

Ophthalmology practice in COVID-19 pandemic: Performance of rapid antigen test versus real time-reverse transcription polymerase chain reaction in a tertiary eye care institute in South India

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Purpose: To assess the rapid antigen test (RAT) against the gold standard reverse transcription-polymerase chain reaction (RT-PCR) to screen COVID-19 infection in asymptomatic patients undergoing ophthalmic procedures. **Methods:** This was a retrospective hospital-based study. Point-of-care (PoC) RAT was performed using nasopharyngeal swab, while RT-PCR for SARS-CoV-2 viral RNA was performed using both nasopharyngeal and throat swabs. **Results:** A total of 629 patients were tested for SARS-CoV-2 by using both RAT and RT-PCR. Only one patient had tested positive for SARS-CoV-2 with both RAT and RT-PCR, while two patients had tested positive with RT-PCR after an initial negative RAT. The positivity rate for RAT was 0.15% (1/629), and that for RT-PCR was 0.47%. Percent agreement or proportion of agreement observed between the two tests was 99.68%, while Cohen's kappa coefficient value was 0.49. The sensitivity of RAT in comparison to RT-PCR was 33.33%, specificity was 100%, positive predictive value was 100%, and negative predictive value was 99.68%. **Conclusion:** The sensitivity and Cohen's kappa coefficient in our study were low but that can be attributed to the overall low positivity rates with both RAT and RT-PCR. However, percent agreement observed between the two tests was very high. Therefore, we recommend initial screening of all the patients for COVID-19 symptoms followed by RAT before performing any ophthalmic surgical procedure to ensure the safety of the health care professionals as well as the patients.

Key words: COVID-19, ophthalmic surgery, rapid antigen test, RT-PCR

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has emerged as a novel human pathogen since it was first reported in the Wuhan province of China in December 2019. It has spread worldwide subsequently in the form of the coronavirus disease 2019 (COVID-19) pandemic.^[1,2] India has witnessed the first and the second waves of the pandemic, and the challenges faced by the country's public health systems are unprecedented. Rapid case identification and isolation are paramount in controlling the rapid spread of SARS-CoV-2 infections.^[1,3] As far as ophthalmic practice is concerned, the current COVID-19 pandemic remarkably impacted routine and emergency eye care services. The All India Ophthalmological Society (AIOS) had formulated a consensus statement for best practices during the first wave of the pandemic.^[4] As per the consensus statement, emergency eye care services continued with temporary suspension of all elective procedures. The elective clinical practice did, however, resume subsequently after a brief hiatus, albeit under a more cautious and safety-first approach. One of the critical components of the safety-first approach is developing appropriate testing strategies for COVID-19 and performing an adequate number of tests for screening and diagnosis.^[5-7]

Real-time reverse transcription-polymerase chain reaction (RT-PCR) is the gold standard for SARS-CoV-2 detection because of its high sensitivity and specificity.^[8]

However, it requires sophisticated equipment and logistics for sample transport to the laboratory. The results are available in batches, and practically it takes up to 24 h to receive the final results. Therefore, we need screening tests that can provide rapid and accurate tests for SARS-CoV-2 to facilitate preoperative screening for COVID-19, especially for emergencies.^[3,9-11] In this regard, immunoassays targeting SARS-CoV-2 antigens using monoclonal antibodies can complement RT-PCR as screening tests provided they have diagnostic accuracies comparable to RT-PCR.^[5,9,12-15]

In this study, we compared the performance of the Accucare™ COVID-19 Antigen Card Test (Mylab Discovery solutions) with the gold standard real-time RT-PCR to detect SARS-CoV-2 antigens in patients undergoing ocular emergency and elective procedures. All the patients included in the study were asymptomatic for COVID-19. This comparative analysis is critical in determining the feasibility and validity of the routine implementation of RAT as a screening tool for SARS-CoV-2 in asymptomatic patients before any ophthalmic procedure.

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Methods

This is a retrospective descriptive hospital data collection study conducted in a tertiary eye care hospital in South India from October 2020 to April 2021. The institutional ethics committee's approval was obtained for the study, and it adhered to the tenets of the declaration of Helsinki. Inclusion criteria included patients undergoing emergency ocular surgeries, elective ocular surgeries, and admission for ocular medical emergencies. Any symptomatic patient for COVID-19 during the initial screening was excluded from the study. Sociodemographic data such as name, age, and gender; systemic comorbidities; ocular diagnosis; and surgery/treatment details were recorded for each patient. As a part of preoperative/pre-admission workup, all patients had undergone nasopharyngeal and throat swabs. Rapid antigen test (RAT) was performed using nasopharyngeal swabs, while RT-PCR for SARS-CoV-2 viral RNA was performed using both nasopharyngeal and throat swabs. RAT was performed as a point-of-care (PoC) test in the Ophthalmology OPD or ward by the ophthalmology residents. All tests were performed under strictly controlled isolated conditions, with the residents wearing all recommended personal protective equipment. The microbiologist initially trained ophthalmology residents to collect swabs and perform the PoC-RAT. The ophthalmology residents initially analyzed and reported the test results. The images of the test cards were shared with the microbiologist. The diagnosis was then further confirmed and authorized by the microbiologist. Nasal swab and nasopharyngeal swabs for RT-PCR were also collected simultaneously and transported to the microbiology laboratory in a viral transport medium (VTM) tube without any delay while maintaining the cold chain conditions.

PoC-RAT was performed using Accucare™ COVID-19 Antigen Card Test (Mylab Discovery solutions), which was approved by the Indian Council of Medical Research (ICMR) in July 2020. All tests were performed and interpretations were made according to the manufacturer's recommendations. The sensitivity and specificity stated by the manufacturer were 84% and 100%, respectively, for this test kit.^[16] For real-time RT-PCR of SARS-CoV-2 viral RNA, samples were extracted using the magnetic bead extraction method (Thermo scientific viral isolation kit—5XMagMAX, Thermo Fischer scientific Baltics UAB, Vilnius, Lithuania) in Kingfisher platform by Thermofisher as per the manufacturer's instructions.

All recruited patients were screened at the OPD and emergency ward entry points for symptoms of COVID-19 (fever, fatigue, myalgia, sore throat, cold, cough, difficulty in breathing), travel history (international travel or travel to other cities in the last 2 weeks), contact history with suspected or confirmed COVID-19 case in previous 2 weeks, etc. as per AIOS operational guidelines and preferred practice patterns (PPPs).^[4] All patients also underwent a mandatory thermal screening. All emergency procedures were performed based on the RAT results, and RT-PCR reports were obtained subsequently. On the contrary, all elective procedures were performed only after obtaining the RT-PCR reports. RAT reports in such cases were used for initial screening for COVID-19 in asymptomatic patients. All surgeries were performed as daycare unless the patient required admission for associated medical conditions as per AIOS guidelines.^[4] Surgeries were performed by the most experienced surgeons of the OT team to ensure the quickest surgeries. RAT tests for elective procedures were done a day prior during preoperative evaluation. Non-contact tests were performed for all patients for preoperative evaluation, including IOP evaluation by non-contact tonometer, fundus evaluation by indirect ophthalmoscopy, and ocular biometry with IOL master

as per AIOS guidelines. The sample for RT-PCR was sent to the laboratory simultaneously, expecting the report to be available on the next day before the scheduled surgery. Any RAT positive report was considered confirmatory for COVID-19 as per ICMR advisory on strategy for COVID-19 Testing in India.^[16] Appropriate PPE was used during the procedures, and all infection prevention and control measures were followed as per MoHFW guidelines. Any patient who had tested positive for COVID-19 via RAT or RT-PCR was advised home isolation or admission in COVID-19 hospital based on MoHFW guidelines. The risks and benefits of emergency surgery carried out in a COVID-19-positive patient were discussed, and appropriate consent was taken. Under these circumstances, surgery was offered with strict isolation of the operating facilities and full personal protective equipment (PPE) for the involved staff.

The data collected were entered and analyzed using the IBM-SPSS program (SPSS version 20.0); SPSS Inc., Chicago, IL. Continuous variables were expressed as mean \pm SD, while categorical variables were expressed as frequency and percentages.

Results

We analyzed the details of 629 patients tested for SARS-CoV-2 by using both RAT and RT-PCR during the study period. The mean age of the patients was 52.37 + 18.11 (range: 0–83) years. Gender distribution was: males-384 (62%) and females-245 (38%). Six hundred (95.4%) patients underwent either elective ocular surgical procedures or admission from the OPD for medical management. The remaining 29 patients were admitted from the emergency. Seventeen cases required surgical management, while 12 needed medical management [Table 1].

Out of the 629 cases, one patient tested positive for SARS-CoV-2 with both RAT and RT-PCR, while two patients tested positive with only RT-PCR after an initial negative RAT. Percent agreement or proportion of agreement observed between the two tests was 99.68% (627/629), while Cohen's kappa coefficient value was 0.49. The positivity rate for RT-PCR was 0.47% (3/629). The positivity rate for RAT was

Table 1: Summary of all cases

Parameters	Value
Age (Mean+SD) years	52.37+18.11
Sex (Male/Female)	384/245
Total no of patients (n)	629
Elective Procedure (n=600)	
Cataract surgeries	372 (59.14%)
Vitreoretinal surgery	85 (13.52%)
Cornea & Refractive surgeries	43 (6.84%)
Glaucoma surgeries	42 (6.67%)
Squint surgeries	23 (3.65%)
Oculoplastic surgeries	15 (2.38%)
Medical management	20 (3.17%)
Emergency Procedure (n=29)	
Surgical management (n=17)	
Corneoscleral tear	15 (2.38%)
Therapeutic PK	2 (0.31%)
Medical Management (n=12)	
Orbital cellulitis	7 (1.11%)
Optic neuritis	5 (0.79%)

0.15% (1/629). Sensitivity of RAT compared to RT-PCR in our study was 33.33%, specificity was 100%, positive predictive value was 100%, and negative predictive value was 99.68%.

Clinical details of three positive cases are as below:

Case 1: Planned for cataract surgery; asymptomatic for COVID-19; RAT negative but RT-PCR positive. The patient was advised of home isolation.

Case 2: Planned for emergency therapeutic keratoplasty; asymptomatic for COVID-19; RAT negative but RT-PCR positive. The patient was advised of home isolation.

Case 3: Case of open globe injury planned for evisceration; asymptomatic for COVID-19; RAT positive, further confirmed by RT-PCR. The patient was admitted in the COVID-19 ward and subsequently underwent emergency surgery maintaining all protocols.

For the emergency surgical procedures done in 17 cases, the mean time gap between the initial assessment at the emergency ward to the initiation of surgery using RAT results was 5.06 + 3.1 h. This included testing time, preoperative planning and evaluation, and preparation of the operation theatre (OT). Test results were available within 30 min of performing the PoC-RAT in all cases. However, the mean time needed for obtaining the RT-PCR results for these cases was 12.88 + 1.45 h. Therefore, PoC-RAT provided the advantage of earlier preoperative planning and preparation in an emergency situation.

Discussion

Following the nationwide lockdown during the first and the second wave of the COVID-19 pandemic, all the eye care hospitals started services in a staggered manner. To minimize the spread of COVID-19 infection, all organizations had implemented protocols in the management of routine OPD services and diagnostic and surgical services.^[17] With the relaxation of the COVID-19 restrictions and reducing COVID-19 infection rates across the country, all the organizations had ramped up the routine health care services, including elective surgical procedures.^[18] However, due to the reluctance of resuming elective procedures during the first and the second waves of the COVID-19 pandemic, the backlog for elective ophthalmic surgical procedures has raised to a paramount level across the country. OPD attendance has, therefore, increased proportionately with the simultaneous increase in the risk of contracting the infection from asymptomatic patients.^[19] Ophthalmic surgeons have an added risk of acquiring nosocomial COVID-19 infection due to the proximity of the surgical field to the patient's nose and face.^[20] The respiratory droplets from the cough or sneeze can spread up to 6 m by exhaled air, which puts all the ophthalmic surgeons at an increased risk.^[21] Recent studies have also shown that tears and conjunctival secretions contain the SARS-CoV-2 virus in systemically asymptomatic patients.^[22] Hence, to prevent the spread of COVID-19 infection and protect the health care team, it is essential to confirm that the patient is not actively infected during an elective or emergency surgical procedure.

Testing strategies employed to detect SARS-CoV-2 include rapid antigen tests (RAT) and real-time RT-PCR. RATs are quick tests for detecting SARS-CoV-2 viral antigen with a rapid turnaround time of 15-30 min, thereby offering a considerable advantage of quick detection of cases, prompt isolation, and treatment.^[23] RAT has an added advantage of point-of-care (PoC) testing. This is very useful as a screening tool in a high volume and quick surgical turnover setup such as ophthalmic surgeries.

However, RAT has the disadvantage of variable sensitivity and specificity as compared to the gold standard RT-PCR in diagnosing COVID-19 infection. Test-track-treat is the strategy adopted by the government to reduce COVID-19 transmission. ICMR has also recommended PoC-RAT to be used in combination with RT-PCR in the hospitals for asymptomatic patients planned for elective procedures.^[24] As newer antigen detection test kits for COVID-19 infection are getting introduced, the overall concern of their performance compared to RT-PCR in terms of sensitivity and specificity is also increasing. As per ICMR guidelines, the minimum acceptance criteria of sensitivity and specificity of RAT kits is $\geq 50\%$ and $\geq 95\%$, respectively, when used as a PoC test without transport to a laboratory setup. When it is validated in a laboratory setup with samples collected in viral transport medium (VTM), sensitivity is $\geq 70\%$ and specificity is $\geq 99\%$. We also need to consider few other points while using RAT as a screening tool. If PoC-RAT is done in the acute stage of the disease or during the first week of the symptom onset, the sensitivity and specificity will be high and comparable to RT-PCR. However, the sensitivity of RAT will be lower late in the disease course.^[25] In addition, the sensitivity of PoC-RAT will be higher in patients with high viral load.^[13] From a practical perspective, knowledge of these factors regarding PoC-RAT is very important to apply it on various scenarios such as screening for asymptomatic health care workers, patients planned for elective or emergency surgical procedures, and in large-scale testing.^[8]

In our study, PoC-RAT was performed for all patients along with the gold standard RT-PCR. All patients were asymptomatic in our study. Percent agreement or proportion of agreement observed between the two tests was 99.68%, which indicates a very high degree of agreement. Cohen's kappa coefficient value was 0.49, which indicates only a moderate agreement. Sensitivity of RAT in comparison to RT-PCR in our study was 33.33%, while specificity was 100%. Cohen's kappa coefficient and sensitivity values calculated in our study were low because of the low positivity rates of RAT (0.15%) and RT-PCR (0.47%). The plausible explanations of the low positivity rates can be that all the patients in our study were asymptomatic for COVID-19 infection. All patients were thoroughly screened at different entry points of the hospital, and multilayered safety protocols were employed at various levels after entry into the hospital to identify any symptomatic COVID-19 patient. Furthermore, the overall positivity rate among the general population in the catchment region for the institute during the study period time was low.

RT-PCR remains the gold standard test for diagnosing SARS-CoV-2 infections. Still, it is a laboratory-based procedure that needs cutting-edge technology and equipment, trained health care workers, transportation of the samples, and finally, the communication of the results. Timing of the clinical sampling and testing with RT-PCR is also critical as the shedding of the virus mainly happens during the early phase of the disease course. Due to a large number of people needing testing and limited recourses, the delay in procuring the RT-PCR results is also an expected issue. In addition, the majority of the care centers in India are standalone hospitals that do not have easy access to National Accreditation Board for Laboratories (NABL)-accredited laboratories to conduct an RT-PCR. Procuring an RT-PCR result in remote parts of India can be as delayed as 48-72 h, which can decide the outcome in an emergency situation. In our study, the initial assessment of surgery using RAT results was 5.06 + 3.1 h, while the mean time for obtaining the RT-PCR results for these cases was 12.88 + 1.45 h. Therefore, we had a mean lead time of around 7 h for surgery in these cases, which is critical in any emergency.

Recently, some studies have shown that RAT is sensitive enough to be comparable with RT-PCR in the diagnosis of SARS-CoV-2 infection. Kumar *et al.*^[7] conducted a similar study where they compared RAT with RT-PCR in asymptomatic patients planned for elective ophthalmic procedures. In their study, only two among 204 patients tested positive with both RAT and RT-PCR, while 10 patients tested negative with RAT but were found to be positive with RT-PCR. However, RAT was done in the laboratory in this study, whereas we performed a POC-RAT test in our study. Tripathy *et al.*^[5] performed POC-RAT in a study on asymptomatic preoperative ophthalmic elective procedure patients. The results showed only 7/224 patients (3.1%) to be COVID-19 positive. Chiamayo *et al.*^[9] in their comparative analysis of RAT versus RT-PCR observed that RAT was capable enough for detecting COVID-19 infection in various samples with comparable sensitivity and specificity (98.33% and 98.73%, respectively). In a study by Porte *et al.*^[13] the diagnostic accuracy of the fluorescence immunochromatographic SARS-CoV-2 antigen test (Bioeasy Biotechnology Co., Shenzhen, China) was compared with SARS-CoV-2 RT-PCR among 127 COVID-19-suspected patients. The sensitivity and specificity of SARS-CoV-2 antigen test was 93.9% and 100%, respectively, with a diagnostic accuracy of 96.1% and Kappa coefficient of 0.9. The sensitivity of the antigen detection test was significantly higher in samples with high viral loads. Yamayoshi *et al.*^[1] in their study compared four RAT kits, and their sensitivity and specificity were compared with RT-PCR with different clinical samples of the COVID-19-suspected patients. The results were quite similar for all four test kits, and it showed higher chance of detection of COVID-19 in individuals who are shedding a large amount of SARS-CoV-2. Cormon *et al.*^[3] conducted a study where they compared seven commercial SARS-CoV-2 rapid point-of-care antigen tests (AgPOCT) with 138 clinical samples that had previously tested positive for SARS-CoV-2 by RT-PCR. Following the study, they concluded that the sensitivity range of most Ag-POCTs overlaps with SARS-CoV-2 viral loads typically in the first week of symptoms. Thus, AgPOCTs can diagnose COVID-19 infection faster and can help in decision-making in various areas of health care and public health. Another study on preoperative COVID-19 testing for elective vitreoretinal surgeries by Kannan *et al.*^[17] in a tertiary eye care center in South India concluded that 1 among 45 asymptomatic patients may become positive on RT-PCR.

Strength of the study

- Rapid antigen test for COVID-19 infection was done as a point-of-care (POC-RAT) test for all patients, thereby facilitating pre-operative screening for COVID-19.
- Double validation of our RAT results was done initially by the ophthalmology resident and was then subsequently confirmed by the microbiologist.
- RAT results were compared with RT-PCR results in all cases.
- High specificity of our study results.

Study limitations

- Cohen's kappa coefficient and sensitivity values calculated in our study were low because of the low positivity rates of RAT (0.15%) and RT-PCR (0.47%) in asymptomatic preoperative patients. Thus, it limits the degree of extrapolation of our study results. Therefore, we need further multicentric large-scale prospective studies in the future in asymptomatic preoperative patients.
- Corresponding viral load or cycle threshold (Ct) values were not estimated. Thus, correlation between the cases missed on RAT could not be determined.

Conclusion

We understand that safety of the health care team and patients is of highest importance. Rapid antigen detection tests may not be able to diagnose every case of SARS-CoV-2 infection as they are not as sensitive as RT-PCR. However, these false-negative cases are less infective, and the chances of transmission are less. The sensitivity and Cohen's kappa coefficient in our study were low, but that can be attributed to the overall low positivity rates with both RAT and RT-PCR. However, the percent agreement observed between the two tests was 99.68%. We, therefore, recommend that all emergency ophthalmic procedures can be performed with only rapid antigen tests by following strict safety protocols and wearing PPE. We have just crossed the second wave of COVID-19 infection, and currently, the positivity rate in the general population has also reduced. Performing RT-PCR for every patient who needs an elective ophthalmic procedure is not practical and economically feasible. Initial screening of all the patients for COVID-19 symptoms at the OPD entry followed by RAT before performing any elective procedure can be the way forward. The surgical team should use adequate PPE and strictly follow all the protocols irrespective of the patient's infection status to reduce the risk of transmission of SARS-CoV-2.

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Conflicts of interest

There are no conflicts of interest.

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