Evaluation of Large-Scale Rapid Antigen Testing of Incoming Passengers at a Dynamic Point of Care Setting Carried Out by Dental Students for Covid-19 Screening – A Field Report

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ABSTRACT

BACKGROUND

Assessment of the results of large-scale rapid antigen diagnostic (RAD) testing for detection of SARS-CoV-2 amongst incoming passengers was carried out by Ahmedabad Municipal Corporation (AMC) Dental College Students at the Central Railway Station of Ahmedabad city. We wanted to determine the sensitivity and specificity of RAD testing for detection of Covid-19 amongst passengers disembarking from scheduled trains arriving at the Central Railway Terminus of Ahmedabad city.

METHODS

Under the campaign "Chase the Virus" launched by Ahmedabad Municipal Corporation (AMC), Interns & Final Year students of AMC Dental College were trained to carry out rapid antigen testing of scheduled trains running on special routes starting from 07 / 09 / 2020 to 05 / 10 / 2020. 14 dental teams were deputed at a temporary testing facility formulated for day-to-day testing at the Central Station using the standalone Standard - Q Covid-19 Ag testing kit (SD Biosensor, South Korea).

RESULTS

In total, 18901 travellers were tested in a span of 26 days out of which 324 tested positive with an overall percentage positivity of 1.71 %. An average number of 727 (± 182) tests were performed with an overall sensitivity of 66.01 % and specificity of 99.71 %.

CONCLUSIONS

In response to the growing Covid-19 pandemic and complexity of laboratory-based molecular tests, rapid antigen detection tests have proved to be efficient in the easier and faster diagnosis of the passengers in such point of care settings.

KEY WORDS

Rapid Antigen Detection Test, Covid-19, SARS-CoV-2

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BACKGROUND

In December 2019, pneumonia of an unknown origin (later called coronavirus disease 2019, Covid-19) was identified in Wuhan, China.¹⁻⁴ Rapid spread of the newly discovered SARS-CoV-2, the seventh member of the coronaviridae family⁵ escalated the concerns of the World Health Organization (WHO) declaring Covid-19 as a global pandemic in March 2020.⁶ Primarily, described as an upper & lower respiratory tract infection due to human - to - human contact, several countries around the world had to implement immediate measures to curb further spread of the disease.⁷

Various strategies like total shutdown and travel restrictions were imposed by different governments, India not being an exception implemented a nationwide lockdown on 24th March 2020.⁸ The lockdown in India was implemented in four phases starting from 25th March 2020 to 31st May 2020 restricting travel via all public and private modes of transportation routes including railways and airways.⁹ Indian railways had suspended passenger mail and express train services from March 25th amidst the nationwide lockdown.⁸

However, special guidelines were issued by the Ministry of Home Affairs (MHA) to facilitate limited movement of trains for domestic travel and transit of migrant workers, students, pilgrims and tourists by operating Shramik special trains from May 2020 followed by running approximately 100 pairs of timetabled trains from June 2020.¹⁰ To avoid overcrowding at the stations, the centre released standard operating procedures (SOP) to ensure appropriate social distancing and compulsory screening of the passengers.¹¹ Simultaneously, Ahmedabad Municipal Corporation (AMC) from Gujarat State Administration launched the campaign called "Chase the Virus" on 01 - 07 - 2020 in an attempt to combat the virus by testing, identifying, isolating asymptomatic as well as symptomatic carriers of Covid-19.¹²

Along with the recommencement of Metro Rail Services from 7th September 2020,¹³ as per the guidelines issued in Unlock 4.0, concurrently on the same day itself, the Ministry of Health, AMC formulated a testing facility at the central railway station of Ahmedabad city to perform rapid antigen screening of incoming passengers to effectively isolate symptomatic individuals thereby blunting the further spread of the virus. Although reverse-transcription polymerase chain reaction (RT - PCR) is considered to be the gold standard for the detection of Covid-19, the requirement of specialized instruments, laboratory facilities and expertise pose a restriction in its usage in point of care settings. In contrast, rapid antigen detection immunoassays (RAD) that can be quickly performed and easily analysed, are cheap and enhance turnaround times.¹⁴ Furthermore, an improved correlation between the infectiousness of the patient especially in the initial days of infection and the results of antigen assay has been observed recently as compared to RT - PCR results.¹⁵

Very few studies depicting the use of standalone antigen kits for screening Covid-19 have been published in an ancillary testing facility near a railway transit station. Therefore, the purpose of this study was to describe the protocol and assess the use of Standard - Q Covid-19 Ag antigen kit (SD Biosensor, South Korea), carried out by dental students who were extensively trained in the state of need.

METHODS

This cross-sectional study was approved by the Institutional review board of AMC Dental College (AMC / IRB / STAFF01 / 20). Under the aegis of MOH - AMC, the Dean of AMC Dental College was directed to form 14 dental teams to conduct rapid antigen testing of incoming passengers at the central railway station, Ahmedabad City from 7th September 2020 to 5th October 2020. Consequently, 14 teams each comprising of two well trained dental students and one helper staff was formulated. Further four faculties of the institute were appointed by the authorities as coordinators to supervise the teams and ensure unequivocal functioning.

RESULTS

Training at the Institution

All the appointed 195 students, 47 subordinate staff as well as four coordinators were thoroughly trained by expert medical professionals of AMC affiliated medical colleges and hospitals by conducting a full day extensive training session. The training commenced with an onscreen presentation on a brief view of Covid-19, rapid antigen test and the conventional way of wearing all the personal protective gears was shown. They elaborated and practically demonstrated the entire protocol right from handling and interpreting the Standard - Q Covid-19 Ag antigen kit (which had a sensitivity of 96.52% and a specificity of 99.68% as claimed by the manufacturer) and taking nasopharyngeal swab samples. Instructions were also given on donning and doffing of PPE's, basic examination of the patient and recording the history according to the format designed by MOH - AMC as per the Indian Council of Medical Research (ICMR) guidelines. The helper staff were explained in their regional language on assisting the students about the proper disposal of the kits and other bio-medical waste as well as helping them in any way possible.

Name of the Train	Time Slot	Day
Rajdhani Express	8:00 am to 2:00pm	Monday to Saturday
Nizamuddin Express	3:00 pm to 7:00 pm	Monday to Saturday
Gorakhpur Express	3:00 pm to 7:00 pm	Monday to Saturday
Howrah Express	8:00 am to 2:00pm	Sunday

Table 1. Trains Allotted by MOH - AMC on a Weekly Basis

Duty Allocation

AMC had set up an onsite testing facility near the exit gate of the Central Railway Station. All incoming travellers had to get mandatorily tested as per the regulations set by the Ministry of Railways (MOR) and MOH - AMC. All the students who received the training were assigned duties, as per the list allotted to coordinators by MOH - AMC on the day-to-day basis, except six students who were spared because of their health conditions after due permissions from the assigned medical board. All dental teams were sent on each day for conducting rapid antigen detection (RAD) in either of the two slots: 8 am to 2 pm and 2 pm to 8 pm. The slot wise everyday distribution of arriving trains from 7th September 2020 to 5th October 2020, during which the dental students were appointed for the duty

is graphically represented and tabulated in Table 1 and Table 2.

Testing

The exiting passengers were screened and directed towards the testing facility and were queued with appropriate social distancing and masks. For every individual, one of the two team members would record all the necessary details in the testing form including personal information, a complete history and their categorization according to ICMR guidelines and then assign a sample number. Any passenger exhibiting three or more of the enlisted clinical symptoms in the history form was considered as a potential "clinically COVID positive" individual. The other team member would cross verify the latter and then perform the RAD test following the ICMR guidelines.¹⁶

1. After explaining to the patient about the procedure and marking the testing strip with the sample number assigned before, the nasopharyngeal swab from both the nostrils was collected with the customized sample collection swab provided with the kit.
2. The swab stick was then dipped and squeezed in the viral extraction buffer, provided with the kit thereby inactivating the virus.
3. Considering the viability of the collected sample to be an hour, the buffer along with the swab was mixed instantaneously.
4. The buffer tube cap was then replaced with a nozzle and 2 - 3 drops of the mixed buffer solution were dispensed into the testing well of the strip. The exact time at this point was noted in the testing form. The test could be interpreted as positive or negative depending upon the appearance of test and control lines in a minimum of 15 minutes and a maximum of 30 minutes after which the test strip had to be discarded.^{16,17}

Date	Number of Train	
	8:00am to 2:00pm	3:00pm to 7:00pm
07/09/2020	1	-
08/09/2020	1	-
09/09/2020	1	-
10/09/2020	1	-
11/09/2020	1	-
12/09/2020	1	-
13/09/2020	1	-
14/09/2020	1	-
15/09/2020	1	-
16/09/2020	1	-
17/09/2020	-	2
18/09/2020	-	2
19/09/2020	-	2
21/09/2020	1	-
22/09/2020	1	-
23/09/2020	1	-
24/09/2020	1	-
25/09/2020	1	-
26/09/2020	1	-
28/09/2020	1	2
29/09/2020	1	2
30/09/2020	1	2
01/10/2020	1	2
02/10/2020	1	2
03/10/2020	1	2
05/10/2020	-	2

Table 2. Number of Trains Allotted Vs. Date

Interpretation of the Test

The test results were interpreted as positive, negative or invalid based on lines at both C and T areas, a single line at only C area or no lines respectively. Those individuals who turned out to be positive in the RAD test were stamped on their hands with an indelible ink by the first team member and were then referred to the onsite medical officer (MO) for further quarantining and necessary treatment. Individuals who were symptomatic and turned out to be negative on the test were referred to the attending medical officer to recommend him / her for RT - PCR testing.

Statistical Analysis and Results

To facilitate constant communication, a WhatsApp group of all the team members and appointed faculty coordinators was formed. The assigned team leaders of each of the 14 teams were instructed to forward all the details of daily recorded passengers in a dedicated format designed by the coordinators of AMC Dental College on an everyday basis. Based on the received information, the coordinators would tabulate the data in Microsoft Excel (MS office 2019) format. Descriptive statistics of the collected data was performed, mean and standard deviations were deduced.

A total of 18901 passengers were tested between 7th September 2020 to 5th October 2020 (total testing days: 26 Days). On an average 727 ($\pm$ 182) tests were performed by the 14 appointed dental teams and an average number of 12 ($\pm$ 8) travellers were screened to be positive by RAD tests. The daily distribution of the total number of samples taken and total positives is represented in Graph 2 & Graph 3. Further, the overall percentage positive rate of the total number of tests carried out by dental teams was found to be 1.71 %. Based on information obtained from the recorded history sheets which were used to identify the "Clinically COVID positives" and the individuals who were onsite positive with RADs and designated as "Test positives", a 2X2 contingency table was prepared. Clinically COVID positives were defined as those having any three symptoms from the enlisted i.e. fever, shortness of breath, cough, generalized weakness/ body ache, loss of smell/taste, diarrhoea according to the antigen testing categorization designed by MOH-AMC.

Wilson score method was used to analyse the data and determine the sensitivity and specificity which resulted in an overall sensitivity of 66.01 % and specificity of 99.71 % (table 3). Also, a positive predictive value of 83.33 % and a negative predictive value of 99.25 % could be deduced. The diagnostic accuracy of RAD tests turned out to be 98.98 % in our study. The overall performance of each dental team on a single testing day was found to be on an average of 52 tests / day.

Test Result	Clinically Positive	Clinically Negative	Total
Test positive	270	54	324
Test negative	139	18438	18577
Total	409	18492	18901
Sensitivity		66.01%	
Specificity		99.71%	

Table 3. 2 * 2 Contingency Table Determining the Sensitivity and Specificity

Graph 2. Samples Collected Vs. Date

Graph 3. Samples Positive Vs. Date

DISCUSSION

Rapid screening and accurate diagnosis for the detection of SARS-CoV-2 are of paramount importance in dynamic, highly crowded settings like Railroad terminus for easy identification, effective isolation and early quarantining of infected individuals. The guarded use of RAD tests has been attributed to its lower sensitivity although it is important to understand that it depends on several factors like viral load, sample type, time from illness onset and setting of patients tested.¹⁸ In the study carried out by Anais Scohy et al. they demonstrated a low overall sensitivity of 30.2 % amongst 148 nasopharyngeal samples collected.¹⁹ Interestingly, another study was carried out by Gannon CK Mak et al. in which RAD tests exhibited an extremely variable sensitivity detecting between 28.6 % and 81.8 % of RT - PCR - positive high viral load respiratory samples whereas between 0 - 21.1 % for normal viral load samples.²⁰ In contrast Eliseo Albert et al. yielded an excellent specificity and a fairly good overall sensitivity (79.6 %) in their study to evaluate the overall performance of RAD assay conducted at a point of care setting itself.²¹ Similarly, in our study the RAD tests exhibited a fairly higher overall sensitivity of 66.01 % and remarkable specificity of 99.71 % amid 18901 nasopharyngeal samples although the reference standard was based on clinical

symptoms. The higher overall sensitivity in our study and the latter study might be attributed to the fact that these studies were carried out on the spot while the earlier studies evaluating RAD assays utilized either retrieved specimens, which were cryopreserved, or those carried out at central laboratories, or both. However, it is important to understand that direct comparison between studies is logically sceptical due to major differences in patients' clinical presentation and age, testing facilities, type of sample preparation and time at which the test was performed along with others. Thereby, this seems to be a favourable approach as faster and comparatively reliable results would have to be delivered for immediate screening in a point of care setting wherein large-scale testing was to be carried out on passengers coming from distant cities with unknown prevalence. European Centre of Disease Control (ECDC) recommends RAD tests in a high prevalence setting due to its high positive predictive value (PPV). This means a positive result in the RAD test is likely to indicate a true infection and need not be confirmed by RT - PCR and a negative test result would have to be confirmed by RT - PCR. A similar approach was adopted in our setting and all the passengers who were screened were coming from such cities which were considered as high prevalence zones. Concurrent findings were demonstrated by Manual Linares et al. in their study wherein they collected 255 nasopharyngeal swabs from symptomatic and asymptomatic patients who were tested

with Panbio RAD testing kits.²² They concluded that RAD tests can be used as an effective substitute for RT - PCR in these types of patients to cut off delays and reduce the excessive labour costs caused by the use of PCRs.

CONCLUSIONS

This study illustrates a prompt initiative taken by the authorities wherein dental students were trained to perform the RAD tests in such a crucial time of urgency and thereby served as front liners to carry out this type of large-scale dynamic testing of passengers coming from different areas with unknown prevalence. Although RAD tests displayed a fairly low sensitivity, their ability to be highly specific, less time consuming, minimally technique sensitive, being inexpensive as compared to PCR assays and accurate in the initial days of infection which justifies their use in a public screening at such point of care settings, therefore, curbing the further spread of the disease.

Limitation

A major limitation of this study was that the reference standard was based on common clinical symptoms associated with SARS-CoV-2 rather than RT - PCR.

Data sharing statement provided by the authors is available with the full text of this article at jemds.com.

Financial or other competing interests: None.

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