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Sensitivity and specificity of rapid antibody diagnostic test for diagnosis COVID 19 in pediatric patients

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***Abstract*---**Objective: Aim of this observational is to evaluate the sensitivity and specificity a rapid diagnostic test for COVID-19 for screening COVID-19 pediatric patients. Study Design: 179 Patients under 18 years old with a history of COVID-19 symptoms, and who underwent PCR and/or reference antibody testing for COVID-19. Results: The sampel of this study consisted of 179 patient who 100 sunject with reactive in rapid antibody diagnostic test COVID 19 which consisting of 40 subject positive SARS-CoV2 PCR swab examination and 60 subject negative SARS-CoV2 PCR swab examination. The patient with nonreactive result in rapid antibody diagnostic test COVID 19 which consisting of 19 subject positive SARS-CoV2 PCR swab examination and 60 subject negative SARS-CoV2 PCR swab examination. The sensitivity of the test was 67%. Specificity was 50%. There was substantial agreement between SARS-CoV2 PCR results and a rapid antibody diagnostic test COVID 19. Conclusion: The current evaluation of antibody-based system shows low sensitivity and low specificity result.

***Keywords*---**COVID-19, SARS-CoV2 infection, SARS-CoV-2 testing, COVID-19 antibody testing, COVID-19 serological testing.

Introduction

On December 31, 2019, the China Health Authority alerted the World Health Organization (WHO) to several cases of pneumonia of unknown aetiology in Wuhan City in Hubei Province in central China. The cases had been reported

since December 8, 2019, and many patients worked at or lived around the local Huanan Seafood Wholesale Market although other early cases had no expo- sure to this market.[1] The COVID-19 pandemic has infected over 37 million people globally, causing over 1 million deaths. The UK has one of the world's highest death tolls, with over 600,000 cases and over 42,000 deaths, equating to 630 deaths per million population.[2] The laboratory reference method for detecting COVID-19 is based on real-time reverse transcriptase PCR (qRT-PCR), to detect the presence of SARS-CoV-2 in nasofaringeal swabs collected from patients suspected to be infected, however it often takes several days to obtain the results in clinical settings.[3] While many measures to mitigate the multifactorial impact of COVID-19 are being implemented, one critical component of this strategy is the widespread testing and identification of individuals currently or previously infected by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[4] Although an unprecedented amount of basic and clinical research has been devoted, so far, to this infection, and a few clear lessons have been learned, many unsolved issues remain on pathogenetic, immunological and clinical aspects.[5,6]

Many antibody-based tests, including rapid diagnostic tests, have been developed, marketed and some have already been evaluated in retrospective studies.[7,8] The main use of all serologic tests is now restricted to screening and epidemiologic purposes. Rapid diagnostic tests is still used in service facilities that do not provide qRT-PCR, however the sensitivity and specificity are still debated. Therefore, this research's purpose to evaluate the sensitivity and specificity a rapid diagnostic test for COVID-19 for screening COVID-19 pediatric patients.

Methods

Type of study is observational, retrospective diagnostic study. The study was performed at Dr Soetomo Hospital, Airlangga Univercity, Surabaya. All consecutive patients presenting to the hospital (march 2020-2021) with clinical suspicion of COVID-19 and submitted to diagnostic tests for SARS-CoV-2 were eligible. There were 179 patient underwent a rapid diagnostic test for COVID-19 and SARS-CoV2 PCR swab examination with inclusion criteria is pediatric patients under 18 years old and exclusion criteria is missing or inadequate samples. Data were analyzed using univariate analysis, then further analysis was carried out on the test results for a rapid diagnostic test for COVID-19 based on the results of the sensitivity and specificity calculations.

Result

The characteristics of the subjects analyzed were gender, age, fever and comorbid. Categorical variables are reported in numbers and percentages, the comparative test is carried out with Chi square.

Table 1
Characteristics of respondents, comorbid, PCR SARS-CoV2 and antibody rapid test results

Characteristics	Antibody		Total (n=179)	P
	Reactive	Non-reactive		
Gender, n(%)				
Male	58 (58%)	52 (65%)	110 (61%)	0,412
Female	41 (41%)	28 (34%)	69 (38%)	
Age				
a month-5 years	64 (64%)	43 (54%)	107 (59%)	0,306
old	36 (36%)	36 (45%)	72 (40%)	
>5-18 years old				
Cilinical manifestation				
Fever	69 (70%)	67 (84%)	136(76%)	0.765
Comorbid n= 89	36 (36%)	53(67%)	89 (50%)	0,015
Malignancy				
Heart Disease	13 (36%)	27 (50%)	40(22%)	
CKD	9 (25%)	10 (12%)	19(11%)	
Autoimmun	3 (8%)	0	3 (2%)	
Obesity	6 (16%)	6 (11%)	12(6%)	
Other	2 (5%)	2 (4%)	4(2%)	
	3 (8%)	8 (15%)	11(6%)	
Examination				0,021
PCR SARS-CoV2				
Positive	40(40%)	19(24%)	59(32,9%)	
Negative	60(60%)	60(75,9%)	120(67%)	

Chi Square test, $p < 0.05$ indicates significance

A total of 179 subjects in this study were divided into 2 groups, namely reactive results on the antibody rapid diagnostic test and non-reactive results antibody rapid diagnostic test of COVID-19. Conformity analysis between the SARS-CoV2 PCR examination and diagnostic rapid antibody test to diagnose COVID-19 using kappa analysis. Can be seen in table 2 shows the results of research with kappa analysis obtained a value of 0.15 with a p value of 0.016.

Table 2
Sensitivity and specificity of antibody rapid test

Rapid Antibody	PCR SARS-CoV2		Total	Sensitivity	Specificity	PCR SARS-CoV2	
	Positive	Negative				Kappa	P
Reavtive	40(68%)	60(50%)	100(55,8%)	67.7%	50%	0,15	0,016
Non	19	60(50%)	79(44,2%)				
Reactive	(32%)	120	179				
Total	59						

From the results of the analysis using a diagnostic test with the gold standard of SARS-CoV2 PCR swab examination, the sensitivity of the rapid antibody seological diagnostic test was obtained with a sensitivity of 67.7%, a specificity of 50%, a positive predictive value of 40%, a negative predictive value of 75.9% and an accuracy of 55.5%.

Discussion

In this study, data were taken from March 1, 2020 to March 30, 2021. It was found that 179 subjects were included according to the inclusion and exclusion criteria. Patients who confirmed COVID-19 with the gold standard swab PCR SARS-CoV2 examination were 59 (32.9%) and while patients who did not confirmed COVID-19 with results were 120 (67%). The 110 patient (61%) are male with 58 patients (58%) reactive result rapid test antibody of COVID-19. This is in accordance with a previous study conducted in Bonston which found that men were 78% more dominant in the confirmed COVID-19 group and in the non-COVID-19 group.[9] In this study, it was reported that in the group of subjects with the age of 1 month-5 years there were 107 more subjects (59%) compared to the age group >5-18 years. The clinical symptom reported in this study was fever. From research data, the group of subjects with reactive results on the rapid diagnostic test for COVID-19 antibodies was 70% while in the group with non-reactive results on the rapid diagnostic test for COVID-19 antibodies, it was 84%. From a previous study in China, 26% asymptomatic subjects, while subjects with clinical symptoms were 74%, with the most symptoms in pediatric patients being fever (36%).[10] This study reported that the group of patients with confirmed COVID-19 had the most dominant malignancy comorbidity as much as 47%. Study conducted in New York, of 178 pediatric patients with malignancy (107 boys and 71 girls) 20 (11.2%) had a positive test result. Of the patients who were specifically tested for screening or positive symptoms (positive screening or symptomatic positive), the positivity rate for SARS-CoV-2 was 29.3%.[11]

This study was conducted to analyze the performance of the COVID-19 antibody diagnostic test as an examination with suspicion of COVID-19. From the analysis using a diagnostic test with the gold standard for the SARS-CoV2 PCR swab examination, the sensitivity of the antibody rapid diagnostic test was 67.7%, and specificity was 50 %. There was substantial agreement (Kappa score 0.016) between the the SARS-CoV2 PCR swab examination results and the antibody rapid diagnostic test. Previous studies obtained results from 57 patients suspected of being infected with COVID-19, the patient confirmed COVID-19 with the gold standard swab PCR SARS-CoV2 examination were 21 and 33 patients were not negative confirmed COVID-19, while the sensitivity results from the IgG and IgM 72.73% and 87.50%.[12]

Conclusion

The current evaluation of antibody-based system shows low sensitivity and low specificity result.

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