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Original Research Article

Comparing the diagnostic performance between Rapid antigen and RT-PCR for the detection of SARS CoV2 in a tertiary care hospital in South India

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Abstract:

Background: COVID- 19 rapid antigen test plays a crucial role in managing the COVID-19 pandemic by diagnosing COVID-19 infection. However, the sensitivity and specificity of rapid antigen tests are not known because there are no adequate studies to substantiate. While PCR-tests are considered as the gold standard assay to confirm infection with the SARS-CoV-2 infection because of their sensitivity as well as specificity, antigen tests offer more advantages in terms of low cost, time, space constraints and personnel involved and are implemented in testing strategies around the world and antigen testing can be deployed for testing many individuals, considering their advantages cited above.

Objectives: The aim of this study was to assess the diagnostic accuracy (sensitivity, specificity, positive predictive value and negative predictive value) of STANDARD Q rapid antigen test kit in diagnosing SARS-CoV-2 infection in a tertiary care testing facility and compare it with the standard RT- PCR test.

Methods: The patients reporting to COVID-19 sample collection center of the tertiary care testing facility were included in the study after getting proper consent. A total of 400 patients were involved in the study. Nasopharyngeal swabs were obtained from the study participants and the STANDARD Q rapid antigen test was run in parallel with real-time PCR tests and both the results were documented.

Results: Among the 400 patients who were included in the study, RT-PCR was positive in 95 individuals, with a prevalence of 23.75% and negative in 305 patients (76.25%). The sensitivity of the rapid antigen test was 88.4% and the specificity was 100 %. The positive and negative predictive values were 100% and 96.52% respectively.

Conclusion: The accuracy of the SARS-CoV-2 STANDARD Q rapid antigen test in diagnosing SARS-CoV-2 infections in a tertiary care testing facility was almost equal when compared with the manufacturer's data. However they can be used for mass screening purposes considering their ease of use, portability and convenience. The Area under the Curve (AUC) is 0.942 which signifies that the kit can distinguish well between the true positive and true negative.

Keywords: Rapid antigen test, RT –PCR, COVID-19

Introduction

The ongoing COVID-19 pandemic has posed a challenge worldwide with 400,000,000 confirmed cases and 5821000 deaths [1]. It has collapsed the global economy and increased heath related expenditure. The changes it has produced, has wrecked the world and led WHO to declare the novel coronavirus (COVID-19) outbreak a global pandemic on March 11, 2020 and called the countries for immediate action to curtail virus transmission [2]. Symptomatic screening, testing and contact tracing are strategies to identify people infected with SARS-CoV-2, so that appropriate measures can be taken to stop the spread of the virus. A robust testing strategy is the need of the hour to stop the spread of SARS-CoV-2, the virus that causes COVID-19 [3].

Universally molecular testing based on Real time Reverse transcription polymerase chain reaction is considered the gold standard test for diagnosing COVID-19 infection because of its high sensitivity. But the assay is cumbersome in terms of the cost involved, sophisticated equipment, robust infrastructure, space, time and well trained personnel. The test has to be run in batches. Yet they are preferred for their accurate results. Though the results are available in few hours, many countries are undergoing delays because of the infrastructure and resources involved. [4,5]

The delays in obtaining molecular tests results can be detrimental because it increases the risk of virus transmission. Although many cartridges based testing platforms have allowed testing to be used outside laboratory settings and provide quick results, these technologies cannot be deployed for use in resource limited countries because of the cost involved. [6]

The major consequences of these drawbacks causes delays in isolation of the patient and contact tracing, leading to increased risk of transmission of the disease [7].

An alternative method that can remove the drawbacks caused by molecular testing would be antigen testing [8]. COVID-19 antigen tests are immuno assays that diagnose active infection by detecting SARS-CoV-2 viral antigens in various specimen types such as nasopharyngeal, oropharyngeal and nasal swabs. They are available as a single use, point of care test, lateral flow, tests and can be used as a small portable device .They are compact, needs less space and provide results within 15 to 20 minutes [9]. These rapid tests are cheaper and can be produced in larger numbers for catering to large scale deployment. However these tests are not as sensitive as molecular tests though they have a high specificity. [10]

Our prospective study aimed to assess the diagnostic accuracy of a rapid antigen test in diagnosing SARS-CoV-2 infection in a tertiary care testing facility.

Methods

Study design and setting

This study was a prospective cross-sectional study conducted at a COVID-19 testing facility of a tertiary care hospital.

Participants

Consecutive individuals presenting with symptoms or individuals who wanted to test for travel purposes or rejoining work and academic institutions including pre-operative patients between September 2020 and May 2021 were included in the study. A total of 400 patients were included after obtaining informed consent.

Eligibility criteria:

Patients of any age group for

(a) Diagnostic purposes-suspected SARS-CoV-2 infection
(b) Patients presenting with influenza like illness (ILI)
(c) Screening purposes (preoperative and travel)

Clinical criteria needed to diagnose SARS-CoV2 infection

- Acute onset or worsening of at least two of the following symptoms or signs: fever, chills, rigors, myalgia, headache, sore throat, nausea or vomiting, diarrhea, fatigue, congestion or runny nose
- Acute onset or worsening of any one of the following symptoms or signs: cough, shortness of breath, difficulty breathing, loss of smell and taste, chest pain ,pale, gray, or blue-colored skin, lips, or nail beds
- Severe respiratory illness with at least one of the following: Clinical or radiographic evidence of pneumonia and Acute respiratory distress syndrome (ARDS).

Laboratory Criteria: Detection of SARS-CoV-2 ribonucleic acid in a clinical specimen using a molecular amplification test

Epidemiologic Linkage: Close contact with a confirmed or probable case of COVID-19 disease (exposure in the prior 14 days) [11]

Ethical committee approval: The study protocol was approved by the institutional ethical committee and all participants who signed informed consent only were included in the study.

Procedure

Antigen test: Nasopharyngeal specimens were collected and processed by the STANDARD Q SARS- CoV-2 rapid antigen test by trained technicians.

The swab was inserted into the nostril of the patient parallel to the palate till resistance was felt and swabbed over the surface of the posterior nasopharynx, leaving the swab for 10 seconds to absorb the secretions.

The nasopharyngeal swab was then withdrawn slowly and was processed immediately without any delay. The SARS- CoV-2 antigen test has 2 pre coated lines, C-control line and T-test line on the nitrocellulose membrane.

Mouse monoclonal anti SARS-CoV-2 antibody was coated on the test line region and mouse monoclonal anti chicken IgY antibody on the control region. The sterile swab was withdrawn and was inserted into an extraction buffer tube. The swab was stirred for more than 5 times in the extraction buffer tube. 3 drops of extracted specimen was added to the well of the test device. The antigen in the sample interacts with the monoclonal anti chicken IgY antibody conjugated with color particles and moves by capillary action to the Mouse monoclonal anti SARS-Cov2 antibody.

The test result was read in 15 to 30 minutes. A colored band in the Control line C section of the result window showed that the test was working properly. A colored line in the region of the test line of SARS-CoV-2 antigen (T) was considered positive. The presence of even a faint line was considered as positive.

The intensity of the color in the test line depends on the amount of SARS CoV2 antigen present in the sample. Quality control check was done daily and strict adherence to manufacturer's instructions was followed. [12]

RTPCR testing

Real time PCR assay was done to confirm the presence of COVID- 19. Specimens were processed in biosafety cabinets 2 Type B2.

The RT PCR assay was done according to the manufacturers' instructions on ROTOR GENE Q by trained laboratory technicians who were not aware of the rapid antigen test results.

Pathodetect COVID-19 qualitative PCR kit is RT PCR assay which is used for the detection of COVID-19 in respiratory specimens, using E as screening gene detected in the red fluorescence channel and RdRp and N as confirmatory genes detected in a green fluorescence channel. The endogenous control is also used in the testing to check the efficiency of sample collection procedure.

Detectable SARS-CoV-2 below or at a cycle threshold of 38 was considered positive. The kit positive and negative controls were used with each run. [13]

Bias: The bias was prevented by blinding the results of the rapid antigen test from the technician who was performing RT-PCR

Statistical analysis: Patient characteristics were presented as numbers (percentages). Specificity, Sensitivity, Positive Predictive Value and Negative Predictive Value (PPV/NPV), Accuracy, Cohen's κ statistics of the rapid antigen test were calculated using the RT-PCR results as the reference test. Fisher's Exact Test and Z proportion test was used to find out the statistical significance between the factors and the test results. The statistical analysis was done by SPSS for Windows 17.

There was no missing data and no patient dropout rate, as there was only first visit and all the selected participants accepted to participate in the study.

Results

Patient characteristics

Table 1: Characteristics Table

	n (%) or Median (Min - Max)
Age	n=400; 32 (6 - 88)
Age Group	
≤25 Years	98 (24.5%)
26 to 35 Years	130 (32.5%)
36 to 45 Years	73 (18.3%)
>45 Years	99 (24.8%)
Gender	
Female	225 (56.2%)
Male	175 (43.8%)
CT - Value	n=95; 28.0 (14.9 - 34.5)
COVID-19 Antigen	
Negative	316 (79%)
Positive	84 (21%)
RT-PCR	

Negative	305 (76.3%)
Positive	95 (23.8%)
COVID-19 Antigen and RT-PCR	
Ag-ve & PCR-ve	305 (76.3%)
Ag+ve & PCR-ve	0 (0%)
Ag-ve & PCR+ve	11 (2.8%)
Ag+ve & PCR+ve	84 (21%)
Symptomatic status	
Symptomatic	152 (38%)
Asymptomatic	248 (62%)
Symptoms	
Fever	106 (26.5%)
Cough	52 (13%)
Cold	33 (8.3%)
Sore Throat	23 (5.8%)
Breathlessness	1 (0.3%)
Vomiting	2 (0.5%)
Head Ache	7 (1.8%)
Dyspnoea	21 (5.3%)
Loss of Smell	5 (1.3%)
Loss of Taste	7 (1.8%)
Myalgia	14 (3.5%)
Loss of Weight	1 (0.3%)
Loss of Appetite	1 (0.3%)
Median Day of testing	3 (Range 2 - 7)

A total of 400 individuals were included in the study. Among them, 175 (43.8%) were males and 225 (56.2%) were females. (Table 1).The median age of the study participants was 32 years (6 years – 88 years). Highest number of participants are between 26 – 35 years of age (32.5%) and lowest number of individuals are between 36 – 45 years of age. (Table 1 & Figure 1)

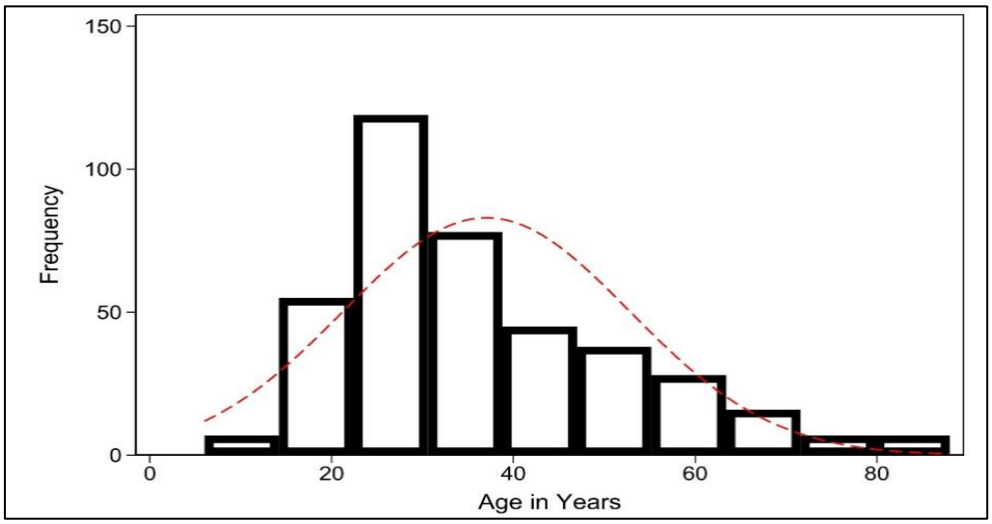

Figure 1: Study population age distribution

Rapid antigen test detected about 84 (21%) positive samples and 316 (79%) negative samples. (Table 1)

Out of 400 samples tested in RT-PCR, 95 (23.8%) samples were reported as positive and 305 (76.3%) samples were reported as negative. The RT-PCR reported positive samples had a median CT value of 28 (14.9 – 34.5). False negative results were reported for 11 samples (2.8%). (Table 1 & Figure 2)

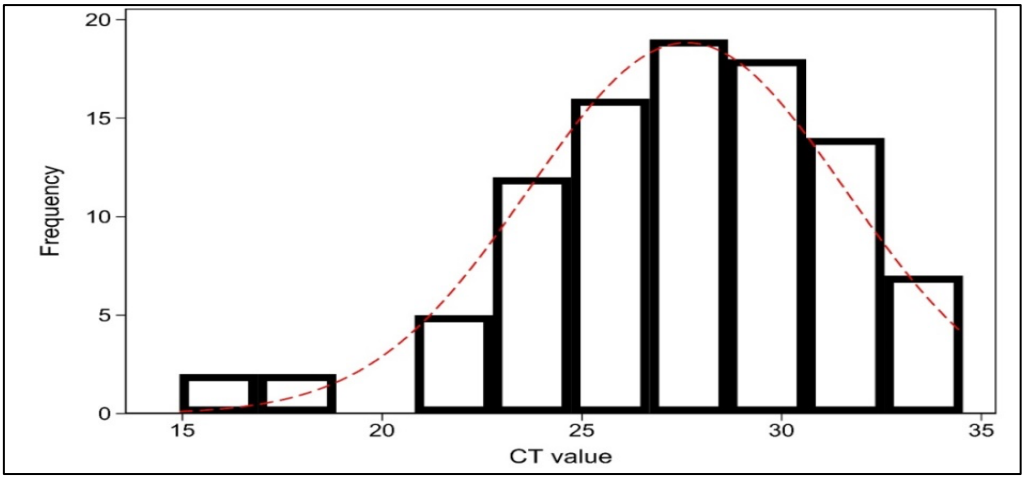

Figure 2: RT-PCR positive samples CT value distribution

The most common reported symptom among the study participants was fever (26.5%) followed by cough (13%) and cold (8.3%). Patients were tested at a median of 3 days (range 2–7) after onset of symptoms. (Table 1)

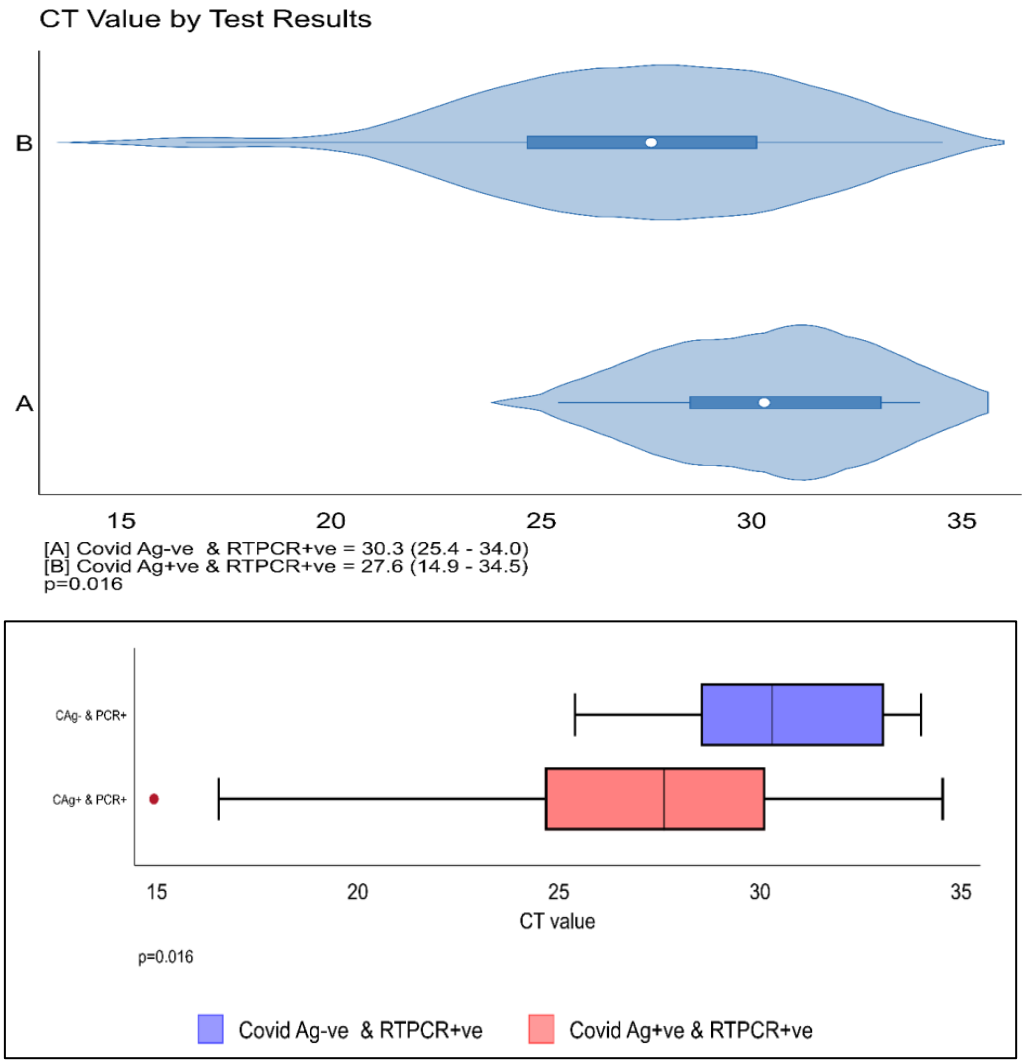

Figure 3: Density distribution graph showing CT values (above) and box plot showing the CT value distribution (below) between COVID-19 Antigen & RT PCR positive samples and COVID-19 Antigen negative & RT PCR positive samples.

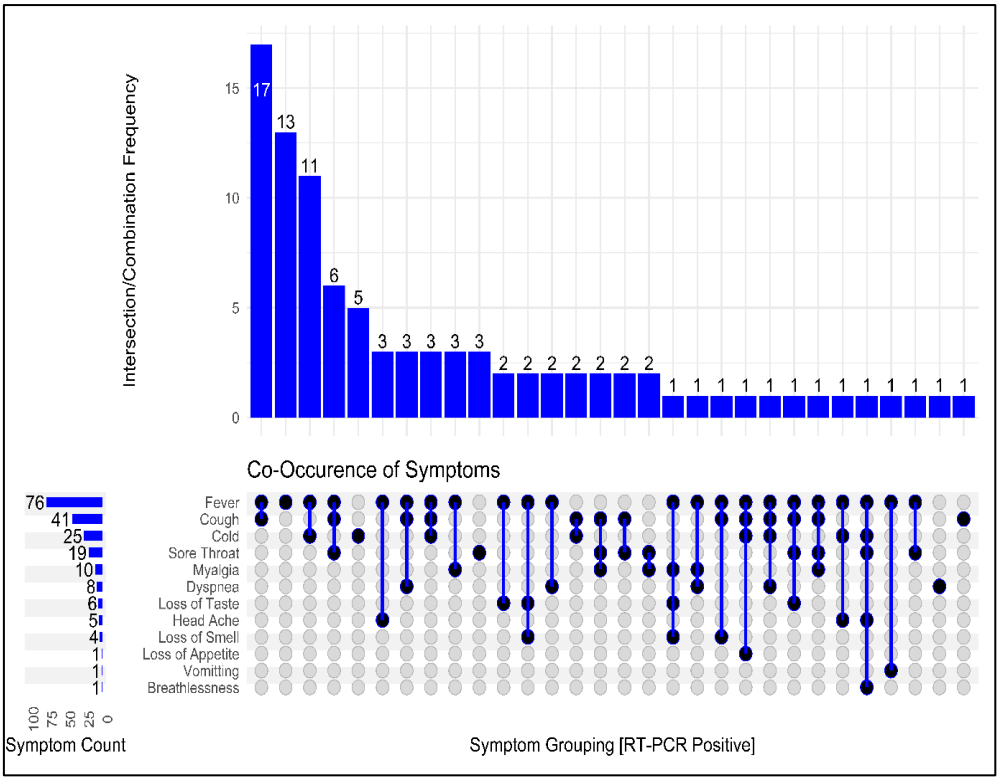

Figure 4: Upset plot showing co-occurrence of symptoms in RT-PCR positive individuals

The most commonly co-occurred symptom in RT-PCR positive patients are fever and cough followed by fever and fever & sore throat. (Figure 4)

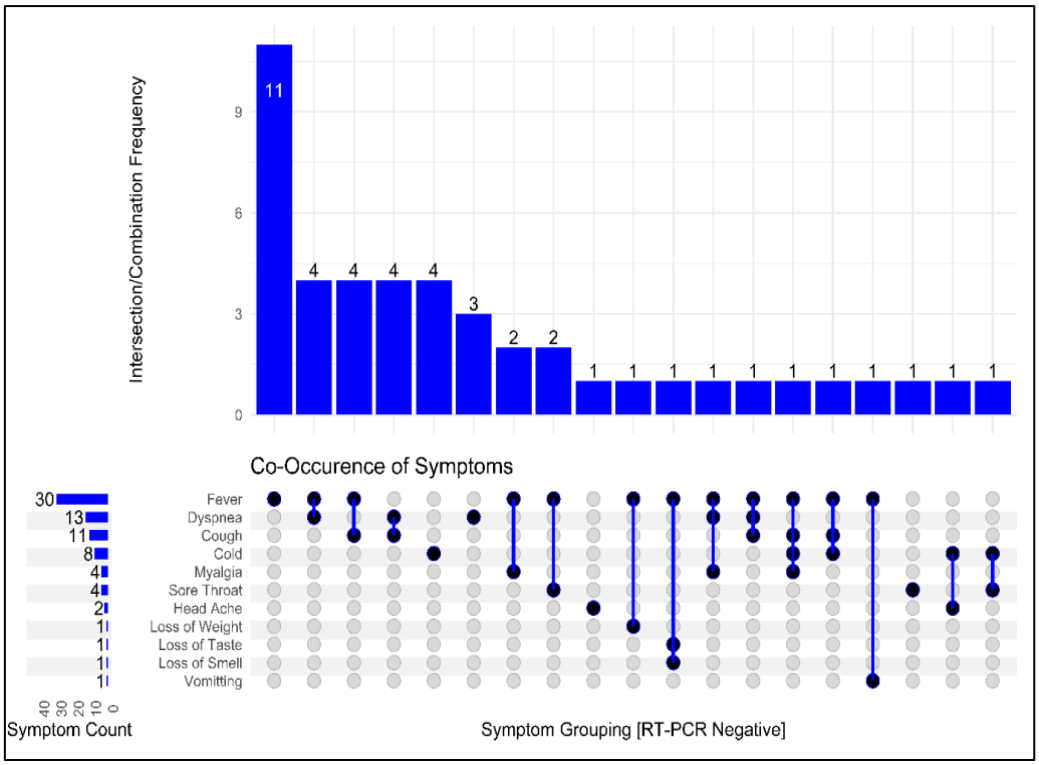

Figure 5: Upset plot showing co-occurrence of symptoms in RT-PCR negative individuals

RT-PCR negative patients showed mostly fever as a common symptom followed by fever and dyspnea as a co-occurred symptom. (Figure 5)

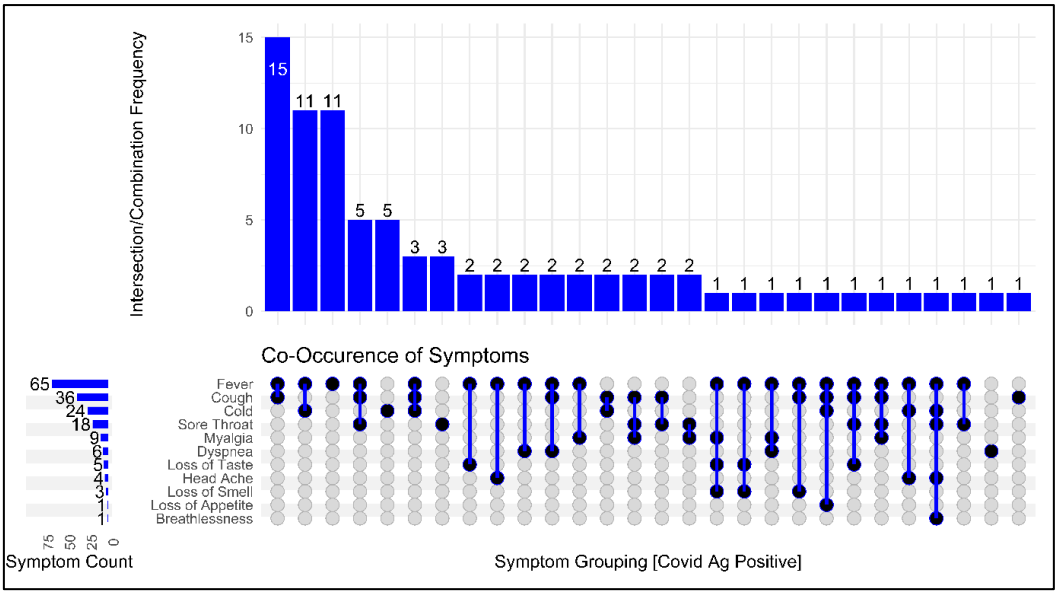

Figure 6: Upset plot showing co-occurrence of symptoms in COVID-19 antigen positive individuals

Fever and cough & Fever and cold are the most prevalent co-occurred symptoms in COVID-19 antigen positive patients. (Figure 6)

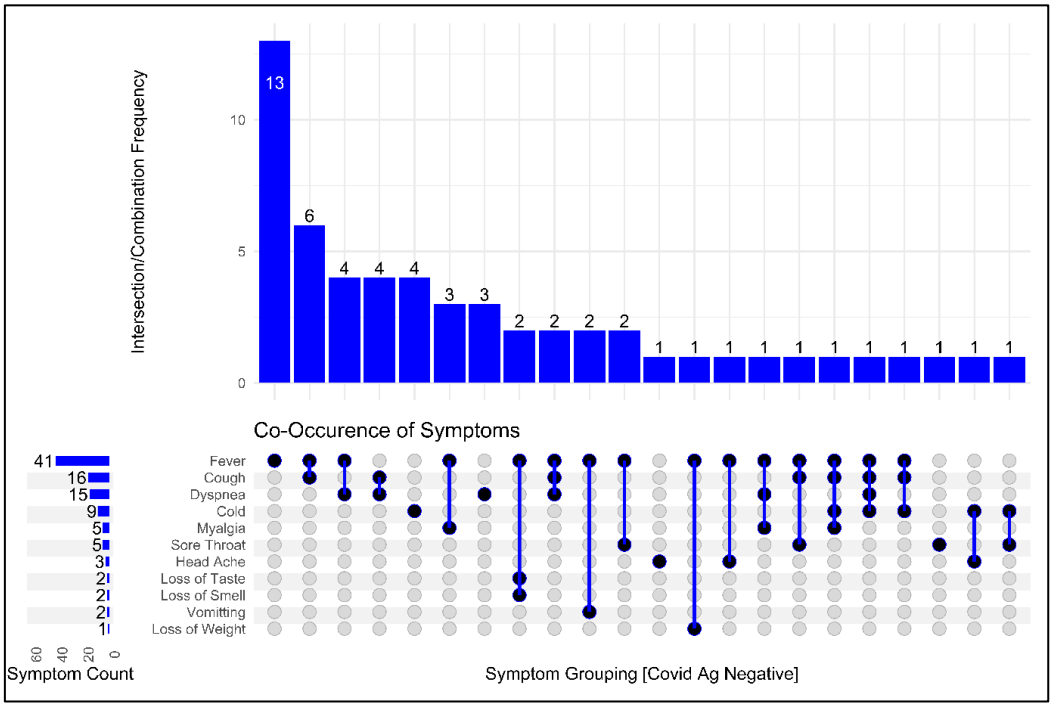

Figure 7: Upset plot showing co-occurrence of symptoms in COVID-19 antigen negative individuals

COVID-19 antigen negative cases shows fever and fever & cough as the highly prevailed co-occurred symptoms. (Figure 7)

Diagnostic characteristics: Totally 95 individuals were tested positive in RT-PCR test, corresponding to a prevalence of 23.75 % and 305 individuals were tested negative in RT-PCR in (76.25%).The STANDARD Q rapid antigen test was positive for 84 individuals (21%) and negative for 316 individuals (79 %). 305 individuals (76.2%) were tested negative by both methods, 11(2.8%) were tested positive by RT-PCR but was tested negative in rapid antigen test, and 84(21%) tested positives by both methods. (Table: 2)

The mean CT value of antigen positive samples tested with RT PCR was 27.10

Table 2: COVID-19 Antigen test performance compared with reference standard RT-PCR

			RT PCR		Total
			Positive	Negative	
COVID Ag Result	Positive	Count	84	0	84
		% within COVID-19 Antigen Result	100.0%	.0%	100.0%
		% within RT PCR	88.4%	.0%	21.0%
	Negative	Count	11	305	316
		% within COVID-19 Antigen Result	3.5%	96.5%	100.0%
		% within RT PCR	11.6%	100.0%	79.0%
Total		Count	95	305	400
		% within COVID-19 Antigen Result	23.8%	76.3%	100.0%
		% within RT PCR	100.0%	100.0%	100.0%

Sensitivity (95% CI)	88.4 (80.2 - 94.1)
Specificity (95% CI)	100 (98.8 - 100)
PPV (95% CI)	100 (95.7 - 100)
NPV (95% CI)	96.5 (93.9 - 98.2)
Accuracy (95% CI)	97.3 (95.1 - 98.6)
Disease Prevalence (95% CI)	21.0 (17.1 - 25.3)
Cohen's κ statistics	92.1 (82.3 - 100)

The overall sensitivity of the STANDARD Q rapid antigen test kit was 88.4% and the specificity was 100 %. The positive predictive value was found to be 100% and the negative predictive value was 96.5%. The accuracy of the test kit was interpreted to be 97.3%. The Cohen's κ statistics method revealed almost perfect agreement between the RT-PCR and STANDARD Q rapid antigen test kit. (Table 2)

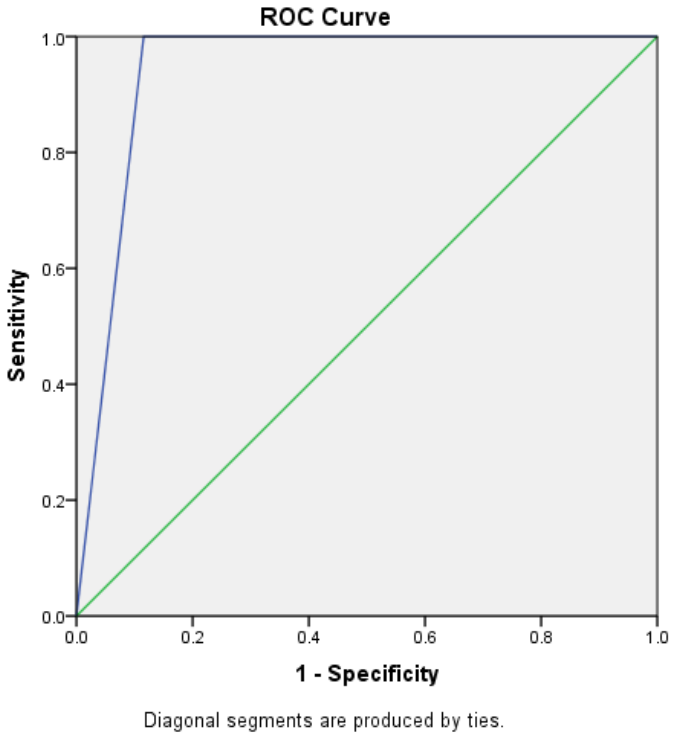

Figure 8: Receiver Operating Characteristic Curve

Table 3: Area Under the Curve

Test Result Variable(s):COVID-19 Antigen Result				
Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.942	.019	.000	.904	.980
The test result variable(s): COVID-19 Antigen RESULT has at least one tie between the positive actual state				

group and the negative actual state group. Statistics may be biased.
a. Under the nonparametric assumption b. Null hypothesis: true area = 0.5

The Area under the Curve (AUC) is 0.942 which signifies that the kit can distinguish well between the true positive and true negative samples. (Table 3 & Figure 8)

Table 4: Cases with discordant results between the STANDARD Q COVID-19 Ag test and RT-PCR test

S.No.	Diagnosis	CT value	Interpretation
1.	URI	33.94	False negative
2.	Pre-operative	28.63	False negative
3.	Pre-operative	28.52	False negative
4.	Fever for evaluation	29.4	False negative
5.	Fever for evaluation	30.89	False negative
6.	COVID-19 Pneumonia	30.3	False negative
7.	Pre-operative	34.78	False negative
8.	Symptomatic	34.1	False negative
9.	Symptomatic	31.69	False negative
10.	Symptomatic	29.67	False negative
11.	Preoperative	29.06	False negative

Table 5: Sensitivity and Specificity Analysis among asymptomatic individuals

		RT PCR Result (Gold Standard)		Total
		Positive	Negative	
COVID-19 Antigen Result (New Test)	Positive	1	0	1
	Negative	0	260	260
Total		1	260	261
Parameter		Estimate	95% CIs	
Sensitivity		100.00%	(20.65, 100.00)	
Specificity		100.00%	(98.54, 100.00)	
Positive Predictive Value		100.00%	(20.65, 100.00)	
Negative Predictive Value		100.00%	(98.54, 100.00)	
Diagnostic Accuracy		100.00%	(98.55, 100.00)	
Likelihood ratio of a Positive Test		'undefined'	-	
Likelihood ratio of a Negative Test		0.0	-	

The sensitivity and specificity among asymptomatic individuals was reported to be 100%. The positive predictive value and negative predictive value was also found to be 100% among the asymptomatic individuals (Table 5). In the case of symptomatic individuals the sensitivity and specificity was reported to be 88.3% and 100% respectively. The positive and negative predictive value was interpreted to be 100% and 80.36% respectively. Among the symptomatic patients the diagnostic accuracy was found to be 92.09% (Table 6)

Table 6: Sensitivity and Specificity Analysis among symptomatic individuals

		RT PCR Result (Gold Standard)		Total
		Positive	Negative	
COVID-19 Antigen RESULT (New Test)	Positive	83	0	83
	Negative	11	45	56
Total		94	45	139
Parameter		Estimate	95% CIs	
Sensitivity		88.3%	(80.25, 93.34)	
Specificity		100.00%	(92.13, 100.00)	
Positive Predictive Value		100.00%	(95.58, 100.00)	
Negative Predictive Value		80.36%	(68.16, 88.66)	
Diagnostic Accuracy		92.09%	(86.38, 95.52)	
Likelihood ratio of a Positive Test		'undefined'	-	
Likelihood ratio of a Negative Test		0.117	(0.098 - 0.140)	

Table 7: Association between the factors & COVID-19Antigen test results and factors & RT PCR test results

	COVID-19 Antigen Test			RT PCR Test		
	Negative (n=316)	Positive (n=84)	p-Value	Negative (n=305)	Positive (n=95)	p-Value

Age	32 (6 - 86)	32 (18 - 88)	0.758	32 (6 - 86)	32 (15 - 88)	0.704
Age Group						
≤25 Years	78 (24.7%)	20 (23.8%)	0.847	75 (24.6%)	23 (24.2%)	0.635
26 to 35 Years	103 (32.6%)	27 (32.1%)		99 (32.5%)	31 (32.6%)	
36 to 45 Years	55 (17.4%)	18 (21.4%)		52 (17%)	21 (22.1%)	
>45 Years	80 (25.3%)	19 (22.6%)		79 (25.9%)	20 (21.1%)	
Gender						
Female	189 (59.8%)	36 (42.9%)	0.005	184 (60.3%)	41 (43.2%)	0.003
Male	127 (40.2%)	48 (57.1%)		121 (39.7%)	54 (56.8%)	
CT - Value	30.3 (25.4 - 34.0)	27.6 (14.9 - 34.5)	0.018	30.3 (25.4 - 34.0)	27.6 (14.9 - 34.5)	0.018
Symptom Status						
Asymptomatic	260 (82.3%)	1 (1.2%)	<0.001	260 (85.2%)	1 (1.1%)	<0.001
Symptomatic	56 (17.7%)	83 (98.8%)		45 (14.8%)	94 (98.9%)	
Presence of Symptoms						
Fever	41 (13%)	65 (77.4%)	<0.001	30 (9.8%)	76 (80%)	<0.001
Cough	16 (5.1%)	36 (42.9%)	<0.001	11 (3.6%)	41 (43.2%)	<0.001
Cold	9 (2.8%)	24 (28.6%)	<0.001	8 (2.6%)	25 (26.3%)	<0.001
Sore Throat	5 (1.6%)	18 (21.4%)	<0.001	4 (1.3%)	19 (20%)	<0.001
Breathlessness	0 (0%)	1 (1.2%)	0.052	0 (0%)	1 (1.1%)	0.073
Vomiting	2 (0.6%)	0 (0%)	0.465	1 (0.3%)	1 (1.1%)	0.382
Head Ache	3 (0.9%)	4 (4.8%)	0.018	2 (0.7%)	5 (5.3%)	0.003
Dyspnoea	15 (4.7%)	6 (7.1%)	0.382	13 (4.3%)	8 (8.4%)	0.113
Loss of Smell	2 (0.6%)	3 (3.6%)	0.031	1 (0.3%)	4 (4.2%)	0.003
Loss of Taste	2 (0.6%)	5 (6%)	0.001	1 (0.3%)	6 (6.3%)	<0.001
Myalgia	5 (1.6%)	9 (10.7%)	<0.001	4 (1.3%)	10 (10.5%)	<0.001
Loss of Weight	1 (0.3%)	0 (0%)	0.606	1 (0.3%)	0 (0%)	0.576
Loss of Appetite	0 (0%)	1 (1.2%)	0.052	0 (0%)	1 (1.1%)	0.073
n (%) or Median (Min - Max)						
Fisher's Exact Test and Z proportion test was used at 5% level of Significance						

Significant association was found between the test results and gender, CT value, symptom status and symptoms such as fever, cough, cold, sore throat, headache, loss of smell, loss of taste and myalgia. (Table 7)

Discussion

The COVID-19 pandemic is a global public health concern, however the diagnosis is difficult because of its atypical clinical manifestations and symptoms. They share symptoms and signs which are common to many respiratory viruses and bacteria [14]. Rapid and reliable diagnostic strategies that can be useful for SARS-CoV-2 diagnosis are an essential requirement because of the mortality associated with certain sectors of people [15]. Our prospective study aimed to assess the diagnostic accuracy of a rapid antigen test in diagnosing SARS-CoV- 2 infection in a tertiary care testing facility. Among the 400 patients included, only 84 patients (21%) were positive by antigen test and 95 patients (23.75%) were positive by RT PCR. The antigen test was negative in 316 (79%) individuals and RT PCR was negative among 305 individuals (76.25%). 305(76.2%) samples tested negative by both methods, 11(2.8%) were positive by PCR but negative by Ag test, and 84(21%) tested positives by both methods.

The overall sensitivity of the STANDARD Q rapid antigen test was 88.4%, which is substantially higher than found in previous studies and the manufacturer's data which estimates around 84% [12]. The positive predictive value was found to be 100% and the negative predictive value was 96.5%. The accuracy of the test kit was interpreted to be 97.3% is similar with the study conducted by Treggiari D. [16] A sensitivity of 70.3% was observed in asymptomatic people which is discordant with our study and in symptomatic people 83.3% sensitivity and specificity of 100% were noted by Diez Flecha et al which is similar to our study [17].

The sensitivity and specificity of Antigen test was 85% and 100%, respectively by Escriva et al. The results of these studies are almost similar to our study [18]. In a study by Brummer et al. a pooled sensitivity and specificity of 71.2% and 98.9% was obtained and an overall sensitivity of 30.2% was noted in a study by Scohy et al which is very much lower compared to our study. [19,20] Sensitivity and specificity of the SARS-CoV-2 Rapid Antigen test published in the manufacturer's recommendations were found to be 84.38% and 100 [12]. The sensitivity in our study was found to be higher and the specificity was found to be equal.

The difference in our test performance from the other manufacturer of antigen kits could be due to various factors, including the quality of the sample collected, sample handling and quick processing techniques, batch of the kit used and the viral load [21].

In addition, we noticed that antigen detection assay–positive samples were from patients who had symptoms suggestive of SARS-CoV2 like fever, fatigue cough, myalgia and those patients who presented in the early days of the infection (median day of positivity-3 days) which is in par with the study done by Chaimayo et al. and Candel et al. [22,23] It was also found that the 11 false negatives had CT values above 28.This is similar to previously published studies by Krutggen et al and Diao et al. [24,25] When choosing which test to use, it is mandatory to know the purpose of the testing, whether it is for diagnostic or screening purposes, the level of community transmission, need for rapid results, and other considerations. Even a highly specific antigen test may have a poor positive predictive value and report a high number of false positives, when used in a community where the prevalence of infection is low [26].

The use of molecular testing in a community with high transmission and high prevalence may result in delays due to the time for processing and data entry. Positive and negative predictive values of both RTPCR and antigen tests vary depending upon the pretest probability. Pretest probability considers both the prevalence of the disease in the community transmission as well as the clinical context of the individual being tested [27, 28]

The performance of diagnostic tests depends on the circumstances in which they are tested. Both antigen tests and molecular tests perform best if the person is tested when their viral load is generally highest (5-7 days). Because antigen tests perform best in symptomatic people and within 5-7 days since symptom onset, antigen tests are used frequently on people who are symptomatic and in persons who has a known exposure to a person with COVID-19 [29,30, 31] Peña M et al has reported in their study that the sensitivity and specificity among the asymptomatic individuals to be 69.86% and 99.61% which is discordant with our study in which we reported the sensitivity and specificity to be 100% [32]. Data from the study conducted by Chu VT et al revealed the sensitivity among the symptomatic individuals to be 77%, which is contradictory to our study as it reported 88.3% sensitivity among the symptomatic individuals the difference in sensitivity may have aroused due to the usage of different rapid antigen kits used in the study [33]. Proper interpretation of both antigen test results and RTPCR is important for accurate clinical management of patients or people with suspected COVID-19, or for identification of infected people when used for screening. [34,35]

In conclusion, the accuracy of the STANDARD Q rapid antigen test in diagnosing SARS-CoV-2 infections in a tertiary care testing facility was higher than the manufacturer's data. The antigen test performs best when done in the early phase of the infection and for symptomatic patients. Therefore, the antigen assay may be an easy to perform alternative to differentiate infected from non-infected individuals.

Strengths and Limitations

The faster test result provided a significant role in COVID-19 screening, testing and contact tracing strategies to control the COVID-19 pandemic in areas that lack suitable laboratories to perform SARS-CoV-2 real-time RT-PCR diagnostics and in areas with high traffic of individuals such as airports, interregional bus and train stations or in any mass testing campaign requiring rapid results.

The participants in this study were suspected COVID-19 patients with symptoms and even asymptomatic individuals were included which was a positive factor in our study But the present study has some limitations. Firstly, our data were obtained in a particular clinical setting in a tertiary care hospital. The overall prevalence of COVID-19 in this population was not known and so the pretest probability could not be determined. Thus, the use of the test in other settings, such as screening, should be evaluated carefully. The infectivity of the positive reported individuals could not be evaluated because viral culture was not performed.

Conclusion

In conclusion, the antigen-based evaluated test is fast, easy to use and highly specific Standard Q Rapid Antigen Test kit is sensitive enough, because the minimum performance requirement for using an antigen test as SARS-CoV-2 diagnostic has a sensitivity higher than 80% compared with RT-PCR, our results are better than the recommended value. While considering its sensitivity, specificity, positive predictive value and negative predictive value this test could be used in basic screening as they provide faster results and is easy to use and cost efficient.

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