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Evaluation of rapid antigen test (RAT) screening test among people attending fever clinic of Shimoga Institute of Medical Sciences, Shivamogga: An analytical cross-sectional study

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ABSTRACT

Background: COVID-19 pandemic continues to be a public health threat. Rapid antigen tests (RATs) for the detection of SARS-CoV-2 infection will help in formulation of clinical and public health strategies for the control of transmission. In India, 49% of COVID-19 tests done are RATs.[1] The sensitivity of RAT is 50.6–84%. RAT has specificity ranging from 99.3% to 100%.[2] The present study aims at evaluating the RAT screening test done on people attending fever clinic of Shimoga Institute of Medical Sciences, Shivamogga. **Aims and Objectives:** The objectives of the study were to evaluate the COVID-19 RAT screening test with reverse transcriptase-polymerase chain reaction (RT-PCR) as the gold standard test done at fever clinic of SIMS, Shimoga. **Materials and Methods:** An observational, cross-sectional analytical study was conducted for a period of 1 month, May 2021. The study participants included all the people attending fever clinic of SIMS, Shimoga. Assuming the sensitivity of RAT to be 85%, power of 80%, and precision of 5%, the calculated sample size was 204. Considering non-response rate of 10%, the final sample size was 224. Secondary data regarding contact number of the people attending fever clinic were collected from the COVID-19 test register. Oral consent was taken after explaining about study and assuring confidentiality. Telephonic interview was done to collect relevant information. Analysis was done using Epi Info software version 7.2.4.0. Descriptive statistics such as percentages and analytical statistics such as Student's t-test and Chi-square test were used. **Results:** Overall positivity rate was 43.7%. About 71% of people had contact history. Sensitivity and specificity of RAT test were found to be 64.2% and 97.2%, respectively, and were comparable with the previous studies. Significant difference was found ($P<0.05$) between RAT and RT-PCR results. **Conclusion:** Significant difference was found between RAT and RT-PCR results which indicate that RAT is not diagnostic for people who test positive in RT-PCR. Sensitivity of RAT is relatively less in our study (but crucial in detecting disease early) and hence we strongly recommend that RT-PCR for those who test negative for RAT test.

Key words: Rapid antigen test; Reverse transcriptase-polymerase chain reaction; Sensitivity; Specificity

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INTRODUCTION

COVID-19 pandemic continues to be a public health threat. COVID-19 testing across India uses a mix of two types of tests. Antigen tests are easy and rapid methods when compared to reverse transcriptase-polymerase chain reaction (RT-PCR) tests. Rapid antigen tests (RATs) are used widely for the detection of SARS-CoV-2 infection. RAT detection of SARS-CoV-2 COVID-19 has increased substantially in the last year. In India, 49% of COVID-19 tests done are RATs.[1] The sensitivity of the RAT test is 50.6–84%. RAT has specificity ranging from 99.3%

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to 100%.[2] The control of the COVID-19 pandemic relies heavily on screening, testing, and contact tracing. The current standard test for laboratory diagnosis of SARS-CoV-2 infection, the real-time RT-PCR, requires at least 4 h of operation by skilled technicians.[3] It is important to improve testing capacity to do this. SARS-CoV-2 RATs may be performed onsite in mass testing, are less expensive than real-time RT-PCR, do not require specialized and expensive equipment, and provide results in 15 min.[3] This allows for faster testing and identification of infected individuals. The RATs accuracy, on the other hand, is questioned. The present study aims at evaluating the rapid antigen screening test done at our setup on people attending the fever clinic of Shimoga Institute of Medical Sciences, Shivamogga.

Aims and objectives

The objectives of the study were as follows:

- To evaluate the COVID-19 RAT screening test with RT-PCR as the gold standard test done at the fever clinic of SIMS, Shimoga.
- To estimate the contact status and vaccination status among people attending fever clinic.

MATERIALS AND METHODS

Study design

This was a cross-sectional analytical study.

Duration of study

Secondary data of 1 month – May 1, 2021–May 31, 2021.

Study population

All the people attending the fever clinic of SIMS, Shivamogga.

Sample size

Assuming the sensitivity of RAT` to be 85%, confidence level of 95%, and precision of 5%, the calculated sample size was 204. Considering a non-response rate of 10%, the final sample size was 224.

Sampling

Simple random sampling.

Data collection

Permission was taken from dean/director for the conduct of the study. Ethical clearance was obtained from the Institutional Ethical Committee of SIMS, Shivamogga. Secondary data regarding the contact number of the people attending the fever clinic were collected from the COVID-19 test register. Participants were selected from the test register using simple random sampling. Oral consent was taken after explaining the study and assuring confidentiality. Each participant was interviewed telephonically by asking questions related to COVID-19 screening test results, COVID-positive history, contact history, and vaccination history. Participants' COVID-19 test results were confirmed by verifying in COVID-19 registers.

Data analysis

The collected data were tabulated and analysis was done using Epi Info software version 7.2.4.0. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and the false-negative rate were calculated. Descriptive statistics such as means and percentages were used and analytical statistics such as the Student's t-test and Chi-square test were used.

RESULTS

We could associate 224 RAT results with 224 RT-PCR tests. The overall positivity rate was 43.7%. About 71% of people had a contact history. Male participants constituted 49.5% and female participants constituted 50.5% (Table 1). Sixty-four people had tested positive for RAT and 160 people tested negative for RAT (Table 2). All tests were validated by RT-PCR. There were three false-positive results in RAT and 34 false negatives in RAT (COVID-19 was not detected by RAT), but then positively identified with RT-PCR (Table 2). A significant difference was found ($P<0.05$) between RAT and RT-PCR results. Our results showed a sensitivity of 64.2% and a specificity of 97.2% (Table 3) and were comparable with the previous studies. The PPV of RAT was good, that is, 95.3% and the negative predictive value was 78.7%. We also collected contact history among RT-PCR-positive people (n=95), 43% had contact with COVID-positive patients (Figure 1). At the time of the study, only 30% of our study population had

Table 1: Gender distribution (n=224)

Gender	Frequency	Percentage
Male	111	49.5
Female	113	50.5
Total	224	100

Table 2: 2×2 RAT and RT-PCR test results comparison

RAT test results	RT-PCR test results		
	Positive	Negative	Total
Positive	61 (64.2%) True positive (TP)	3 (2.3%) False positive (FP)	64
Negative	34 (35.8%) False negative (FN)	126 (97.7) True negative (TN)	160
Total	95	129	224

RAT: Rapid antigen tests, RT-PCR: Reverse transcriptase-polymerase chain reaction

received COVID vaccination (Figure 2). Among this, 30% were vaccinated, CoviShield coverage was more (18%) compared to Covaxin (12%) (Figure 3).

DISCUSSION

Rapid antigen tests will help in the early detection and control of transmission of SARS-COV-2 infection. Overall, 224 individuals were included (mean age: 37.33 years, SD: 14.45 years). Our results showed a sensitivity of 64.2%, which tells us that 64.2% of the people with COVID were correctly identified by the RAT test. The specificity of the test was 97.2%, which tells us that 97.2% of the people without COVID were correctly identified by the RAT test. The sensitivity of 64.2% shows that RATs should not replace RT-PCR in the diagnosis and surveillance of SARS-CoV-2 infection, which is in line with the Centers for Disease Control and Prevention's recommendation on the use of antigen testing.[4] Antigen testing, on the other hand, had a PPV of 95.3%, showing that asymptomatic/asymptomatic people with positive antigen results are infected with SARS-CoV-2 and do not need a confirmatory real-time RT-PCR. Antigen testing had an NPV of 78.7%, indicating that asymptomatic/symptomatic people with negative antigen results are likely to have COVID-19 infection and better get RTPCR test done.

Table 3: Evaluation of RAT test

Particulars	Formula	Results
Sensitivity	(TP/TP+FN) X100	64.2 %
Specificity	(TN/FP+TN) X100	97.2 %
Positive Predictive Value	(TP/TP+FP) X100	95.3 %
Negative Predictive value	(TN/FN+TN) X100	78.7 %
% of False negatives	(FN/TP+FN) X100	35.7 %
% of False positives	(FP/FP+TN) X100	2.32 %

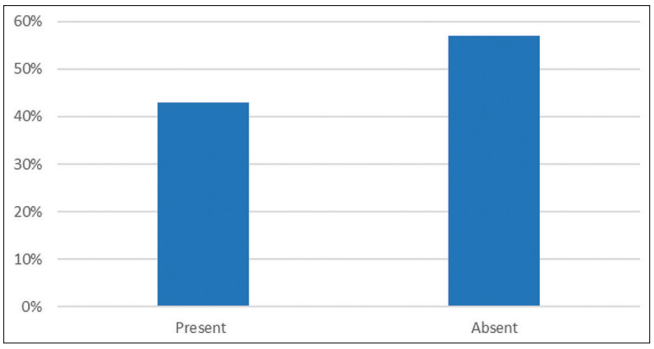

Figure 1: Contact history among RT-PCR-positive people (n=95)

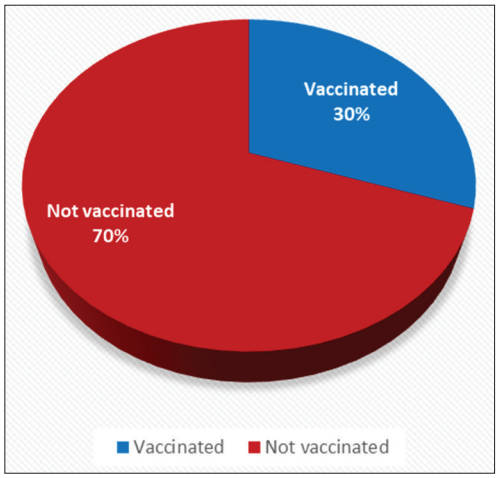

Figure 2: Vaccination history (n=224)

Another study included 4811 paired conclusive test results from the RT-PCR and antigen tests, 221 (4.6%) RT-PCR tests were positive. The overall sensitivity and specificity of the antigen test were 69.7% and 99.5%, the positive and negative predictive values were 87.0% and 98.5%.[5] This was comparable with our study results.

A study done by von Ahnen et al., compared 919 RATs to 919 RT-PCR tests. In RAT, 12 people tested positive. RT-PCR had been used to validate all 12 tests. In RAT, there was not a single false positive. COVID-19 was not identified by RAT in one person but was later positively identified by RT-PCR and findings revealed a 92.3% sensitivity and a 100.00% specificity.[6] The higher sensitivity and specificity of this study compared to our study could be because the timing of the test also depends on the proficiency of the technicians who take nasopharyngeal swabs and on the setting in which they are utilized.[7] Furthermore, most currently available Ag-RDTs have a high false-negative rate, health-care providers should be aware that a single negative test cannot definitively rule out SARS-CoV-2 infection.[8-10]

Limitations of the study

Our study was conducted at a single fever clinic and secondary data were used for the study. Further studies with larger sample sizes are to be involved. This could affect the generalizability of our study results. RAT kits used by different hospitals will be from different manufacturers, this might have affected the various study results.

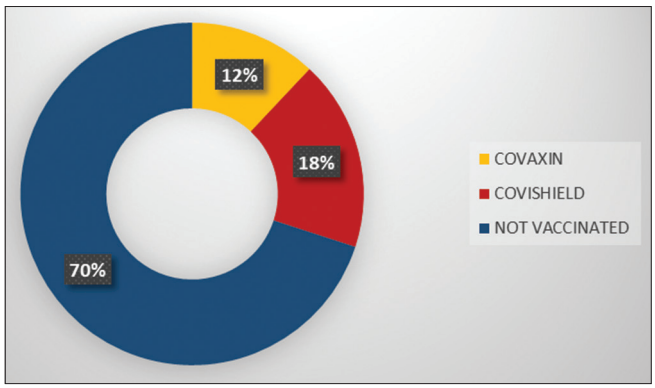

Figure 3: Vaccination coverage

CONCLUSIONS

1. Significant difference was found between RAT and RT-PCR results which indicate that RAT is not diagnostic for people who test positive in RT-PCR. Sensitivity of RAT was very less, and hence, we strongly recommend that RT-PCR is must for those who test negative for RAT test.
2. High predictive value of RAT implies that the test can be used in faster detection of cases and helps in rapid isolation and containing the disease spread.
3. Sensitivity of RAT was relatively less, and hence, we strongly recommend and reiterate that RT-PCR is must for those who test negative for RAT test.
4. About 2/3rd of people did not have contact history that indicates that the disease might be air borne and COVID-19 appropriate behavior should be followed.

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DR- Concept and design of the study, reviewed the literature, and prepared first draft of manuscript; **SK-** Interpreted the results; reviewed the literature and manuscript preparation; **KN-** Concept, preparation of manuscript, and revision of the manuscript; **RK-** Statistical analysis and interpretation; and **AB-** Coordination and revision of the manuscript.

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