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Retrospective study to evaluate the reliability of rapid SARS-Cov-2 antigen detection assay in the diagnosis of COVID-19 in comparison with real-time RT-PCR assay

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Abstract:
Background*:*
Since the onset of the Covid-19 pandemic, there is a serious need for the development of reliable, easy-to-implement, and rapid diagnostic methods that can be used in the early diagnosis of SARS-CoV-2. A rapid and convenient method based on fluorescence immunochromatographic (FIC) assay to detect the SARS-CoV-nucleocapsid antigen has been widely used in both first and second waves of Covid-19 pandemic situation in India. However, there is a need to examine the accuracy of this diagnostic method in real-time hospital practice.
Materials and Methods*: Data were collected retrospectively from four hundred and thirty-two medical records out of which hundred and sixty-nine patients were found to have both Rapid SARS-CoV-2 antigen detection test and RT-PCR performed. To establish the reliability of Rapid SARS-CoV-2, the sensitivity and specificity of the method were evaluated by comparing with the gold standard SARS-CoV-2 RT-PCR.*
Results*: Out of 169 patients reported to the hospital to whom both RT-PCR and Rapid antigen detection performed 96(56.8%) were found to be positive and 73(43.2%) were negative for RT-PCR assay, Three false positive and one false negative result were observed by considering RT-PCR as the gold standard. The rapid antigen detection test's sensitivity and specificity were found to be 98.97% (95% CI, 94.39–99.97%) and 96.05% (95% CI, 88.89-99.18%), respectively.*
Conclusion: *Our results elucidate that Rapid-SARS-CoV-2 antigen detection kit can be considered as a reliable method for screening of SARS-CoV-2 infection when warranted in limited resource health care facilities*
Key Word*: Rapid SARS-Cov-2 antigen detection assay; Covid-19; RT-PCR, India*

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I. Introduction

The Coronavirus disease 2019 (COVID-19) pandemic caused by novel Coronavirus 2 infection (SARS-CoV-2) has spread worldwide since its first recorded case in China in December 2019. More than 200 countries have been infected. In India, the first case of COVID-19 infection was reported in Kerala, India. On January 27, 2020, a 20 yr old female presented to the General Hospital, Thrissur, Kerala, with a history of dry cough and sore throat. There were no complaints of fever, rhinitis, or shortness of breath. She confirmed that she had returned to Kerala from Wuhan city, China, on January 23, 2020, owing to the COVID-19 outbreak situation there[1]. Severe cases of SARS-CoV-2 may develop acute respiratory distress syndrome (ARDS) and death with an average mortality rate of 6% (range 1-14.4%)[2].

The real-time reverse transcription-polymerase chain reaction (RT-PCR) assay, which is the current standard test for laboratory diagnosis of SARS-CoV-2 infection, requires at least four hours of operation performed by skilled technicians. Therefore, rapid and accurate tests for SARS-CoV-2 screening are essential to expedite disease prevention and control, as well as screening during pre-operative management for invasive

procedures. Lateral flow immunoassays using monoclonal anti-SARS-CoV-2 antibodies, which target SARS-CoV-2 antigens, can be the complimentary screening tests if their accuracy were comparable to that of the real-time RT-PCR assay, in this study we evaluated specificity and sensitivity of rapid SARS-CoV-2 assay by comparing with gold-standard RT-PCR assay

II. Material And Methods

This Retrospective study was carried out at a private multispecialty hospital, Vishakhapatnam, Andhra Pradesh, out of 432 medical records of Covid-19 patients admitted to the hospital 169 patients with both rapid test and RT-PCR was performed were considered for analysis

Study Design: Retrospective observational study

Study Location: This was a tertiary care multispecialty hospital-based study done in the Department of Critical care, at a private multispeciality hospital, Vishakhapatnam, Andhra Pradesh.

Study Duration: Medical records of patients admitted to the hospital from 1st April 2021 to 30th July 2021 were considered for the analysis

Sample size: 169 patients

Sample size calculation: Being a retrospective study no definitive sample size has been considered for the analysis, the study was intended to include as many as medical records available in hospital records with both rapid and RT-PCR performed, our study managed to gather 169 patients out of 432 medical records of patients reported to the hospital with Covid-19 symptoms

Subjects & selection method: The study analysis was done retrospectively on patients with both rapid and RT-PCR analysis performed

Inclusion criteria:

Patient data with all of the following criteria were considered for the study:

1. Subjects records with COVID-19 symptoms patients admitted to hospital
2. Presenting symptoms within the last 14 days of reporting to the hospital
3. Subjects records with both Rapid antigen detection assay and RT-PCR were performed to diagnose COVID-19

Exclusion criteria:

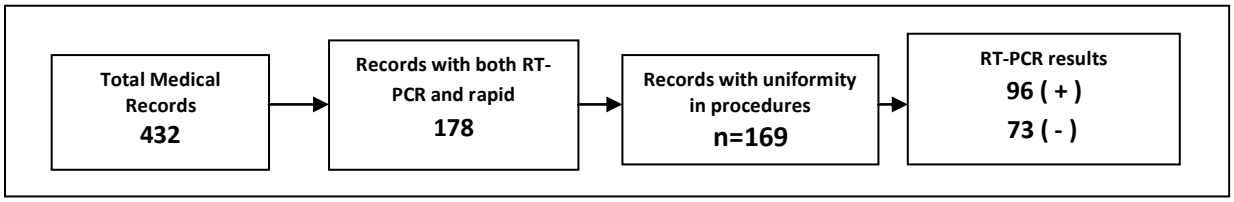
1. Subjects with the onset of COVID-19 symptoms more than 14 days
2. Subjects who had not undergone both Rapid antigen detection assay and RT-PCR

Procedure methodology

Proforma was used to collect the data of the patients retrospectively. The proforma included socio-demographic characteristics such as age, gender, along with the date of onset of Covid-19 symptoms, day of reporting to hospital, co-existing conditions, saturation on room air, and results of rapid and RT-PCR assays

Medical records of the patients admitted to the study hospital from 1st April to 30th July were considered for screening and out of 432 medical records of Covid-19 patients, 178 pateints with both rapid and Rt-PCR was performed were identified of which 09 records were excluded due to non-uniformity in procedures used in rapid test or RT-PCR assays, a total of 169 patients with uniform method followed for Rapid SARS CoV-2 antigen detection assay (Meriscreen COVID-19 antigen detection test manufactured by Meril) and RT-PCR assay (Cepheid, GeneXpert RT-PCR system) were considered for analysis as sown in fig 1. The sensitivity and specificity value of the Rapid-CoV-2 antigen detection assay was determined by comparing it with gold-standard RT-PCR assay.

Fig 1. Selection of Medical records for study analysis



Statistical analysis

General information of patients was described by using descriptive statistics. Continuous data were presented in mean, standard deviation (SD), median, and range. Categorical data were presented in numbers, percentages, and 95% confidence interval (95% CI). Sensitivity, specificity was calculated using an online statistical tool (Schoonjans F. MedCalc's Diagnostic test evaluation calculator. MedCalc.MedCalc Software; 2020)[3]

III. Results

In the collected medical records patients with symptoms of COVID-19 were laboratory-confirmed by the gold-standard RT-PCR assay for laboratory diagnosis of COVID-19[4]. Of 169 medical records considered the respiratory samples were collected through nasopharyngeal (NP) swabs and throat swabs and sent for RT-PCR assay after initially performing rapid SARS-CoV-2 antigen detection assay at the hospital facility, the rapid test was performed as preliminary screening to admit into the hospital while RT-PCR test will take 24-48hrs for the result to be reported at that peak situation of Covid-19 2nd wave in India. All the subjects have been kept in an isolation ward until RT-PCR results were communicated. The median age of analyzed COVID-19 cases (n = 169) was 34.5 years (range 16–62). Male patients were found to be more infected 55.6% (n = 96), Of the total COVID-19 cases, Most patients showed signs and symptoms of fever (86%;n=146), upper respiratory tract infections (37%; n = 63), pneumonia (27%;n=47), The median time from onset to laboratory tests for SARS-CoV-2 infection (both RTPCR and rapid antigen detection assays) was four days (range 1–14), as shown in Table 1

Table 1 Characteristics of Covid-19 cases reported studying hospital

Characteristics	Results
Number of Covid-19 cases	n=169
Age (years) Median(range)	34.2(16-62)
Gender Male	n=96(55.6%)
Symptoms	
Fever	n=146 (86%)
Pneumonia	n=47 (27%)
URI	n=63 (37%)
SpO_2 < 95%	n=46 (27%)
Co-existing conditions	
Diabetes	n=32(18%)
Hypertension	n=39(23%)
Both Diabetes and Hypertension	n=16(9.4%)

Other co-morbidities	n=22(13%)
Time from onset to laboratory test (days) Median (range)	4(1-14)
Results of RT-PCR assay	
Positive Negative	n=96/169 (56.8%) n=73/169 (43.2%)
Results Rapid antigen detection assay	
Positive Negative	n=98/169 (57.9%) n=71/169 (42.1%)

Table 2 specificity and sensitivity of Rapid SARS CoV-2 antigen detection assay

Procedure	**Positive**	**Negative**
RT-PCR	96	73
Rapid antigen detection assay	98	71
True Positive	96	
True Negative	73	
False Positive	03	
False Negative	01	
Sensitivity	98.97% (95% CI, 94.39–99.97%)	
Specificity	96.05% (95% CI, 88.89-99.18%)	

In a rapid SARS-Cov-2 antigen detection assay, the results were interpreted as positive when both control (C) and SARS-CoV-2 antigen (T) lines appeared within 30 min. Of the samples tested for COVID-19 (n = 169) by both real-time RT-PCR and Rapid SARS-CoV-2 antigen detection assay 96 were found to be positive and 73 were found negative in RT-PCR assay while 03 were found to be positive in rapid SARS-Cov-2 and negative in RT-PCR assay and 01 negative in Rapid antigen detection assay and positive on RT-PCR assay. Comparing SARS CoV- 2 antigen detection to RNA detection by RT-PCR assay, the sensitivity, and specificity of rapid SARS-CoV-2 antigen detection to identify COVID-19 were 98.97% (95% CI, 94.39–99.97%) and 96.05% (95% CI, 88.89-99.18%), respectively as shown in table 2. While the sensitivity and specificity by Rapid antigen kit provider (Meril, Meriscreen Covis-19 antigen detection assay) is 96.6% and 100%,[5] Our study findings suggested greater sensitivity 98.97% vs 96.6% and lesser specificity 96.05% vs 100% as reported by the manufacturer antigen detection kit. In agreement with previous studies on the reliability of rapid antigen detection assay,[6,7] our analysis also suggests the method can be adopted as a reliable source in preliminary diagnosis of Covid-19

IV. Conclusion

Given the results, our study analysis elucidates that rapid SARS-Cov-2 can be considered as a potential method that can be used as a preliminary test for diagnosis of COVID-19 in limited hospital settings or in time constraint situation

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