Serological Rapid Test for Diagnosis of Sars-Cov-2 Works on Gastro-Intestinal Tissue Samples of Covid-19 Patients: Practical Aspects of Single Center Observational Study

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ABSTRACT

SARS-COV-2 infection spreading becomes a long and challenging medical question. The possibility to improve the diagnosis of SARS-COV-2 infection in digestive endoscopy is important because gastrointestinal symptoms can be the presenting symptoms of COVID-19. We tried to obtain a fast and "bedside" diagnosis of gastrointestinal COVID-19 by performing serological rapid test to verify the presence of SARS-COV-2 in gastrointestinal mucosal specimens. From the 3rd to the 31th January 2022, regular mucosal biopsies were taken from stomach, ileum or colon of 10 COVID-19 patients (7M, 3F, mean age: 49.7 years) and from 10 negative patients (6M, 4F, mean age: 50 years) according to standard clinical indications.

One specimen for each patient was placed in a sterile test-tube with 5 drops of standard reagent for rapid serological test for 10 minutes. After that period, both the specimen and the drops were put on the platform for serological rapid tests. In all COVID-19 patients, tests were positive for both IgG and IgM bands (and control bands, confirming that the test worked properly). Otherwise, the analysis of gastrointestinal specimen of negative patients showed only the control band. No differences were found for different specimens (stomach, colon or ileum).

Statistical analysis conducted to compare the results of the two groups confirmed the difference between COVID-19 positive and negative groups. Applying this kind of analysis, we can immediately verify if gastrointestinal symptoms (especially diarrhea) of a non-tested patient are related to SARS-COV-2 infection and we can use this test as a rapid test in case of suspected endoscopic findings to confirm the association with SARS-COV-2 infection. In the end, the test can contribute to help in the differential diagnosis of gastrointestinal manifestations considering the long term management of SARS-COV-2 infections.

Keywords: COVID-19; SARS-COV-2; Serological rapid test; Gastrointestinal COVID-19; Gastrointestinal symptoms

INTRODUCTION

SARS-COV-2 infection spreading becomes a long and challenging medical question. Serological rapid tests are now increasingly used worldwide to detect previously or actively infected patients or health care providers from COVID-19, especially in ambulatory settings [1,2]. Considering that gastrointestinal involvement is not uncommon and can represent the only manifestation of COVID-19 [3], the possibility to improve the diagnosis in digestive endoscopy is important.

We tried to obtain a fast and "bedside" diagnosis of gastrointestinal COVID-19 by using serological rapid test to verify the presence of SARS-COV-2 in mucosal specimens of gastrointestinal system. No previously available literature analyzed this potential application. The hypothesis is that if serological rapid tests detect the antibodies anti-SARS-COV-2 present in blood, the same test can be able to detect the same antibodies on other tissues.

METHODS

From the 3rd to the 31th January 2021, regular mucosal biopsies were taken from stomach, ileum or colon of 10 COVID-19 patients (7M, 3F, mean age: 49.7 years) according to standard clinical indications. One specimen for each patient was placed in a sterile test-tube with 5 drops of standard reagent for rapid serological test for 10 minutes. After that period, both the specimen and the drops were put on the platform for serological rapid tests. The serological rapid tests studied both IgG and IgM with a declared sensitivity of 100% for IgG and 85% for IgM.

To confirm the results, 10 negative patients (6M, 4F, mean age: 50 years) undergoing biopsies for standard indications were also included in the study using the same process. Eligibility criteria were the standard indication for digestive endoscopy, standard indication to take biopsies and signature of informed consent for the present study. The main outcome was to verify the application of serological rapid tests on tissue samples in terms of positive or negative results. The assessment method for the same for the two groups. Uncertain diagnosis of positive or negative cases was considered a potential confounder and recent contact with patients positive to SARS-COV-2 infection was considered a potential bias. Thus, both conditions were exclusion criteria for the study.

The study size was arrived at the described number on the base of the patient total number during the study period and to reach statistically significance. Statistical analysis was conducted to compare the results of the two groups of patients using Chi-squared test.

DISSCUSION

In all 10 positive cases, serological tests on tissue specimen were positive for both IgG and IgM bands (and control bands, confirming that the test worked properly) (**Figure 1**). No differences were found for different specimens (stomach, colon or ileum). The analysis of the specimen of negative group by serological rapid tests showed only the control band in all the cases. Statistical analysis conducted to compare the results of the two groups of patients using Chi-squared test confirmed the difference between COVID-19 positive and negative groups ($p<0.05$). Few interesting practical implications may come into view from this finding.

Firstly, we can immediately verify if gastrointestinal symptoms (especially diarrhea) of a non-tested patient are related to SARS-COV-2 infection just taking few biopsies. Secondly, we can use this test as a rapid test (i.e. for H. pylori) in case of suspected endoscopic findings i.e. peptic ulcers, gastric erosions [4,5] to confirm the association with SARS-COV-2 infection.
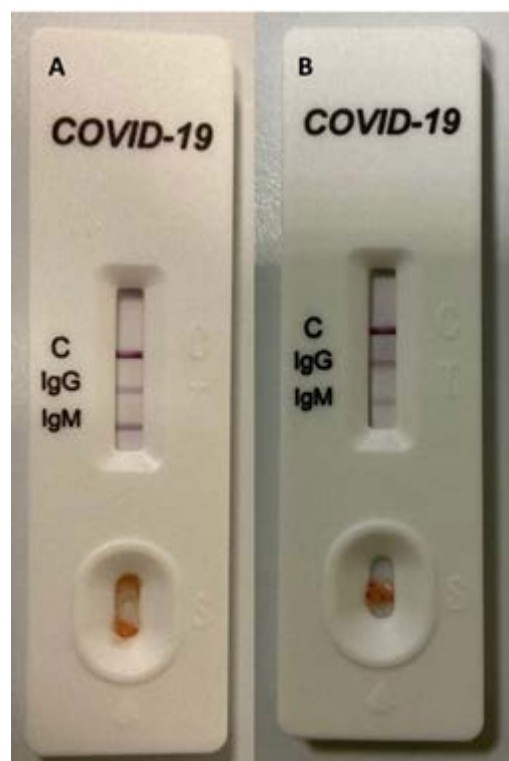

Figure 1: Results of rapid serological test on gastric specimen of a patient infected by SARS-COV-2; B. Results of rapid serological test on colonic specimen of a patient infected by SARS-COV-2.

CONCLUSION

Limitations of our study are the variability of the tissue specimen and the single center experience. For these reasons, further studies would be able to confirm the external validity of our results. In the end, the test can contribute to help in the differential diagnosis of gastrointestinal manifestations considering the long term management of SARS-COV-2 infections.

ACKNOWLEGEMENT

CONFLICT OF INTEREST

The authors declare no conflict of interest related to the present paper.

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ETHICS APPROVAL

The study was approved by our internal Ethical Committee (n.008/2022).

CONSENT TO PARTICIPATE

The patients signed informed consent to participate to the study.

CONSENT FOR PUBLICATION

The patients approved the publication of the sensible and personal data included in the paper.

AVAILABILITY OF DATA AND MATERIAL

Database and statistical analysis process are available.

AUTHOR'S CONTRIBUTIONS

LD and MM wrote the paper; EF and FP collected the data; GB and MB analyze the data; MM revised the manuscript. All the authors approved the final version.

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