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Validation of rapid SARS-COV-2 antigen detection test as a screening tool for detection of Covid-19 infection at district hospital in northern India

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ABSTRACT

Background: Testing of samples from suspected SARS-CoV-2 patients with reverse transcription polymerase chain reaction (RT-PCR) may result in delayed detection of infection. Given the number of people affected in pandemic, it is important to use a test that gives faster results and can be used on large number of sample size to cope with the increased testing capacity. Rapid Antigen detection test fulfills both the criteria. **Aims and Objectives:** The study aims to evaluate the diagnostic accuracy of rapid antigen detection test compared to RT-PCR on the same patients in District Hospital. **Materials and Methods:** Subjects were tested by both Rapid antigen detection testing and RT-PCR in District Hospital. The present study compared RAT and RT-PCR for detection of SARS-CoV-2 in nasopharyngeal specimen.756 Nasopharyngeal samples were obtained from suspected cases of SARS-CoV-2, Contacts of CoV2 patients, pre-operative patients in District Hospital. **Results:** Of 756 nasopharyngeal samples, 81 (10.71%) were positive and 675 (89.28%) were negative for SARS-CoV-2 by RT-PCR. The rapid SARS-CoV-2 antigen detection test's sensitivity 55.04% and specificity was 99.2%, respectively. Positive predictive value 93.42%, Negative predictive value 91.47%, Diagnostic Accuracy 91.67%, Cohen's Kappa Coefficient 0.6482, 95% CI: 0.5801–0.7163. **Conclusion:** The rapid antigen detection test showed comparable sensitivity and specificity with RT-PCR assay. These results support the fact that RAT is an accurate alternative to RT-PCR in areas where there is increased testing burden, for screening of asymptomatic carriers, in areas that lack suitable laboratories to perform RT-PCR, in areas such as airport, train stations, and bus stands.

Key words: Rapid antigen detection; RT-PCR; SARS-CoV-2

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INTRODUCTION

The novel coronavirus is responsible for the coronavirus disease 2019 (COVID-19) pandemic and thereby moving an unprecedented public health emergency all around the world.[1] The SARS-CoV-2 pandemic is ruling every facet of health care across the globe. The corona virus that caused the disease outbreak was identified in the case of viral pneumonia in Wuhan in 2019[2,3] and was named as SARS-CoV-2 by the World Health Organization.[3-6] SARS-CoV-2 belongs to the coronavirus genus β with a single stranded, non-segmented positive-sense RNA genome,[7] which is the seventh known corona virus capable of infecting humans.[2-8]

COVID-19 pandemic is also termed, as "Systemic Human Development Crisis" by the United Nations Development Programme.[9] Early diagnosis of SARS-CoV-2 is critical for prevention and control of Pandemic. Prompt and accurate detection of SARS-Cov-2, the virus that causes

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COVID-19, has been important for containing the spread of COVID-19,[10-12] exemplifying the dire need for accurate and rapid diagnostic assay.

The RT-PCR test stands for real time reverse transcription polymerase chain reaction test. It is used for the qualitative detection of SARS-CoV-2 in upper and lower respiratory samples collected from COVID-19 suspects. The RT-PCR assay is widely used as molecular diagnosis standard for the detection of SARS-CoV-2. The RT-PCR assay requires special equipments, high cost and at least 4 h of operation performed by skilled staff. Whereas RAT don't require expensive equipments and the results are available within 15 min.

Our goal was to compare the analytical efficiencies and sensitivity of rapid antigen detection test with RT-PCR assay in the area of interest for rapid diagnosis and screening of SARS-CoV-2 infected individuals.

Aims and objectives

The study aims to evaluate the diagnostic accuracy of rapid antigen detection test compared to RT-PCR on the same patients in District Hospital.

MATERIALS AND METHODS

The study was conducted in Department of Microbiology of Sonam Norboo Memorial Hospital Leh from April 2021 to NOV 2021. The study was approved by the Institutional Ethical Committee. 756 respiratory samples, mainly nasopharyngeal swabs were collected from suspected SARS-CoV-2 cases by healthcare workers wearing full personal protective equipment. Two nasopharyngeal swabs samples were collected from same patient. One swab was immediately tested using rapid antigen detection test and result was interpreted as per the manufacturer's guidelines. The second swab Sample was mixed in 2 ml of viral transport media. The samples were transported to microbiology lab at 2–8°C for processing by RT-PCR assay within few hours.

Rapid antigen detection test

The SD Biosensor, Inc. in the Republic of Korea, antigen test is a rapid lateral flow immunoassay for qualitative detection of SARS-CoV-2 specific antigens present in the human nasopharynx.

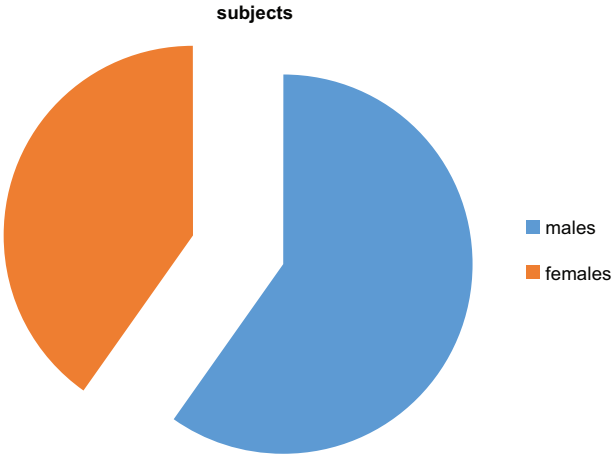
RT-PCR assay

Extraction of Viral RNA from the nasopharyngeal swabs using QIAamp Viral RNA Mini Kit (Qiagen) as per the manufacturer's protocol. The RT-PCR amplification from isolated RNA was done using Meril COVID-19 One-Step RT-PCR Kit (Meril Diagnostics).

The result was interpreted according to the manufacturer's guidelines. A cycle threshold value of <35 was reported as positive.

RESULTS

The performance of SARS-CoV-2 RAT compared with real time PCR for detection of SARS-CoV-2. A total of 756 nasopharyngeal samples were tested for SARS-CoV-2 by RT-PCR assay and rapid antigen detection test. Out of 756 SARS-CoV-2 patients tested, 452 (59.7%) were males and 304 (40.2%) were females (Table 1).



Out of total 756 samples tested for COVID 19 by RT-PCR assay and RAT, 76 samples were RAT positive and 129 were RT-PCR positive (Table 2).

RAT sensitivity was 55.04%, specificity was 99.2%, PPV was 93.42%, and NPV was 91.47%. Accuracy between the two techniques was 91.67% and Cohen's Kappa Coefficient 0.6482 (Table 3).

DISCUSSION

With an increasing number of potential cases, the SARS-CoV-2 poses a major threat to global public health.[13] Advances in SARS-CoV-2 diagnosis with easy, rapid, and cost-efficient approaches are straightaway required to control the pandemic. The present study demonstrates that using rapid antigen detection test can reliably and accurately detect SARS-CoV-2 and is comparable to RT-PCR. Our study provides an inclusive and independent comparison

Table 1: Gender distribution of SARS-CoV-2 cases

Sex	Number of Subjects
Male	452
Female	304

Table 2: Comparison between RAT test results and RT-PCR results

RAT	RT-PCR Positive	RT-PCR Negative	Total
Positive	71	5	76
Negative	58	622	680
Total	129	627	756

Table 3: Agreement between RT-PCR test results and Rapid antigen detection test results

Analytic parameters	Value	95% CI
Sensitivity	55.04%	46.43–63.35
Specificity	99.2%	98.15–99.66
Positive Predictive Value	93.42%	85.51–97.16
Negative Predictive Value	91.47%	89.13–93.34
Accuracy	91.67%.	89.48–93.43
Kappa	0.6482	0.5801–0.7163

of analytical performance of rapid antigen detection test for SARS-CoV-2 detection.

Although molecular tests are the standard tests for laboratory diagnosis of SARS-Cov-2, rapid antigen immunoassay with comparable sensitivity and specificity to RT-PCR assay will help speed up the screening of disease. In this study, for the detection of SARS-CoV-2, the commercially available rapid antigen detection test (Standard Q COVID-19 Ag test) was compared with RT-PCR assay.

Total 756 samples were tested by both RT-PCR and RAT. Out of 756 SARS-CoV-2 patients tested 452 (59.7%) were males and 304 (40.2%) were females which is in accordance with study done by Chaimayo and Kaewnaphan.[14] Out of total 756 samples tested for COVID 19 by RT-PCR assay and RAT, 76 samples were RAT positive and 129 were RT-PCR positive. RAT sensitivity was 55.04%, specificity was 99.2%, PPV was 93.42%, and NPV was 91.47% which is corresponding to study done by Peña et al.[15] Accuracy between the two techniques was 91.67%. (Kappa Coefficient=0.6482, 95% CI: 0.5801–0.7163) as depicted by Table 3. Thus, the Standard Q COVID-19 Antigen detection test might be helpful in high dominance area.

The pro of Standard Q COVID-19 antigen detection test as a screening test for SARS-CoV-2 is its simple procedure and rapid result availability. Rapid SARS-CoV-2 antigen detection test can benefit all the healthcare providers in managing people infected with the disease in time effectively, especially in outbreaks and in rural areas.

Limitations of the study

The patient selection criteria for the above study is arbitrary.

CONCLUSION

The rapid antigen detection showed comparable sensitivity and specificity with RT-PCR assay. These results support the fact that RAT is an accurate alternative to RT-PCR in areas where there is increased testing burden, for screening of asymptomatic carriers, in areas that lack suitable laboratories to perform RT-PCR, in areas such as airport, train stations, and bus stands.

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Authors' Contributions:
SC- Concept and Design of the study, Manuscript Preparation; **AI**- Interpretation of results, reviewed literature, statistical analysis, preparation and revision of manuscript

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