

Research Article

Prospective Study on the Usefulness of SARS Cov-2 Self-Testing Antigen Kits in Nephrology Practice

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Abstract

SARS CoV-2 virus detection using rapid Antigen diagnostic kit, is now widely used for detection and screening purposes. Self-testing antigen kits are recommended for high-risk individuals. The present study was done to see the utility of self-testing SARS CoV-2 kits as routine screening in hospital frequented by patients in nephrology services. Patients were divided into two groups those who can self-test themselves using self-antigen detection test and another group who were assisted in doing the same test and results compared. Out of 206 individuals who were involved in the study, 43 out of 206 (20.8%) showed positive results. 137 persons who self-tested had a significantly higher rate of failed tests in the first attempt compared to those who were in assisted antigen detection test group ($p < 0.05$). All patients who were found positive underwent mandatory RTPCR test. The detection of viral positive cases was similar in both groups and the sensitivity of the test was above 92% in both groups when compared with RTPCR results.

Conclusion: Self- Antigen detection test as routine screening during pandemic is useful point of care test for early detection and prevention of the spread of COVID-19 infection in hospital frequent visitors. Assisted antigen test must always be encouraged to avoid first time failure.

INTRODUCTION

Early detection, isolation, contact tracing, vaccination, and treatment are the main steps followed for the prevention and spread of Covid-19 disease [7]. sAg-RDT is approved by the Indian Council of Medical Research (ICMR) that can be used by individuals as a home screening method [8].

Renal disease patients are frequent hospital visitors for their various treatments and in the case of dialysis patients, they need to visit the dialysis unit weekly twice or thrice. Renal transplant patients and many renal disease patients take immunosuppression for their kidney disease and maintenance of graft function thus they are at high risk of contracting the virus compared to those who are not exposed in the community [9]. Though the reliability of the tests depends largely on the test performance and the respective sampling method sample collection and experience of the trained personnel to do the test, still the sensitivity and specificity of the index tests, i.e., rapid antigen detection tests are cheaper and preferred for rapid screening based on comparison to RT-PCR results acting as the reference standard [10]. The present study was done to see the utility of self-antigen testing as a routine screening method in kidney disease patients, their contacts, and health care workers who frequent the hospital. This prospective study was done during the second wave of the COVID-19 pandemic.

BACKGROUND

Timely and accurate diagnostic testing for SARS-CoV-2, the virus that causes COVID-19, is an essential part of a comprehensive COVID-19 response strategy. Of the two types of tests currently used for the diagnosis of SARS-CoV-2, 1) Detection of viral RNA, such as real-time reverse-transcription polymerase chain reaction (RT-PCR); and 2) Detection of viral antigens through immunodiagnostic techniques such as lateral flow assays, commonly called antigen rapid diagnostic test (Ag-RDT) [1, 2]. Ag-RDTs is a faster and reliable option for SARS-CoV-2 diagnosis and is often less expensive. Additionally, Ag-RDTs are effective for identifying most infectious people, whereas a limitation of RT-PCR is that it can lead to persistent positive results well past the period of transmission and recovery [3-5].

COVID-19 self-testing can be considered for diagnostic purposes in settings with ongoing community transmission and when used by symptomatic individuals or those who have been recently exposed to SARS-CoV-2. COVID-19 self-testing can also be considered for screening purposes irrespective of the level of community transmission [6]. Its usefulness in hospital frequent visitors as in nephrology practice in low or middle income countries are not studied well.

This present study aimed to see the usefulness of SARS-CoV-2 self-testing antigen rapid diagnostic test (sAg-RDT) in

nephrology practice. Compare the results between the test done by individuals themselves and those done under assistance.

MATERIALS AND METHODS

Individual selection: After obtaining hospital ethical committee approval, all individuals who were frequent hospital visitors needing to visit frequently the hospital for various reasons such as patients, their attenders, hospital workers, doctors, paramedical staff, and students were included in this study. Excluded from the study were individuals, as listed by the manufacturer including those with HIV and Hepatitis B and C positive individuals, those who were not willing to undergo the test, those who did not give consent, and those who were already admitted to hospital, individuals who had already undertaken sAg-RDT test.

Methods

@sight lateral flow immunochromatographic assay kits for the qualitative detection of COVID-19-specific antigens manufactured by Mediclone biotech were used in the present study. The kit had approval from the European Commission device identification no 277 indicated on their web site <https://covid-19-iagnostics.jrc.ec.europa.eu/devices/detail/277> Selected cases were given information as how the test is to be performed by simple video demonstration and dummy demonstration. Each individual who was willing to undergo the test was given two test kits and asked to follow the instructions shown in the video clip or the diagram given to them by the manufacturer. Patients were

divided into two groups, with one group who was agreeable to perform the test by themselves without assistance and Group II those who were assisted by trained personnel in performing the test. The assisted test method used a pharyngeal sample by way of individuals giving a sputum sample from the posterior part of their throat in a predetermined quantity.

Those who were found antigen test positive were automatically asked to do a mandatory RTPCR test and their identity was sent to the local covid intimation helpline for tracking and management. Statistical package for social science (SPSS) Version 25.0 Using this software frequencies and percentages were calculated for qualitative variables. To find association between categorical variables chi-square test were used. p value less than <0.05 considered as significant.

RESULTS

Demographic details of the study subjects are shown in table 1. Out of 206 individuals who formed the total study group, 147 were male and 69 female, sAg-RDT N= 137 formed Group I (Gp I) 78 were Male and 59 Female. In Assisted Ag-RDT group II (Gp II) there were 69 individuals, 59 male, and 10 female.

In GpI total of 85 individuals result was negative of which 41 were male and 44 females. 30 demonstrated positive tests, 20 were male and 10 female. 22/137 (16%) individuals did the test wrong in their first attempt of which 17 were male and 5 Female.

In Gp II out of 69 individuals who underwent assisted Ag-RDT, 59 were male and 10 female. 50 of 69 tested negative, 45

Table 1: Shows details of those who have undergone screening test for SARS CoV2 virus.

S No	N=206	S Ag-RDT GpI N=137	+ve GpI N=30	Fail GpI N=22	-Ve GpI N=85	A Ag-RDT GpII N= 69	+ve GpII N=13	-Ve GpII N=50	Failed GpII N=6	RTpccr +ve N=40	RTpccr -ve N=3
Male	147	78	20	17	41	59	8	45	6	23	5
Female	69	59	10	5	44	10	5	5	0	14	1
AGE											
<50	94	64	10	11	36	25	4	35	0	8	2
>50	112	73	20	11	49	44	9	15	6	32	1
CKD	10	6	2	4	0	4	1	0	3	3	0
HD	89	43	9	6	28	29	4	10	5	13	1
Tx	29	26	4	0	22	3	3	0	0	5	2
Immuno Sup	14	14	9	4	1	0	0	0	0	9	0
Attende-rs	26	12	1	1	10	10	4	5	1	5	0
Donors	8	4	0	0	4	4	0	4	0	0	0
Drs/HW/SW	19	19	3	2	14	0	0	0	0	3	0
Misc.	11	8	2	3	3	0	0	0	0	2	0
Comorbid											
DM	30	19	5	7	10	5	4	11	1	11	1
HBP	118	88	20	10	60	50	5	15	1	22	2
CVD	2	0	0	0	2	2	0	2	0	1	0
Others	37	30	5	5	13	12	4	2	4	6	0
Death	6	4	2	0	0	2	2	0	0	4	0
Admitted	22	12	8	2	2	10	6	4	0	22	4
Quarant-ined	32	21	10	11	0	11	7	3	1	26	2

ABBREVIATIONS: CKD- Chronic Kidney Disease; HD- Hemodialysis; Tx -Transplant; Drs- Doctors; HW- Health Workers; SW- Social Workers; Misc- Miscellaneous; DM- Diabetes Mellitus; HBP, High Blood Pressure; CVD- Cardio Vascular Disease.

were male, and 5 were female. The test result was positive in 13 individuals of which 8 were male and 5 female. 6/69 (8.6%) tests were failed tests. The reason for failure in Gp-I was adding too much diluent or dropping the sample all over the well observed in 16 individuals and 4 did not read the result in stipulated time wherein the control was negative and test positive, 2 dropped the kit during the procedure. In Gp II in all six the diluent drops were more than what was prescribed leading to flooding and wastage.

All 43 out of 206 individuals who tested positive had their RTPCT test done in which 40 were positive and 3 results came negative. In study Gp I 64 Individuals was less than 50 Yrs age and 73 were more than 50 yrs. In Gp II 35 were less than 50 yrs and 15 above 50 yrs, In the study group, 142 individuals overall had educational qualifications less than 10th grade and 61 above 10th grade. In Gp I, 43 had less than 10th grade and 26 below 10th grade. Hypertension was seen in 111/206, diabetes in 33/206, renal disease like end-stage kidney disease, chronic kidney disease, immunosuppressed and transplant patients formed 22/33(66.66%) and 11/33 were comorbid individuals with high blood pressure and diabetes. Of 6 Individuals who died 4 were patients were on hemodialysis. In Gp II both cases were post-transplant patients. In this study group of which 10 required hospitalization and Covid -19 specific monoclonal antibody concoction was used in two post-transplant individuals who relapsed after the first infection. In the study group, overall 66 were not vaccinated, 66 had vaccination first dose less than a week before the study, 12 had more than 2 weeks after the first dose and 7 had a second dose. 17 individuals who were not vaccinated were Ag-RDT positive, 14 who were positive had been exposed to the vaccine less than a week after the first dose and 4 beyond 2 weeks of first dose vaccination, and 7 had their second dose vaccinated

In gp1 the Ag-RDT sensitivity was 93% and in Gp II 92.3%. Individuals recovered with various treatments ranging from observation in 6, antibiotics, ivermectin, and steroids in 17, additional IV remdesivir given in four, and three received monoclonal antibody concoction two of whom were post-transplant and one lupus patient on immunosuppression. There was a significant test being failed in the GP I compared to Gp II $p < 0.05$.

There was no significant difference between Gp I and Gp II in the positivity and age or education status or gender difference in the antigen test.

DISCUSSION

Covid-19 Antigen tests are an important tool to detect infection [9]. Rapid antigen test kits are primarily recommended for the early detection of patients suspected of having COVID-19, particularly in countries with limited resources and laboratory equipment [10]. One of the main advantage of an antigen test is the speed of the test, which can provide results in minutes. Early detection of Covid 19 infection is important to treat and prevent the spread of infection. Though sAg- RDT is approved for individual use there are no data on the utility of sAg- RDT when used in diverse populations as in India that includes patients with lower income groups and lower literacy levels to understand how the test needs to be done.

In the present study, we found that the first-time users had a significantly higher failure rate in patients who were male, those with kidney failure and age less than 50 compared to when trained personnel did the test. This significant difference in failure of the self-testing antigen kits in first time users may be due to various reasons like fear and not being able to understand the steps which includes collection of sample, fixing it in diluent and placing the samples into the well in proper measures. This study showed no correlation concerning positive result incidence among gender, age, or educational standard between sAg-RDT Gp I and assisted Ag- RDT group II.

Though WHO initially advised not to rely on Ag-RDT as the point of care testing, subsequently the recommendation changed. Rapid screening was approved to use in crowded places or gatherings for screening [11]. In nephrology practice where patients despite illness or COVID-19 symptoms have to visit the hospital for their life-saving procedures, this test helps in the early detection of covid-19 [12, 13]. In our study, the incidence was around 20% overall which would have been not detected if routine screening was not done.

Regular screening by the RTPCR method is expensive. In the present study, we found that a rapid antigen test was able to detect asymptomatic individuals who would otherwise have been passed off as normal. Only three individuals who were Ag-RDT positive were found negative in RTPCR. The sensitivity and specificity was above 92%. Similar such results obtained prompted to use rapid antigen test as point of care test for detecting COVID -19 infection [14]. Causes of severe disease in the second COVID-19 episode are residual lung function abnormalities due to previous SARS-CoV-2 infection, as well as host susceptibility with recent use of antirejection treatment, Mortality was 6(2%) overall this is lower than the many other studies done in other centers during the covid -19 pandemic [13, 15, 16]. This lower rate is because we had done routine screening and early detection was the reason why we could treat the patients early.

The sensitivity among the first-time users who were found positive was no different from the Gp II. Mortality in covid infected hemodialysis patients is 30% more than the general population and renal transplant patients have 1.28 times more mortality than hemodialysis patients [15, 16]. In the present study, all mortality was in those who were on dialysis and post-transplant patients. Early detection is key to successfully managing patients and making a rapid recovery.

Vaccination is a powerful weapon to protect CKD patients from COVID-19, but it may cause recurrence or deterioration of kidney disease [10, 11]. In the present study, the vaccination was predominantly done for health care workers and only one case of covid that was found positive was asymptomatic all others were vaccinated at the first dose including 10 who received Gp 2.

CONCLUSION

sAg-RDT in routine use is a very useful test for early detection and prevention of the spread of COVID-19 infection hospital frequent visitors and nephrology practice. Assisted Ag-RDT must be always encouraged to reduce first-time failure rate.

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