

Point-of-care rapid antigen testing for COVID-19 at a tertiary eye care facility: Role in commencement of elective surgeries, contact tracing and implementation of back-to-work policy

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Purpose: The aim of this study was to report the use and the impact of a point-of-care rapid antigen test (PoC-RAT) at a tertiary eye care facility in facilitating commencement of elective surgeries, contact tracing of exposed health care professionals (HCPs) and ancillary hospital staff, and implementation of back-to-work (BTW) policy for them. **Methods:** Retrospective analysis of subjects undergoing PoC-RAT for COVID-19 infection at a tertiary level dedicated eye care facility. Decision making with regard to commencement of elective surgeries post COVID-19 related discontinuation of services, contact tracing of HCPs and ancillary hospital staff exposed to known COVID-19 cases and implementation of back-to-work policy for all staff based upon the results of PoC-RAT were studied. **Results:** A total of 311 subjects (224 patients and 87 hospital staff) were tested. Overall positivity rate was around 7%. Asymptomatic patients who were screened preoperatively had a lower positivity rate at around 3% compared to the staff (who were either known contacts or were symptomatic) at around 17%. Contact tracing found three-quarters of the staff at low risk and only one quarter at medium or high risk. Among patients, 97% of those followed up for at least 2 weeks after the test remained healthy. For staff, this was around 65%. **Conclusion:** Based on our preliminary results, we suggest that PoC-RAT may be considered routinely for indication-based preoperative screening of asymptomatic patients, and for on-campus screening, contact tracing and implementation of BTW policies for HCPs and ancillary hospital staff at a tertiary level eye care facility.

Key words: Contact tracing, COVID-19, elective surgery, point-of-care rapid antigen test

The ongoing COVID-19 pandemic caused by the SARS-CoV-2 virus has seen an unprecedented impact on eye care services. The government-mandated country-wide lockdown saw a temporary suspension of all routine eye care services with only emergency care being available as guided by the consensus statement of the All India Ophthalmological Society.^[1] This was followed by a gradual, cautious return towards routine elective clinical practice. The moot question under consideration was – for how long can the return to elective practice be

pushed back? A recent editorial opined that one must prepare or perish.^[2] The need was to adapt to the “new normal” and continue with professional activities in a safe and effective manner.^[2]

Safety remains the cornerstone in the resumption of elective eye care services. To establish norms of safety, tests and testing strategies for COVID-19 play equally critical roles. A recent checklist by the American Academy of Ophthalmology recommends use of set protocols to screen patients for COVID-19 prior to surgery.^[3] However, guidelines for a testing protocol are not provided. A plethora of tests (molecular, antigen, serological, ancillary) are currently available to diagnose COVID-19, each with its distinct role, limitations, and applications.^[4,5] The Indian Council of Medical Research (ICMR), while stating that real-time reverse transcription-polymerase chain reaction (RT-PCR) is the gold standard for diagnosis of

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COVID-19, also mentions that several logistical issues (need for specialized laboratory equipment, biosafety, and biosecurity, longer turnaround times, comparatively higher costs and issues regarding collection and transportation of samples) limit the widespread use of this testing modality.^[6] Added to this, the vast majority of standalone eye care centers in India do not have specialized in-house National Accreditation Board for Laboratories (NABL) accredited laboratories to conduct an RT-PCR. Realizing these challenges, we formulated a testing strategy at our tertiary eye care center using a PoC-RAT aimed at screening patients for COVID-19 before taking them up for elective ophthalmic surgeries, screening on-campus HCPs and other staff, and to implement an effective in-house BTW policy to address the issue of critical staff shortages. This report documents our experience with the PoC-RAT over 7 weeks in the midst of the ongoing COVID-19 pandemic.

Methods

Institutional review board approval was duly obtained for this study. Data collected over a period of 7 weeks (July 24 to September 13, 2020) was included for study. During this period the staff (HCPs and ancillary staff) worked as two groups. Each group manned duties over three working days covering one half of the working week. Intermingling was avoided as strictly as possible. A Standard Operating Protocol (SOP) by the Hospital Infection Control Committee (HICC) based upon recommendations of the appropriate health authority^[7,8] for infection prevention and control was strictly in force. Monitoring of adherence to the SOP was carried out through daily audits and weekly review meetings. At the time of writing, this SOP remains in force and the staff continues to work as two teams.

The PoC-RAT was initiated at our institute with the following objectives: 1) to preoperatively screen all asymptomatic patients undergoing elective ophthalmic surgical procedures that were deemed to be potentially aerosol generating (any procedure under general anesthesia including examination under anesthesia for children, invasive procedures involving the nasal and oral mucosa and those using radiofrequency cautery, bone drill or burr), 2) to test on-campus staff who either self-reported or were detected with symptoms suggestive of COVID-19 (acute respiratory infection with fever $\geq 38^{\circ}\text{C}$ and cough),^[6] or who were risk-stratified as contacts on tracing after exposure to a confirmed COVID-19 case, and, 3) to implement an in-house BTW policy aimed at mitigating critical staff shortages at the workplace.

The rapid Standard Q COVID-19 Ag testing kit manufactured by SD Biosensor, South Korea was used for the tests. At the time of procurement in July 2020, this was the sole company that had been authorized by the Government of India to make rapid antigen test kits commercially available for purchase and the unit price was four-hundred and fifty Indian rupees (INR 450) with additional applicable taxes. The test was conducted and interpreted as per the manufacturer's recommendations^[9] on samples collected by a nasopharyngeal swab. The manufacturer officially states the test to have a sensitivity of 96.52% (95% CI, 91.33–99.04%) and a specificity of 99.68% (95% CI, 98.22–99.99%).^[8] In two separate studies reported by the ICMR, the test sensitivity ranged between 50.6–84% (with higher sensitivity correlating with higher viral loads) and specificity 99.3–100% in the Indian population.^[6] The tests were conducted under

strictly controlled isolated conditions with all recommended personal protective measures for the testing personnel.

The testing strategy followed for the PoC-RAT was based on the advisory issued by the ICMR on June 23, 2020 as outlined in the algorithm in Fig. 1.^[10]

For patients scheduled to undergo elective surgery, the PoC-RAT was administered one day prior. Those who tested positive were immediately isolated and the information was shared with the appropriate public health authorities for further necessary management.^[11] All patients who tested negative underwent a screening pulse oximetry with a resting SpO_2 of $\geq 95\%$ being considered acceptable.^[12] Those with a resting SpO_2 of $< 95\%$ were advised a physician consultation with a chest X-ray screening as needed.

HCPs and staff within the institute were sensitized about the need to make sure that emergency globe and vision salvaging surgeries were to be taken up regardless of the result of the PoC-RAT. If such patients were positive on testing, a counseling session with the concerned family was mandatorily conducted. The risks and benefits of emergency surgery carried out in a known 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 and appropriate personal protective equipment (PPE) for the involved staff as per protocol outlined in the SOP.

For risk stratification of staff on contact tracing, a tiered approach was used with categorization into high-, medium-, and low-risk levels.^[13] The details are presented in Table 1.

Staff who self-reported or were detected with symptoms suggestive of COVID-19 were subjected to the PoC-RAT. If positive, they were deemed to be true positives, and were advised isolation for at least 14 days from the day of development of symptoms.^[7] If negative, they were subjected to the RT-PCR test for further confirmation of COVID-19 infection [Fig. 1].^[10]

For staff who were detected through contact tracing and were categorized as high or medium risk, 14 days of quarantine from the day of the last exposure was advised [Table 1].^[13] The BTW policy was implemented based on this risk stratification. When asymptomatic, they were tested by the PoC-RAT between day 5 and day 7 after the last exposure. When symptomatic, testing was expedited. In case of a negative PoC-RAT in presence of symptoms, RT-PCR testing was undertaken as per protocol [Fig. 1].^[10] If medium-risk contacts tested negative on the PoC-RAT and remained asymptomatic, they were advised to report back at work after 7 days of quarantine. Thereafter, they continued work with appropriate PPE and under strict monitoring of symptoms over the next 7 days.

Those deemed to be at low risk were allowed to work with strict personal protection and monitoring [Table 1].^[13] Testing was carried out if any individual became symptomatic while under supervision. Initial testing was with the PoC-RAT, and if negative, was followed up with RT-PCR testing as per protocol.^[10]

Table 1: Epidemiologic Risk Classification for Asymptomatic Healthcare Personnel Following Exposure to Patients with Coronavirus Disease 2019 (COVID-19) or their Secretions/Excretions in a Healthcare Setting, and their Associated Monitoring and Work Restriction Recommendations^[13]

Epidemiologic risk factors	Exposure category	Recommended Monitoring for COVID-19 (until 14 days after last potential exposure)	Work Restrictions for Asymptomatic HCP
Prolonged (more than 15 minutes) close contact with a patient with COVID-19 (beginning 48 hours before symptom onset) who was wearing a cloth face covering or facemask (i.e., source control present)			
HCP PPE: None	Medium	Active	Exclude from work for 14 days after last exposure
HCP PPE: Not wearing a facemask or respirator	Medium	Active	Exclude from work for 14 days after last exposure
HCP PPE: Not wearing eye protection	Low	Self with delegated supervision	None
HCP PPE: Not wearing gown or gloves ^a	Low	Self with delegated supervision	None
HCP PPE: Wearing all recommended PPE (except wearing a facemask instead of a respirator)	Low	Self with delegated supervision	None
Prolonged (more than 15 minutes) close contact with a patient with COVID-19 (beginning 48 hours before symptom onset) who was not wearing a cloth face covering or facemask (i.e., source control absent)			
HCP PPE: None	High	Active	Exclude from work for 14 days after last exposure
HCP PPE: Not wearing a facemask or respirator	High	Active	Exclude from work for 14 days after last exposure
HCP PPE: Not wearing eye protection ^b	Medium	Active	Exclude from work for 14 days after last exposure
HCP PPE: Not wearing gown or gloves ^{a,b}	Low	Self with delegated supervision	None
HCP PPE: Wearing all recommended PPE (except wearing a facemask instead of a respirator) ^b	Low	Self with delegated supervision	None

^aThe risk category for these rows would be elevated by one level if HCP had extensive body contact with the patients (e.g., rolling the patient). ^bThe risk category for these rows would be elevated by one level if HCP performed or were present for a procedure likely to generate higher concentrations of respiratory secretions or aerosols (e.g., cardiopulmonary resuscitation, intubation, extubation, bronchoscopy, nebulizer therapy, sputum induction). For example, HCP who were wearing a gown, gloves, eye protection and a facemask (instead of a respirator) during an aerosol generating procedure would be considered to have a medium-risk exposure. The highest risk exposure category that applies to each person should be used to guide monitoring and work restrictions. While respirators confer a higher level of protection than facemasks and are recommended when caring for patients with COVID-19, facemasks still confer some level of protection to HCP, which was factored into assessment of risk. "Close contacts" were defined as individuals who were within approximately 2 meters (6 feet) of a known COVID-19 case with or without any mask or other protection (protective eyewear, gown or gloves) for a continuous period of 15 minutes or more or were in the same room as the patient for more than one hour

Patients, staff, and contacts who tested negative with the PoC-RAT and remained asymptomatic were followed up over telephone after at least 2 weeks to determine whether symptoms developed in this time period. This could also be done for a smaller subset of patients and staff who had completed ≥ 2 weeks follow up after the test.

Results

Within the study period, a total of 311 subjects underwent the PoC-RAT. Of these, 27.9% (87 cases) were hospital staff (HCPs and ancillary staff) and 72.1% (224 cases) were asymptomatic patients screened for COVID-19 before elective surgery. An overview of the results is presented in Fig. 2.

The overall positivity rate for the entire set of subjects tested was 7.01%. Patient positivity rate was 3.1% and staff positivity rate was 17.2%. Among staff who tested positive, most were detected on contact tracing of confirmed COVID-19 cases, but some had either self-reported symptoms or were detected with symptoms while at work and were recommended a screening test.

On contact tracing, 190 staff were detected as contacts of confirmed COVID-19 cases. Of these 74.2% were at low risk,

24.2% at medium risk and 1.6% at high-risk exposure [Fig. 3] based on the stratification outlined in Table 1.^[13] All three high risk contacts (100%) went on to develop symptoms and tested positive for COVID-19. On the other hand, only seven of the medium risk contacts (15.2%) and two of the low-risk contacts (2.1%) became symptomatic and tested positive for the disease. Among the medium risk contacts, 47.8% who were asymptomatic and tested negative on PoC-RAT, were allowed to join back work after 7 days of quarantine. Among the staff testing positive, 26.7% were HCPs who were directly involved with patient care and the remaining 73.3% were involved in ancillary services within the campus that were not directly related to patient care. Sixty percent of the staff testing positive were symptomatic at the time of the test.

A phone call at least 2 weeks or more after the PoC-RAT allowed an assessment of the health status of 137 patients. Staff who had completed at least 2 weeks of follow up after PoC-RAT numbered 47 at the time of writing. This exercise was undertaken primarily to monitor for possible development of symptoms that could be suggestive of onset of COVID-19 infection. Among the patients, 133 cases reported good health and had not developed any symptoms till the end of the 2 weeks follow up period. Three patients had expired due

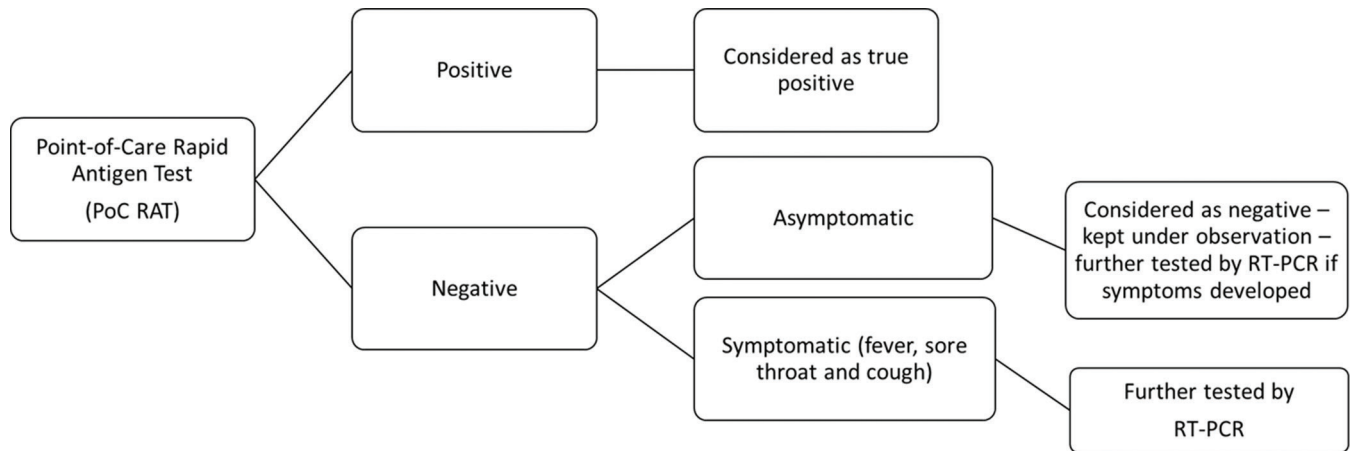


Figure 1: Testing strategy followed for the PoC-RAT

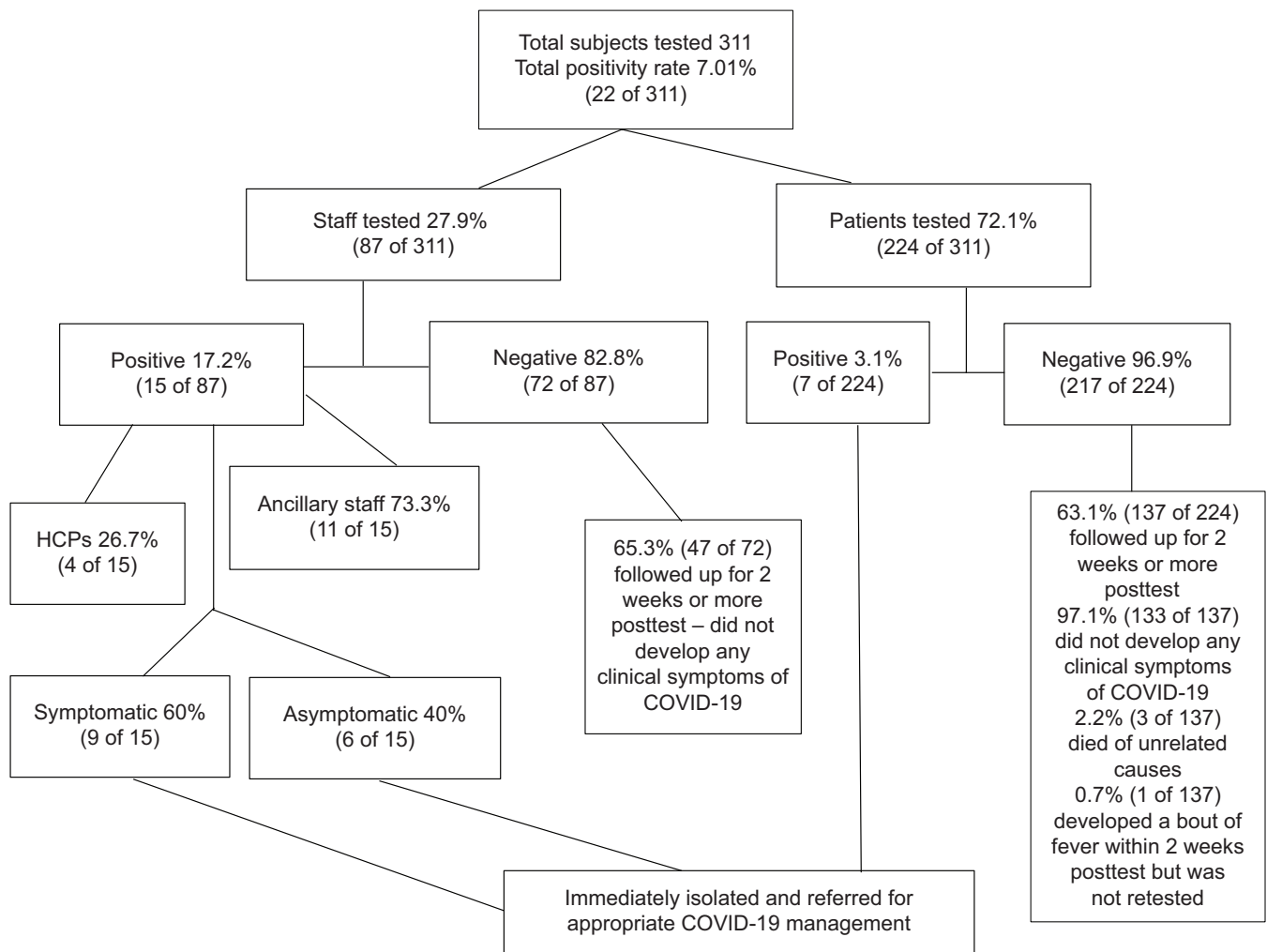


Figure 2: An overview of the results

to unrelated causes. One case had non-specific fever but had not been tested further. All 47 of the hospital staff remained asymptomatic till the end of the 2 weeks follow up period. At the time of writing, none of the positive cases detected among the hospital staff had required inpatient admission for their infection and had either recovered well or were convalescing

under home or institutional isolation with conservative medical management.

Over the period of 7 weeks, the operation levels of the institute vis-à-vis outpatient and surgery numbers in parallel with the percentage of staff who were available for work and the percentage of the total sanctioned staff strength who

were off work for COVID-19 related reasons (staff who tested positive for the disease on the PoC-RAT and those quarantined on contact tracing) is depicted graphically in Fig. 4. While operations of the institute gradually increased over a period of 7 weeks, staff absenteeism also rose over the same period. While this was around 5% at the beginning (close to the pre-COVID-19 average absenteeism of 4%), it steadily climbed to nearly three-fold of the initial level (to over 15%) by the end of the study period consequent to a rise in the number of staff testing positive on the PoC-RAT and the increasing quarantine numbers on contact tracing.

Discussion

Eye care organizations in India are often standalone health facilities and rarely have an in-house NABL accredited laboratory. Following a complete nation-wide lockdown, the unlocking phase saw eye care organizations gradually commence services and ramp up operations from emergency to elective services in a phased manner. Most of them put in place safety protocols as mandated by the government – triage

at entry points, dividing HCPs into teams, PPE and strict surveillance to mitigate transmission in health care settings. With *test-track-treat* remaining the core strategy opted by the government to mitigate transmission, the ICMR recommended use of PoC-RAT in hospitals for symptomatic HCPs and asymptomatic patients planned for elective aerosol-generating procedures.^[6,10] The ICMR guidelines also mandated RT-PCR for symptomatic HCPs who test negative with PoC-RAT.^[6,10] This was advised because of the moderate sensitivity of the PoC-RAT.

Our experience over 7 weeks showed an overall 7% cases (22/311) testing positive with a lower positivity rate observed among patients (3%) and a relatively higher positivity rate (17%) among the healthcare facility staff. This difference in rates is likely due to the fact that the patients screened preoperatively were all asymptomatic in contrast to the staff who were either contacts of known COVID patients or had developed de-novo symptoms. A rapid result from the PoC-RAT facilitated an early and quick isolation of the COVID positive personnel and prevented further risk of exposure among HCPs and other staff. A multi-tiered safety protocol ensured three quarters (74%) of the staff were at low-risk of exposure despite contact with known COVID positive individuals. Hospital-to-patient transmission was low with 97% of screened patients not developing any symptoms even 2 weeks after elective surgery. COVID-related absenteeism, however, was almost three-fold higher among the staff in COVID times as compared to the pre-COVID era, and eye care organizations are well advised to keep adequate reserve bench strength to ensure the continuity of their services.

To facilitate ramping up of operations on an elective basis, staff were distributed into 2 teams from June 2020. Each team was divided such that all functional departments were represented and the team members could ensure smooth

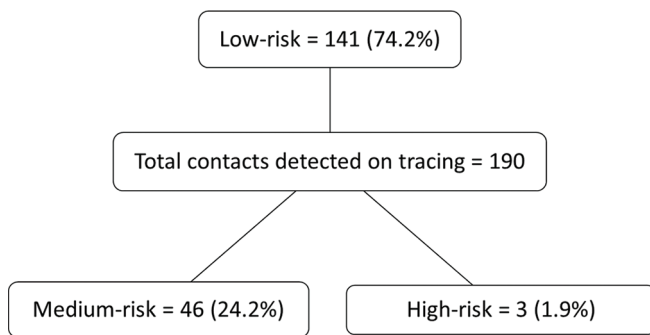


Figure 3: Stratification and distribution of contacts on contact tracing

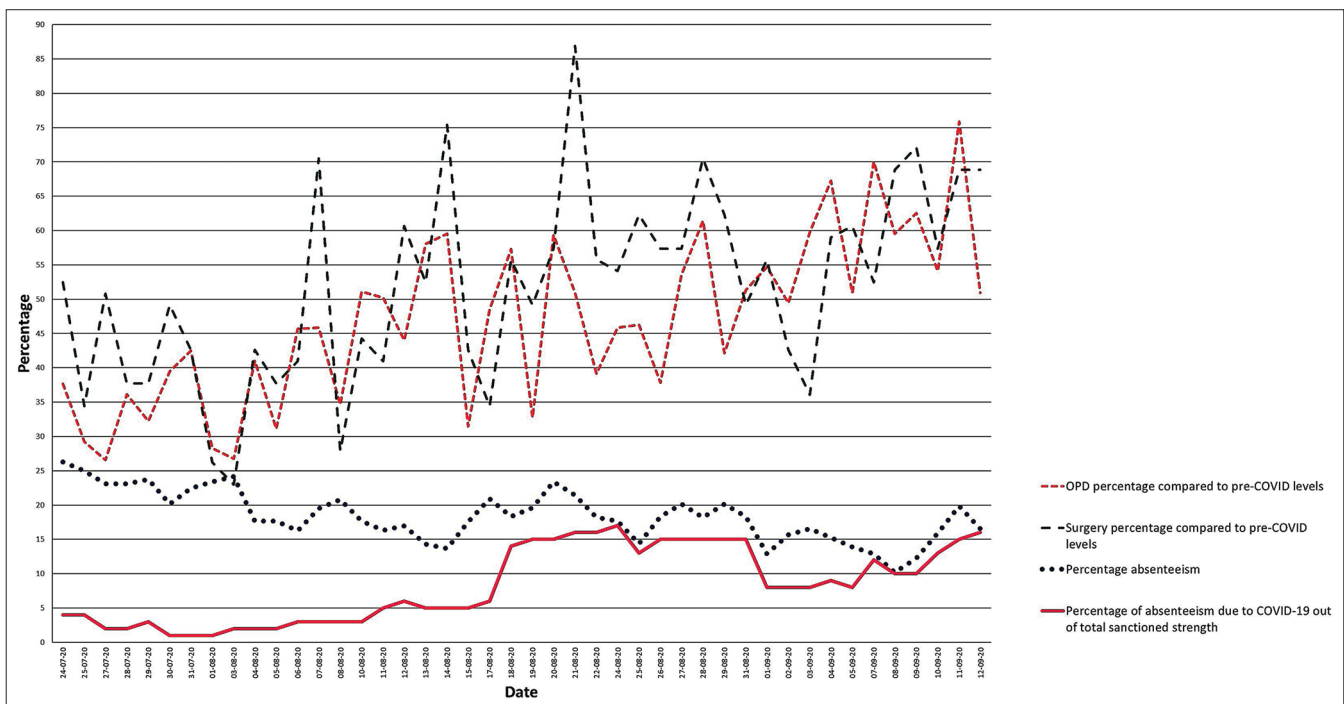


Figure 4: Graph depicting trends in OPD, surgery and absenteeism rates

functioning of all services. A code grey SOP was formulated that defined testing strategies for all staff and surgical patients, risk stratification and quarantine guidelines, and BTW policy. Over 7 weeks, the contact tracing team found a quarter of the staff (26%) were at middle – high risk of exposure [Table 1] and thus were advised quarantine for 2 weeks. A large majority of the staff (74%) were at low risk of exposure. This may be attributed to strict adherence of the staff to prescribed safety protocols. Staff at low-risk continued to work with adequate PPE and this helped maintain the work force to remain above critical threshold levels essential for functionality. In the rare scenario when gaps in the work force became wider than manageable, supervisors were allowed the liberty to draw replacements from the members of the other team.

Based on the PoC-RAT results, staff positivity was around 17%. Among these, 60% developed symptoms, and 40% remained asymptomatic during the course of their infection. At the time of writing, none of those infected had needed admission as inpatients to COVID facilities, and had either completely recovered or were convalescing from their illness. Staff (83%) who were negative on PoC-RAT remained asymptomatic, with 65% of these having completed >2 weeks of follow-up and doing well.

One of the major challenges eye care organizations have faced during the pandemic is the simultaneous ramping up of their own operations and the added responsibility of allaying fears of patients of getting infected on a routine visit to seek eye care services. This is particularly relevant as a large majority of patients seeking eye care services tend to belong to the elderly age groups known to be vulnerable to COVID-19. PoC-RAT for asymptomatic patients planned for possible aerosol generating procedures brought in a third layer of safety in addition to the triaging protocols and use of personal protection (masks/gloves/face visors). Recent recommendations strongly advocate routine preoperative screening of asymptomatic patients for elective surgery.^[14] In our set up, we found only a 3% (7/224) positivity rate among the patients who were screened. Of these, 57% (4/7) had mild symptoms and no fever, and were therefore able to slip past the triage at the point of entry. No patient who tested negative on PoC-RAT was found to have low oxygen saturation. Telephonic conversation with 63% (137/224) patients who had completed ≥ 2 weeks follow up after the test and surgery revealed that 97% had not developed any symptoms and were doing well. Three had succumbed to unrelated pre-existing co-morbidities and only one had developed fever. Unfortunately, none of them had been re-tested for COVID-19.

Among the staff who were COVID positive, a quarter were HCPs (positivity 27%) and three quarters worked in ancillary departments (positivity 73%). This trend pointed towards a possibility of contracting the infection while not at work – possibly out at community interactions including the place of residence. It has been described that depending on the phase of the pandemic, patients with COVID-19 disease may not be the major source of infection in a healthcare setting.^[14] This has special significance for a standalone eyecare institution as these facilities are less likely to encounter COVID positive patients on a regular basis as compared to a multidisciplinary healthcare facility. Nevertheless, HCPs and staff can be exposed to multiple other sources of infection like infected family members and other contacts or COVID positive patients out in

the community especially if they reside in geographical areas of active transmission.^[15] This was also demonstrated within our study period where the increase in staff absenteeism due to COVID-19 related reasons [Fig. 3] paralleled an increase in the community transmission rates. Here again, contact tracing, risk stratification and rapid testing to isolate positive contacts played a key role in the infection containment measures within the campus of the institute. Administrative personnel need to recognize this challenge and need to have appropriate strategies lined up to deal with it.

At our center, the overall positivity rate was 6.3% in contacts of COVID-19 patients with the PoC-RAT. To put things into perspective, the clinical positivity rate (total number of symptomatic patients in the entire study population) was 4.2% (13 of 311 cases) and the total testing positivity rate was 7.01% (22 of 311 cases). Positivity rates among contacts tested with RT-PCR reported in studies with much larger sample sizes from other bigger, tertiary level multidisciplinary hospitals are around 3%.^[16] Contact tracing and risk stratification play key roles in deciding quarantine protocols. This is critical at a healthcare institution regarding operational efficiency. Availability of an on-campus point-of-care test that provides rapid results is a huge advantage in this scenario and helps significantly in implementation of BTW policies. In our case, nearly half (47.8%) of medium risk contacts were able to come back to work earlier as they tested to be negative on the PoC-RAT and continue to remain asymptomatic. In absence of testing, these staff would have been quarantined for 14 days only on the basis of risk stratification [Table 1]. This helped in a major way to ensure that operational efficiency did not suffer significantly.

Conclusion

While we acknowledge that a limitation of this study is the lack of a comparison between PoC-RAT and the gold standard for diagnosis (RT-PCR), based on our experience, we still believe that the PoC-RAT is an extremely useful tool. We suggest that it may be considered routinely for indication-based preoperative screening of asymptomatic patients, for on-campus contact tracing of hospital staff and as a basis for implementation of BTW policies for HCPs and ancillary staff for eye care facilities at the tertiary level.

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Conflicts of interest

There are no conflicts of interest.

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