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DIAGNOSTIC ACCURACY OF SARS-COV-2 ANTIGEN TEST IN THE PEDIATRIC POPULATION: SYSTEMATIC REVIEW

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ABSTRACT

The early identification and subsequent isolation of SARS-CoV-2 infected individuals are two of the most important methods for avoiding the COVID-19 population spread. It's possible that about forty percent of those infected with high viral loads won't show any symptoms at all. Asymptomatic individuals are thought to be responsible for roughly 40% to 45% of SARS-CoV-2 infections, and they are able to spread the virus to others for a lengthy period of time, maybe more than 14 days. Antigen testing has many benefits, including a low overall cost and a short turnaround time, which all contribute to its ability to rapidly detect infected individuals. Testing using RT-PCR should be investigated when it has been determined that symptomatic patients have a negative response to antigen testing and that asymptomatic individuals have a positive response to antigen testing. The quantities of the SARS-CoV-2 virus found in children are significantly lower than those found in adults. It is essential to take into consideration the fact that the Ct values of those who are symptomatic and those who are asymptomatic do not differ considerably from one another. Before these tests are widely used in either national or international prevention strategies, it is necessary to carry out additional large studies in order to evaluate the clinical utility of these tests in the community. This evaluation must be carried out in order to conduct additional large studies. Antigen tests are shown to have an accuracy that is very near to being perfect in this article. Despite the fact that the majority of nations adhere to the agreement that PCR testing is required in order to diagnose COVID-19.

KEYWORD: *Antigen test, Children, COVID-19, Diagnosis, SARS-CoV-2*

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INTRODUCTION

The global coronavirus disease 2019 (COVID-19) pandemic has been caused by the spread of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). It is estimated that at least 50% of COVID-19 patients got the virus from asymptomatic people.[1] Rapid diagnosis and isolation of SARS-CoV-2 infected persons are key techniques for preventing COVID-19 population dissemination. Around 40% of people infected with high virus loads may be asymptomatic. Asymptomatic persons seem to account for approximately 40% to 45% of SARS-CoV-2 infections, and they can transmit the virus to others for an extended period, perhaps longer than 14 days.[2]

The World Health Organization and the Centers for Disease Control and Prevention have made reverse-transcription polymerase chain reaction (RT-PCR) technique the gold standard for SARS-CoV-2 detection.[2] For SARS-CoV-2, RT-PCR has a high sensitivity. Despite its high sensitivity, RT-PCR has drawbacks such as the need for professional lab experience, expensive chemicals, and centralized equipment. As a result, antigen assays for SARS-CoV-2 viral proteins in respiratory samples have been established. Individuals with COVID-19 who are highly contagious, i.e. those with a high viral load, can be identified using antigen tests.[3]

The advantages of antigen testing, such as their inexpensive cost and quick response time, help to identify infected persons quickly. After negative antigen test findings in symptomatic persons and positive antigen test results in asymptomatic individuals, RT-PCR testing should be explored. Children have much lower SARS-CoV-2 virus levels than adults. This might explain why antigen testing in the pediatric population are less sensitive. In the early disease phase, studies evaluating the COVID-19 antigen test in the adult population found a sensitivity of around 80.4%. Nonetheless, there is little data to support the diagnostic accuracy of antigen testing in children. Furthermore, adult patients had stronger sensitivity than juvenile patients.[4–6]

The diagnostic accuracy of the SARS-CoV-2 antigen test is investigated in this research using a pediatric population to conduct the study.

METHODS

Protocol

The approach of this investigation was based on the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020 criteria. These factors influenced the legislation that were passed.

Criteria for Eligibility

This review of the literature aims to demonstrate the diagnostic accuracy of the SARS-CoV-2 antigen test in the pediatric population by assessing or analyzing previous research on the subject. This is a significant concern raised in the current research. Researchers participate in research that meets the following criteria: 1) Articles must be written in English and highlight or focus on the diagnostic accuracy of the SARS-CoV-2 antigen test in the pediatric population to be considered for publication. 2) This evaluation took into account articles published after 2020, but before the period of this systematic review. Editorials, submissions without a DOI, review articles that have already been published, or entries that are very similar to those that have already been published in a journal, for example, will not be considered for publication.

Search Strategy

The search for studies to be included in the systematic review was carried out from January, 19th 2023 using the PubMed and SagePub databases by inputting the words: "diagnostic accurarcy", “SARS-CoV-2 antigen test”, and "pediatric population". Where *("diagnosis"[MeSH Terms] OR "diagnosis"[All Fields] OR "diagnostic"[All Fields] OR "diagnostical"[All Fields] OR "diagnostically"[All Fields] OR "diagnostics"[All Fields]) AND "accurarcy"[All Fields] AND ("sars cov 2"[MeSH Terms] OR "sars cov 2"[All Fields] OR "sars cov 2"[All Fields]) AND ("antigen s"[All Fields] OR "antigene"[All Fields] OR "antigenes"[All Fields] OR "antigenic"[All Fields] OR "antigenically"[All Fields] OR "antigenicities"[All Fields] OR "antigenicity"[All Fields] OR "antigenized"[All Fields] OR "antigens"[MeSH Terms] OR "antigens"[All Fields] OR "antigen"[All Fields]) AND ("research design"[MeSH Terms] OR ("research"[All Fields] AND "design"[All Fields]) OR "research design"[All Fields] OR "test"[All Fields]) AND ("paediatrics"[All Fields] OR "pediatrics"[MeSH Terms] OR "pediatrics"[All Fields] OR "paediatric"[All Fields] OR "pediatric"[All Fields]) AND ("populate"[All Fields] OR "populated"[All Fields] OR "populates"[All Fields] OR "populating"[All Fields] OR "population"[MeSH Terms] OR "population"[All Fields] OR "population groups"[MeSH Terms] OR ("population"[All Fields] AND "groups"[All Fields]) OR "population groups"[All Fields] OR "populations"[All Fields] OR "population s"[All Fields] OR "populational"[All Fields] OR "populous"[All Fields])* is used as search keywords.

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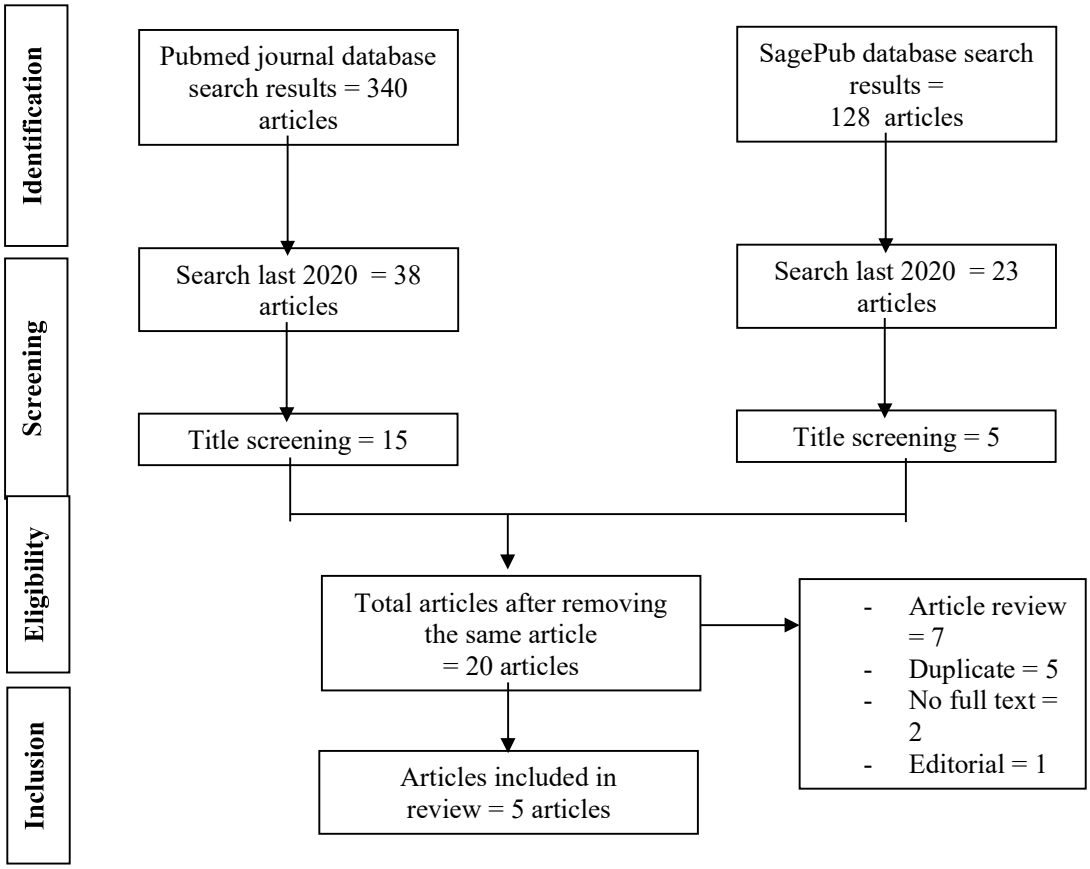

Figure 1. Article search flowchart

Data retrieval

The author modified the inclusion and exclusion criteria after conducting a literature review that included a review of the titles and abstracts of previous research. The revised criteria are included in the supplementary materials for the study. This clarified the scope of the problem and highlighted the aspects that need to be investigated further. After conducting research on additional studies with a similar format, the author came to this conclusion. During the systematic review process, only studies that met all of the inclusion criteria were considered.

This ensured that only relevant information was discovered. We did not consider any research proposals that did not meet all of our requirements. This ensured that a thorough examination would take place. This effort produced information relevant to the studies, such as their titles, authors, publication dates, locations, research investigation types, and parameters. These are the item categories that are available. These are abilities that can be honed. Depending on the information source, these data can be presented in a variety of formats.

Quality Assessment and Data Synthesis

Before deciding which articles to investigate, each author conducted an independent investigation of a piece of research mentioned in the titles and abstracts of the papers. The full texts of publications that meet the systematic review's inclusion criteria will then be reviewed to determine which papers will be included in the review. This is done to determine which articles will be included in the review. To facilitate the selection of articles for the review. Which studies are of sufficient quality to be included in the review?

RESULT

First study showed P-RDT sensitivity among the 119 (14.5%) RT-PCR-positive patients was 0.66 (95% confidence interval [CI] = 0.57 to 0.74) Patients with a positive P-RDT test had a greater mean viral load (VL) than those with a negative test (P <0.001). In specimens with a VL of >1.0E6 IU/ml, the sensitivity was 0.91 (95% CI = 0.83-0.99) and fell to 0.75 (95% CI = 0.66-0.83) when the VL was >1.0E3 IU/ml. Among symptomatic individuals, the P-RDT

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exhibited a sensitivity of 0.73 (95% CI 0.64 to 0.82), which peaked at 1.00 at 2 days post-onset of symptoms (DPOS) (95% CI = 1.00-1.00) and then declined to 0.56 (95% CI = 0.23-0.88) at 5 DPOS.[7]

Table 1. The litelature include in this study

Author	Origin	Method	Sample Size	Period	Age	Result
L'Huillier, 2021	Switzerland	Single-center prospective diagnostic study	822 participants	10 November 2020 to 26 March 2021	9-15 years old	P-RDT sensitivity among the 119 (14.5%) RT-PCR-positive patients was 0.66 (95% confidence interval [CI] = 0.57 to 0.74) Patients with a positive P-RDT test had a greater mean viral load (VL) than those with a negative test (P <0.001). In specimens with a VL of >1.0E6 IU/ml, the sensitivity was 0.91 (95% CI = 0.83-0.99) and fell to 0.75 (95% CI = 0.66-0.83) when the VL was >1.0E3 IU/ml. Among symptomatic individuals, the P-RDT exhibited a sensitivity of 0.73 (95% CI 0.64 to 0.82), which peaked at 1.00 at 2 days post-onset of symptoms (DPOS) (95% CI = 1.00-1.00) and then declined to 0.56 (95% CI = 0.23-0.88) at 5 DPOS. There was a tendency toward decreased P-RDT sensitivity in symptomatic children 12 years of age (0.62 [95% CI = 0.45-0.78]) compared to symptomatic children 12 years of age (0.80 [95% CI = 0.69-0.91]; P = 0.09). In asymptomatic patients, the sensitivity of the P-RDT was 0.43 (95% [CI = 0.26-0.60). Specificity in sick and asymptomatic children was 1.00 (95% confidence interval [CI]: 0.99 to 1.00). The total P-RDT sensitivities of 73% and 43% in symptomatic and asymptomatic youngsters, respectively, fell below the World Health Organization-recommended threshold of 80%.
Eleftheriou, 2021[9]	Greece	Prospective study	744 children	September 25th, 2020 to February 28th, 2021	1-14 years old	The RAD test was able to identify 42 of the 51 children who had positive PCR findings, and there were no false-positive results. Overall, the sensitivity was 82.35 percent (95% = 71.9–92.8%), while the specificity was 100 percent. In symptomatic youngsters, the sensitivity was more than 95%. The test was not very accurate in detecting infections in children who were asymptomatic.
Sood, 2021[8]	USA	Cross sectional	783 children	November 25, 2020 to December 9, 2020	5-17 years old	226 children tested positive for RT-PCR, with 127 (56.2%, 95% CI = 49.5% to 62.8%) also testing positive for the fast antigen test. Positive concordance was greater in symptomatic children (64.4%; 95% CI = 53.4% to 74.4%) than in asymptomatic children (51.1%; 95% CI = 42.5% to 59.7%). Positive concordance was inversely related to Ct levels and was 93.8% (95% CI = 69.8% to 99.8%) for children with Ct values less than or equal to 25. 548 children tested negative on RT-PCR; 539 (98.4% 95% CI = 96.9% to 99.2%) of them also tested negative on the quick antigen test. Asymptomatic children had a greater level of negative concordance.
González-Donapetry, 2021[10]	Spain	Cross sectional	440 children	September 25 and October 14, 2020	0-15 years old	There were a total of 440 nasopharyngeal swabs that were examined. The quick antigen test was able to detect 14 out of the 18 RT-qPCR positive samples, which results in an overall sensitivity of 77.7% for the test. Every single sample that was found to be positive with the antigen fast test was also shown to be positive with the RT-qPCR.
Villaverde, 2021[11]	Spain	Descriptive, retrospective, multicenter clinical validity study	1,620 pediatric patients		0-16 years old	A multicenter clinical validity study of the Panbio coronavirus disease 2019 Antigen Rapid Test of nasopharyngeal samples in pediatric patients with coronavirus disease 2019–compatible symptoms of 5 days of evolution was carried out by Villaverde et al. (2021). This test was used to diagnose patients with coronavirus disease 2019–compatible symptoms. Our research revealed that nasopharyngeal antigen testing had only a moderate degree of accuracy: the total sensitivity was 45.4%, while the specificity was 99.8%, and the positive-predictive value was 92.5%.

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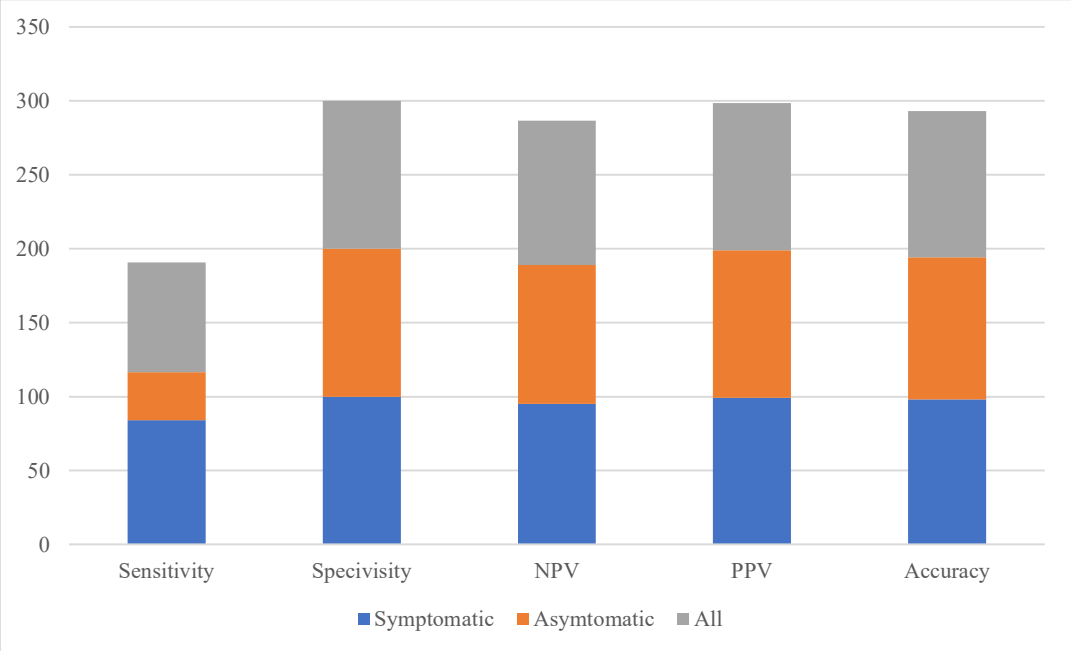

Figure 2. Accuracy antigent test for COVID-19

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A multicenter clinical validity study of the Panbio coronavirus disease 2019 Antigen Rapid Test of nasopharyngeal samples in pediatric patients with coronavirus disease 2019–compatible symptoms of 5 days of evolution was carried out by Villaverde et al. (2021).[11] This test was used to diagnose patients with coronavirus disease 2019–compatible symptoms. Our research revealed that nasopharyngeal antigen testing had only a moderate degree of accuracy: the total sensitivity was 45.4%, while the specificity was 99.8%, and the positive-predictive value was 92.5%.

DISCUSSION

Due to the continuing pandemic caused by COVID-19, an ever-increasing number of diagnostic tests for the early diagnosis of SARS-CoV infection are required. There has been a rise in the demand for diagnostic testing, but there has also been an increase in the capacity of laboratories to do testing. These tests may be carried out quickly and easily by medical professionals with a low level of education, and specialized tools are not required. They also have lower costs, may be conducted at the point of care, and the results are usually always accessible right away. However, RAD tests were shown to have poor performance for the COVID-19 diagnosis in a number of early investigations, which hindered the widespread adoption of these tests.[12,13]

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At the start of the COVID-19 pandemic. The rapid screening technique used is antibody testing. For comparison before we start everything. The sensitivity of antibody testing (both IgM and IgG) for COVID-19 ranges from 0.66-0.97, which is encouraging. In addition, it was shown that increased antibody levels occurred during the second week after the beginning of symptoms. Antibody testing is absolutely necessary for individuals with a mild to severe disease who may appear late, more than two weeks after the beginning of symptoms. After the first two weeks following the beginning of symptoms, a rise in antibody levels was seen.[7,14]

Testing for antibodies is also extremely important for both understanding the seroprevalence of COVID-19 in the population and determining whether or not people are immunoreactive to SARS-CoV-2. This is because testing for antibodies can determine whether or not people have an immune response to SARS-CoV-2. The diagnostic technique known as reverse transcription-PCR is considered to be the gold standard for use in SARS-CoV-2 testing (RT-PCR). In the majority of instances, the explanation for false-negative RT-PCR findings was an incongruous timing of specimen collection in relation to the commencement of symptoms, in addition to a deficiency in the sampling technique. In other words, the time of the specimen collection was not appropriate.[15]

Individuals who are showing symptoms should have antigen testing, and they should consider getting retested if the result of their antigen testing was negative. This is especially important for patients who had a high pre-test chance of having SARS-CoV-2 infection. It is suggested that asymptomatic people who have a known exposure to SARS-CoV-2 undergo antigen testing within 5–7 days following the exposure. In the event that the antigen test yields a negative result, it is suggested that these asymptomatic persons submit themselves to further testing two days later.[15]

The more recent RAD tests have enhanced diagnostic qualities, which makes it possible to use them in a variety of settings as a component of a larger approach for the diagnosis and control of COVID-19.[16] The main conclusion of L'Huillier's (2021)[7] work is that the assay's overall sensitivity is 66%, ranging between 43% and 73% in asymptomatic and symptomatic youngsters, respectively. Specificity, on the other hand, was 100% independent of the presence or absence of symptoms. As a result, it appears highly unlikely that youngsters be taken into quarantine needlessly, which is essential from a public health standpoint. The WHO RDT target product profile cutoffs of 80% for sensitivity and 97% for specificity were met, but not for sensitivity.[17]

The PANBIO RAD test had a low success rate in individuals who had an asymptomatic SARS-CoV-2 infection, which was in line with the findings of prior investigations. The World Health Organization (WHO) suggests that RAD tests should not be utilized in persons who are asymptomatic unless those individuals are contacts of a confirmed case. This advice acknowledges the ambiguities surrounding their usage for screening purposes that have been established by a number of studies. On the other hand, a number of authorities believe that regular testing with a RAD test that is uncomplicated, low-cost, and rapid will help to restrict the asymptomatic spread of SARS-CoV-2 and will allow for the resumption of educational, professional, and social activities.[18,19]

It is essential to take into consideration the fact that the Ct values of those who are symptomatic and those who are asymptomatic do not differ considerably from one another. Before these tests are widely used in either national or international prevention strategies, it is necessary to carry out additional large studies in order to evaluate the clinical utility of these tests in the community. This evaluation must be carried out in order to conduct additional large studies. The location in which RAD tests are conducted as well as the number of people who are affected by the illness both play a significant role in the accuracy of the results.[18,19]

Children exhibited symptoms less frequently, had a smaller total number of symptoms, and they did so for a shorter period of time than adults did. Children with asymptomatic SARS-CoV-2 infection or moderate sickness had viral loads that were somewhat lower than those of adults with equally mild SARS-CoV-2 infections. This was the case regardless of whether or not the children had disease. Even while symptomatic children had greater viral loads than asymptomatic children, researchers have not shown that viral loads can accurately predict the severity of the disease in children.[20,21]

According to the findings of the subgroup analysis that was carried out as a part of our meta-analysis, antigen testing may provide a moderate degree of sensitivity when it comes to detecting SARS-CoV-2 in symptomatic patients who are juvenile patients. Antigen testing indicated a poorer sensitivity for identifying SARS-CoV-2 in the asymptomatic pediatric population, as indicated by the findings of another subgroup analysis of studies comprising participants who were asymptomatic pediatric patients. This was the conclusion reached by the researchers after looking at studies that included participants who were pediatric patients.[8,20]

CONCLUSION

This article demonstrates that antigen assays have an accuracy close to 100%. Although the consensus used in many countries must use PCR to establish a diagnosis of COVID-19.

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