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Commentary: Can we depend on the point-of-care rapid antigen testing for SARS-CoV-2 for routine ophthalmic procedures and high volume ophthalmic settings?

The first confirmed case of SARS-CoV-2 was reported in 2019 from China, and more than 24 months have passed since the reports of the first coronavirus case in India. The global coronavirus pandemic impacted the world deeply, challenging public health care systems, and had an unprecedented impact on ocular services.[1] The rapid surge in COVID-19 cases mandated lockdown measures across the globe, and this led to a reduction and near-total halt of routine and elective ophthalmic procedures in every hospital. Only emergency surgeries were undertaken based on the consensus statement and guidelines suggested by the All India Ophthalmological Society (AIOS).[2] This deeply impacted the routine delivery of eye care services, economic and financial downfall, and increased emergency cases like phacolytic glaucoma, advanced diabetic eye disease, acute angle-closure glaucoma, and non-resolving corneal ulcers. Once the lockdown phase was over, this was followed by a slow and careful return to routine eye care services. But there was still a fear of performing elective surgical procedures due to contact transmission and the spread of the virus through the ocular surface. The AIOS guidelines suggested a safety approach with appropriate COVID-19 testing before ophthalmic surgical procedures. Thus, there was a definitive need to develop new testing strategies to continue the professional activities safely. It is well known that the most sensitive and specific gold standard test for COVID-19 detection is reverse transcription-polymerase chain reaction (RT-PCR) using a throat swab, saliva, or nasopharyngeal swab. It is not always feasible to perform an RT-PCR due to the high cost, barriers in sample procurement, transport, lab facility, sophisticated and costly equipment, and results in batches usually available after 24 hours. Hence, there was a need to develop antigen detection kits (immunoassays) that could be rapid and available for point-of-care testing (PoC) to facilitate screening for elective ophthalmic procedures and backlog of cases at high-volume tertiary eye care centers, Especially the cataract surgery.

Moreover, while developing these kits, it was mandated that these kits should be comparable in diagnostic accuracy to avoid false-positive and false-negative results. This issue was also considered by the Indian Council of Medical Research (ICMR).[3] They suggested using a validated rapid chromatographic immunoassay called the Standard Q COVID-19 Ag detection kit (SD, Biosensor, South Korea) for qualitative SARS-CoV-2 antigen detection for hospital health care staff and asymptomatic patients undergoing aerosol-generating procedures.

Recently, a large number of studies were performed on this similar concept, giving insights on the point-of-care rapid antigen test (PoC-RAT). Tripathy *et al*.,[4] in their retrospective analysis of 311 subjects with PoC-RAT, showed an overall positivity rate of 7%. They concluded that these tests could be considered for routine screening of asymptomatic patients, contact tracing, and testing of hospital health care staff at a high-volume tertiary eye care hospital. Gans *et al*.[5] in their

analysis from Canada showed that 903,408 RATs conducted for 537 workplaces had 1,322 (0.15%) positive results, of which 1,103 were PCR positive. The false-positive samples were 0.05% (462) out of 42% PCR positive samples. They concluded that the overall false-positive rate of RAT is very low and in accordance with other studies. Chiamayo *et al*.[6] did a comparative analysis of Standard Q COVID-19 Ag kit for RAT SARS-CoV-2 detection versus Allplex 2019-nCoV Assay (RT-PCR) in 454 respiratory samples. They found that 60 patients (13.2%) were positive, and 394 patient samples (86.8%) were negative for COVID-19 by RT-PCR. The sensitivity and specificity of RAT were 98.33% and 98.73%, respectively, which was comparable to RT-PCR. Hence, they concluded that RAT could be employed as a screening test in a large volume setting with comparable results. Similarly, Pena *et al*.[7] did a comparative analysis of RAT versus RT-PCR in 842 asymptomatic Chilean individuals. Their results depicted a sensitivity of 69.86% and specificity of 99.61%. The positive predictive value (PPV) was 94.44%, and the negative predictive value (NPV) was 97.22%, with a Ct value >27 that was comparatively higher in patients with false-negative RAT. They concluded that RAT is a valuable tool for screening asymptomatic individuals in places that lack suitable NABH accredited RT-PCR laboratory facilities or where immediate results are warranted. A Cochrane review by Dinnes *et al*.[8] detailed the accuracy of multiple RATs. They found that out of 37 evaluations for symptomatic individuals, the average sensitivity was 72%, while in 12 evaluations from asymptomatic individuals, the sensitivity was 59.1%.

In the present study,[9] the authors analyzed a large sample of 629 asymptomatic individuals undergoing ophthalmic procedures by assessing the PoC-RAT against RT-PCR for screening of the COVID-19 virus. The analysis depicted that one patient turned out to be positive with both RAT and RT-PCR while two patients who were initially negative with RAT tested positive with RT-PCR later. The percent accordance between the two tests was very high, 99.68% and Cohen's kappa coefficient was 0.49, indicating moderate agreement. The RAT rate was 0.15% (1/629), RT-PCR was 0.47% (3/629), and sensitivity was 33%, specificity was 100%, PPV 100% and NPV 99.68%. Since only asymptomatic individuals were tested, the positivity rate was low from the analysis. The Cohen kappa coefficient was also low due to the low positivity of RAT and RT-PCR. The results from the study are highly encouraging and can be taken as a benchmark for future studies. Thus, to conclude, PoC-RAT tests are rapid antigen tests that provide quick results in 15–30 minutes, and help in faster diagnosis, prompt isolation and treatment. RAT is a useful tool for high volume throughput screening and rapid surgical turnover during routine ophthalmic surgical procedures with a disadvantage of variable sensitivity and specificity. Currently, there are more than 170 RAT kits available in the market with variable results, but few are extensively validated. Based on the literature available, it can be concluded that we can very well depend on PoC-RAT for SARS-CoV-2 for routine ophthalmic procedures and high-volume ophthalmic settings.

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