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# Comparative sensitivity and specificity of common COVID investigations – an observational study from a tertiary care centre in North Bengal, India

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**ABSTRACT**
**Introduction:** Novel Corona virus or Covid 19 pandemic Started in early 2020 and is still continuing though with much less severity. In this study we aim to look into the sensitivity of common diagnostic methods employed and also determine the features of infection in radiology specifically Computed tomography.
**Methods**: This is a non-randomized open label study of patients admitted with suggestive symptoms of Covid 19 infection analysed retrospectively.
**Results**: 216 patients both Covid& Non-Covid was included in the study. 154 male patients (71.3%) and 62 female patients (28.7%) were included. Males have a higher risk of getting Covid (RR 1.8483, 95% CI 1.2965 to 2.6350). Older age was associated with higher risk (95% Confidence Interval [CI] -10.9653 to -2.1147, p value .004). Most common presenting symptoms among Covid patients were Shortness of Breath (SOB – 77.66%) followed by fever (75.53%) and Cough (42.55%). Study results showed that RAT has a sensitivity of 57.14% (39.35-73.68 95% C.I) and specificity of 100% (82.35 -100.00 95% C.I). Rt-PCR has a sensitivity of 12.5% (6.41 - 21.27 95% C.I) & specificity of 100% (95.14-100.00 95% C.I). HRCT showed a sensitivity of 94.31% (88.63-97.68 95% C.I) & specificity of 92.39% (84.95-96.89 95% C.I). Mean CT severity score was 11.99± 4.45 and mean CO-RADS was 4.9± 0.54. Ground Glass opacities (GGO) & consolidation was the commonest CT findings in our patients.
**Conclusion**: Very high sensitivity & specificity CT scan when combined with any other antigen detection method will be valuable for diagnostic as well as prognostic purposes.
**Key Words** :Covid 19, HRCT, RAT, RTPCR, CORADS, CT severity scores

## I. BACKGROUND/ INTRODUCTION:

The current pandemic corona virus Disease-2019 has been caused by the infection of a newly discovered species of corona virus(named 2019-novel coronavirus,2019nCov called severe acute respiratory syndrome (SARS-COV2) corona virus 2 and belongs to genera Beta corona virus family Coronavidae[1]. SARS CoV2 is a positive sense,non-segmented single stranded RNA virus with a genome of ~30000 bases[1]. Coronavirus disease 2019 (COVID-19), was firstdescribed in a case series of 41 individuals presenting with undeterminedforms of pneumonias in Wuhan, China, duringDecember 2019[2.]

Transmission in asymptomatic cases, early symptomatic phase, as well as limited access to testing in different settings are factors that have led to the rapid spread of infection. On March 11, 2020, WHO, after assessing the situation across the globe, declared COVID19 as a pandemic[3]. India reported its first case of COVID19 on January 30, 2020. This rose to three cases by February 3, 2020. No further cases were reported in February 2020. However, by mid-March, the number of infected cases started to increase, and many cases were reported from all over India. The first COVID-19 related death in India was reported on March 12, 2020. By the second week of April, the disease spread to all states in India except Sikkim[4].

## II. METHODOLOGY:

This is an open label non-randomized retrospective observational study conducted in a tertiary care centre in North Bengal with Covid admission facility along with critical care set up. Patients who were admitted with suggestive features of corona virus infection was included in the study. No randomization was carried out. All patients admitted with symptoms of viral infection was included in the study from August 2021 to October 2021. Confirmation of Covid infection was done by either Rapid Antigen Test(RAT) or

Reverse Transcription Polymerase Chain Reaction (Rt-PCR). All admitted patients were also subjected to High Resolution Computed tomography (HRCT) for further reconfirmation and radiological grading. COVID-19 Reporting and Data System scorings i.e CO-RADS and CT severity score was calculated for each patient. CO-RADS was calculated as per the published article by Mathias Prokop et. el. in 'Radiology' in 2020[5]. Similarly, CT severity score was calculated by the proposed method of Yang et. al. published in 'Radiology' in March 2020[6].

## III. STATISTICAL ANALYSIS:

All data were collected, compiled & subjected to suitable statistical analysis using appropriate methods with SPSS Version 20 with prior tabulation of data on office excel 2010. No missing Data imputation will be done to avoid potential bias in the results. Descriptive statistics will be obtained for all study variables. Quantitative data will be evaluated for normal distribution using Kolmogorov-Smirnov test. Parametric data will be expressed as mean ± SD (Standard Deviation). Comparison between different groups were carried out by comparison of means or Chi square test. For diagnostic methods, sensitivity & specificity were calculated

## IV. RESULTS:

A total of 216 patients' data was included in the study. All patients were admitted with suspected Covid symptoms.

154 male patients (71.3%) and 62 female patients (28.7%) were included in the study. Out of these, 82.11 % male & 17.89% females were suffering from confirmed Covid and rest were non-covid cases (Table 1). Chi square statistics showed that males are more prone to develop/contract covid infection (p= .000053). Males have a Relative risk (RR) of 1.8483 (95% CI 1.2965 to 2.6350) compared to females to contract Covid infection.

Most patients recruited were elderly. Age ranging from 12 to 90 years. Average age of all patients was 51.98±16.63 years (Mean±SD), that of Covid patients was 54.8±15.16 years, and non-covid patients was 48.26±17.78 years (Table 2). Average age of male patients was 53.98± 15.86 years and that of female patients was 47.03±17.54 years (Table 2a). Comparison of means between covid& non-covid suggested that higher the age more chance of getting Covid infection (95% Confidence Interval [CI] -10.9653 to -2.1147, p value .004). This finding was also corroborated by independent t-test with a p value of .002147.

Most common presenting symptoms among Covid patients were Shortness of Breath (SOB – 77.66%) followed by fever (75.53%) and Cough (42.55%). Even in non-covid patients, shortness of breath was commonest presenting symptom (69.15%) followed by fever (45.74%) & cough (20.21%). Weakness and bodyaches which were commonly present during the first phase of covid pandemic was present in very few patients. Table 3 provides more detailed information on presenting symptoms of both Covid& non-covid patients.

All included patients (n=216) undergone either RAT (n=54) or Rt-PCR (n=162) to detect Covid 19 infection. On addition 215 patients also undergone CT to radiologically confirm the diagnosis as well as for scoring purpose. Table 4 provide the details of detection of viral infection by different methods.RAT has a sensitivity of 57.14% (39.35-73.68 95% C.I) and specificity of 100% (82.35 -100.00 95% C.I). Rt-PCR has a sensitivity of 12.5% (6.41 - 21.27 95% C.I) & specificity of 100% (95.14-100.00 95% C.I). HRCT showed a sensitivity of 94.31% (88.63-97.68 95% C.I) & specificity of 92.39% (84.95-96.89 95% C.I). Positive predictive value of for both RAT & Rt-PCR came out to be 100%. Negative predictive value of RAT was 55.88% (46.35-65.00 95% C.I) and that of Rt-PCR was 49.01% (47.04-50.98 95% C.I). Positive predictive value of CT scan was found to be 94.31% (89.03-97.13 95% C.I) and negative predictive value was 92.39% (85.51-96.15 95% C.I). Test accuracy was lowest for Rt-PCR (52.47%) followed by RAT (72.22%) and CT scan has the highest accuracy (93.49%). Table 4a shows investigation/method specific comparative statistics.

CT scan plays an important role in categorizing the patients according the risk of developing serious disease in Covid19. CT severity score was obtained of 113 patients out of 123 Covid positive patients. CO-RADS was obtained in 115 patients (Table 5). Mean CT severity score was 11.99± 4.45 (range 2 to 21) and mean CO-RADS was 4.9± 0.54 (range 3 to 6). According to CT severity score 23.77% showed mild degree of lung involvement, 45.9% showed moderate disease & 22.95% showed extensive/severe disease or lung involvement (Table 5a).

Commonest CT feature in Covid19 patients was Ground Glass Opacities (GGO) which was found in 95.12% of patients followed by consolidation in 51.22% of patients. Septal thickening was found in 25.2% patients and crazy paving pattern was also present in 13.01% patients. Organizing pneumonia was present in 8.94% Covid

patients but not in any non-Covid patients. Table 6 shows detailed list of CT features in both Covid& non-Covid patients who were included in the study.

## V. DISCUSSION:

On January 30, 2020, the World Health Organization declaredCOVID-19 as pandemic calling all countries to take necessary preventives measures. COVID-19 is highly infectiousand after even early warning has developed into a pandemic affecting every country across the world. Strategies for disease containment and patientmanagement mostly depend on disease diagnosis (7,8,9).COVID-19 testing has been challenged by limitedlaboratory facilities and inadequate supply of nucleic acid kits(10). More so in semi-urban and rural areas and non-metro cities in India, there is always lack of ample testing kits. All types of diagnostic methods were applied to detect as many cases of Covid19 as possible. In this study also, we have carried out either RAT or Rt-PCR followed by HRCT to confirm diagnosis of Covid19.

Male patients showing more preponderance to contract Covid infection compared to females is probably due to more time spent outside for work, daily chores and even for recreational purposes. This was corroborated by a meta-analysis on demographic risk factors of Covid19 by Pijls BG et. al. where men had a higher risk of contracting the infection (RR 1.08)[11.] But another study from China by Liu T et. al. found women have higher relative risk of 1.66 compared to men[12.]

Elderly people are always prone to infectious diseases including Covid19 due to comorbidities, decreased immunity and other socio-economic factors. This was also corroborated in meta-analysis done by Liu T et. al. &Pijls BG et. Al. as mentioned earlier. In Pijls BG study, patients aged 70 years and above have a higher infection risk (RR 1.65, 95% CI 1.50 to 1.81), a higher risk for severe COVID-19 disease (RR 2.05, 95% CI 1.27 to 3.32), a higher need for intensive care (RR 2.70, 95% CI 1.59 to 4.60) and a higher risk of death once infected (RR 3.61, 95% CI 2.70 to 4.84) compared with patients younger than 70 years. In Liu t meta-analysis, old people aged 60–69 years has found to have higher risk (RR: 5.29, 95%CI: 3.76–7.46) of getting Covid19 infection.

Common Covid19 symptoms that were seen in patients in our study was breathlessness followed by fever & cough. Centre of Disease Control (CDC)[13] also states that common/possible symptoms are fever, cough, shortness of breath, fatigue, muscle pain/body ache, soar throat etc. Similar symptoms were reported elsewhere in National institute of health website[14.]

All patients were subjected to either RAT or Rt-PCR for confirmation of diagnosis. Though Rt-PCR is the gold standard for confirmatory diagnosis but due to limited resource every available method was used in our study. The sensitivity of RAT test came out to be 57.14%. Similar studies by Sabrina Jegerlehner et. al. found the sensitivity to be 65.3%[15]. Tim Peto and his colleagues showed a sensitivity of 78.8%[16] in their study. The sensitivity of Rt-PCR is very high according to published literature if done correctly. A study by Elisa Cortela et. al. reported an overall sensitivity of 89.9%, 85.7% in inpatients and 95.5% in outpatients[17]. Similar study by Williams TC et. al. reported sensitivity of 82.2% for single upper respiratory tract Rt-PCR in Covid 19 patients[18]. In our study the sensitivity was very low, only 12.5%. This is probably due to untrained technician, failure to collect samples properly for Rt-PCR testing and heavy load of patients, all of these are major issues in all peripheral centres. It should be noted that specificity for both RAT & Rt-PCR came out to be around 100% in our studies.

HRCT of chest showed highest sensitivity to diagnose Covid19 in comparison to both RAT & Rt-PCR. This finding was corroborated in many published literatures. Nadia Hanif et. al. reported that comparative sensitivity of CT is higher than that of Rt-PCR in a study from Pakistan (92% vs 45%)[19]. A study from China by Fang et. al. reported sensitivity of initial CT scan of 98% which is far grater than first Rt-PCR (71%)[20]. A meta-analysis published in The Egyptian Journal of Otolaryngology by Heba Mahmoud et. al. reported a pooled sensitivity of 89% for CT and 70% for Rt-PCR and concluded that CT can improve initial detection of Covid19 cases[21].

Out of total 216 patients, 123 were diagnosed of Covid 19 infection. 113 of these 123 patients was categorised according to CT severity score and CORAD scoring. Average CORAD score in our study was around 4.9 suggesting high pulmonary involvement[5]. This scoring seems to be a good screening method to determine the diagnosis & prognosis of patients with suspected Covid 19. Different studies have assessed the usefulness of CORAD. In one study with 14 patients concluded that the average sensitivity was 87.8% (range, 80.2–93.4%), specificity was 66.4% (range, 51.3–84.5%), and AUC was 0.859 (range, 0.847–0.881)[22]. Another larger study with 859 patients & 1138 controls showed that CO-RADS had good diagnostic performance ($P < 0.001$) in both symptomatic (AUC = 0.89) and asymptomatic

(AUC = 0.7) individuals. They concluded that the incidental detection of CO-RADS ≥3 in asymptomatic individuals should trigger testing for respiratory pathogens[23].Van Berkel et. al. in their study showed accuracy of CORAD ranging from 86 to 90.5%, sensitivity around 88% and specificities from 84 to 91%[24].

CT severity scores provides a semi-quantitative method to determine the severity of infection by lung involvement. In our study, majority percentage fall into moderate as per CT-SS. Our mean CT score of 11.99±4.4 was comparable to a similar Egyptian study of 11.2 by Hafez et. al[25]. Study by Francone et. al. the mean severity score was 12.3±11.1[26].

GGO & consolidation was the two commonest features found in our study. Similar findings were corroborated by published studies in different part of the world. In a study by Hani et. al. peripheral & sub-pleural GGO mixed with focal consolidation was the commonest findings[27]. Salehi et. al. reported GGO was observed in 88.0% of patients, consolidation in 31.8%, bilateral involvement in 87.5% and peripheral distribution in 76.0% of patients[28].

## VI. CONCLUSION

Overall, our study provides further insight into common diagnostic methods employed in the field to detectCovid 19. Low specificity of RtPCRshows the difficulty of obtaining samples as well as training needs of the paramedics to carry out the procedure. CT scan being widely available now a days, can be used together with any of the antigen detection methods to increase the sensitivity & specificity of the diagnostic investigations to an acceptable level.

**REQUEST OF WAIVER FOR INFORMED CONSENT**

Our patients were from 30.09.20 to 10.01.21.The investigators got permission to proceed for the work from competent authority of SwasthyaBhawan on 20.04.21.Next the laboratory data were collected from Mission Hospital by one of our collaborators, by the time it was closed Finally, CPMS data (COVID Patient Management Data) was procured on 26.05.21. Under these circumstances, the investigators pray to the members of the IEC, M.J.N MC&H to waive informed consent from the patients some of whom died. In this work,we have not seen the patients. We only used blood test results as well as their CPMS data from Govt. of West Bengal. Furthermore, cause of our request was also included in the latest guidelines of ICMR[27].

**LIMITATION OF THE STUDY:**

Data on co-morbidities of the patients were not taken into consideration & their admission in ICU/HDU/SDU (ICU- Intensive Care Unit, HDU- High Dependent Unit, SDU- Step Down Unit) as CPMS data do not include these & we could not retrieve these from the office of CMOH. A paper by Liu et al did not use or mention co-morbidities[28].Furthermore, in presence of co-morbidities, values of these ratios increase which suggest these patients need to be managed with special attention.

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The authors need permission from IEC to publish the results of the study.

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**Tables & Figures**

Table 1: Gender distribution among Covid& Non-covid patients

| Total | | | Covid | | | Non-Covid | | |
|---|---|---|---|---|---|---|---|---|
| Sex | n | % | Sex | n | % | Sex | n | % |
| M | 154 | 71.30 | M | 101 | 82.11 | M | 53 | 56.99 |
| F | 62 | 28.70 | F | 22 | 17.89 | F | 40 | 43.01 |

Table 2: Age wise distribution of patients

| Age | n | Mean± SD |
|---|---|---|
| Total | 216 | 51.98± 16.63 |
| Covid | 123 | 54.8± 15.16 |
| Non Covid | 93 | 48.26± 17.78 |

Table 2a: Mean age according to gender

| Age | n | Mean± SD |
|---|---|---|
| M | 154 | 53.98± 15.86 |
| F | 62 | 47.03± 17.54 |

Table 3. Presenting symptoms in confirmed covid& non-covid cases.

| Presenting Symptoms | | | | | | |
|---|---|---|---|---|---|---|
| Symptoms | All patients | | Covid | | Non-Covid | |
| | n | % | n | % | n | % |
| Fever | 114 | 52.78 | 71 | 75.53 | 43 | 45.74 |
| Cough | 59 | 27.31 | 40 | 42.55 | 19 | 20.21 |
| Shortness of breath | 138 | 63.89 | 73 | 77.66 | 65 | 69.15 |
| Chest Pain | 15 | 6.94 | 8 | 8.51 | 7 | 7.45 |
| Chest heaviness/Tightness | 1 | 0.46 | 1 | 1.06 | 0 | 0.00 |
| Acute gastroenteritis | 6 | 2.78 | 1 | 1.06 | 5 | 5.32 |
| Weakness | 4 | 1.85 | 4 | 4.26 | 0 | 0.00 |

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| | | | | | | |
|---|---|---|---|---|---|---|
| Body ache/Joint pain | 3 | 1.39 | 1 | 1.06 | 2 | 2.13 |
| Loss of taste | 1 | 0.46 | 1 | 1.06 | 0 | 0.00 |
| Convulsions | 2 | 0.93 | 0 | 0.00 | 2 | 2.13 |
| Psychosis | 1 | 0.46 | 0 | 0.00 | 1 | 1.06 |
| Headache | 1 | 0.46 | 0 | 0.00 | 1 | 1.06 |
| Stammering of speech | 1 | 0.46 | 1 | 1.06 | 0 | 0.00 |

Table 4. Detection of Covid19 infection by antigen testing and Radiology

| test | n | true pos | true neg | false pos | false neg |
|---|---|---|---|---|---|
| RAT | 54 | 20 | 19 | 0 | 15 |
| Rt-PCR | 162 | 11 | 74 | 0 | 77 |
| CT | 215 | 116 | 85 | 7 | 7 |

Table 4a. Comparative efficacy of diagnostic methods employed in Covid19.

| RAT | | | RAT | | | CT scan | | |
|---|---|---|---|---|---|---|---|---|
| **Statistic** | **Value** | **95% CI** | **Statistic** | **Value** | **95% CI** | **Statistic** | **Value** | **95% CI** |
| Sensitivity | 57.14% | 39.35% to 73.68% | Sensitivity | 57.14% | 39.35% to 73.68% | Sensitivity | 94.31% | 88.63% to 97.68% |
| Specificity | 100.00% | 82.35% to 100.00% | Specificity | 100.00% | 82.35% to 100.00% | Specificity | 92.39% | 84.95% to 96.89% |
| Positive Predictive Value (*) | 100.00% | | Positive Predictive Value (*) | 100.00% | | Positive Predictive Value (*) | 94.31% | 89.03% to 97.13% |
| Negative Predictive Value (*) | 55.88% | 46.35% to 65.00% | Negative Predictive Value (*) | 55.88% | 46.35% to 65.00% | Negative Predictive Value (*) | 92.39% | 85.51% to 96.15% |
| Accuracy (*) | 72.22% | 58.36% to 83.54% | Accuracy (*) | 72.22% | 58.36% to 83.54% | Accuracy (*) | 93.49% | 89.32% to 96.39% |
| Positive Predictive Value (*) | 100.00% | | Positive Predictive Value (*) | 100.00% | | Positive Predictive Value (*) | 94.31% | 89.03% to 97.13% |
| Negative Predictive Value (*) | 55.88% | 46.35% to 65.00% | Negative Predictive Value (*) | 55.88% | 46.35% to 65.00% | Negative Predictive Value (*) | 92.39% | 85.51% to 96.15% |
| Accuracy (*) | 72.22% | 58.36% to 83.54% | Accuracy (*) | 72.22% | 58.36% to 83.54% | Accuracy (*) | 93.49% | 89.32% to 96.39% |

Table 5. Radiological scoring of Covid 19 patients.

| scoring | N | Mean± SD |
|---|---|---|
| CT severity Score | 113 | 11.99± 4.45 |
| Co-RADS | 115 | 4.9± 0.54 |

Table 5a. Disease categorization according to CT Severity score.

| CT severity | n | % |
|---|---|---|
| Mild | 29 | 23.77 |
| Moderate | 56 | 45.90 |
| Severe | 28 | 22.95 |

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Table 6. CT features of patients included in the study – Covid& Non-covid.

| | All | | Covid | | Non-covid | |
|---|---|---|---|---|---|---|
| CT features | N | % | n | % | n | % |
| Normal | 22 | 10.19 | 1 | 0.81 | 21 | 22.58 |
| Ground glass opacities | 127 | 58.80 | 117 | 95.12 | 10 | 10.75 |
| Nodular opacities | 17 | 7.87 | 2 | 1.63 | 15 | 16.13 |
| micronodular opacities | 2 | 0.93 | 1 | 0.81 | 1 | 1.08 |
| Fibrotic opacities | 10 | 4.63 | 5 | 4.07 | 5 | 5.38 |
| Fibrocalcific/Clacific lesions | 16 | 7.41 | 5 | 4.07 | 11 | 11.83 |
| Consolidation | 89 | 41.20 | 63 | 51.22 | 26 | 27.96 |
| Collapse | 7 | 3.24 | 1 | 0.81 | 6 | 6.45 |
| Emphysema/Bullae | 18 | 8.33 | 8 | 6.50 | 10 | 10.75 |
| pleural effusion | 32 | 14.81 | 6 | 4.88 | 26 | 27.96 |
| pleural thickening | 7 | 3.24 | 2 | 1.63 | 5 | 5.38 |
| Intrafissural effusion | 3 | 1.39 | 2 | 1.63 | 1 | 1.08 |
| pneumothorax | 1 | 0.46 | 0 | 0.00 | 1 | 1.08 |
| Crazy paving pattern | 16 | 7.41 | 16 | 13.01 | 0 | 0.00 |
| tree in bud appearance | 3 | 1.39 | 0 | 0.00 | 3 | 3.23 |
| Cavity | 5 | 2.31 | 1 | 0.81 | 4 | 4.30 |
| Cysts | 5 | 2.31 | 4 | 3.25 | 1 | 1.08 |
| septal thickening | 53 | 24.54 | 31 | 25.20 | 22 | 23.66 |
| Organizing pneumonia | 11 | 5.09 | 11 | 8.94 | 0 | 0.00 |
| Bronchiectatic change | 21 | 9.72 | 8 | 6.50 | 13 | 13.98 |
| Interstitial lung fibrosis changes | 2 | 0.93 | 0 | 0.00 | 2 | 2.15 |
| Flattening of diaphragm | 1 | 0.46 | 0 | 0.00 | 1 | 1.08 |
| Eventration of diaphragm | 1 | 0.46 | 0 | 0.00 | 1 | 1.08 |
| mediastinal shift | 3 | 1.39 | 1 | 0.81 | 2 | 2.15 |
| Cardiomegaly | 5 | 2.31 | 0 | 0.00 | 5 | 5.38 |
| pericardial effussion | 3 | 1.39 | 1 | 0.81 | 2 | 2.15 |