Review Article

What is the role of COVID-19 IgM/IgG rapid diagnostic tests in the preoperative cosmetic plastic surgery period?

Qual é o papel dos testes rápidos de diagnóstico de COVID-19 IgM/IgG no pré-operatório de cirurgia plástica estética?

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■ **ABSTRACT**

Introduction: The disease caused by the new coronavirus 2019 (COVID-19) emerged in China and spread with sustained worldwide transmission from human to human. The COVID-19 IgM/IgG rapid diagnostic tests performed at the time of hospital admission, before elective surgery, are among the most widely used preoperative screening methods. **Objective:** This study evaluates the COVID-19 antibody rapid test's role as screening in outpatients in aesthetic plastic surgery. **Methods:** A systematic review has been carried out on studies published since December 2019 using several search terms related to the rapid antibody test for COVID-19 and SARS-CoV-2. The relevant articles were selected through the evaluation of titles and abstracts. The relevant articles were reviewed, and data on the level of evidence, sensitivity, and specificity were collected. **Results:** The review strategy produced 409 manuscripts. A total of 357 studies were duplicated or proved to be irrelevant to the research question. Among the remaining articles, 28 were studies without precision information, and 24 were manuscripts describing precision measures. Sensitivity varied from 18.4 to 100%, the positive predictive varied value between 19.7 and 100%, the specificity varied from 94 to 100%, and the negative predictive value was between 20 and 100%. **Conclusion:** COVID-19 IgM/IgG rapid diagnostic tests may be inaccurate. We found no evidence to support the rapid antibody test COVID-19 or SARS-CoV-2 for outpatients in cosmetic plastic surgery.

Keywords: Coronavirus infections; Preoperative care; Surgery, Plastic; Epidemiology; Severe acute respiratory syndrome.

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■ **RESUMO**

Introdução: A doença pelo novo coronavírus 2019 (COVID-19) surgiu na China e se espalhou globalmente com transmissão mundial sustentada de humano para humano. Os testes de diagnóstico rápido COVID-19 IgM/IgG realizados no momento da admissão hospitalar, antes de cirurgia eletiva, estão entre os métodos de rastreamento pré-operatórios mais amplamente utilizados. **Objetivo:** O objetivo deste estudo é avaliar o papel do teste rápido de anticorpos COVID-19 como triagem em pacientes ambulatoriais em cirurgia plástica estética. **Métodos:** Uma revisão sistemática foi realizada para estudos publicados desde dezembro de 2019 com vários termos de pesquisa relacionados ao teste rápido de anticorpos para COVID-19 e SARS-CoV-2. Os artigos relevantes foram selecionados por meio da avaliação de títulos e resumos. Artigos pertinentes foram revisados. Dados sobre o nível de evidência, sensibilidade e especificidade foram coletados. **Resultados:** A estratégia de revisão produziu 409 manuscritos. Um total de 357 estudos foram duplicados ou mostraram-se não relevantes para a questão de pesquisa. Entre os artigos restantes, 28 eram estudos sem informações sobre precisão e 24 eram manuscritos descrevendo medidas de precisão. A sensibilidade variou de 18,4 a 100%, o valor preditivo positivo variou entre 19,7 e 100%, a especificidade variou entre 94 e 100%, e o valor preditivo negativo ficou entre 20 e 100%. **Conclusão:** Os testes de diagnóstico rápido COVID-19 IgM/IgG podem ser imprecisos. Não encontramos nenhuma evidência para apoiar o teste rápido de anticorpos COVID-19 ou SARS-CoV-2 para pacientes ambulatoriais em cirurgia plástica estética.

Descritores: Infecções por coronavírus; Cuidados pré-operatórios; Cirurgia plástica; Epidemiologia; Síndrome respiratória aguda grave.

INTRODUCTION

The disease caused by coronavirus 2019 (COVID-19) emerged in China and spread globally with sustained transmission among humans[1]. Due to its highly contagious nature, its unprecedented global spread, its aggressive clinical presentation, and the lack of effective treatment, coronavirus 2 acute respiratory infection syndrome (SARS-CoV-2) is causing the loss of thousands of lives and unparalleled repercussions on health systems worldwide[2].

The infection caused by COVID-19 is a highly transmissible disease that presents a significant risk for both patients and health professionals[3]. It was recently demonstrated that high virus levels are present in respiratory secretions during the pre-symptomatic period, which can last from days to weeks before the appearance of the characteristic symptoms of COVID-19[4]. The virus's ability to be transmitted by people without symptoms is one of the main reasons for the pandemic[5].

The diagnosis of COVID-19 is made using clinical, laboratory, and radiological characteristics[6]. As the symptoms and radiological findings of COVID-19 are nonspecific, SARS-CoV-2 infection must be confirmed by laboratory tests. Polymerase chain reaction tests with reverse transcriptase (RT-PCR) are the gold standard for the diagnosis of COVID-19; however, it is a difficult test to collect, and its results are not immediately available[7]. The COVID-19 IgM/IgG rapid diagnostic tests were developed using lateral flow technology to find antigens from the SARS-CoV-2 virus and detect antibodies produced by patients infected with COVID-19[8].

Screening tests are widely used to assess the probability that members of a defined population have a specific disease. With few exceptions, screening tests do not diagnose the disease[9]. The rapid serological diagnostic test performed at the time of admission, before elective surgery, is among the most widely used preoperative screening methods for COVID-19[10-18].

OBJECTIVES

This study aims to evaluate the role of COVID-19 antibody rapid test in outpatients being admitted for aesthetic plastic surgery.

METHODS

A systematic literature review was carried out using search engines in PubMed, Web of Science, and SciELO journals for studies with animals and humans published between December 2019 and July 30, 2020. We consider specific terms about COVID-19 or SARS-CoV-2 and plastic surgery. The following descriptors were used: "plastic surgery", "elective surgery", "COVID-19", "COVID-19 diagnostic test", "COVID-19 blood antibody test" and "SARS-CoV-2 test". Many terms and words were displayed similarly when searching for articles. Words like "preoperative," "surgical," and "surgery" had similar results. The results of the words and phrases investigated were analyzed by quantity and quality. Written documents were included in English, Spanish, French, Italian, and Portuguese. Videos, posters, and letters to the editor were not considered. Two independent researchers selected the relevant articles through the evaluation of titles and abstracts. A third researcher reviewed the relevant articles. Data on the level of evidence, sensitivity, specificity, and predictive values of rapid diagnostic tests were collected. This study complies with the Declaration of Helsinki and does not require an ethics committee's evaluation, since it does not directly involve collecting data or tissues from human beings, being only research carried out exclusively in scientific texts.

RESULTS

Using our active search strategy, the database review found 409 articles (Figure 1). A total of 357 studies were duplicated or considered not relevant to our research question. Among the remaining articles, 28 were studies without information on the accuracy of rapid diagnostic tests, and 24 were studies describing measures of accuracy[7,8,19-40].

The level of evidence varied from V to III. Sensitivity ranged from 18.4 to 100%, specificity varied from 94 to 100%, the positive predictive value between 19.7 and 100%, and the negative predictive value was between 20 and 100%.

DISCUSSION

The limited experience accumulated during the COVID-19 pandemic has shown that the management

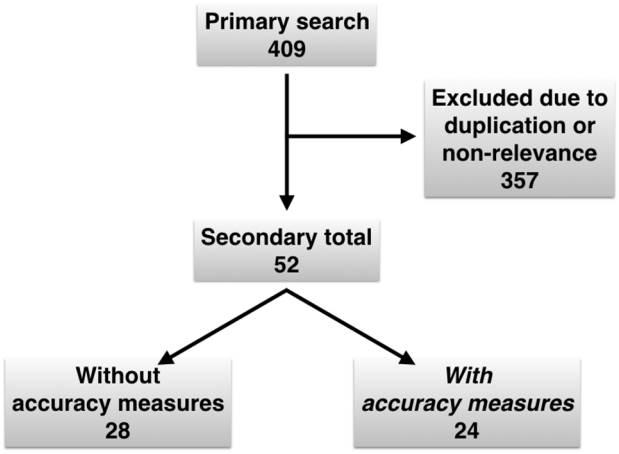

Figure 1. Systematic review algorithm.

of all medical conditions, including elective surgeries, has undergone some degree of change[2]. We all want to go back to work without the COVID-19 spectrum. The ideal strategies for treating individually aesthetic patients are unknown during the extraordinary conditions of the COVID-19 pandemic. There is no literature consensus regarding preoperative care, except for the fact that all patients should be screened for symptoms before being taken to the operating room, and that those who report symptoms of COVID-19 should be referred for additional evaluation.

The rapid diagnostic test can be produced quickly and cheaply. This qualitative test is small and portable, usually similar to a pregnancy test, showing the user colored lines to indicate positive or negative results[8]. Rapid diagnostic tests do not measure the number of antibodies in the patient's serum or whether they can protect against future infections, but they can detect exposure and identify asymptomatic people and people who have cleared the virus. Many of the rapid diagnostic tests available so far lack analytical performance concerning sensitivity and specificity, and need to be better validated before being used preoperatively[21].

For a medical diagnosis, the sensitivity of the test is its ability to correctly identify those with the disease (true positive rate), while the specificity of the test is its ability to correctly identify those without the disease (true negative rate). In this research, sensitivity ranged from 18.4 to 100%, reflecting a potential inability to identify people who have antibodies to COVID-19 correctly. Specificity varied between 94 and 100%, demonstrating a high ability to identify all patients who did not have COVID-19 antibodies.

The negative predictive value is the probability that patients with a negative result in a rapid diagnostic test do not have COVID-19 antibodies; in our research, their values were between 20 and 100%, we can say

that, in some circumstances, 80% of individuals with a negative test may have COVID-19 antibodies. Positive predictive value is the likelihood that individuals with a rapid positive diagnostic screening test will have the disease; in our research, their variation was between 60 and 100%. Consequently, we can affirm that, in some circumstances, 40% of the individuals with positive rapid tests may not have antibodies to COVID-19. Therefore, the rapid test results appear to be scientifically unreliable, and the recommendation to perform this test in general, by patients or hospitals, seems inadequate.

It is estimated that SARS-CoV-2 IgM antibodies can be detected in a blood sample after three days and IgG antibodies eight days after the onset of symptoms[7]. The seroconversion rate for IgM and IgG was described as 82.7% and 64.7%, respectively[5]. To date, we do not know whether everyone who has recovered from COVID-19 has developed antibodies, and we do not know to what extent these antibodies protect patients from reinfection. Antibody tests do not detect an active infection but look for signs that a person has been previously infected, shown by the antibodies that his immune system has produced to fight the coronavirus. With other diseases, the presence of antibodies usually means acquired immunity for at least some period, but this is not yet known in COVID-19[4].

Patients should be screened only if a positive test results in mandatory action. This is not the case for rapid diagnostic tests for COVID-19 before cosmetic surgery because the procedure will be performed regardless of antibody detection status. In the case of the new COVID-19 virus and the SARS-CoV-2 disease that it causes in humans, the objective of preoperative testing would be straightforward: to identify infected patients and isolate them by postponing their surgeries, trying to reduce the morbidities of the procedure and thus reducing the risk of infection for health professionals[8]. Nevertheless, without a perfect test, false positives and false negatives can lead to significantly worse outcomes.

Both false positives and false negatives have their unique dangers, wherever testing occurs, but false negatives are particularly dangerous for COVID-19. Two weeks after surgery, some patients may be positive for COVID-19, despite the negative preoperative result, and critical medico-legal implications may arise. Was the infection contracted during hospitalization? Did the surgeon or his team contaminate the patient during outpatient postoperative follow-up? Did seroconversion occur because the surgery induced immunosuppression? A negative result in a rapid diagnostic test for COVID-19 performed preoperatively can be dangerous medico-legal evidence for surgeons and hospital entities.

Antibody tests are polyvalent: these serological tests are of critical importance to determine seroprevalence, prior exposure, and to identify highly reactive human donors for the generation of therapeutic convalescent serum[4]. They will also support contact screening for healthcare professionals to identify those who are already immune.

It is plausible that several limitations may have influenced the results obtained in this research. The exclusion of articles in Asian languages is one of them since much of the knowledge about COVID-19 comes from this geographic area; however, there was none among the researchers with knowledge of these languages , and we consider that electronic translators are not reliable. However, many of these studies would provide information with limited external validity for patients in the Americas since COVID-19 mutations are frequent, and most of the rapid diagnostic tests used there are not available on our continent. A well-designed systematic review benefits the evolution of knowledge, identifying where there is a lack of scientific information, and providing a synopsis of the available evidence. The credibility of systematic reviews can be compromised by reporting biases, which arise when the results' nature influences the dissemination of published articles. Our findings are based on a limited number of articles; therefore, the results of such analysis should be treated with utmost caution.

Controlled clinical trials are lacking, and future studies should examine the safety and efficacy of COVID-19 IgM/IgG rapid diagnostic tests to obtain more consistent results and establish recommendations for their appropriate use.

CONCLUSION

The COVID-19 IgM/IgG rapid diagnostic tests appear to be inaccurate. We found no evidence to support the rapid testing of COVID-19 or SARS-CoV-2 antibodies as screening for outpatients for cosmetic plastic surgery. Future studies on the topic are needed to validate different laboratory diagnostic tests.

COLLABORATIONS

RKZ	Analysis and/or data interpretation, Conception and design study, Conceptualization, Data Curation, Final manuscript approval, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Realization of operations and/or trials, Writing - Original Draft Preparation

SSV Analysis and/or data interpretation, Conception and design study, Conceptualization, Data Curation, Final manuscript approval, Formal Analysis, Investigation, Methodology, Project Administration, Realization of operations and/or trials, Visualization, Writing - Original Draft Preparation

DSV Analysis and/or data interpretation, Conception and design study, Conceptualization, Data Curation, Final manuscript approval, Formal Analysis, Investigation, Methodology, Realization of operations and/or trials, Supervision, Visualization, Writing - Original Draft Preparation, Writing - Review & Editing

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