Public Health in Practice 5 (2023) 100347

Contents lists available at ScienceDirect

Public Health in Practice

journal homepage: www.sciencedirect.com/journal/public-health-in-practice

Comparison of capillary blood and plasma samples for the evaluation of seroprevalence to SARS-CoV-2 antibodies by lateral flow immunoassay in a university population in Medellín, Colombia, 2020

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ARTICLE INFO

Keywords:
COVID-19
Predictive values
Youden statistic
Sensitivity and specificity

ABSTRACT

Objectives: The aim of this study was to estimate the seroprevalence of anti-SARS-CoV-2 antibodies using the SARS-CoV-2 antibody test in a university population. Capillary blood and plasma samples were compared and correlated with symptomatology to establish rapid treatment processes and develop a public health strategy within the community.
Study design: Descriptive study of seroprevalence of anti-SARS-CoV-2 antibodies in a university population.
Methods: Standardised and validated laboratory serological tests were used to assess the immune response detected in capillary blood and plasma samples. In this study, 280 participants from the University Colegio Mayor de Antioquia in the Municipality of Medellín, Colombia, were tested for SARS-CoV-2 antibodies in capillary blood and plasma samples between November 2020 and January 2021.
Results: In total, 29 (11.2%) individuals had positive results for anti-SARS-CoV-2 antibodies (IgG/IgM); 28 (96.6%) had positive results in plasma samples and 11 (37.9%) in capillary blood samples. The two tests were compared, and the overall sensitivity and specificity of capillary vs plasma samples was 36.7% and 99.6%, respectively.
Conclusions: Anti-SARS-CoV-2 antibodies (IgG/IgM) can be used to estimate the seroprevalence in populations, including immunity by vaccination; however, capillary blood samples should not be used to detect previous infection as they provide low sensitivity compared to plasma samples.

1. Introduction

COVID-19 is the infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), which has spread rapidly throughout the world resulting in a global pandemic. Colombia confirmed its first case of COVID-19 in the capital, Bogotá, on March 6, 2020 in a man who had recently visited Milan, Italy.

Seroprevalence studies provide an important role in the evaluation of immune response against a virus. For the timely management of the COVID-19 pandemic, accurate, standardised and validated laboratory serological tests were required to assess the seroprevalence and immunisation status of the population [1,2]. Sensitivity, specificity and precision of the technique in relation to the type of sample are important factors in providing accurate results in epidemiological studies.

Laboratory tests can directly or indirectly identify infection caused by SARS-CoV-2 in different sample types. Immunoassay techniques are designed to detect antibodies in blood samples by identifying specific anti-SARS-CoV-2 antibodies that are present approximately 10 days after the first clinical manifestation of infection [3]. A positive result confirms contact with the virus and is of great value from an epidemiological perspective because it enables detection of asymptomatic individuals. Asymptomatic individuals can be a source of infection; thus, identification of these individuals allows a more accurate calculation of the seroprevalence of COVID-19 infection in the population.

The sensitivity and specificity of the COVID-19 seroprevalence assays quickly led to the recognition that robust internal validation and

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https://doi.org/10.1016/j.puhip.2022.100347
Received 17 August 2022; Accepted 24 November 2022
Available online 15 December 2022

regulatory control was required. In addition, research was required to link specific serological variables with immunity against SARS-CoV-2 [4], including vaccination; thus, seroprevalence studies provided information about the duration of vaccine immunity and the induced herd immunity.

Globally, the COVID-19 pandemic required the expansion of commercial rapid serological tests for use on different sample types to enable mass screening and testing of the entire population. In Colombia, the approved tests by the INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos) jurisdiction, must be validated and verified before their use in clinical assays. The SARS-CoV-2 Antibody Test (Lateral Flow Method) (Guangzhou, Wondfo Biotech Co., Ltd.) has been used to detect antibodies in serum, plasma and capillary blood; however, one study suggested that this test showed a low sensitivity when performed with capillary blood and therefore not be performed using capillary blood samples [5].

The current study aimed to estimate the seroprevalence of anti-SARS-CoV-2 antibodies using the SARS-CoV-2 Antibody Test in a university population. Capillary blood and plasma samples were compared and correlated with symptomatology to establish rapid treatment processes and develop a public health strategy within the community.

2. Methods

2.1. Study population

A descriptive study was conducted in a population of men and women from the Institución Universitaria Colegio Mayor de Antioquia in the Municipality of Medellín, Colombia, between November 2020 to January 2021. Eligible participants (N = 280) were aged ≥18 years, and were able to read and sign informed consent documents. All participants voluntarily agreed to take part in the study. A survey collected data from participants, including the dates of any previous COVID-19-related symptoms, such as headache, fatigue, fever or respiratory signs. To calculate sensitivity, individuals who had previously tested positive for COVID-19 by RT-PCR (n = 10) were included. To calculate specificity, both individuals who had previously tested negative for COVID-19 by RT-PCR (n = 10) and plasma samples collected before the SARS-CoV-2 outbreak and stored at −80 °C (n = 10) were included. This low-risk study was conducted during the COVID-19 pandemic and under a declaration of a state of emergency. An approval certificate was obtained from the research committee of the Faculty of Health Sciences of the University Institution Colegio Mayor de Antioquia and the study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

2.2. Specimen collection and procedures

The SARS-CoV-2 Antibody Test (Lateral Flow Method) (Guangzhou, Wondfo Biotech Co., Ltd.) Cat N° W195 is based on the principle of capture immunoassay for determination of SARS-CoV-2 IgG/IgM antibodies in humans. When the SARS-CoV-2 antibody levels in the specimen are at or above the cut-off value (the detection limit of the test), the antibodies bound to the antigen-dye conjugate are captured by anti-human IgG antibody and anti-human μ chain antibody immobilised in the Test Region (T) of the device; this interaction produces a coloured test band that indicates a positive result. When the SARS-CoV-2 antibody levels in the specimen are zero or below the cut-off value, the coloured band is not visible in the Test Region (T) of the device. The test cassette was used at the site according to manufacturer's instructions for plasma and capillary whole blood.

To collect capillary blood samples, a lancet was used to prick the side of the fingertip resulting in the formation of a large drop of suspended blood. This blood sample was collected with a dropper (10 μl approximately, included in the kit) and deposited on the appropriate well of the test cassette. In addition, following the standard venous blood collection procedure, a whole blood specimen was collected in a tube containing EDTA. Immediately, the plasma was separated from blood by centrifugation at 3500 rpm for 5 min at 25 °C. This plasma sample was collected with a 10 μl micropipette that filled automatically and was deposited in the appropriate well of the test cassette.

2.3. Data analyses

All data were entered into an Excel file and analysed by Software SPSSv25. The validity of the capillary blood sample was evaluated by determining the sensitivity and specificity of the test, and the Youden statistic was also calculated. The safety of the capillary blood sample was evaluated by means of the positive (PPV) and negative (NPV) predictive values. The recommended sample (plasma) was considered as the reference standard.

3. Results

The SARS-CoV-2 Antibody Test (Lateral Flow Method) for detecting anti-SARS-CoV-2 IgM/IgG antibodies was evaluated using plasma and capillary blood samples. The serology was performed on 260 participants. In total, 29 (11.2%) individuals were positive for anti-SARS-CoV-2 antibodies (IgG/IgM); 28 (96.6%) had positive results in plasma samples and 11 (37.9%) in capillary blood samples. Thus, 10 (34.4%) participants had positive results in both plasma and capillary blood samples. The sensitivity and specificity for detecting IgM/IgG in capillary blood was 36.7% and 99.6%, respectively. The PPV was 91% and the NPV was 93%. The Youden statistic was 36.3%.

In participants who had previously been diagnosed with COVID-19 (positive control) from July to November 2020 (2–20 weeks before the test), the sensitivity for detecting IgM/IgG in plasma and capillary blood samples was 100% (10/10) and 90% (9/10), respectively. Thus, the sensitivity was not affected over time and IgM/IgG antibodies were detected in plasma. Of the 10 negative controls, all 10 tested negative for IgM/IgG antibodies (100%) in both plasma and capillary blood samples. Of 10 plasma samples collected before the SARS-CoV-2 outbreak, no samples tested positive. The overall specificity of the Wondfo test was 100%.

4. Discussion

According to the COVID-19 Testing Project, the Wondfo test has an overall sensitivity of 86.4% 20 days after onset of symptoms and a specificity of 99% in serum samples [6]. In the current study, capillary blood samples (obtained by finger prick) were shown to exhibit comparable sensitivity to plasma samples for detecting anti-SARS-CoV-2 IgM/IgG antibodies in patients with severe COVID-19 symptoms and who had previously been diagnosed with COVID-19 by RT-PCR. However, when the results for capillary blood and plasma samples were compared in the whole study population, they did not show consistency. Similar findings were previously reported for the same serological test, showing a low sensitivity with capillary blood samples (55%) [5]. Several factors impact the performance and quality of the tests, including the stage of disease, the handling of the test procedures, the type of sample used, as well as the understanding of the strengths and limitations of such tests [7].

Of the 29 IgG/IgM positive participants in this study, 25 (86.2%) reported not having had severe COVID-19 symptoms; from these 25 individuals, 16 (64%) had negative test results with capillary blood samples. This observation might be explained by lower antibody levels in asymptomatic individuals compared with symptomatic patients, thus leading to poor detection in capillary blood samples. Other studies have reported a higher detectable SARS-CoV-2 viral load was associated with increased symptoms [8]. These results highlight the need for regular testing of asymptomatic individuals to reduce the possibility of transmission and to help combat the COVID-19 pandemic [9].

5. Conclusion

Serological testing is essential to verify the immune status. The SARS-CoV-2 Antibody Test (Lateral Flow Method) (Guangzhou, Wondfo Biotech Co., Ltd.) for detecting anti-SARS-CoV-2 IgM/IgG antibodies can be used to estimate the seroprevalence in a population, including immunity by vaccination, to help guide public health policies. However, we recommend that the Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) should not be used with capillary blood samples as this type of specimen showed low sensitivity in asymptomatic COVID-19 individuals and is not suitable for detecting previous infection when compared with plasma samples. Additional longitudinal serological studies in asymptomatic COVID-19 populations are required to determine the duration of antibody-mediated immunity.

Ethical approval

This low-risk study was conducted during the pandemic and under a declaration of a state of emergency. An approval certificate (004_03072018) was obtained from the research committee of the Hospital General de Medellín and the study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

Funding

None declared.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

The authors wish to express thanks to Saúl Colorado, Santiago Franco and Santiago Cardona.

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