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TO ESTIMATE THE SENSITIVITY AND NEGATIVE PREDICTIVE VALUE OF RAPID ANTIGEN TEST IN COMPARISON NAATS FOR DIAGNOSIS OF COVID-19 INFECTION IN PREGNANT WOMEN.

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ABSTRACT

INTRODUCTION: This unprecedented pandemic has proved to be a challenge to treat and early detection and isolation has been an important management strategy. Various tests available are the bedside rapid antigen test and the more complex nucleic acid amplification tests. **MATERIAL AND METHODS:** The study was done on all obstetric patients admitted under the department of Obstetrics and Gynaecology, Government Medical College, Amritsar from 14/8/2020 to 30/11/2020. These patients were tested with Rapid antigen test (RAT) as a screening test for COVID infection, irrespective of the symptoms. All the patients who tested negative with rapid antigen test were subjected to one of the confirmatory nucleic acid amplification tests (NAAT) like RT-PCR or TrueNat. The study excluded all the patients who were known Covid-19 positive at the time of admission. **RESULTS:** 1574 patients were included in the study. Sensitivity and negative predictive value of the rapid antigen test was 27.9% and 94.8% and that of TrueNat and RT-PCR were 90.9%; 99.09% and 72.34%; 98.86% respectively. **CONCLUSION:** In times of high prevalence, Rapid antigen test (RAT) continue to be relevant in spite of disappointing sensitivity due to their role in decreasing the risk of transmission in hospital setting but continued research needed to develop better bedside tests with higher sensitivity.

KEYWORDS

Covid-19, RAT=Rapid antigen test, TrueNat, RT-PCR test.

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INTRODUCTION:

Covid-19, a pandemic caused by SARS-CoV-2, has posed unprecedented challenges for health care infrastructure of both developing and developed countries. Having started in December 2019 in Wuhan, China and affecting the western world in early months of 2020, India has recently been stormed by a massive second wave and is already gearing up for a probable third wave even with a concurrent massive vaccination campaign going on. With limited treatment modalities, the management of pandemic rested on social distancing in general, aggressive screening and segregating infected individuals from the general population. For the prevention of future waves, an ideal diagnostic test with high sensitivity and specificity and rapid results is a major management tool.1

In the initial months, the sole accepted diagnostic modality was Covid RT-PCR but in August 2020, ICMR gave acceptance to use of RAT for use as one of the screening modalities.2 In September 2020, ICMR advised that RT-PCR, TrueNat, CBNAAT or RAT (in order of priority) may be conducted in all pregnant women who are hospitalized for delivery.[2,3]

Gold standard for diagnosis of acute SARS-CoV-2 infections remains the detection of viral sequences by nucleic acid amplification tests (NAAT) like reverse-transcription polymerase chain reaction (RT-PCR).[3]

RAT on the other hand, directly detect viral proteins produced by replicating virus in respiratory secretions for near-patient use. As compared to nucleic amplification tests, there is no amplification or multiplication of the target that is detected, rendering them less sensitive. The virus may be detectable in the upper respiratory tract (URT) 1-3 days prior to the onset of symptoms. The concentration of SARS-CoV-2 in the URT is highest at the time of onset of symptom, which shows a gradual decline afterwards and thus, sensitivity of RAT depends a lot on time since exposure of the individual to the virus.

Sensitivity of RAT compared to NAAT in nasal or pharyngeal swab samples appears to be highly variable, ranging from 0-94% but specificity has been reported to be high (>97%).1,4

This study was aimed at estimating the sensitivity and negative predictive value of rapid antigen test in comparison to NAATs in diagnosing Covid 19 infection.

MATERIAL AND METHODS:

The study was done in the department of Obstetrics and Gynaecology, Government Medical College which is a designated tertiary level covid care facility. Study period was from 14/8/2020 to 30/11/2020. All the obstetric patients needing admission were tested with RAT as a screening test for COVID infection, irrespective of the symptoms. Nasopharyngeal sample was taken following all standard precautions for RAT testing and results were interpreted at 10 minutes of the test. RATs kits utilized had colloidal gold pad with lateral flow immunochromatography assays. The kits claimed a sensitivity of 84% and specificity of 100%. All the patients who tested positive with Rapid antigen tests were treated as positive and no further confirmation was done to avoid any controversy regarding diagnosis and need for isolation.

All the patients who tested negative with RAT were subjected to one of the confirmatory nucleic acid amplification tests (NAAT) like RT-PCR or TrueNat. Sampling for the confirmatory tests was done at the time of admission itself. Both nasopharyngeal and oropharyngeal samples were taken and preserved and transported to Covid testing laboratory at less than 4°C temperature following all biosafety norms. TrueNat testing was available only in day hours and was reserved for cases in labour or those in which some interventions were urgently required. In all others, RT-PCR was the confirmatory test utilized.

Amongst the patients who were negative by both RAT and NAAT, third test was done only if signs and symptoms were strongly suggestive of Covid 19 infection. All the patients diagnosed as Covid positive were shifted to Covid isolation wards and were treated as per contemporary standard guidelines given by GOI.

RESULTS:

During the study period, overall positivity rate of the samples taken in our study was 7.05% (111/1574). 1.97% (31) of positive cases were diagnosed by RAT, 2.1% (33) were diagnosed by TrueNat and 2.98%(47) were diagnosed by RT-PCR.

During the study period, a total of 1574 RAT were done, 31 were positive and there were 80 false negatives which were eventually proven to be Covid positive by parallel NAAT i.e. TrueNat or RT-PCR. Thus RAT test which was found to have a 27.9% sensitivity and a negative predictive value of 94.8%.

Amongst 362 patients tested with TrueNat, sensitivity was 90.9% and

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negative predictive value was 99.09%. A total of 1181 patients were tested with RT-PCR, 34 were diagnosed as positive while 13 were initially negative and on repeat testing came out to be positive. Sensitivity was 72.34% and negative predictive value was 98.86% on the basis of the results of the first RT- PCR test done in RAT negative cases. [Figure 1]

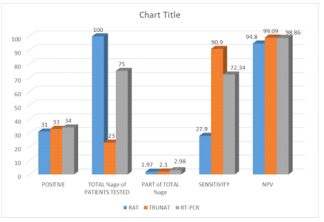

Figure 1. Sensitivity and negative predictive value of RAT, TrueNat & RT-PCR.

DISCUSSION:

Rapid diagnosis and isolation is an important strategy in controlling the spread of infection at the peak of the pandemic. It becomes even more important in the hospital settings to prevent the spread of infection amongst health care workers and further cross infection amongst others who are already hospitalized due to some morbidity or emergency and are vulnerable.

Our results of 27.9% sensitivity of RAT are similar to Schoy who reported a sensitivity of 30.2% although different RATs were employed in their two studies.[5]

Cochrane analysis by Dinnes reported sensitivity from 0% to 94%, the average sensitivity was 56.2% (95% CI 29.5 to 79.8%) and average specificity was 99.5% (95% CI 98.1% to 99.9%); based on 943 samples taken in 5 studies.[1]

WHO recommends a minimum of 80% sensitivity in RAT compared to NAATs.3 Fitzpatrick reported that manufacturers may be reporting inflated sensitivity of these tests.[6]

As disappointing and inadequate, the sensitivity of RATs may be in diagnosis of Covid-19 infection, there is no denying the fact that in times of high prevalence, they surely have a major role to play. In our study, almost one third of the cases were diagnosed by RAT testing. The remaining two thirds were diagnosed by NAATs but the admission diagnosis interval in RAT diagnosis was within 30 minutes while it ranged from 12-48 hours with NAAT due to massive work load in our BSL-3 level laboratory.

An early diagnosis in our study meant minimum exposure of HCWs, other pregnant women admitted with various comorbidities and the newborn. So, the need of the hour is to continue search for rapid bedside tests with high sensitivity and in the meanwhile, using the available RATs as a screening test and NAATs for confirmation.

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CONFLICTS OF INTEREST

All authors have participated in conception and design, or analysis and interpretation of the data and drafting the article. The authors have no affiliation with any organization with a direct or indirect financial interest in the subject matter discussed in the manuscript.

REFERENCES:

1. Dinnes J, Deeks JJ, Adriano A, Berhane S, Davenport C, Dittrich S, Emperador D, et al. Cochrane COVID-19 Diagnostic Test Accuracy Group. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. Cochrane Database Syst Rev. 2020 Aug 26;8:CD013705. doi: 10.1002/14651858.CD013705. PMID: 32845525.
2. Ministry of Health and Family Welfare. Government of India. [INTERNET] Advisory on Strategy for COVID-19 Testing in India (Version VI, dated 4th September 2020) Recommended by the National Task Force on COVID-19. Accessed on: September, 2020. Available from: https://www.mohfw.gov.in/pdf/AdvisoryonstrategyforCOVID19TestinginIndia.pdf
3. World Health Organization, Geneva, Switzerland. [INTERENT] Diagnostic testing for SARS-CoV-2 Interim guidance WHO/2019-nCoV-19/laboratory/2020.6 Updated on: 11 September 2020. Accessed on: September, 2020. Available from: https://apps.who.int/iris/handle/10665/334254
4. Ministry of Health and Family Welfare. Government of India. [INTERNET] Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays Interim guidance WHO/2019-nCoV/Antigen Detection/2020.1 Updated on: 11 September 2020 Accessed on: September, 2020. Available from: https://apps.who.int/iris/rest/bitstreams/1302653/retrieve
5. Scohy A, Anantharajah A, Bodéus M, Kabamba-Mukadi B, Verroken A, Rodriguez-Villalobos H. Low performance of rapid antigen detection test as frontline testing for COVID-19 diagnosis. J Clin Virol. 2020 Aug;129:104455. doi: 10.1016/j.jcv.2020.104455. Epub 2020 May 21. PMID: 32485618; PMCID: PMC7240272.
6. Fitzpatrick MC, Pandey A, Wells CR, Sah P, Galvani AP. Buyer beware: inflated claims of sensitivity for rapid COVID-19 tests. 2021;397(10268):24-5 DOI: https://doi.org/10.1016/S0140-6736(20)32635-0