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Research Articles

Description of complaints/clinical symptoms and examination results of the SARS-CoV-2 rapid test in Brata Medika Laboratory Clinic Pare - Kediri in February 2021

Acivrida Mega Charisma[1], Arif Rahman Nurdianto[2,3*], Rizal Fauzi Nurdianto[4], Fery Setiawan[5], Heribertus Agustinus B. Tena[6]

1) Lecturer in Universitas Anwar Medika Hospital, Sidoarjo, Jawa Timur, Indonesia
2) Lecturer in Universitas Anwar Medika Hospital, Sidoarjo, Jawa Timur, Indonesia
3) Head of Education and Training Section, Rumah Sakit Umum Sidoarjo Barat, Jawa Timur, Indonesia
4) Student of Medical Faculty, Universitas Wijaya Kusuma Surabaya, Jawa Timur, Indonesia
5) Doctoral Student, Faculty of Medicine, Universitas Airlangga
6) Head of Biodokkes Polda Nusa Tenggara Timur

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Correspondence:

didins99@gmail.com

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ABSTRACT

SARS-CoV-2 antigen rapid test is one of the examinations widely used for early detection of Covid-19 infection. Rapid test is considered to have more advantages, is faster, and is cheaper than molecular PCR testing, and more accurate than rapid antibody tests. Its weakness is especially in detecting samples with small quantities of the virus. The study was conducted using a retrospective method. The data was taken from the patient's medical record of the SARS -CoV-2 antigen rapid swab test at Brata Medika Pare Clinical Laboratory for the period of February 2021. Data inclusion criteria including the examination, complete identity, results of anamnesis examination and rapid test examinations. Data were analyzed in a tabular form containing frequency and percentage. There were 18 (22.5%) patients with positive SARS-CoV-2antigen rapid swab test results, 16 (89%) with complaints/symptoms, and 2 (11%) without complaints/symptoms. Meanwhile, 62 (77.5%) were found with negative SARS-CoV-2 antigen rapid swab test results where 18 (29.0%) were patients with complaints/symptoms and 44 (71.0%) were patients without complaints/symptoms. The high percentage of negative SARS-CoV-2 antigen rapid swab test results in patients with complaints/symptoms (29.0%), it is recommended that a confirmatory examination with the molecular PCR test be carried out.

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INTRODUCTION

The Covid-19 disease was first reported at the end of December 2019 in Wuhan, China. Later in early 2020, the World Health Organization (WHO) announced the Covid-19 disease as a pandemic that had spread in more than 200 countries. This disease is caused by the virus Severe Acute Respiratory Syndrome Coronarius-2 (SARS-CoV-2), which is round with a diameter ranging from 60-200 nm with many spikes in the viral capsid and is classified as a single-stranded RNA virus (26-32 kb) (Xiaolong, 2020). This disease is transmitted between humans through droplets from the nose or mouth of a person infected with Covid-19 when coughing, sneezing, or talking (World Health Organization, 2020a). WHO estimates SARS-CoV-2has a relatively high reproductive number (RO) ((RO: 1,4-2,5) although not as high as SARS-CoV (RO: 2-5), but higher than MERS-CoV (RO: <1) (Chen 2020; Setiawan et al. 2020; Setiawan and Nurdianto 2021; Setiawan et al. 2021; Nurdianto AR, Tena HAB 2021).

Standard recommendations to prevent the spread of this viral infection are through washing hands regularly using soap and clean water, wearing a mask, establishing the ethics of coughing and sneezing, and carrying out social boundaries. In addition, it has been recommended to maintain distance when in crowded areas or with other people showing symptoms of respiratory diseases such as coughing and sneezing (Guo et al., 2020). In respiratory viruses, diagnosis depends on two clinical manifestations such as fever, fatigue, dry cough, dyspnea, and gastrointestinal symptoms, as well as an accurate diagnostic examination (Burhan E, Isbaniah F, Susanto A, Yoga Y, Tjandra A, 2020). According to WHO, the latest symptoms of Covid-19 include fever, dry cough, and fatigue. Other symptoms of losing taste/smell, runny nose, conjunctivitis (red eye), sore throat, headache, muscle or joint pain, skin rashes, nausea, vomiting, diarrhea, dizziness, chills, and shortness of breath, and many more. The symptoms experienced are usually mild and appear gradually (M. K. Rohmah & Rahman Nurdianto, 2020; M. Rohmah & Nurdianto, 2020; World Health Organization, 2020a)

At the beginning of the Covid-19 pandemic, WHO only recommends laboratory tests with nucleic acid amplification (NAAT) such as real-time Reverse Transcription-Polymerase chain reaction (RRT-PCR) to detect SARS-CoV-2which is the disease maker virus (World Health Organization, 2020b). The RT-PCR method detects the presence of the virus in the patient's body through a polymerase chain reaction with a primer or probe that specifically targets the SARS-CoV-2genome so that the amount of SARS-CoV-2 DNA in the specimen can be counted (Xiaolong, 2020). The other tests that are much simpler, cheaper, and faster, often called rapid diagnostic tests (RDT). RDT is a rapid test for detecting antibody (IgG and Ig M) SARS-CoV-2 where the blood sample is developed. The response of human antibodies to fight the virus in early infection can be used to support the diagnosis of a viral infection. Detection of IgM antibodies can indicate recent exposure to SARS-CoV-2, whereas detection of IgG antibodies indicates long-standing viral exposure (Li et al., 2020; The Association of Indonesian Clinical Pathology and Laboratory Medicine Specialists (PDS PatKLIn), 2020)

Most of the rapid atomic tests for Covid-19 use the sandwich immunodetection method with the easy-to-use lateral line test format and are commonly used for testing for HIV, malaria, and influenza. The rapid antigen test typically consists of a plastic cassette with a sample cavity and buffer and a nitrocellulose matrix strip with a test line with an antibody bound to the target conjugated antigen-antibody complex and a control line with an antibody bound to the conjugated antibody (World Health

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Organization, 2020c). The specimens used in this test are a swab nasopharynx or rub the oropharynx (swabs airways) (The Association of Indonesian Clinical Pathology and Laboratory Medicine Specialists (PDS PatKLIn), 2020). If the concentration of the target antigen in the sample is sufficient, the antigen will bind to the antibodies on the test strip. It will produce a visual signal, usually within 10 - 30 minutes (Koczuła & Gallotta, 2016). The detected antigen can only be expressed when the virus is actively replicating. Therefore, this test is best used to identify infection in the acute phase or early stage of infection.

METHODS

Study setting

The study was conducted using a retrospective method. Data was taken from the patient's medical record for the SARS-CoV-2 rapid antigen test at the Brata Medika Pare Clinical Laboratory for the period of February 2021, with complete data inclusion criteria including the examination carried out in February 2021, complete identity, analysis examination results, and the results of the rapid antigen test SARS-CoV-2. Data were analyzed in a tabular form containing frequency and percentage. This study has been ethically approved (The certificate number of ethical clearance is 893.3/022/438.6.7/2022).

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Sample size calculation

The number of samples taken is using the formula Slovin n = N / (1 + (N x e^2)), where N is the population: 1 0 0, e: margin of error 5% (0.05), with a degree of confidence of 95% obtained n the number of samples: 8 0. This study uses the Covid-19 brand test reagent (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) from Anhui Deepblu Medical Technology Co. Ltd, with the Indonesian Ministry of Health license number AKL 20303028147.

RESULTS

Characteristics of Respondents

Table 1. Characteristics of respondents

Age (Year)	Frequency (n)	Percentage (%)
0-10	2	2.5
11-20	11	13.8
21-30	18	22.5
30-40	14	17.5
>40	35	43.7
Gender		
Men	39	48.8
Women	41	51.2
Total	80	100

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Table 2. Distribution of Respondents with and without Clinical Complaints/Symptoms.

Anamneses	Frequency (n)	Percentage (%)
With symptoms (fever, dry cough, fatigue, losing taste/smell)	34	42.5
No symptoms	46	57.5
Total	80	100

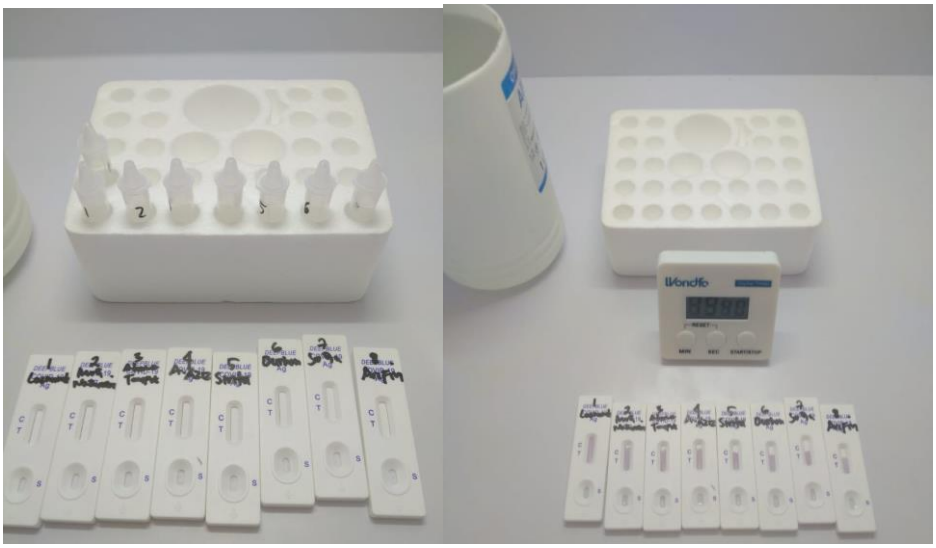

Figure 1. The process and final result of the rapid antigen test

Table 3. Distribution of SARS-CoV-2Antigen Rapid Test Results.

Checkup result	Frequency (n)	Percentage (%)
Positive (+)	18	22.5
Negative (-)	62	77.5
Total	80	100

Table 4. Distribution of Anamnese Results and Results of the SARS-CoV-2 Rapid Antigen Test.

Result	Results of the SARS-CoV-2 Rapid Antigen Test		Total
	Positive (+)	Negative (-)	
Anamnese	n (%)	n (%)	n (%)
With symptoms (fever, dry cough, fatigue, losing taste/smell)	16 (88.9)	18 (29.0)	34 (100)
No symptoms	2 (11.1)	44 (71.0)	46 (100)
Total n (%)	18 (100)	62 (100)	80 (100)

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The data in table 1 shows that the age range> 40 years is the largest age among respondents in this study with a total of 35 (43.7%) and the lowest is in the age range 0 - 10 years as much as 2 (2.5%).

Distribution of Respondents

Table 2 shows that 34 (42.5%) respondents in this study experienced clinical complaints/ symptoms when carrying out a rapid antigen test examination and 46 (57.5%) respondents experienced no clinical complaints/symptoms.

Figure 1 shows the process and final result of rapid antigen test examination. The former shows the initial result of rapid antigen test examination. The latter shows the final result of the rapid antigent test examination.

Table 3 illustrates that in this study, out of 80 respondents, it was found that 18 (22.5%) respondents had positive results on the SARS-CoV-2rapid antigen test, and 62 (77.5%) had negative results. 22.5% is a fairly high prevalence. For that, it is necessary to take further action in coordination with the tracing team from the nearest health center to carry out a confirmation check with RT-PCR, close contact tracing to prevent wider spread, and advice to do quarantine or independent isolation according to the criteria and apply PHBS (healthy lifestyle: washing hands, applying cough etiquette, using masks, maintaining stamina) and physical distancing.

Table 4 shows that in this study, 16 (88.9%) respondents from 18 who had positive SARS-CoV-2antigen rapid test results had clinical complaints/symptoms, and 2 (11.1%) had no complaints/symptoms. Meanwhile, the respondents with negative rapid test results were found to be 18 (29.0%) with clinical complaints/symptoms and 44 (71.0%) without clinical complaints/symptoms.

DISCUSSION

Immune status is indeed a factor that needs to be considered in the transmission/spread of Covid-19 infection, and age affects immunity status. According to experts from Imperial College, London, UK, the immune system will decrease with age due to reduced quality of the cells you have, for example, naive T-Cell, which is a group of immune cells. Usually, these cells will go around warning them when they find an infection. However, when cells age, less naive T-Cells are formed. This is because the small glands behind the breastbone (thymus) where they develop have shrunk (Budi et al, 2020).

Meanwhile, based on gender, there was no significant difference in numbers and percentages. Both men and women had the same risk of being infected with Covid-19. The immune system is not influenced by the sexual fetus but rather by the health status of the individual (Aspinall, 2005)

Clinical complaints/symptoms and contact with a confirmed patient with Covid-19 are the conditions recommended for the SARS-CoV-2 rapid antigen test. Symptoms commonly experienced by respondents in this study include weakness and fatigue (such as fainting), nasal congestion, hoarseness, fever, body aches, and dizziness. WHO mentioned these clinical complaints/symptoms as typical signs of Covid-19 infection (World Health Organization, 2020a).

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to the criteria and apply PHBS (healthy lifestyle: washing hands, applying cough etiquette, using masks, maintaining stamina) and physical distancing. Whereas respondents with negative rapid antigen test results do not rule out the possibility of being infected with SARS-CoV-2so that they are still at risk of transmitting to others, it is recommended to do a repeat test or confirmatory test with NAAT (nucleic acid amplification test) if the pretest probability is relatively high, especially if the patient is are symptomatic or known to have had contact with a person confirmed to have Covid -19, and negative results can also occur when the quantity of antigen in the specimen is below the level of detection of the instrument (The Association of Indonesian Clinical Pathology and Laboratory Medicine Specialists (PDS PatKLIn), 2020).

Table 4 shows that in this study, 16 (88.9%) respondents from 18 respondents who had positive SARS-CoV-2antigen rapid test results had clinical complaints/symptoms, and 2 (11.1%) had no complaints/symptoms. Meanwhile, the respondents with negative rapid test results were found 18 (29.0%) with clinical complaints/symptoms and 44 (71.0%) without clinical complaints/symptoms. The high percentage of respondents with clinical complaints/symptoms with negative results of the rapid antigen test can be a suspicion of false-negative results. This is due to the data and the fact that the rapid antigen test can only detect components of the SARS-CoV-2virus in the early case detection. It is the phase where the viral load is still high. Therefore, the virus replication period is still ongoing and will decline as the disease progresses (Agustina & Fajrunni'mah, 2020). Besides that, the inability of the staff to collect specimens can also affect the results obtained. A low quantity of antigen below the test detection level can also be the cause of false-negative results. So that in cases like this, it is recommended to do an examination or confirmation test with a NAAT-based examination such as RT-PCR (The Association of Indonesian Clinical Pathology and Laboratory Medicine Specialists (PDS PatKLIn), 2020).

CONCLUSION

From this research, it can be concluded that from the 18 respondents with antigen rapid test results, SARS -CoV-2 positive get the 16 (89%) with complaints/symptoms and 2 (11%) without any complaints/symptoms. From 62 (77, 5 %) with negative SARS-CoV-2 rapid antigen test results, 18 (29.0%) were patients with complaints/symptoms and 44 (71.0%) were patients without complaints/symptoms. The high percentage of negative SARS-CoV-2 rapid antigen test results in patients with complaints/symptoms (29.0%) could be due to a decrease in viral load (old infection). Thus it is suspected of producing false negatives as a follow-up, and it is recommended to perform a confirmatory examination with the RT- PCR molecular test. Complaints/clinical symptoms experienced by patients who test positive for rapid antigen in this research include runny nose, weakness, fatigue (such as fainting), hoarseness, fever, body aches, cough, and dizziness.

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