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Original Research Article

Comparison of rapid antigen testing and RT-PCR in the diagnosis of COVID-19 in Kashmir division

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ABSTRACT

Background: Accurate diagnosis and widespread use of diagnostic tests with easy access is important to contain the spread of SARS-CoV-2. A Real-time reverse transcription polymerase chain reaction (RT-PCR) has high cost and can be performed in special laboratories. There have been several easy to perform rapid antigen detection tests developed and recommended to use at point of care for timely detection of positive patients and their isolation to limit the spread of infection. The aim of the study was to compare the cost effectiveness and the role of RT-PCR and rapid antigen testing in diagnosing different suspects of COVID-19.
Methods: In this cross-sectional study the data of all the suspected cases who underwent COVID-19 testing over a period of seven weeks at divisional level was used for analysis.
Results: The widespread use of rapid antigen testing makes it more cost effective in detecting COVID-19 cases than the highly sensitive and specific RT-PCR testing.
Conclusions: Rapid antigen tests can be used as a screening testing tool in high-risk groups to identify the infected persons quickly and for preventing the transmission of infection particularly in low resource settings.

Keywords: COVID-19, Rapid antigen testing, RT-PCR testing

INTRODUCTION

Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus.To detect SARS-CoV-2,laboratories have been using Reverse transcription polymerase chain reaction (RT-PCR) assays, the gold standard to detect the virus. The access and affordability to perform such tests is very challenging for the developing countries. Rapid antigen tests had already been used in the diagnosis of various respiratory pathogens like H1N1influenza, Aviam influenza etc.

So, from the beginning of the COVID-19 pandemic there was a search to identify a rapid diagnostic test for the identification of SARS-CoV-2. After, the development of many such tests in early stages of pandemic, ICMR approved Antigen-detection diagnostic tests in June 2020 to be used all over India. The FDA also granted Emergency use authorization (EUA) for antigen tests that can identify SARS-CoV-2.[1]

Besides being relatively inexpensive, the Rapid antigen tests (RAT) can be used at the point-of-care and provide results in approximately 15 min. Antigen tests for SARS-CoV-2 are generally less sensitive than viral tests that detect nucleic acid using Reverse transcription polymerase chain reaction (RT-PCR) but the usefulness of rapid antigen diagnostic tests largely depends on the circumstances in which they are used.

As is accurate diagnosis essential to limit the spread of SARS-CoV-2 so is the timely testing and the time period within which the results are available crucial for its containment and mitigation. RTPCR test usually take 1-3 days for the results and during this period the person being

unaware of his/her COVID-19 status has a serious potential to spread infection to others. Comparatively the RAT provide results within 15 min and thus helps in preventing COVID-19 spread in the community to a larger extent when you have limited human resources available to do the gold standard tests.

Moreover, the less cost of RAT makes it more suitable for wider use which indirectly contributes to COVID-19 mitigation efforts. The aim of the study was to compare the benefits of RAT and gold standard RT-PCR at the community level in a developing country.

Objectives

The objectives of this study were (a) to compare the rate of RAT and RT-PCR in diagnosing different categories of COVID-19 suspects; and (b) to estimate and compare cost of RAT and RTPCR in diagnosing COVID-19.

METHODS

All the COVID-19 related activities in Kashmir division of Jammu and Kashmir UT from collection, segregation and transportation of samples, isolation of cases, contact tracing, containment measures, collection of data and interpretation of the results are being coordinated by the divisional COVID-19 Control Room Kashmir. During the early phase of COVID-19 pandemic the gold standard test RT-PCR was performed on all samples collected from Kashmir division in three Government laboratories which were approved by ICMR.

In June, 2020 Indian Council of Medical Research (ICMR) approved the use of Standard Q COVID-19 Ag detection assay (Rapid antigen detection test) as a point of care diagnostic test for testing COVID-19. In July, 2020 the Government was able to procure Standard Q COVID-19 Antigen kits for use in Kashmir division.

All the laboratory technicians from all the districts of the Kashmir division were trained for use of such kits and their services were utilized at the point of care and testing was started by ending July, 2020. Simultaneously the RT-PCR testing continued in all districts.

Study area

The data regarding testing of COVID-19 through RTPCR and RAT from all the ten districts of Kashmir division of Jammu and Kashmir, India was used for the study.

Study design

This was a cross-sectional observational study.

Study period

The duration of study was 7 weeks starting from 1st August 2020 to 18th September 2020.

Study participants

All the study subjects who were suspected/ primary/secondary contact cases of COVID-19 infection were tested during the period of the study.

Exclusion criteria

Subjects who were travelers, police/defense personnel and who were doing repeat tests were excluded.

Sample size

A data of total 2,63,374 subjects was available as per the selection criteria of which 50,918 subjects underwent RT-PCR testing and 2,12,456 subjects underwent RAT testing during the 7 weeks of study period.

Data collection

The data for RT-PCR testing was collected on RT-PCR app as developed and recommended by ICMR. For RAT testing the data was collected on a self-designed excel sheet similar to that of RT-PCR reporting formats. The data regarding demographic characteristics and purpose of testing was entered in both the software.

Study procedure

A total number of 2,63,374 subjects were subject to RT-PCR and RAT testing. For RT-PCR 50,918 study subjects were tested and the samples of pharyngeal swab were collected by trained laboratory technicians and were transported from all the districts on same day to the three ICMR approved Government laboratories with in Kashmir Division under strict cold chain maintenance.

All the three laboratories are attached with tertiary care institutions of the Kashmir division and are under the control of respective Microbiology departments with special emphasis on biosafety level was maintained. The samples were processed and reported within 48 hours under the supervision of senior resident microbiologists of their departments.

A total number of 2,12,456 study subjects were subject to RAT testing. RAT testing only posterior nasal swabs from both the nostrils were taken as recommended by the manufacturer and tests were carried out at the point of care by the trained laboratory technicians as per the manufacturer protocol.

The study was approved by the In-charge Divisional COVID-19 Control Room Kashmir.

Data analysis

The data was either downloaded or entered in excel format and analyzed using SPSS (version 20.0). The data was presented as frequency and percentage.

RESULTS

The difference in RT-PCR and RAT positivity within different suspected categories of COVID-19 infection is shown in Table 1. The positivity was highest in symptomatic subjects (SARI/ILI) in both RT-PCR and RAT followed by COVID-19 positive contacts and others. The difference in positivity was highest (8.29%) in symptomatic group followed by 3.42% in contacts and 2.20% in others. Overall, the difference in positivity between RT-PCR and RAT was found to be 2.59%.

The cost estimation for every positive case detected through RT-PCRs and RATs is shown in Table 2. The cost for every positive case detected through RT-PCR was found Rs.32,850 and that through RAT was found to be only Rs.4586. Therefore, for every positive case detected through RAT there were savings of Rs.28,264 in comparison to RT-PCR. The comparison of RT-PCR and RAT COVID-19 positivity rate over the 7 weeks is shown in Table 3. It can be seen that the positivity rate was higher in RAT for first three weeks but declined rapidly for next 4 weeks in comparison to RT-PCR which did not fluctuate much over the 7 weeks. In overall the positivity of RT-PCR remained 9.13% and that of RAT remained 6.54%. The positivity rate in detection of casesthrough RTPCR was better than RAT in 8 of the 10 districts as shown in Table 4. District 4 and 7 had more positivity on RAT in comparison to RT-PCR.

Table 1: Comparison of RT-PCR and RAT positivity within different suspected categories of COVID-19 infection of Kashmir division.

Suspected categories	Real time PCR (RT-PCR)			Rapid antigen testing (RAT)			Difference in positivity %
	Total tests	Positive	Positive %	Total tests	Positive	Positive %	
SARI/ ILI	2112	425	20.12	30431	3601	11.83	8.29
Contacts	20063	2231	11.12	56479	4351	7.70	3.42
Others	28743	1994	6.94	125546	5945	4.74	2.20
Total/average	50918	4650	9.13	212456	13897	6.54	2.59

Table 2: Cost comparison of RT-PCR and RAT in Kashmir division.

Variables	RT-PCR	RAT
Total tests	50918	212456
Total positive	4650	13897
Total cost (approximately)*	Rs.152.7 million	Rs.63.7 million
Approximate cost/positive report	Rs.32,850	Rs.4,586
Savings per positive report		Rs.28,264

Note: *-costs were estimated on the rates of Rs 300/- per RAT test and Rs 3000/- per RTPCR test at the time of study.

Table 3: Comparison of RT-PCR and RAT positivity over time in Kashmir division

Duration	Real time PCR (RT-PCR)			Rapid antigen testing (RAT)		
	Total tests	Positive	Positive %	Total tests	Positive	Positive %
Week 1	7240	614	8.48	6652	650	9.77
Week 2	8054	701	8.70	17005	1608	9.46
Week 3	7633	708	9.28	17029	1818	10.68
Week 4	7930	829	10.45	18319	1609	8.78
Week 5	7105	608	8.56	26471	1631	6.16
Week 6	7385	679	9.19	57733	3235	5.60
Week 7	5571	511	9.17	69247	3346	4.83
Total/average	50918	4650	9.13	212456	13897	6.54

Table 4: Comparison of RT-PCR and RAT within various districts of Kashmir division.

Variables	Real Time PCR (R-TPCR)			Rapid antigen testing (RAT)		
	Total tests	Positive	Positive %	Total Tests	Positive	Positive %
District 1	6233	460	7.38	21593	1252	5.80
District 2	9960	1222	12.27	15109	1025	6.78
District 3	3963	357	9.01	21674	1321	6.09
District 4	9961	859	8.62	15780	1738	11.01
District 5	2137	395	18.48	19061	1167	6.12
District 6	1597	44	2.76	23144	437	1.89

Continued.

Variables	Real Time PCR (R-TPCR)			Rapid antigen testing (RAT)		
	Total tests	Positive	Positive %	Total Tests	Positive	Positive %
District 7	2768	195	7.04	17259	1451	8.41
District 8	6191	570	9.21	14103	868	6.15
District 9	6482	349	5.38	6795	89	1.31
District 10	1626	199	12.24	57938	4549	7.85

DISCUSSION

In this study, we showed to compare the case detection rate over time of both RAT as well as gold standard RT-PCR for COVID-19 infection in a low-resource situation of our division, where economic considerations as well as intrinsic limitations of different categories of tests dictate that a mix of different types of tests be used rather than a single type. We considered the case of a combination of a relatively inexpensive but less sensitive point-of-care rapid antigen test (RAT) with a more sensitive but also more expensive RT-PCR test. We assessed optimal testing regimes, taking into account test sensitivity and specificity, test pricing in the states of India at the study. We found that even 100% RAT test regimes should be acceptable, from both an epidemiological as well as an economic standpoint, provided a number of conditions were met. Intuition for our results can be obtained by observing that the effectiveness of any testing strategy depends on whether the number of tests administered per day are sufficient to locate all the *new* cases each day. A testing rate of 0.5% will be effective in suppressing the epidemic if the number of daily new cases is less than 0.5% of the population (for purely PCR tests) or ≈0.6% (for pure RAT with 80% sensitivity), which explains why we see reasonable results with RAT: PCR mixtures. This intuition provides an easily estimated upper bound on the required testing rate; in fact, the tests need only catch enough of the new cases to bring the reproduction number below 1, but that is harder to estimate. Variation in the infection model parameters which result in more asymptomatic cases would reduce the number of cases caught and increase the required testing rate. Current ICMR-recommended testing protocols in India list a number of different categories for which testing is required.[2] First, for routine surveillance in containment zones and screening at points of entry, where all symptomatic cases, including health care workers and frontline workers, are required to be tested. In addition, all asymptomatic direct and high-risk contacts of a laboratory-confirmed case within a few days of contact, together with all asymptomatic high-risk individuals in containment zones, are to be prioritized for testing. The order of priority is, in sequence, an RAT and an RT-PCR test (or TrueNat or CBNAAT in place of the RT-PCR test). Second, routine surveillance in non-containment areas involves the testing of all symptomatic cases with a history of international travel in the last 14 days, testing of symptomatic contacts of a laboratory-confirmed case as well as of symptomatic health care workers and frontline workers who are involved in containment and mitigation activities. The RAT is recommended here as the first choice of test. It is only in hospital settings, for patients with SARI (Severe acute respiratory infection), symptomatic patients presenting in a healthcare setting, asymptomatic high-risk patients who are hospitalized or seeking immediate hospitalization such as immuno-compromised individuals and a number of related categories, that individuals are to be tested first by RT-PCR and then by RAT.

It was observed that the positivity rate was higher in RAT for first three weeks as compared to RTPCR but declined over time for next 4 weeks in comparison to RT-PCR which did not fluctuate much over the 7 weeks. In overall the positivity of RTPCR remained 9.13% and that of RAT remained 6.54 %. So, from this inference we can draw is that in a low-resource situation, where economic considerations as well as intrinsic limitations of different categories of tests dictate that a mix of different types of tests be used rather than a single type.

In our study we found the positivity rate of RT-PCR was better than RAT in 80% of our districts. Rest 20% of districts had more positivity on RAT in comparison to RT-PCR. In real situations, the sensitivity of RT-PCR tests in the community based cross sectional studies have been reported to be in the range 85-95%.[3] This will once again reinforce our conclusion that by using a high percentage of RAT tests can nevertheless provide good epidemiological outcomes. Pekosz et al found that for patients within 7 days of onset of symptoms, RAT results correlate with the presence of culturable virus better than RT-PCR- this would also strengthen our conclusion.[4]

In our study we showed the comparison of RT-PCR and RAT within different suspected categories of COVID-19 infection. It was seen that the positivity rate was highest in symptomatic subjects (SARI/ILI) in both RT-PCR and RAT followed by COVID-19 positive primary contacts and others (asymptomatic/pre-symptomatic cases). The difference in positivity was highest (8.29%) in symptomatic group followed by 3.42% in contacts and 2.20% in others. Overall, the difference in positivity between RT-PCR and RAT was found to be 2.59%. Despite the difference we suggest that both RT-PCR and RAT can be used effectively in controlling and mitigation of COVID-19 pandemic in symptomatic suspected cases.[5] As we live in economically constraint division, we can do the testing of these suspected cases with the RAT more frequently in this pandemic. In this study we showed the cost comparison estimated for every positive case detected through RT-PCR and RAT. The cost for every positive case detected through RT-PCRs was Rs.32,850/- approximately and that through RAT was only Rs.4,586/- approximately. Therefore, for every positive case detected through RAT there were savings of Rs.28,264/- in

comparison to RT-PCR at the time of our study. Current costs of RT-PCR testing in the state of UP are between INR 700 ($9.5) and INR 900 ($12.28), down from INR 4,500 ($61.38) in private laboratories at the beginning of the pandemic.[6] The state of Bihar has capped its RT-PCR rates at INR 800 ($10.91), while RAT tests cost INR 400 ($5.46).[7] The state of Orissa, offers RATs at INR 100 ($1.36 while RT-PCR test costs are capped at INR 400 ($5.46).[8] (The Supreme Court of India is currently hearing a plea that asks to have the cost of RT-PCR tests capped at INR 300 ($4.03) across India). These rate estimates in other states determine only the cost of the test at a given point of time while in our study we estimated the total cost expenditure spend by the government institutions for every positive case detected through both RT-PCR and RAT.

As we want to point out here, the most important determinant of controlling a pandemic at intermediate levels is sero-prevalance along with RAT in an economically constraint country. It is here that we expect that all-RAT regimes may make more economic sense. We also need to understand the importance of reducing delays between getting results from RT-PCR can be reduced tremendously by RAT in containment zones along with sero-prevalence during these tough times of pandemics.[9,10]

Therefore, our conclusion is that doing RAT testing is much better option for us than the RT-PCR in our setting as hence prove to be a cost-effective measure in our country. This may be a more realistic approach in resource-constrained situations at intermediate stages of the pandemic. We can make inference from our study that the use of just RAT tests could yield epidemiological outcomes comparable to those obtained through RT-PCR-based testing, in terms of reducing both the peak numbers of infected and the total infected by the end of the epidemics there was some difference in the positivity rate of mix testing as RT-PCR is a gold standard for detecting the virus.

CONCLUSION

Rapid antigen tests can be used as a screening testing in high-risk groups to identify the infected persons quickly and for preventing the transmission of infection particularly in low resource settings. Therefore, access to reliable rapid diagnostic tests, in particular rapid antigen tests for COVID-19, could alleviate the pressure on laboratories and expand testing capacity to meet the most urgent medical and public health needs. Those with strong suspicion of having the infection and returning negative results on RDT must be tested sequentially through RT-PCR and managed accordingly.

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Ethical approval: The study was approved by the Incharge Divisional COVID Control Room, Kashmir

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