repeat RT-PCR tests were performed every other day to determine whether the COVID-19 infection had resolved. At the time of their participation in the study, all patients in the positive group were confirmed to be positive for SARS-CoV-2. The negative RT-PCR group contained subjects with a negative result obtained on RT-PCR in screening for COVID-19.

These subjects evaluated acute respiratory symptoms and signs, fever, myalgia, and other clinical abnormalities such as chest pain and diarrhea. In addition, past medical history including hypertension, diabetes mellitus, heart disease, chronic renal diseases, chronic liver disease, and pulmonary disease were also assessed. The design of this study was reviewed and approved by the Institutional Review Board of Daegu Catholic University Medical Center (MDCR-20-002-L).

2.2 | RT-PCR assay

Nasopharyngeal swabs and sputum were obtained from each patient for RT-PCR, which was performed using the CFX96 Real-time PCR Detection System (Bio-Rad Laboratories, Hercules, CA) with a PowerChekTM 2019-nCoV Real-time PCR kit (Kogenebiotech Co, Ltd, Seoul, Korea) according to the manufacturer's instructions. The primers and probes were designed to target the E and RdRp genes of the SARS-CoV-2 viral sequence.

2.3 | Immunochromatography assay

We used serum from blood samples obtained from the study population for immunochromatography. The serum samples were stored in a refrigerator at 4°C in serum separating tubes until immunochromatography analysis. In accordance with the manufacturer's instructions, a 10 μL blood serum sample was dropped into the sample hole of the experimental device using a disposable dropper, and 60 μL of diluent was added via the same sample hole. After 10 to 15 minutes, the results were confirmed. Any results that were obtained 20 minutes after addition of diluent were not read or recorded.

The immunochromatography tool used to detect COVID-19 IgG and IgM antibodies for SARS-CoV-2 infection was the PCL COVID-19 IgG/IgM Rapid Gold (PCL, Inc, Seoul, Korea). The test device is pre-embedded with recombined COVID-19 antigens including nucleocapsid (N) protein expressed by *Escherichia* coli and RBD domain of spike (S) protein expressed by HEK293S cells. The Cohen's kappa (κ) coefficient between immunochromatography and RT-PCR as a reference assay for assessment of COVID-19 infection was 0.893. The agreement between the two methods of immunochromatography was 96.0%.

2.4 | Statistical analysis

Data were described as mean ± standard deviation (SD) for quantitative variables and frequency and percentage (%) qualitative variables. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated, along with the 95% confidence interval (CI). A diagnostic value test of the immunochromatography method was performed with MedCalc software, version 19.2.0 (Mariakerke, Belgium). Receiver operating characteristic (ROC) analysis was performed to assess the sensitivity and specificity of cut-off points for a combination of IgM and/or IgG antibodies. The area under the ROC curve (AUC) for a combination of IgM and/or IgG antibodies as a global measure of the diagnostic performance of this modality was calculated. The statistical analyses for the κ coefficient and agreement were performed using IBM SPSS Statistics, version 19.0 (IBM Corp, Armonk, NY).

3 | RESULTS

Baseline characteristics of the study population were described at Table 1. Seventy subjects (40 females, 57.1%) positively confirmed by RT-PCR for SARS-CoV-2, and 79 subjects (32 females, 40.5%) without SARS-CoV-2 infection were enrolled in this study. The mean age of positive and negative RT-PCR subjects was 67.9 years old (SD: 15.6) and 60.7 years old (SD: 15.2), respectively ($P = .043$). In positive RT-PCR subjects, the mean disease duration defined period from diagnosis to enrollment in this study was 23.7 days (SD: 10.2). There was no

TABLE 1 Baseline characteristics of enrolled study population

	Positive COVID-19 (n = 70)	Negative COVID-19 (n = 79)	*P* value
Age, y	67.9 ± 15.6	60.7 ± 15.2	.005
Gender, female, n (%)	40 (57.1)	32 (40.5)	.043
Disease duration, d	23.7 ± 10.2	…	…
Past history, n (%)			
Hypertension	25 (35.7)	28 (35.4)	.972
Diabetes mellitus	17 (24.3)	20 (25.3)	.884
Heart disease	11 (15.7)	11 (13.9)	.759
Chronic renal disease	5 (7.1)	5 (6.3)	.843
Chronic liver disease	4 (5.7)	11 (13.9)	.096
Pulmonary diseases	14 (20.0)	8 (10.1)	.090
Clinical features, n (%)			
Fever	33 (47.1)	21 (26.6)	.009
Myalgia	12 (17.1)	10 (12.7)	.441
Dyspnea	31 (44.3)	13 (16.5)	<.001
Sore throat	9 (12.9)	11 (13.9)	.849
Cough	33 (47.1)	10 (12.7)	<.001
Headache	11 (15.7)	4 (5.1)	.031
Chest pain	8 (11.4)	3 (3.8)	.075
Diarrhea	12 (17.1)	13 (16.5)	.911
Current medications, n (%)			
Antibiotics	58 (82.9)	…	…
Antivirals	41 (58.6)	…	…
Antimalarials	39 (55.7)	…	…

Note: Data were described as mean ± standard deviation or number and percentage (%).
Abbreviations: COVID-19, coronavirus disease 2019; RT-PCR, real-time reverse transcription-polymerase chain reaction.

significant difference in the past history such as hypertension, diabetes mellitus, heart disease, chronic renal diseases, chronic liver disease, and pulmonary disease between positive and negative COVID-19 group. In comparison to clinical features, the frequency of fever, dyspnea, cough, and headache in positive COVID-19 group was higher than that of the negative group ($P = .009$, $P < .001$, $P < .001$, and $P = .031$, respectively).

In the analysis of immmunochromatography for COVID-19, there were no subjects in the RT-PCR positive group and two subjects (2.5%) in the RT-PCR negative group who only produced the IgM antibody (Table 2). In addition, 19 patients (27.1%) with active COVID-19 infections and one subject (1.3%) without COVID-19 infection had only IgG antibody positivity without the presence of IgM antibody.

Both IgM and IgG antibodies were noted in 46 subjects (65.7%) in the RT-PCR positive group and in none of the RT-PCR negative group. In addition, 92.9% (n = 65) of the subjects with SARS-CoV-2 infection and 3.8% (n = 3) of those without SARS-CoV-2 infection showed either IgM or IgG positivity as determined by immunochromatography. Neither IgM nor IgG antibodies for SARS-CoV-2 were found in five subjects (7.1%) in the RT-PCR positive group or in 76 subjects (96.2%) in the RT-PCR negative group.

TABLE 2 Results of IgM and IgG antibody for SARS-CoV-2 by immunochromatography

	RT-PCR	
Immunochromatography	Positive COVID-19 (n = 70)	Negative COVID-19 (n = 79)
IgM (+) and IgG (−)	0 (0.0)	2 (2.5)
IgM (−) and IgG (+)	19 (27.1)	1 (1.3)
IgM (+) and IgG (+)	46 (65.7)	0 (0.0)
IgM (+) or IgG (+)	65 (92.9)	3 (3.8)
IgM (−) and IgG (−)	5 (7.1)	76 (96.2)

Note: Data were described as number and percentage (%).
Abbreviations: COVID-19, coronavirus disease 2019; IgG, immunoglobulin G; IgM, immunoglobulin M; RT-PCR, reverse transcription-polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

TABLE 3 Comparison of diagnostic values for immumochromatography

	Immunochromatography			
	IgM or IgG		IgM and IgG	
	Values	95% CI	Values	95% CI
Sensitivity	92.9%	84.1-97.6	65.7%	53.4-76.7
Specificity	96.2%	89.3-99.2	100.0%	95.4-100.0
Positive predictive value	95.6%	87.7-98.5	100.0%	
Negative predictive value	93.8%	86.7-97.3	76.7%	70.4-82.0

Note: Data were described as percentage (%) and 95% CI.
Abbreviations: CI, confidence interval; COVID-19, coronavirus disease 2019; IgG, immunoglobulin G; IgM, immunoglobulin M; RT-PCR, reverse transcription-polymerase chain reaction.

Sensitivity and specificity for IgM or IgG antibodies positivity was 92.9% (95% CI: 84.1-97.6) and 96.2% (95% CI: 89.3-99.2), respectively (Table 3). We noted 100% specificity and 65.7% sensitivity (95% CI: 53.4-76.7) for positivity of a combination of both IgM and IgG antibodies.

This study analyzed the PPV and NPV for either IgM or IgG antibody positivity according to changes in disease prevalence. The PPV ranged from 19.8% to 96.1% and rapidly increased as disease prevalence increased (Figure 1A). A gradual decrease in NPV of either IgM or IgG positivity from 99.9% to 95.3% was observed with increasing from 1% to 50% disease prevalence (Figure 1B). The NPVs for both IgM and IgG positivity gradually decreased with increasing prevalence, but these values remained relatively stable to 50% prevalence (data not shown). The PPVs for both IgM and IgG antibody positivity were 100% regardless of disease prevalence. The AUC obtained from an ROC curve analysis was 0.945 (95% CI: 0.903-0.988) for either IgM or IgG positivity and was 0.829 (95% CI: 0.757-0.900) for both IgM and IgG positivity (Figure 2).

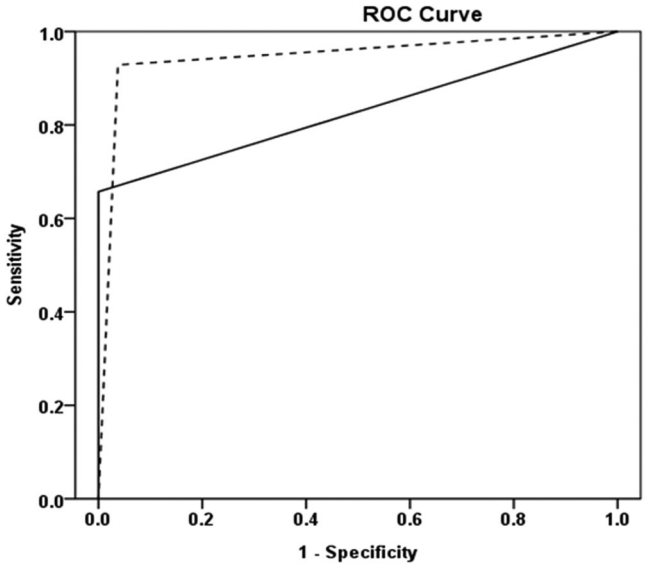

FIGURE 2 ROC curve of immunochromatography-based IgM/IgG rapid assay for COVID-19. The dashed line for either IgM or IgG positivity and solid line for both IgM and IgG positivity are presented in the ROC curve. COVID-19, coronavirus disease 2019; IgG, immunoglobulin G; IgM, immunoglobulin M; ROC, receiver operating characteristic

4 | DISCUSSION

Epidemic outbreak of COVID-19, a viral disease accompanied by mild to severe respiratory symptoms and signs of unknown causes, developed in December 2019 in China.[1] In the early period of the COVID-19 outbreak, its diagnosis was made based on clinical, laboratory, and radiographic findings before the introduction of a diagnostic technique that could directly identify this coronavirus.[1,5-8] The WHO announced that Chinese authorities had identified a novel type of coronavirus on 7 January 2020.[9] Presently, RT-PCR, a nucleic acid amplification test (NAAT), has been routinely used to detect COVID-19 infection in many countries around the world.[1,2,5,6] In this study, we assessed the diagnostic value of a new immunochromatography assay to detect IgM and IgG antibodies for SARS-CoV-2 infection.

Coronaviruses are single-stranded RNA viruses with a spike glycoprotein that plays a role in the binding of their receptors and the subsequent entrance of the virus into host cells and consist of four genera: alphacoronavirus, betacoronavirus, gammacoronavirus,

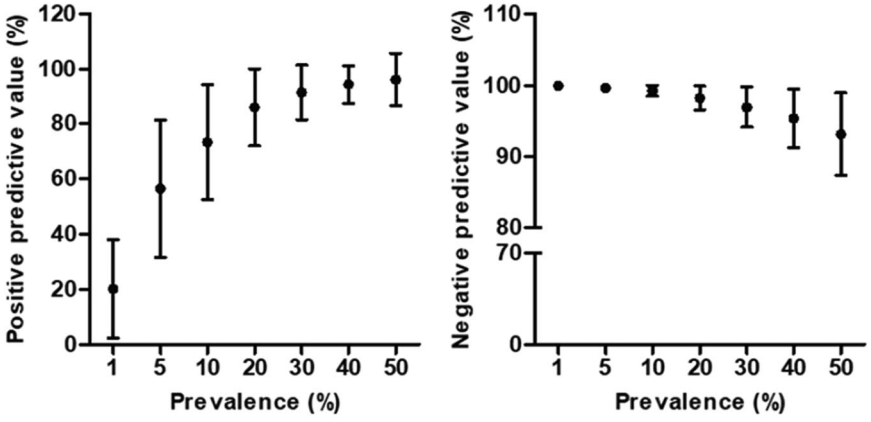

FIGURE 1 Estimated changes in PPV and NPV for IgM/IgG positivity according to disease prevalence by immunochromatography assay. A, PPV in either IgM or IgG positive group, (B) NPV in either IgM or IgG positive group Data were described as mean ± standard deviation. IgG, immunoglobulin G; IgM, immunoglobulin M; NPV, negative predictive value; PPV, positive predictive value

and deltacoronavirus.[10,11] The genome structure of coronaviruses includes four structural proteins: spike (S), membrane (M), envelope (E), and nucleocapsid (N) proteins.[2,10] SARS-CoV-2, which has been identified as the cause of COVID-19, is a type of betacoronavirus, along with SARS-CoV and MERS-CoV.[11] In clinical practice, diagnosis of COVID-19 infection is made via viral RNA detection using NAATs, including RT-PCR. In earlier studies, SARS-CoV-2 virus detection was mainly performed using RT-PCR that targeted the N, S, or E, RdRp gene region of the viral sequence and the open reading frame 1 ab fragment of coronavirus.[1,6,12,13] The present study also used an RT-PCR assay that targeted the E gene and RdRp gene for detection for SARS-CoV-2. However, it was necessary to thoroughly evaluate the diagnostic value of these RT-PCR methods, especially their sensitivity and specificity, using different viral gene sequences. Corman et al[12] demonstrated that the E gene and RdRp gene assay were sensitive based on SARS coronavirus virions and in vitro-transcribed RNA identical to the SARS-CoV-2 target gene. In addition, they also confirmed no nonspecific reactions with other nucleic acids and demonstrated that there was no cross-reactivity with other respiratory viruses or bacterial pathogens, including some other human coronaviruses, MERS-CoV, influenza, respiratory syncytial virus, legionella, and mycoplasma.[12] This finding suggests that RT-PCR method that targets at least two SARS-CoV-2 genes is a reliable test for screening for or confirming COVID-19 infection.

However, there are some limitations or weaknesses in the areas of confirmation of COVID-19 diagnosis by RT-PCR testing alone, such as the inability to distinguish virus viability and production of indeterminate or false-negative results due to low numbers of target cells in specimens, although RT-PCR remains a powerful technique for microbial diagnostics.[14] Laboratory assays such as ELISA and immunochromatography that use serum or blood sampled from suspected or established patients with COVID-19 infection have been proposed to overcome or supplement these limitations. One study using In-house anti-SARSr-CoV IgG and IgM ELISA to target the N gene showed that the IgM antibody level increased rapidly in the early stages of COVID-19 infection and then decreased in the later stages.[13] Furthermore, the IgG antibody was insignificantly expressed in the early stages of infection but increased rapidly in the later stages. Interestingly, titers of both IgM and IgG antibodies in COVID-19 patients were significantly higher than those assessed in healthy subjects. Infections have been reported to be reactivated in patients and confirmed by RT-PCR testing.[15] Therefore, serial quantitative results using ELISA may help not only confirm the diagnosis but also predict the clinical course of a patient.

Immunochromatography is another diagnostic alternative that has been proposed to detect COVID-19 infection. This technique was developed in the late 1960s to detect antigens in the blood and has recently been used as a rapid diagnostic method for various viral infections, such as Norovirus and influenza.[16,17] The benefits or advantages of immunochromatography include its ability to be performed at bedside without special laboratory equipment, its ease of performance, its simple interpretation, and its rapid time to produce results, which may compare favorably to other diagnostic tools, such as RT-PCR and ELISA methods. However, the sensitivity and specificity of immunochromatography are greatly dependent on duration of infection and the antigens produced by manufacturers of the tests. Immunochromatography for rapid detection of Noroviruses showed a relatively low sensitivity from 54.2% to 78.9% and a higher specificity from 93% to 100%.[18]

Until now, there have been no available data on the sensitivity and specificity of immunochromatography for identifying SARS-CoV-2 infection. In the present study, detection of IgM or IgG antibodies showed good sensitivity (92.9%) and specificity (96.3%), indicating a recent symptomatic infection or subclinical infection. However, the sensitivity decreased to 65.7% when requiring both IgM and IgG antibodies, as indicated by other studies.[18] We unexpectedly observed two subjects (2.5%) with only IgM antibodies and one subject (1.3%) with IgG antibodies alone in people without prior evidence of COVID-19 infection. These three subjects who were positive for either IgM or IgG (but not both) on immunochromatography had been tested repeatedly using RT-PCR every other day and were confirmed negative RT-PCR. All of the bacterial and respiratory viral infection tests performed at the same time were also negative. The diagnostic kit used in this study is known to have no cross-reactivity with influenza, respiratory syncytial virus, hemoglobulin, cholesterol, or heparin sodium. We also identified five subjects who did not produce any detectable antibody for SARS-CoV-2 but had been diagnosed with COVID-19, which means that they had experienced false-negative results. First, false-negative results may result from weak or no antibody formation against SARS-CoV-2 infection. This may be insufficient time for the virus to amplify to high enough levels to be detected, depending on the individual. To overcome the limitation of false-negative results in immunochromatography, it is necessary to verify other methods such as the ELISA test. Second, the inherent limitations of the immunochromatography assay technique must also be considered. This method showed a variable range of false-negative results in diverse viral diseases, such as Norovirus and human influenza virus.[18,19] The possibility of obtaining a false-negative result with the IgM/IgG Rapid Gold test kit for SARS-CoV-2 used in this study was lower than that reported by other earlier studies. Third, target gene selection can also affect the sensitivity of immunochromatography and produce a false-negative result. The diagnostic kit used in this study targets the S and N genes of the viral sequence. Corrman et al[12] demonstrated a lower sensitivity of the N gene compared with the E and RdRp genes. Therefore, the false-negative results observed in the present study were presumed to be related to the low sensitivity of the N gene.

This study found that one subject with IgG and two subjects with IgM for SARS-CoV-2 in immunochromatography assay were positive among RT-PCR negative subjects. Although RT-PCR test was repeated two to three times using samples of the upper and lower respiratory tracts of these patients, they were all confirmed negative. They also showed negative results for various respiratory pathogens such as influenza A/B, parainfluenza, respiratory syncytial virus, Chlamydophila pneumoniae, and Mycoplasma pneumoniae and other human coronaviruses including coronavirus 229E, coronavirus HKU1, coronavirus OC43, and coronavirus NL63. The Immunochromatography

test used in this study was confirmed to have no cross-reactivity to most of these pathogens. However, there is no data about cross-validation of coronavirus in the immunochromatography test kit used in this study. Although there was no evidence of infection with other human coronaviruses, the possibility of false positives by cross-reactivity with other coronaviruses cannot be ruled out.

There are some limitations to this study. First, it was not possible to observe changes in antibodies from the time of patient diagnosis to the time of participation in the study because this study was conducted in a cross-sectional manner. Second, the quantitative titer for each antibody expressed in the test kit could not be confirmed and is, therefore, a methodological limitation of immunochromatography. Third, it may be difficult to fully represent the diagnostic values, especially the sensitivity and specificity, of the diagnostic kit due to the small size of the study population.

In conclusion, immunochromatography demonstrated higher sensitivity and specificity for SARS-CoV-2 infection in the presence of either IgM or IgG antibodies. In addition, this IgM/IgG rapid immunochromatography technique produced a good diagnostic PPV and NPV. Therefore, the immunochromatography-based IgM/IgG rapid test for SARS-CoV-2 may be more practical for rapid and large-scale screening of coronavirus infections in the current outbreak of COVID-19 within the larger community and provides information to help predict patients' clinical progress by identifying the presence of IgM and/or IgG antibody formation against this viral infection.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

ORCID

Jung-Yoon Choe https://orcid.org/0000-0003-0957-0395
Ji-Won Kim https://orcid.org/0000-0002-0498-5762
Hyun Hee Kwon https://orcid.org/0000-0002-8509-3968
Hyo-Lim Hong https://orcid.org/0000-0003-2147-1381
Chi Young Jung https://orcid.org/0000-0002-8958-0886
Chang-Ho Jeon https://orcid.org/0000-0002-7450-7117
Eun-Jin Park https://orcid.org/0000-0001-7137-6150
Seong-Kyu Kim https://orcid.org/0000-0002-7780-0167

REFERENCES

1. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet*. 2020;395:497-506.
2. Lu R, Zhao X, Li J, et al. Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. *Lancet*. 2020;395:565-574.
3. World Health Organization. Coronavirus disease (COVID-19) outbreak (https://www.who.int).
4. Baud D, Qi X, Nielsen-Saines K, Musso D, Pomar L, Favre G. Real estimates of mortality following COVID-19 infection [published online ahead of print March 12, 2020]. *Lancet Infect Dis*. 2020;S1473-3099(20):30195-X. https://doi.org/10.1016/S1473-3099(20)30195-X
5. Chen N, Zhou M, Dong X, et al. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. *Lancet*. 2020;395:507-513.
6. Guan W, Ni Z, Hu Y, et al. Clinical characteristics of coronavirus disease 2019 in China. *N Engl J Med*. 2020;382:1708-1720. https://doi.org/10.1056/NEJMoa2002032
7. Chan JFW, Yuan S, Kok KH, et al. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster. *Lancet*. 2020;395:514-523.
8. Xiong Y, Sun D, Liu Y, et al. Clinical and high-resolution CT features of the COVID-19 infection: comparison of the initial and follow-up changes. *Invest Radiol*. 2020;55:332-339. https://doi.org/10.1097/RLI.0000000000000674
9. World Health Organization. Novel Coronavirus (2019-nCoV) situation report-1. https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200121-sitrep-1-2019-ncov.pdf
10. Chen Y, Liu Q, Guo D. Emerging coronaviruses: genome structure, replication, and pathogenesis. *J Med Virol*. 2020;92:418-423.
11. Ou X, Liu Y, Lei X, et al. Characterization of spike glycoprotein of SARS-CoV-2 on virus entry and its immune cross-reactivity with SARS-CoV. *Nat Commun*. 2020;11:1620.
12. Corman VM, Landt O, Kaiser M, et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. *Euro Surveill*. 2020;25(3):2000045. https://doi.org/10.2807/1560-7917
13. Zhou P, Yang XL, Wang XG, et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. *Nature*. 2020;579:270-273.
14. Kralik P, Ricchi M. A basic guide to real time PCR in microbial diagnostics: definitions, parameters, and everything. *Front Microbiol*. 2017;8:108.
15. Ye G, Pan Z, Pan Y, et al. Clinical characteristics of severe acute respiratory syndrome coronavirus 2 reactivation. *J Infect*. 2020;80:e14-e17. pii: S0163-4453(20)30114-6.
16. Buesa J, Montava R, Abu-Mallouh R, et al. Sequential evolution of genotype GII.4 norovirus variants causing gastroenteritis outbreaks from 2001 to 2006 in Eastern Spain. *J Med Virol*. 2008;80:1288-1295.
17. Velasco JMS, Montesa-Develos ML, Jarman RG, et al. Evaluation of QuickVue influenza A+B rapid test for detection of pandemic influenza A/H1N1 2009. *J Clin Virol*. 2010;48:120-122.
18. Thongprachum A, Khamrin P, Chaimongkol N, et al. Evaluation of an immunochromatography method for rapid detection of noroviruses in clinical specimens in Thailand. *J Med Virol*. 2010;82:2106-2109.
19. Dziąbowska K, Czaczyk E, Nidzworski D. Detection methods of human and animal influenza virus-current trends. Biosensors (Basel.). 8, 2018:E94.

How to cite this article: Choe J-Y, Kim J-W, Kwon HH, et al. Diagnostic performance of immunochromatography assay for rapid detection of IgM and IgG in coronavirus disease 2019. *J Med Virol*. 2020;92:2567–2572. https://doi.org/10.1002/jmv.26060