DOI: 10.7860/NJLM/2023/59393.2744

Original Article

Microbiology Section

Pre-surgical Screening for SARS-CoV-2 Testing in Elective Procedures in High Burden Resource Limited Settings: A Retrospective Observational Study

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ABSTRACT

Introduction: Pre-surgical screening of patients for COVID-19 by Reverse transcription-Polymerase Chain Reaction (RT-PCR) is essential before surgeries as a precautionary measure in view of preventing COVID-19 to the health care workers. The inception of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-COV-2) posed major hurdles and challenges in conducting elective surgeries. Considering that COVID-19 is expected to continue to be a problem for the public health system in the near future, institutions will need to create risk mitigation strategies with meticulous resource management especially in high burden centers.

Aim: To assess the role and need of repeat RT-PCR testing after an initial negative at a tertiary care center in view of the ever changing dynamics of COVID-19.

Materials and Methods: A retrospective observational study was conducted at the Mobile Virology Research & Diagnostic Laboratory in the Department of Microbiology, ESIC Medical College & Hospital, Hyderabad between September 2020 to May 2021. Pre- surgical cases admitted at the facility during the study period with ≥72 h duration of stay who have been tested for SARS-COV-2 RT-PCR more than once within a period of one week were included. RT-PCR testing was performed according to standard protocols. Clinical and demographic data were collected, including reasons for re-testing.

Results: A total of 2398 patients were admitted for surgeries during the study period, out of which 697 cases had a prolonged stay ≥72 h. In all of the cases, the initial test was negative, but 11 (1.58%) of them converted to positive. During the zenith of the second wave, the conversion rate was 4%, whereas it was only 0.2% during non peak periods.

Conclusion: Hence, it was concluded that to optimise the usefulness of pre-surgical screening test for SARS-COV-2, repeat testing may be avoided in a low burden setting with timely reassessment based on local positivity rate. Each facility should continuously reassess their needs based on sudden local surges to optimise utilisation, especially when faced with resource constraints and changing paradigm of the pandemic.

Keywords: Coronavirus disease, Reverse transcriptase polymerase chain reaction, Severe acute respiratory syndrome coronavirus-2

INTRODUCTION

The COVID-19 pandemic has resulted in a slew of modifications in patient care standards across the globe. Elective operations in India were suspended from March to May 2020. During the lockdown, outpatient consultations and non emergency surgery dropped from around 20 per day and 40 per month to nearly zero [1]. A 28.4 million surgeries were canceled globally during the pandemic [2].

Asymptomatic carriage affects one in every fourteen patients in their facility, according to an Indian research, and 24.51% of patients overall, according to another [2,3]. Asymptomatic carriage and its role to transmission are 30%, according to a CDC Atlanta study [4]. According to a study, enhanced, more precise reporting of methodologies and sample frames are needed due to asymptomatic carriage and its potential for community transmission [5]. The ordering of serial testing for those under investigation was prompted largely by concerns about transmission prevention especially by asymptomatic carriers, case reports of false-negative initial test results and a lack of information on test performance. Furthermore, there was a conundrum due to various specialty associations laying down separate guidelines due to international emergency and lack of clarity resulting in repeat testing of samples within a week in admitted patients [6-14].

Sparse literature is available in the Indian scenario with strategies for RT-PCR testing for COVID-19 in elective cases as a part of pre-surgical screening protocols [10]. Hence, this study aimed to investigate the value of repeat RT-PCR testing in preoperative surgical cases for SARS-CoV2 in relation to the COVID-19 surges in India at a high burden resource limited tertiary care institute in Hyderabad.

MATERIALS AND METHODS

This retrospective observational study was conducted at the Mobile Virology Research and Diagnostic Laboratory in the Department of Microbiology, ESIC Medical College and Hospital, Hyderabad. The study was undertaken between September 2020 to May 2021. The study period coincided with the COVID-19 outbreak in India, which was between two peaks (First Peak- September 2020 and Second Peak- April-May 2021) [15]. Ethical clearance was obtained from the Institutional Ethical Committee (IEC-F292/05-2021). Informed consent was taken from all the patients for SARS-COV-2 RT-PCR testing prior to sample collection.

Inclusion criteria: All patients requiring surgical intervention who had a prolonged stay ≥72 hours after an initial negative SARS-COV-2 RT-PCR with more than one Nasopharyngeal (NP) swab tested within a week (7 days) were included.

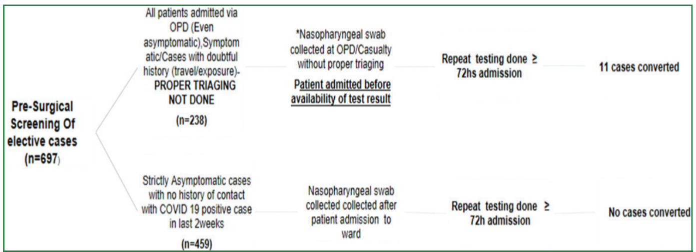
Exclusion criteria:

- Patients shifted from other hospitals with initial SARS-COV-2 RT-PCR done at other labs.

- Patients undergoing emergency surgeries were excluded.

Study Procedure

The NP swab of the patients were collected, transported and tested as per the National guidelines laid down by ICMR [12]. All the patients were tested prior to admission and before the procedure as per the flowchart (Strategy 1) [Table/Fig-1] during the study period. Following identification of COVID-19 cases in India as per the guidelines issued by MOHFW and ICMR, the screening of the patients was done using COVID-19 RT-PCR prior to admission for any surgical procedure [6]. As per Institutional Policy framed in consensus with National Surgery Society [8] and International Anesthesiology Society guidelines [9], pre-surgical retesting for SARS-COV2 RT-PCR was carried out. This was done with a view of providing higher safety to the healthcare workers during any surgical intervention that entailed aerosol-generating procedures, general anesthesia or close contact with the patients during the procedure.



[Table/Fig-1]: Pre-surgical screening protocol at the institute.

Sample processing: The COVID-19 RT-PCR was performed as per the guidelines in a ICMR approved BSL-2 laboratory [6,12]. Due to frequent shortages of reagents, different ICMR approved multiplex RT-PCR kits were used as per the availability. The RT-PCR kits used were: COVID sure, NIV pune (ICMR-NIV), Meril COVID-19 one Step RT-PCR Kit (Meril), VIRALDTECT-II Multiplex RT-PCR Kit for COVID-19 Genes2me, nCOV-19 RT-PCR detection kit (Multiplex) (Q line) AllplexTM 2019-nCoV Assay (Seegene).

Sample interpretation: In all reactions, positive and negative controls were used and they were tested in parallel with the clinical specimens to ascertain validity. Only reaction with valid controls was considered for reporting. Samples were considered positive if the cycle threshold (Ct) value was ≤35.

STATISTICAL ANALYSIS

Data was collected and analysed using MS Excel and SPSS 24.0 software. All the categorical variables were expressed in frequency and percentages. Chi-square test was done to assess the significance in between the groups. Continuous variables were expressed as means. The Pearson correlation was used to determine the relationship between the conversion rate and the calculated positivity rate for each month. Receiver Operator Characteristic curve (ROC curve) was used to assess the best cut-off, sensitivity and specificity. The probability less than 0.05 was considered as significant. The rate of conversion of the patients was compared with the institutional positivity rate. The Area Under the Curve (AUC) is a useful tool for summarising the overall diagnostic accuracy of repeat testing when the positivity rate is high. It accepts numbers between 0 and 1, with 0 indicating a perfectly inaccurate test and 1 indicating a perfectly accurate test. An AUC=0.5 suggests no discrimination ability to predict disease.0.7 to 0.8 is considered acceptable, 0.8 to 0.9 is considered excellent ability to predict conversions in a setup of high positivity [16].

RESULTS

During the study period, 2398 patients were admitted for surgical procedures, out of which 697 patients had a prolonged pre-surgical stay of ≥72 h in the hospital with more than one NP swab tested for SARS-COV-2 RT-PCR within a week. Three hundred and eighty three (48.4%) patients, belonged to age group of 25-40 years.

Out of 697, 11 (1.58%) patients [Table/Fig-2] were found to be positive on repeat testing. The Casualty department (without proper triaging) was traced as initial first point of contact among the patients who tested positive after an initial negative SARS-CoV-2 RT-PCR test, whereas no conversions were seen in planned in patients admission after getting the initial negative test results [Table/Fig-2].

	No. of patients	No. of patients positive on testing after >72h of admission
Total number patients admitted for surgical intervention	2398	-
No. of patients admitted for more than 72 h prior to surgical intervention	697	11 (1.58%)
Mode of admission		
Casualty/out-patient admission (Without proper triaging)	238	11 (4.6%)
Planned inpatient admissions	459	0
Age wise distribution		
<12 y	13	1 (7.2%)
12-24 y	98	0
25-40 y	338	7 (2.07%)
>40 y	248	3 (1.21%)
Gender		
Male	257	6 (2.33%)
Female	440	5 (1.13%)

[Table/Fig-2]: Distribution of the patients admitted for surgical intervention during Sept 2020 to May 2021.

During the peak period (September-October 2020 and April-May 2021), the conversion rate was 4% much higher than during the non peak season 0.2%.On comparing the conversions in peak and non peak periods, the chi-square statistic was 14.9265 and the p-value was 0.000112, which was statistically significant. Among the total conversions that were 11 overall, 63.6% (7/11) and 27.7% (3/11) of the conversions occurred during the 2nd wave (April & May 2021, respectively). These findings were statistically significant ($p < 0.05$) [Table/Fig-3].

The Pearson correlation measures the strength of the linear relationship between two variables. The Pearson correlation was calculated for the number of conversions in relation to month wise positivity rate. The conversion rate was much greater during the months when the positivity rate was higher. The correlation r-value was 0.172, ($p<0.05$) [Table/Fig-4]. A significant relationship between conversion and positivity rate was observed on applying the ROC curve analysis with the AUC being 0.793. The conversion rate exhibited sensitivity of 90.9% and specificity of 66.1% at a best cut-off peak positivity rate of 17.5%. This implied it's an acceptable predictor of conversions in a set-up of high positivity [Table/Fig-5,6].

Total positivity rate in males was 54.4% compared to females' 45.5%. The conversion were seen to be predominant in age group 25-40 years in females and >40 years in males. Among those who converted, 54.54% subjects had comorbidities. Reasons for repeat testing were found to be being a primary contact of known positive cases or development of symptoms of COVID-19 prior to surgery in 63.6%, whereas 27.27% were sent for routine pre-surgical screening [Table/Fig-7].

Based on these findings preoperative screening strategy was reformulated [Table/Fig-8].

It was observed that during the 1st strategy [Table/Fig-1] patients were tested without a strict proper triaging at the casualty and were admitted in wards before receiving the results of the SARS-COV-2 RT-PCR tests, whereas during the 3rd wave the strategy for testing was re-framed [Table/Fig-7] in January 2022 ensuring a prior triage, transmission based precautions and admission policy into the ward only after receiving a negative SARS-COV-2 RT-PCR result.

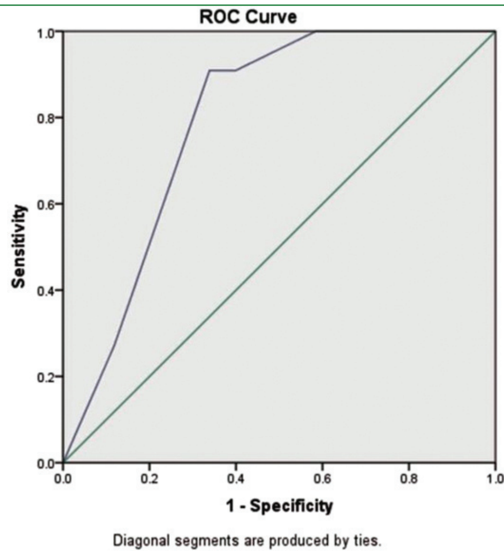
Month	Patients tested at 72 h: No. of patients tested (A)	Patients tested at 72 h: % of patients found positive (A1)	Patients tested >72 h (within 1 week of first negative RT-PCR): No. of patients tested (B)	Patients tested >72 h (within 1 week of first negative RT-PCR): % of patients found positive (B1)	Total no. of patients retested (A+B)	Total no. of patients negative on retesting	% of total patients found positive	Positive rate at institute	Test period	% of overall conversion during peaks/ non peak
September	10	0 (0)	20	0	30	30	0 (0)	10.1%	Peak of 1st wave	0
October	16	0 (0)	24	0	40	40	0(0)	6.1%		
November	28	0 (0)	68	0	96	96	0 (0)	7.78%	Non peak	1*
December	36	0 (0)	58	0	94	94	0 (0)	7.48%		
January	44	0 (0)	49	2.04 (01)	93	92	1.08 (1)	7.20%		
February	36	0	48	0	84	84	0 (0)	2.50%		
March	36	0	46	0	82	82	0 (0)	6.18% (245)		
April	57	3.51(02)	59	8.4 (05)	116	109	6.03 (7)	25.15%	Peak of 2nd wave	10*
May	28	7.14 (02)	34	2.94 (01)	62	59	4.84 (3)	25.5% (1467)		
Total	291	1.76 (04)	406	10.44 (07)	697	686	1.58 (11#)			

Conversions	Peak	Non peak	Marginal row total	Chi-square
Negative-Positive	10	1	11	Chi-square 14.9265
p-value 0.00112				
Negative-Negative	238	448	686	
Total	248	449	697	

[Table/Fig-3]: Month wise distribution of the cases.
*1/449 (0.2%) conversions in non peak period and 10/248 (4%) conversions in peak periods; #Among 11 conversions, 7/11 (63.6%) & 3/11 (27.2%) coincided with the peak of 2nd wave when positivity period was the highest

Statistical significance		Percentage positivity
Conversions mark only conversions as 1	r-value	-0.172**
	p-value	0.001 (<0.05)

[Table/Fig-4]: Table depicting the statistical 'p' and 'r' values for Pearson correlation test of conversion rate during the months.
Conversions on repeat testing were marked as "1" and no conversion marked as "0"



[Table/Fig-5]: Receiver operating characteristic curve (ROC curve) analysis showed Area Under the Curve (AUC) to be 0.793, with a significant relation between conversion on repeat testing and positivity rate.

Area	Std. error[a]	Asymptotic sig.[b]	Asymptotic 95% Confidence Interval: Lower bound	Asymptotic 95% Confidence Interval: Upper bound
0.793	0.041	0.001	0.712	0.875

[Table/Fig-6]: Depicting area under ROC curve between conversion and positivity rate.

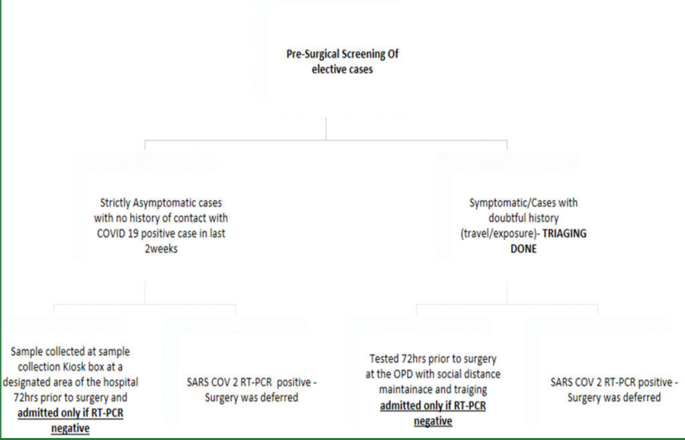
Patients ID	Age (Years)	Gender	Department	Co-morbidities	Reason for retesting
Patient 1	59	M	Surgical ward	Choledochal cyst with bilateral inguinal hernia	Primary contact of known positive case. Acute onset of cough post surgery
Patients 2	27	F	Surgical ward	Nil	Primary contact of known positive case
Patients 3	28	F	Obstetrics	Gestational hypertension	Primary contact of known positive case.Symptomatic day 5 days postsurgery
Patients 4	36	F	Surgical ward	Nil	Routine pre-surgical screening
Patients 5	39	M	Surgical ward	Nil	Primary contact of known positive case
Patients 6	25	M	Orthopaedic	Nil	Routine pre-surgical screening
Patients 7	27	F	Obstetrics	Type 1 DM, Hypothyroidism, Twin Pregnancy	Primary contact of known positive case
Patients 8	30	F	Obstetrics	Nil	Routine pre-surgical screening
Patients 9	39	M	Surgical ward	Nil	Symptomatic, Primary contact of known positive case
Patients 10	1	M	Surgical ward	Chronic sinus over scalp with associated osteomyelitis	Routine pre-surgical screening
Patients 11	60	M	Surgical ward	Chronic subacute leukaemia	Primary contact of known positive case, onset of cough

[Table/Fig-7]: Comorbidities in cases showing conversions from negative to positive on repeat testing.

DISCUSSION

The vision of this retrospective study was to make recommendations for formulating institutional principles and establishing a pre-operative testing policy at the Institute. Cancellation or rescheduling of procedures also necessitates testing 48 to 72 h before the procedure, as per the established criteria [7-11].

In the present study, 11 cases (1.58%) converted from negative to positive. In all of these patients, the first swab for testing was taken at the Casualty Department (first point of contact), which is consistent with Long DR et al., wherein a study was conducted



[Table/Fig-8]: Proper triaging & infection control practice among pre surgical patients was implemented strictly to avoid mixing with other patient who was undergoing screening for SARS-COV-2 RT-PCR test.

in two large healthcare facilities with 22/626 (3.5%) conversions from negative to positive. As per the data, the initial testing site in majority of conversions was the emergency/outpatient department [17]. Another multicentric research states that most of the samples were collected in the outpatient setting (82%), with a small percentage collected in the emergency department (13%) or inpatient setting (5%) & 22/1113 (2%) tested positive [18]. Lepak AJ et al., found that among inpatients undergoing a repeat asymptomatic screen test, none of the samples on repeat testing within a week showed any change in results [7]. This could indicate community exposure in the casualty/emergency departments in absence of proper triaging. The variation in conversions could be attributable to differences in the incidence of positive rates in certain geographic regions, the mutant strain in circulation at the time the study was done, and the reproducibility rate, which is a measure of the virus's transmissibility.

Males converted at a higher rate (54.54%) than females (45.45%). Males over the age of 40 were the most impacted, while females between the ages of 25 and 40 were the most affected. Many studies have shown that older males have a higher incidence of COVID-19 due to various factors like smoking, cardiovascular illness, and COPD [19,20]. Liu R et al., concluded that male (40.43%) and older population had a significant higher positive rates, and Green DA et al., stated that repeat-tested positive patients (52.2%) were more likely to be older, male, and of non Caucasian race [21,22]. The preponderance of conversions was seen in older males in the current study, which is consistent with the aforementioned literature.

In the current study, the correlation between conversions from negative to positive in relation to the positivity rate at the institute during to the 2^{nd} wave in India has been analysed. The month of April accounted for 63.6% of all conversions, followed by the months of May with 27.3%. A study conducted in New York revealed that 60% of conversions occurred after the peak commenced, with a p-value of 0.001 [22] which is consistent with the findings of the current study [22].

The link between conversions with a higher number of positives was determined to be significant (p-value <0.05) using chi-square analysis and Pearson's correlation test. Reproduction numbers (Rt >1) is an estimate of the real time surges in infection [15,22]. Most of the Indian states had a reproduction number Rt >1 during the 2nd wave implying faster transmission in comparison to the 1st wave [15]. Reproduction numbers (Rt >1), less stringent lockdowns during the 2^{nd} wave could have contributed to the higher positivity rate and increased conversions.

When comparing conversion rates during peak and non peak times, it was observed that peak periods (high incidence periods) had a much greater conversion rate (4%) than non peak periods (low incidence periods) (0.2%). A study conducted in high prevalence setting showed the conversion rates as high as 18.6% [22], whereas in low prevalence settings a study showed conversions as low as 0.9% [7]. These finding imply that in low prevalence setting repeat testing of SARS-COV-2 RT-PCR may be avoided within the seven day time interval which reasonably reduces the waiting time for surgical procedures and also lessens the physical and psychological implications on a patients.

Limitation(s)

The strains recovered from patients who had conversions in results from negative to positive could not be further examined at the genomics level to assess variants and mutations, which is the study's present limitation. Since, its a single center, retroprospective observational study, demographics, and reason for resting may vary from center to center hence the results may not be generalised to the entire population.

CONCLUSION(S)

The present study suggests that repeat pre-surgical screening for SARS-COV-2 RT-PCR within one week for asymptomatic cases is unnecessary especially in low prevalence settings in high throughput center. Proper infection control management, triaging and admission of patients after initial negative screening into wards may help utilise the finances and manpower in a better way and reduces the waiting time for surgical procedures. These results helped re-frame a strategy which helped proper channelisation of resources. Thus, a proper diagnostic stewardship must be in place to direct the resources in a high burden center.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Aug 10, 2022
- Manual Googling: Jan 21, 2023
- iThenticate Software: Jan 25, 2023 (5%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? No
- For any images presented appropriate consent has been obtained from the subjects. No

Date of Submission: **Aug 04, 2022**
Date of Peer Review: **Sep 29, 2022**
Date of Acceptance: **Jan 27, 2023**
Date of Publishing: **Jul 01, 2023**