



Study of RTP-CR test versus covid antibody testing in covid-19 patients in Bihar Population

Gaurav Verma¹, Bhartendu Kumar (Corresponding Author)²

1. Associate Professor Department of Dentistry Narayan Medical College and Hospital Sasaram-821305, Bihar.
2. Professor Department of General Surgery (SKCH) Srikrishna Medical College and Hospital, Muzaffarpur -842001, Bihar.

Abstract

Background: As covid-19 is declared as public health emergency since January-2020 Medical Professionals and researches were eager to test the lethal virus. One test was Real time polymerase chain reaction (RT-PCR) and another was Antibody tests have emerged as vital technique to prove positivity of the virus.

Method: 92 patients having clinical symptoms of covid-19 and 92 controlled have studied. Throat swab is collected by using a foam swab with transport medium for detection by RT-PCR detection. Blood sample (5 ml) was collected from each patient for antibody test.

Results: RT PCR was 75% positive sensitivity was 81.5 % and specificity was 100%. Antibody positivity was 80%, sensitivity was 86.9%, and specificity was 84.7%. In combined (Antibody + RT-PCR) test 96.7% positive 96.7% was sensitivity, 93.4% was specificity.

Conclusion: RT-PCR test gives an idea if people within the immediate proximity of newly confirmed patients are infected by the virus. However first negative result does not completely lack of infection. Therefore (two) 2 weeks quarantine isolation is essential. In such scenario antibody test data gives an important insight on spread of

the virus. Hence both tests are equally important to confirm the diagnosis of covid-19.

Keywords: RT-CPR, Antibody, CMIA kits, RLU, Sensitivity, specificity.

Introduction

Corona virus is a new challenge for the medical fraternity and scientist world over ⁽¹⁾, be it in its prevention or detection. There is lot of debate in media regarding the two types of test to detect the virus infection one is the RT-PCR based and another antibody based ⁽²⁾. Regarding both tests quality and results there were so many controversies. Hence it was imperative to understand the efficacy of both test, which is the better or best. The controversy of one test over the other is misplaced. Both are important, but their purpose is different. The core technique behind RT-PCR is PCR which is the abbreviation of polymer chain reaction, conducted by special enzyme "polymerase" by which a targeted fragment of DNA is doubled at every cycle of reaction. However this technology can be used only for DNA as starting material. It cannot be directly used for detection of DNA viruses, like corona virus. That is why RNA needs to be converted into DNA by another enzyme called Reverse transcriptase before it is subjected to PCR that is why name is RT-PCR can actually give us a quantitative estimation of number of viruses in a given sample ⁽³⁾. The antibody test is based on biological phenomena. In response to entry of any foreign invader antibodies are generated by over immune system. Hence it can be detected the presence of specific antibodies in blood sample Antibodies continued to be present in the blood for some time even after the invaders is completely eliminated from the body ⁽⁴⁾ and there are no clinical symptoms. Hence apart from comparing both, combined positive test results were also evaluated.

Material and Method

95 covid patients aged between 18 to 60 years admitted at Narayan Medical College and hospital Susaram Bihar were studied.

Inclusive Criteria: The patients having severe respiratory distress, chest pain or pressure, loss of speech or movements were selected for study and same number of healthy volunteers swab was collected (controlled group).

Exclusion Criteria: Patients having history of Bronchial asthma, COPD cardiomegaly, exercised induced asthma, immune compromised patients were excluded from the study.

Method: Throat swab collected by using a foam swab with transport medium (sigma virocult from) 92 covid-19, and 92 healthy volunteers

Specimens were then put in a biosefty transport box and then sent to the laboratory located in our own campus, for RT-PCR detection immediately.

Blood samples (5 ml) were collected from each patient before patients were discharged from the hospital. Sample taking varied from 0-10, 11-20, >20 days after illness onset. Specimen of 92 covid patients and 92 controlled were collected at one of the aforementioned three time periods. The samples were centrifuged at 1500-2000 of for 10 minutes and the serum was aliquoted and tested to determine the total antibody against SARS Cov-2.

RT-PCR

Virus RNA was extracted from throat swab with a nucleic acid kit (Roche Mannheim Germany). The whole process of extraction was performed according to the guide lines. Real time reverse transcriptional Bio-Systems vii A7 Dx (Applied Bio-system Mumbai) and RT-PCR reagent BioGerm (Shangai BioGerm Medical Technology Co. Ltd) were commercially obtained and used for virus detection, As per the (Wang etal 2020 c) guidelines and methods.

Total antibody measurements: The total antibody is against SARS cov-2 serum samples was determined by chemiluminescence micro particle immunoassay (CMIA) kits (Xiamen wantal Kairuk Biological technology Co. Ltd China) According to manufactures instructions. Briefly like in the wantal Elisa (Geurtsvan Kessel etal 2020; Lass ayniere etal. 2020). The total antibody detection is based on double-antigen sand which principle that detects total antibody. Recombinant antigens containing the receptor binding domain (RBD) of the SARS-cov-2 spike protein are utilized to develop a total antibody assay (Lou et.al 2020). The amount of luminescence is quantified by relative light unit (RLU). The amount of RLU can be measured and is proportional to the amount of antibody captured inside the tube. The carries 200

calculates S/co (Signal to cut off ratio). Values <1.0 are considered to be negative for SARS-cov-2 antibody, where values ≥ 1.0 are considered to represent antibody positivity. Both Positive and Negative controls are routinely performed with each batch of tests.

The duration of study was March-2020 to December-2020.

Statistical analysis: The data collected from covid-19 patients and controls sensitivity and specificity were analysed in each groups and both groups also. The statistical analysis was carried out in SPSS software. The ratio of the male and females was 2:1.

Observation and Results

Table-1: Positivity test results in RT-PR was 75, 81.5% sensitivity and 100% specificity.

In total antibody test – The positivity was 80%, 86.9% was sensitivity and 84.7% specificity.

In combined (Antibody + RTPCR) test 89 was positive result 96.7% was sensitivity 93.4% was specificity.

Discussion

In the present study of RT-PCR test versus antibody testing in covid-19 patients of Bihar Population – 75% of positive test, 81.5% sensitivity 100% specificity was observed in RT-PCR test. In total antibody 80% was positive 86.9% was sensitivity 84.7% was specificity. In combined (antibody + RT-PCR test) 89 cases were positive, 96.7% case had sensitivity and 93.4% had specificity (Table-1). These findings are more or less in agreement with previous studies ⁽⁵⁾⁽⁶⁾⁽⁷⁾.

To solve the diagnostic problem guide lines of National health commission on the People's Republic china recommends serological testing for covid-19 diagnosis. Several groups determined the antibody response to SARS-cov-2 and compared new commercial serological assay ⁽⁸⁾⁽⁹⁾. The total antibody test of wantal has good sensitivity and specificity as compared to other tests ⁽¹⁰⁾. Wantal antibody test provides semi-quantitative result Total antibodies are determined by CIMA which is an automated rapid and high through assay, objective and quantitative but it requires expensive instrument carries 200. The combination of the results of both methods, the RT-PCR and CMIA antibody test, does improve the sensitivity up to 96.7%. High sensitivity is beneficial for screening and confirming covid-19 patients. No doubt RT-PCR played an important role at an early stage. Antibodies against SARS-Cov-2 appear around 7-14 days after the onset of disease. Therefore the total antibody test displays next to the RT-PCR a powerful diagnostic efficiency at a later stage. A combination of two assays is superior and results in the diagnosis of more covid-19 patients. By testing only one sample, the laboratory should carefully interpret these test results, and use additional blood samples, and/or other criteria like RT-PCR, CT-Scan and disease history to confirm recent infection.

Summary and Conclusion

The study of RT-PCR versus covid antibody testing in covid-19 patients combined has contributed a novel method of both assays which shows high degree of sensitivity and specificity which is tool for physician to treat such covid patients efficiently to present morbidity and mortality But this demands further immunological, serological, histo-pathological, pharmacological, genetic and nutritional study because exact pathogenesis of covid-19 is still un-clear.

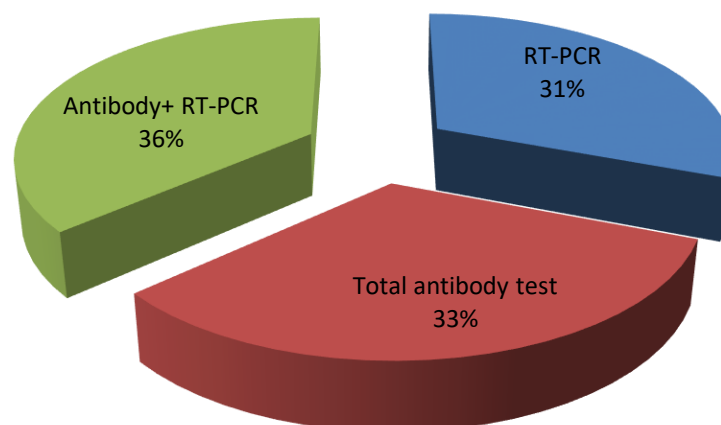
Table – 1

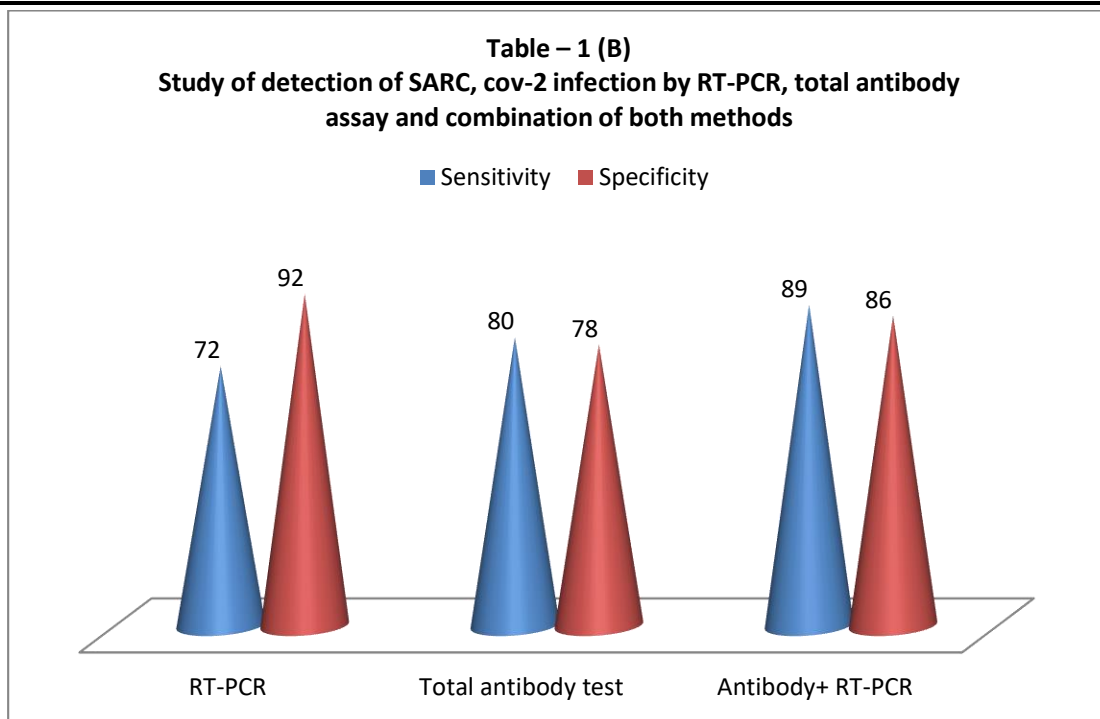
Study of detection of SARC, cov-2 infection by RT-PCR, total antibody assay and combination of both methods

Group	Day after onset	RT-PCR	Total antibody test	Antibody+ RT-PCR
Covid (N=92)	Days	Positive test	Positive test result	Combined positive test results
	0-10	76/92	3/25	82
	11-20	4/16	2/22	5
	> 20	2/12	1/20	2
	Total	75	80	89
Control (92)	0	0	2	2
Sensitivity		81.5% (72/92)	86.9% (80/92)	96.7% (89/92)
Specificity	0	100% (92/92)	84.7 (78/92)	93.4% (86/92)

Table – 1 (A)

Study of detection of SARC, cov-2 infection by RT-PCR, total antibody assay and combination of both methods





References

1. Zhu N, Zhang D, Wang W – A novel corona virus from patients with pneumonia in china 2019, N. Eng. J. Med. 382, 727-733.
2. Xic X, Zhang G – Chest CT for typical 2019-n-cov pneumonia relationship to negative RT-PCR testing. Radiology-2020 <http://doi.org/10.1148/radio/20202003443>
3. Zhao JJ, Youan Q – Antibody responses to SARS-cov-2 in patients of novel corona virus disease 2019, clin. infect Dis.
4. Lou B, L;TD, Zhang SF – Serology characteristics of SARS-Cov-2 infection since the exposure and post symptoms onset 2020. <https://doi.org/10.1101/2020.03.23.20041707>.
5. Al-T, Yang – Correlation of chest CT and RT-PCR testing in corona virus disease 2019 (covid-19) in china. A report of 1014 cases. Radiology <https://doi.org/10.1148/Radiol.20202000647>.
6. Liu R, Han H, Liu F – Positive rates of RT-PCR detecting of SARC-Cov-2 infection in 4880 cases from one hospital in wahun china from Jan. To Feb 2020 Clin. Chin. Acta 2020 5050 172-175.
7. Sandeep sewlikar – It antibody test the key to measure immune response to the novel corona virus? ET Health world September 2020 13; 45 IST

8. Kovyá Narayan – covid-19 testing how antibody antigen, RT-PCR, True Nat test differ. Their strengths and limitations – July09 2020 17.0026 IST.
9. Geurtsvan Kessel C4, OKBA, NMA – Towards the next phase : evaluation of serological assays for diagnostics and exposure assessment 2020 med. Rxiv.
10. Robertson T, Carter ED – Early estimates of the indirect effects of the covid-19 pandemic on maternal and child mortality in low-income and middle income countries a modelling study 2020 Lancet 395, 470-473.

