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COMPARISON OF RT PCR AND RAT IN COVID-19 PATIENTS ATTENDING TRIAGE AT GOVERNMENT GENERAL HOSPITAL, MAHABUBNAGAR, TELANGANA

Clinical Microbiology

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ABSTRACT

Rapid diagnosis of Novel Corona virus was important to develop at earliest, because Polymerase chain reaction (PCR) test takes more time for the procedure and during the wave sample load will be more. This study is done to identify the sensitivity and specificity of Rapid Antigen Test(RAT) using Standard Q antigen kit. **Material and methods:** Samples from July 2020 to March 2021 were taken into study. Nasopharyngeal swabs were collected and tested for COVID-19 using Rapid antigen test (RAT) and PCR test. **Results:** 612 samples were tested for COVID-19 using Rapid antigen test and PCR test. Among the patients, Male predominance (58%) was seen and most of them were in the age group of 21-30 years (21.90%). Sensitivity was 18.8% and specificity was 98.18%. **Summary:** RAT kit used in this study has low sensitivity and high specificity, but for rapid and accurate detection of COVID-19, RAT kits with high sensitivity and high specificity should be developed.

KEYWORDS

COVID-19, RAT, RTPCR, Sensitivity.

INTRODUCTION

Situation report -1 of Novel Corona Virus (2019-nCoV) was released by World Health Organization (WHO) on 21st January. In the report it was stated that pneumonia cases of unknown etiology were identified from 4 countries where maximum cases were from China (Hubei province), Also report informed the event highlights from 31st December 2019 to 20th January 2020. China has shared the genetic sequence of the novel virus for diagnostic development. A preparedness and response was also mentioned where activation of (Research and Development) R & D was essential for accelerated diagnostics[1]. Situation report-2 released by WHO on 22nd January 2020 stated that Japan has developed in-house PCR assay[2]. Situation report-3 released on 23rd January 2020 mentioned that Centre for Disease Control and Prevention (CDC) has developed Real time Reverse transcriptase polymerase chain reaction (rtRT-PCR) test kit for the diagnosis of 2019-nCoV[3]. 1st case in India was stated in situation report-11 dated 31st January 2020[4]. rtRT-PCR is the gold standard test for diagnosis of 2019 nCoV. However, this test requires specialized molecular/ virology laboratory with specialized equipments (biosafety cabinets, nucleic acid extraction machine, PCR machine, low temperature deep freezers), trained man power and also is a time taking process. To develop a point of care testing (POCT), Indian Council of Medical Research (ICMR) has issued an advisory on 14th of June 2020 for the use of Standard Q COVID-19 Antigen Rapid Antigen test (RAT) detection kit[5]. The RAT testing kits were validated and made available to the healthcare facilities. This study was conducted to observe the sensitivity and specificity of the Standard Q COVID-19 RAT detection kit by taking rtRT-PCR as the gold standard for the diagnosis of COVID-19.

Material And Methods

A retrospective study was conducted at a tertiary care hospital in Mahabubnagar, Telangana, India. Samples collected during July 2020 to March 2021 were considered for the study. Patients who have undergone both RAT and rtRT-PCR test at the time (date of test) were included in the study.

Nasopharyngeal swab was collected from the patient and subjected to RAT test according the manufacturer guidelines using STANDARD Q COVID-19 Ag (SD Biosensor) test kit.

Interpretation of RAT results:

The test result was interpreted after 15 minutes. The test device contains two lines: 'C', a control line, and 'T', a test line. If a red band was formed at both 'C' and 'T' positions, the result was taken as positive. All red bands, whether they were faint or light at the 'T' position, were taken as positive. If the red band was formed only at the 'C' position, it was interpreted as negative whereas it was considered invalid if the band was not formed at the 'C' position. A repeat test was performed in such situations.

Another Nasopharyngeal swab was collected for rtRT-PCR and placed in viral transport medium (VTM) and transported to Virology laboratory.

Inclusion Criteria for rtRT-PCR:

1. Patients with signs and symptoms of COVID-19
2. Sample Collection according to guidelines given by ICMR.
3. Samples with ICMR sample requisition form.
4. Samples properly transported.

Exclusion Criteria for rtRT-PCR:

1. Leaked samples
2. Samples without ICMR sample requisition form.

Sample Processing for rtRT-PCR:

After the samples were received at virology laboratory, the condition of the sample was checked and if not appropriate it was rejected. Patient demographic details were collected from the sample requisition form. Accepted samples were subjected to Ribose Nucleic Acid (RNA) extraction using ICMR approved kits – Q line manual extraction (POCT services private limited, New Delhi, India) in BSL-2 cabinet (Thermo Fischer Scientific A2 1300 series).

After extraction, the RNA was subjected to rtRT-PCR using ICMR approved Kits (NIV RT-PCR Pune Kit, Q line RT-PCR Kit, Genes 2 Me RT- PCR Kit). Various rtRT-PCR tests targeting viral genes nucleocapsid (N), envelope (E), spike (S), RNA dependent RNA polymerase (RdRp) and open reading frames (ORF) were performed depending on the availability of test kits. Procedure was done according to the instructions given by the manufacturer. rtRT-PCR was done in Quant studio 5 Thermo Fisher Scientific machine. Result of each sample was given based on the CT Values of the genes given in the Kit insert provided by the manufacturer.

Taking rtRT-PCR as gold standard, sensitivity, specificity, positive predictive value, negative predictive value and accuracy were calculated with confidence interval.

RESULTS

From July 2020 to March 2021 a total of 11,153 RAT tests were done and 10,686 rtRT-PCR tests were done. Out of which, samples collected from 612 patients were tested using both RAT and rtRT-PCR at same time. Among the patients, Male predominance (58%) was seen and most of them were in the age group of 21-30 years(21.90%).

Chart 2: Age distribution

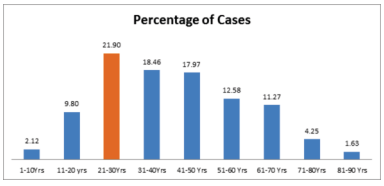

Table 1: Comparison of RAT and rtRT-PCR:

	rtRT-PCR Positive	rtRT-PCR Negative	Total
RAT Positive	22	9	31
RAT Negative	95	486	581
Total	117	495	612

Table 2: Statistical values:

	Statistic	Value	Confidence interval
1	Sensitivity	18.80%	12.18% to 27.07 %
2	Specificity	98.18%	96.58% to 99.17%
3	Positive predictive value	70.97%	-
4	Negative predictive value	83.65%	-
5	Accuracy	83.01%	-

DISCUSSION

In India, till July 2020, Rapid antigen detection test kits for diagnosis of COVID-19 were not available. From July 2020, Government of India has made Standard Q COVID-19 Ag detection test kits available for rapid detection. This study was conducted to know the sensitivity and specificity of RAT by analyzing the data acquired after testing the samples collected over a period of 9 months.

The sensitivity of the Standard Q COVID-19 Ag detection kit used in this study was 18.80% where as in the studies performed by Ashok Kumar etal[6] it was 53.6%, Sidonie Lambert-Niclot et al[7] it was 50.0%, Victoria T. Chu etal[8] it was 50% and John G. Routsias etal [9] it was 74%. Specificity of this study was 98.18%, which was in line with the above studies[6,7,8,9]. To conclude, the RAT kit used in our virology laboratory had very low sensitivity and high specificity, still research is needed to develop rapid detection kits which have both high sensitivity and specificity.

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Author Conflicts: there are no conflicts between authors.

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