SARS-CoV-2 is not present in the vaginal fluid of pregnant women with COVID-19

Mehmet Musa Aslan, Hilal Uslu Yuvacı, Osman Köse, Hande Toptan, Nermin Akdemir, Mehmet Köroğlu, Arif Serhan Cevrioğlu & Selçuk Özden

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Mehmet Musa Aslana, Hilal Uslu Yuvacıa, Osman Kösea, Hande Toptanb, Nermin Akdemira, Mehmet Koroğlub, Arif Serhan Cevrioç and Selçuk Özdena

Obstetrics and Gynecology, Sakarya Training and Research Hospital, Sakarya, Turkey; bMedical Microbiology Department, Sakarya University, Sakarya, Turkey

ABSTRACT

Background: Data concerning the presence of SARS-CoV-2 in the female genital system is scarce; however, this information is important for understanding whether the virus can transmit sexually or from mother to child. The aim of this study was to investigate whether pregnant women with COVID-19 have virus in their lower genital tract.

Methods: In this cross-sectional study, we present an analysis of prospectively gathered data collected at a single tertiary university hospital from 19 April to 19 May 2020. We included 13 pregnant women hospitalized with suspected COVID-19. Results of laboratory tests, imaging tests, and nucleic acid tests on vaginal swabs for SARS-CoV-2 were also analyzed for pregnant women with a clinical diagnosis of COVID-19.

Results: Twelve pregnant women with confirmed COVID-19 were included in this study. Mean age was 32 ± 7.9 years. All patients had mild symptoms and were followed in the maternity ward, with none of them needing critical care unit follow-up. All lower genital tract samples were negative for SARS-CoV-2.

Conclusion: We demonstrated that SARS-CoV-2 was not present in the vaginal fluid of pregnant women. This finding may indicate that the female genital tract is not a route of SARS-CoV-2 transmission.

INTRODUCTION

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has become one of the most significant public health problems of modern times [1,2]. Although the exact mechanism of transmission of SARS-CoV-2 has not yet been demonstrated, initial trials show that the virus mainly spreads through respiratory droplets [3]. Recent studies have revealed that the virus is detectable in the throat, blood, urine, anal swabs, tears and even in feces [4,5]. In the genital system, the virus has been identified in testicular tissue but not in the ovaries or in the uterus [6]. Data about the presence of SARS-CoV-2 in the female genital system is scarce; however, this information is important for understanding whether the virus can transmit either sexually or from mother to child. Understanding whether the virus is present in the female genital tract will help guide obstetricians in their decisions about the ideal mode of delivery.

The aim of this study was to investigate whether pregnant women with COVID-19 have virus in their lower genital tract.

MATERIALS AND METHODS

In this cross-sectional study, we present an analysis of prospectively gathered data collected at a single tertiary university hospital, which has become a dedicated pandemic hospital following increased numbers of COVID-19 patients in Sakarya Province, Turkey.

All pregnant women hospitalized between 19 April and 19 May 2020 with suspected COVID-19 who agreed to participate were included in the trial. The local institutional ethical committee approved the study (No:16214662/050.01.04/89). All participants gave written informed consent.

CONTACT Mehmet Musa Aslan (jinopdmma@gmail.com) Obstetrics and Gynecology, Sakarya Training and Research Hospital, Sakarya, Turkey

Due to the urgent and developing nature of the topic, this paper was accepted after an expedited peer review process. For more information about the process, please refer to the Instructions for Authors.

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Twelve patients tested positive for SARS-CoV-2 by Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) analysis of samples from the respiratory tract. RT-PCR assays were performed in accordance with the protocol established by the WHO [7,8].

Clinical laboratory examinations, including blood analyses, serum biochemical tests and coagulation function tests, were performed. A thorax CT was performed for one case and revealed findings consistent with COVID-19. Abdominal ultrasound was performed for all cases. Vaginal swabs were obtained from all confirmed cases during the inpatient period. Vaginal swabs were inserted 2–3 cm into the vagina and rotated for 3–5 s. Swabs were transferred to the laboratory immediately, and RT-PCR procedures were completed within two hours. We obtained the clinical findings, laboratory and radiological findings, therapeutic interventions and outcomes for all patients.

**Table 1.** Demographic and clinical parameters of study population.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>32 ± 7.9</td>
</tr>
<tr>
<td>Pregnant week</td>
<td>26.0 ± 10.3</td>
</tr>
<tr>
<td>Gravity</td>
<td>2.3 ± 1.6</td>
</tr>
<tr>
<td>Parity</td>
<td>0.8 ± 1.0</td>
</tr>
<tr>
<td>Fever</td>
<td>5 (41.7%)</td>
</tr>
<tr>
<td>Cough</td>
<td>8 (66.7%)</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>2 (16.7%)</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
</tr>
<tr>
<td>Azitromycin</td>
<td>7 (58.3%)</td>
</tr>
<tr>
<td>Hydroxychloroquine</td>
<td>12 (100%)</td>
</tr>
<tr>
<td>LMWH</td>
<td>7 (58.3%)</td>
</tr>
<tr>
<td>WBC</td>
<td>6.7 ± 2.5</td>
</tr>
<tr>
<td>Hemoglobin (g/dl)</td>
<td>11.1 ± 1.3</td>
</tr>
<tr>
<td>Platelets</td>
<td>182,000 ± 68.9</td>
</tr>
<tr>
<td>CRP</td>
<td>15.5 ± 20.1</td>
</tr>
<tr>
<td>Saturation</td>
<td>97.5 ± 1.6</td>
</tr>
</tbody>
</table>

LMWH: low-molecular-weight heparin; WBC: White blood cell CRP: C-reactive protein.

Twelve patients tested positive for SARS-CoV-2 by Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) analysis of samples from the respiratory tract. RT-PCR assays were performed in accordance with the protocol established by the WHO [7,8].

Clinical laboratory examinations, including blood analyses, serum biochemical tests and coagulation function tests, were performed. A thorax CT was performed for one case and revealed findings consistent with COVID-19. Abdominal ultrasound was performed for all cases. Vaginal swabs were obtained from all confirmed cases during the inpatient period. Vaginal swabs were inserted 2–3 cm into the vagina and rotated for 3–5 s. Swabs were transferred to the laboratory immediately, and RT-PCR procedures were completed within two hours. We obtained the clinical findings, laboratory and radiological findings, therapeutic interventions and outcomes for all patients.

**Statistical analysis**

IBM SPSS Statistics (version 21.0; IBM Corporation, Armonk, NY) was used to perform the statistical analysis. Demographic variables are reported as the mean ± standard deviation (SD), median ± interquartile range (IQR) and frequency for the relevant items.

**Results**

Twelve pregnant women with confirmed COVID-19 were included in the study. Mean age was 32 ± 7.9 years, mean gravidity was 2.3 ± 1.6, mean parity was 0.8 ± 1.0 and mean gestational age was 26.0 ± 10.3 weeks. All patients had moderate symptoms and were followed in the maternity ward, with none of them needing critical care unit follow-up. The main symptom was fever in five (41.7%) patients, cough in eight (66.7%) patients and dyspnea in two (16.7%) patients.

All patients were administered hydroxychloroquine, whereas azithromycin and low-molecular-weight heparin was delivered to seven (58.3%) women. Only one women had a chest CT scan that revealed the typical finding of ground glass shadows.

All samples from the lower genital tract were negative for SARS-CoV-2. Laboratory, clinical and demographic parameters are given in Table 1.

**Discussion**

In this study, we investigated whether SARS-CoV-2 is present in the vaginal fluid of pregnant women diagnosed with COVID-19. We have shown that SARS-CoV-2 is not detectable in the vaginal fluid and lower genital system in female COVID-19 patients. To the best of our knowledge, this is the first study investigating the external genital system for the presence of SARS-CoV-2 in pregnant women. These findings will serve as an important guide for obstetricians during this outbreak in choosing delivery options. Although several guidelines and position papers have been released, obstetrical management during the pandemic is still not clear [9,10]. Although the virus spreads mainly by respiratory droplets, sexual transmission of SARS-CoV-2 has been neither clearly demonstrated nor excluded. The present trial helps shed light on this issue.

Qiu et al. [11] reported that ten women in the ICU with severe COVID-19 were tested for SARS-CoV-2 in vaginal fluid by RT-PCR assay, and all samples were negative for the virus. Their study included only post-menopausal patients, while our patient population consisted of pregnant women. It is well established that both hormonal and epithelial changes occur after menopause, so it is not possible to expand their findings to pregnant women.

Cui et al. [12] carried out a similar study. They included 35 women with a COVID-19 diagnosis. They also reported that all samples taken from vaginal swabs were PCR-negative for SARS-CoV-2. In this study, 28 patients had entered menopause and one patient was in the post-partum period. Another important difference from our trial was their inclusion criteria; they included eight women according to clinical criteria despite a negative PCR test, while we only included PCR-positive patients.

Liao et al. [13] recently reported an analysis of vaginal delivery outcomes for pregnant women with COVID-19 diagnoses. They compared ten COVID-19
pregnant women with 53 healthy pregnant women. There were no significant differences in gestational age, postpartum hemorrhage and perineal resection rates between the two groups. There were no significant differences in neonatal birth weights or asphyxia rates between the two groups. Moreover, PCR tests for SARS-CoV-2 were negative for all new-borns. In a review article published recently in this journal has concluded that no strong evidence to support the possibility of vertical transmission [14].

Although these trials consisted of a small number of patients, at least three different trials representing different populations have confirmed that SARS-CoV-2 is not found in vaginal fluid. These findings suggest that sexual transmission of SARS-CoV-2 is not a risk, and vertical transmission during vaginal delivery is also unlikely.

There are several limitations of this trial. First, this was a single-centre study with a relatively small number of patients. Second, all pregnant women in our trial had moderate disease, and thus expanding these findings to severely diseased patients would not be appropriate.

Conclusions
We demonstrated that SARS-CoV-2 is not present in vaginal fluid of pregnant women. This important finding indicates that the female genital tract is not a route of SARS-CoV-2 transmission.

Disclosure statement
No potential conflict of interest was reported by the author(s).

ORCID
Mehmet Koroğlu http://orcid.org/0000-0001-8101-1104

References