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ORIGINAL ARTICLE

Role of Covid Antigen in the Diagnosis of Covid Positive in Obstetric Patients

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ABSTRACT

Background and Aim: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) rapid emergence postured significant challenges on the health system in recent years. The early detection of cases is thought to be critical in preventing this pandemic by coronavirus disease (COVID-19), especially important in the obstetrical population due to theirs numerous interactions with another parturient when hospitalized for delivery. Therefore, the present study aimed to assess the COVID antigen test performance in COVID-positive obstetrics patients.

Materials and Methods: This cross-sectional study was conducted on 1296 Covid-19 asymptomatic women admitted to the Obstetrics and Gynaecology Department of Muhammad Teaching Hospital & Medical College, Peshawar and Fauji Foundation Hospital, Rawalpindi for the duration of six months from February 2021 to July 2021. Antigen-based test rapid diagnostic test (RDT) was used for screening out COVID-19 positive obstetrics patients or women through nasopharyngeal swabs. Women with negative rapid antigen test results were confirmed with RT-polymers chain reaction test of nucleic acid amplification tests (NAAT). Ethical approval and informed consent were taken from the hospital ethical committee and each individual respectively. All the known positive COVID-19 patients during admission were excluded. SPSS version 24 was used for data analysis.

Results: The overall prevalence of rapid antigen-positive tested patients was 13.2% (171/1296). The prevalence of positive tested women through rapid antigen test, Nucleic Acid Amplification Test (NAAT), and RT-PCR were 27 (2.1%), 51 (3.9%), and 93 (7.2%) respectively. Of the total 1296 rapid antigen tests, 27 were positive, and the false-negative confirmed positive by NAAT was 144.Thus the sensitivity of the rapid antigen test was 15.8% and the negative predictive value was 93.7%. Of the total 298 Nucleic Acid Amplification Tested had sensitivity and negative predictive value of 89.6% and 99.06% respectively. RT-PCR was carried out on 972 patients, positive diagnosed cases were 36 while 15 were initially negative and were positive with the test was repeated. The sensitivity and negative predictive value was 71.45% and 95.8% respectively.

Conclusion: Our study found that Ag-RDT plays a significant role in SARS-CoV-2 early detection in infected individuals, with high specificity and sensitivity to disease infectious stage, whether symptomatic or asymptomatic, and can be used as a decision supported tool. Early detection of COVID-19 status in women admitted for delivery could benefit neonatal protection care.

Keywords: Covid-19; Rapid antigen test; RT-PCR test

INTRODUCTION

Covid-19, a pandemic caused by SARS-CoV-2, has posed unprecedented challenges to health-care infrastructure in both developing and developed countries. This pandemic began in December 2019 and affected the entire world. With few treatment options, the pandemic's management relied on social distancing in general, aggressive screening, and segregating infected individuals, particularly those who were asymptomatic. An ideal diagnostic test with high sensitivity and specificity and rapid results for the prevention of future waves could be a game changer in management and containment [1]. The coronavirus disease 2019 (COVID-19) is the diseases caused by novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It has been related to maternal and perinatal morbidity and mortality [4, 5]. All the COVID_19 patients had the positive results of antiviral immunoglobulin G (IgG) test post 10 to 20 days duration of symptom onset. However, for both pregnant and non-pregnant women, antibodies test clinical value has not been determined. Antibodies to SARSCoV-2 can be tested in a variety of ways. IgM and IgG titers measured by ELISA (enzyme-linked immunosorbent assay), and a rapid antibody test [6]. Previous study reported antibodies test sensitivity and specificity of 48%, 89% and 89% respectively [7] whereas another found 100%, 91% and 91% respectively [8].

RAT sensitivity in nasal or pharyngeal swab samples appears to be highly variable, ranging from 0-94%, but specificity has been reported to be high (>97%) [9]. Identification of IgG positive but potentially rehabilitated women never tested with RT-PCR using specimen of nasopharyngeal swabs and women prone to COVID_19 infection risk could have several benefits of COVID-19 antibodies response in pregnant women testing. The purpose of this study was to determine the utility of rapid antigen tests versus NAATs in diagnosing Covid 19 infection in pregnant women who were asymptomatic. Pregnancy is a condition that not only affects the health of pregnant women, but also newborns who may be at risk, and in our social setup, pregnancy is associated with a lot

of socialization, which may become a source of infection for relatives.

MATERIAL AND METHODS

This cross-sectional study was carried out on 1296 Covid-19 asymptomatic women admitted to the Obstetrics and Gynaecology Department of Muhammad Teaching Hospital & Medical College, Peshawar and Fauji Foundation Hospital, Rawalpindi for the duration of six months from February 2021 to July 2021. Antigen-based test rapid diagnostic test (RDT) was used for screening out COVID-19 positive obstetrics patients or women through nasopharyngeal swabs. Women with negative rapid antigen test results were confirmed with RT-polymers chain reaction test of nucleic acid amplification tests (NAAT). Ethical approval and informed consent were taken from the hospital ethical committee and each individual respectively. All the known positive COVID-19 patients during admission were excluded.

Regardless of symptoms, all obstetric patients requiring admission were tested with RAT as a screening test for COVID infection. Following all standard precautions for RAT testing, a nasopharyngeal sample was taken, and the results were interpreted after 10 minutes. RAT kits with colloidal gold pads and lateral flow immunochromatography assays were used. The kits claimed a sensitivity of 84% and a specificity of 100%. To avoid any confusion about the diagnosis and the need for isolation, all patients who tested positive with rapid antigen tests were treated as positive and no further confirmation was performed. All patients who tested negative for RAT underwent one of the confirmatory nucleic acid amplification tests (NAAT) such as RT-PCR or TrueNat. The confirmatory tests were sampled during the admission process. Both nasopharyngeal and or pharyngeal samples were collected, preserved, and transported to the Covid testing laboratory at temperatures less than 4°C, in accordance with all biosafety standards. When both the RAT and the NAAT tests came back negative, the third test was performed only if the signs and symptoms were strongly suggestive of Covid 19 infection. All patients who tested positive for Covid were transferred to Covid isolation wards and treated according to standard protocols.

RESULTS

The overall prevalence of rapid antigen-positive tested patients was 13.2% (171/1296). The prevalence of positive tested women through rapid antigen test, Nucleic Acid Amplification Test (NAAT), and RT-PCR were 27 (2.1%), 51 (3.9%), and 93 (7.2%) respectively as shown in Figure-1. Of the total 1296 rapid antigen tests, 27 were positive, and the false-negative confirmed positive by NAAT were 144.Thus the sensitivity of the rapid antigen test was 15.8% and the negative predictive value was 93.7%. Of the total 298 Nucleic Acid Amplification Tested had sensitivity and negative predictive value of 89.6% and 99.06% respectively. RT-PCR was carried out on 972 patients, positive diagnosed cases were 36 while 15 were initially negative and were positive with the test was repeated. The sensitivity and negative predictive value was 71.45% and 95.8% respectively. Figure-2 illustrates the RAT, NAAT, and RT-PCR negative predictive values and sensitivity. The rapid antigen test had several advantages over NAAT. The comparison made between both RAT and NAAT is shown in Table-1.

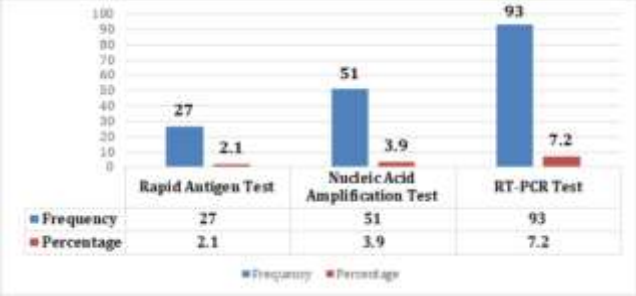

Figure-1 Prevalence of RAT, NAAT, and RT-PCR positive tested women

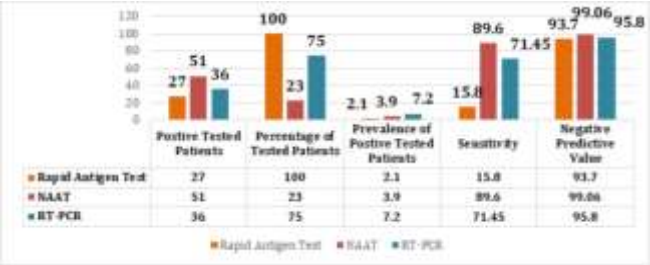

Figure-2 RAT, NAAT, and RT-PCR negative predictive value and sensitivity

Table-1 Rapid Antigen Test and NAAT comparison

Parameters	Rapid Antigen Test	NAAT
Swabs	Nasal or Throat	Nasal or Throat
Diagnostic time	10 to 30 minutes	6 to 24 hours
Sensitivity	low	High
Specificity	high	High
Practical Implementation	Applicable	Not applicable

DISCUSSION

Rapid diagnosis and isolation are critical strategies for controlling the spread of infection during the pandemic's peak. It is even more critical in hospital settings to prevent the spread of infection among health care workers and further cross infection among those who are already hospitalized due to a morbidity or emergency and are vulnerable. Furthermore, pregnancy is a condition that affects not only the health of the mother and child, but also family members and relatives. Our RAT sensitivity of 23% is comparable to Scohy's sensitivity of 30.2%, despite the fact that different RATs were used in their two studies [10].

Dinnes' Cochrane analysis reported sensitivity ranging from 0% to 94%, with the average sensitivity being 56.2% (95% CI 29.5 to 79.8%) and the average specificity being 99.5% (95% CI 98.1% to 99.9%); based on 943 samples collected in 5 studies [11-13]. When comparing RATs to NAATs, the WHO recommends a minimum sensitivity of 80% [14]. According to Fitzpatrick, manufacturers may be reporting inflated sensitivity of these tests [15]. As disappointing and insufficient as RATs' sensitivity in diagnosing Covid-19 infection may be, there is no denying that in times of high prevalence, they undoubtedly play a significant role. RAT testing was used

to diagnose nearly one-third of the cases in our study. Although RAT was not as sensitive as NAATs, the time to diagnosis provides a significant advantage in terms of early diagnosis and segregation [16].

The present stud mainly focused on rapid antigen test role in positive infected COVID-19 obstetrics patients. Previously, rapid diagnostic tests (RDTs) had transfigured the infectious diseases, most notably malaria and streptococcal throat infections diagnosis and treatment [17, 18]. Despite its lower sensitivity, the rapid antigen test had several advantages over PCR. The obvious benefits of a rapid antigen test include quick diagnostic results, kit handling and storage, ease of operation, cost effectiveness, and point-of-care performance. Prior to delivery, pregnant women should be tested for COVID-19 disease because there is a high risk of transmission to other health professionals. RAT has the advantage (over NAATs) of providing quick results, which can be critical in an emergency. Kumar et al. [19] emphasised the importance of preoperative testing. The remaining two-thirds were diagnosed using NAATs, but the admission diagnosis interval in RAT diagnosis was less than 30 minutes.

CONCLUSION

According to our findings, Ag-RDT plays a significant role in SARS-CoV-2 early detection in infected individuals, with high specificity and sensitivity to disease infectious stage, whether symptomatic or asymptomatic, and can be used as a decision supported tool. Early detection of COVID-19 status in women admitted for delivery could benefit neonatal protection care.

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