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Original article

Observational cohort study of perinatal outcomes of women with COVID-19

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ABSTRACT

Background: Understanding the impact of SARS-CoV-2 infection on pregnancy outcomes and of pregnancy on COVID-19 outcomes is critical for ensuring proper prenatal and antenatal care. No similar studies have been published in Saudi Arabia.

Methods: We performed a prospective cohort study of pregnant women with confirmed SARS-CoV-2 infection who presented at King Faisal Specialist Hospital and Research Center (KFSHRC) in Riyadh, Kingdom of Saudi Arabia. COVID-19 staging was performed, pregnancy-related complications were assessed, and neonatal infection was evaluated.

Results: We enrolled 81 patients (mean age 31.75 years, SD 5.25) of which there were 17 cases in the first trimester, 20 in the second trimester, and 34 in the third trimester. The distribution of COVID-19 severity was 40 patients with Stage A, 36 with Stage B, 4 with Stage C, and 1 with Stage D. Complications were pregnancy loss in 2 patients (one in each first and second trimester) and 1 fetal death after 20 weeks of pregnancy, 7 patients with fetal growth restriction, and 8 with pre-term delivery.

Conclusions: We did not observe an unusual frequency of pregnancy-related complications due to SARS-CoV-2 infection in this high-risk obstetric population and there was no evidence of vertical transmission in newborns from women who delivered while positive for the virus.

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1. Introduction

In March 2020, the World Health Organization (WHO) classified the outbreak of a novel coronavirus disease, COVID-19, as a pandemic. SARS-CoV-2 is a novel virus that was identified as the cause of an outbreak of pneumonia in the city of Wuhan, Hubei Province, China, in December 2019 [1]. This disease was named COVID-19, for “coronavirus disease 2019.”

Genetically, SARS-CoV-2 and SARS-CoV (Severe Acute Respiratory Syndrome Coronavirus) are similar [2], yet these beta coronaviruses cause a different disease spectrum and have different transmission properties [3]. Data to assess fetal outcomes and risks resulting from infection during the prenatal period are emerging [4,5]. Various reviews find little evidence supporting increased risk of miscarriage, preterm birth, pre-eclampsia, cesarean delivery, and perinatal death; others report evidence supporting increased risk of these outcomes in pregnant women with COVID-19 [6–10].
Some societies have published statements that pregnant women do not appear to be more susceptible than the general population to becoming infected with SARS-CoV-2 [11] and various studies support these statements [12]. However, other sources indicate that pregnant women are at higher risk of worse sequelae from the infection [13–17]. Indeed, this is an active area of research [18].

The currently available data on pregnant women with COVID–19 indicates that transmission from infected mother to infant is rare but possible. Whether transmission occurs through perinatal transmission [16,17,19,20–22] or during breast feeding [19,22,23] is unclear. There are case reports for neonates positive for COVID–19, including one in the United Kingdom [24] and 2 cases in China [22,25]. It is unknown whether this transmission to the newborns was in-utero, during delivery, or due to contact with infected subjects [4].

Ding et al. reported a case of a newborn with elevated IgM antibodies to SARS-CoV-2 born to a mother diagnosed with COVID–19 [26]. The antibodies were detected two hours after birth. Zeng et al. evaluated virus-specific antibodies in 6 pregnancy cases and found that two infants had elevated IgM concentrations [27]. Due to their large macromolecular structure, IgM antibodies do not cross the placenta, suggesting that these neonates produced IgM antibodies in response to intrauterine infection with SARS-CoV-2. However, Kimberlin and Stango argued that more data are needed due to the high rate of false positives associated with IgM assays [28].

Here, we report the results of a prospective cohort study of pregnant women with documented COVID–19 infection. We evaluated pregnancy-related complications and the possibility of vertical transmission.

2. Methods

This study is a prospective cohort study, conducted at King Faisal Specialist Hospital and Research Center (KFSHRC) in Riyadh, Kingdom of Saudi Arabia. The study population included all pregnant women infected with SARS-CoV-2, based on a positive polymerase chain reaction (PCR) test of a nasopharyngeal swab sample, presenting at KFSHRC between May 2020 to February 2021. COVID–19 disease severity was classified, and pregnancy-associated complications were assessed. Pregnancy-related complications included gestational diabetes, thrombophilia, connective tissue autoimmune diseases, thyroid diseases, and hematological diseases. COVID–19 disease in the patient was staged as A, B, C, or D:

- Stage A patients were asymptomatic.
- Stage B patients had mild to moderate disease, had O₂ saturation > 94 %, and did not require O₂ supplementation.
- Stage C patients had severe disease, had O₂ saturation < 94 %, required supplemental O₂, had a respiratory rate > 30 breaths per minute (BPM), and exhibited infiltrates in > 50 % of the lung.
- Stage D patients were critical, exhibiting respiratory failure and multi-organ failure.

Patients were subdivided into 3 groups based on trimester. Pregnancy-related complications evaluated were fetal growth restriction (FGR), preterm labor (defined as delivery prior to 37 weeks), and miscarriage (defined as occurring before 20 weeks of gestation) or intrauterine fetal demise (IUFD, defined as spontaneous fetal death after 20 weeks of gestation). We also evaluated type of delivery, either Cesarean or vaginal delivery.

Fig. 1. Enrollment of pregnant women who tested positive for SARS-CoV-2 between May 2020 and February 2021. Left shows the raw data, right shows a box and whisker plot with the majority of infected subjects indicated with a red bracket.
Eight of the pregnant women were positive for SARS-CoV-2 intrapartum. Four patients were stage A and the remaining 4 patients were stage B. We tested all 8 of the babies delivered by these women for SARS-CoV-2. The newborns were immediately isolated from the mother and tested after birth and 48 h after delivery. These tests, as well as the tests of the amniotic fluid, placenta, and cord blood, were negative. It was noted that all 8 patients had a normal antenatal course and delivery apart from the infection. Six patients were delivered by Cesarean section for obstetric indications, and 2 delivered vaginally.

4. Discussion

In March 2020, SARS-CoV-2 had reached Saudi Arabia and COVID-19 has become a significant threat to the population’s health and a burden to the healthcare system. As the pandemic hit Saudi Arabia, concern for pregnant women rose, and experts were concerned about the potential for vertical transmission from infected mothers to the newborns.

Based on reports from leading societies reported before the pandemic, the frequency for first- trimester miscarriage and FGR is 10 % [29,30] and pre-term labor is 12 % [31]. We noted a similar prevalence in our infected group of patients regardless of stage of disease. In a study with the largest series of patients with COVID-19 in the first trimester of pregnancy, showed no significant difference in the cumulative incidence of COVID-19 in women who experienced spontaneous abortion [32] in a systematic review with 2375 women with signs and symptoms of COVID-19, who were in the second and third trimester of pregnancy, neonates do not represent any additional risk for adverse outcomes neither during the prenatal period nor after birth. [33] However as the evidence on risk for adverse outcomes from coronavirus disease 2019 (COVID-19) among pregnant women is still emerging other systematic reviews concluded there were associations with adverse pregnancy outcomes, maternal complications, and indicators of severe illness. However, the absolute risks were low, [34] and in a comprehensive overview of 66 systematic reviews, supports that pregnant woman with COVID-19 may be at increased risk of adverse pregnancy and birth outcomes. [35]

The preterm births are a live birth that occurs before 37 completed weeks of pregnancy. Approximately 15 million babies are born preterm annually worldwide, indicating a global preterm birth rate of about 11 % in studies pre-pandemic period. [36,37]

The iatrogenic preterm delivery, also called provider-initiated preterm birth is a relevant term that is defined as a birth that occurs before 37 weeks of gestation because of to a planned delivery in the absence of spontaneous labor. There have been conflicting data on perinatal outcomes in systematic reviews there was a reduction in preterm birth at less than 37 weeks (OR 0.89, 95 % CI 0.81–0.98) and 34 weeks (OR 0.56, 95 % CI 0.37–0.83) for iatrogenic births and in singleton pregnancies. The reduction in preterm births in regions with high mitigation measures against SARS-CoV-2 infection is likely driven by a reduction in iatrogenic births [38], in contrast with the conclusion of other two systematic reviews that claimed that iatrogenic preterm birth is the main adverse obstetric outcome [39,40].

The patients who presented with a thrombosis-related risk factors (such as thrombophilia) received low molecular weight heparin or unfractionated heparin, which may have aided in maintaining the pregnancy and minimizing thrombotic events induced by the virus. It should also be noted that the only patient that suffered from severe COVID-19 (Stage D) was delivered preterm at 36 weeks to prevent harm to herself and her unborn child due to complications of her psychiatric illness.

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**Table 1**

Clinical variables in the 81 pregnant patients positive for SARS-CoV-2.

| Variables                      | Mean (SD) or Frequency counts and percentages |
|-------------------------------|---------------------------------------------|
| Age (years)                   | 31.75 (5.25)                                |
| Gestational age at positive test (days) | 177.38 (71.42)                               |
| Trimester at positive test:   |                                             |
| First                         | 17 of 81 (20%)                              |
| Second                        | 30 of 81 (37%)                              |
| Third                         | 34 of 81 (41%)                              |

**COVID-19 Stage:**

A (asymptomatic Covid-19) 36 of 81 (44%)

B (mild to moderate disease) 4 of 81 (4.9%)

C (severe disease) 1 of 81 (1.2%)

D (critical) 4 of 81 (4.9%)

**Risk factors:**

- DM: 7 of 81 (8.6%)
- Thrombophilia: 2 of 81 (1.6%)
- Connective tissue autoimmune disease: 12 of 81 (9.7%)
- Thyroid disease: 3 of 81 (2.4%)

**Hematological disease:**

- Hematological disease: 1 of 81 (1.2%)

**Table 2**

Pregnancy or delivery-related complications in SARS-CoV-2–positive women followed to delivery or loss of pregnancy. N = 80.

| Variables                   | Mean (SD) or Frequency counts and percentages |
|-----------------------------|---------------------------------------------|
| Miscarriage                 |                                             |
| First trimester (up to week 12) | 1 of 81 (1.2%)                             |
| Second trimester (13–20 weeks) | 1 of 81 (1.2%)                             |
| FGR                         |                                             |
| First trimester (up to week 12) | 7 of 81 (8.6%)                             |
| IUFD or still birth         | 1 of 81 (1.2%)                              |
| Pre-term delivery           | 8 of 81 (10%)                              |
| Gestational age at delivery (days) | 266 (16.51)      |
| Mode of delivery            |                                             |
| Cesarean section            | 41 of 80 (52%)                              |
| Spontaneous vaginal delivery |                                             |

**IUFD, intrauterine fetal demise (fetal loss from 20 to 23 weeks), stillbirth (≥ 24 weeks gestation), FGR: Fetal growth restriction**

Among the 81 women, 80 were followed to delivery. One patient was diagnosed with a missed abortions and underwent medical termination of pregnancy. Among the 80 women followed to delivery, pre-term delivery (10 %) and FGR (8.6 %) were the most common complications (Table 2). The frequency of Cesarean section delivery or vaginal delivery were similar, 48 % by Cesarean and 52 % by vaginal delivery.

We evaluated the frequency of any of the detected complications (miscarriage, FGR, IUFD, or pre-term delivery) in the 81 patients followed through to delivery or loss of pregnancy (Table 3). By Fisher’s Exact test, we found a significant difference in the frequency of pregnancy-related complications in patients with different stages of COVID-19. Surprisingly, the complication frequency was higher for asymptomatic patients (22.5 % of Stage A) than for those with mild symptoms (9.1 % of Stage B).

**Table 3**

Association of COVID-19 disease stage with pregnancy-related complications.

| Stage                          | Frequency counts and percentages | P value |
|-------------------------------|----------------------------------|---------|
| A (asymptomatic Covid-19)     | 9 of 40 (22.5 %)                 | 0.017   |
| B (mild to moderate disease)  | 3 of 36 (9.1 %)                  |         |
| C (severe disease)            | 2 of 4 (50 %)                    |         |
| D (critical)                  | 1 of 1 (100 %)                   |         |

Significance was determined with Fisher’s Exact test

Delivered preterm at 36 weeks due to complications of psychiatric illness.
The main debate on deciding a cesarean section in the absence of obstetrical causes, is to prevent vertical transmission to the baby. In our result the mode of delivery by a Cesarean section or spontaneous vaginal delivery did not show a statistically significant number of delivery-related complications 38 of 80 (48 %) vs 41 of 80 (52 %). Mode of delivery was dictated by the obstetric indication not because of the infection status.

We found no evidence of vertical transmission from the 8 SARS-CoV-2–positive women who gave birth while infected. No virus was detected in amniotic fluid, placenta, or cord blood, and none of the newborns tested positive. Such results were in line with the conclusions from large international systematic reviews. A meta-analysis on COVID-19–pregnancy-related placental pathologies shows no typical placental changes. Another systematic review failed to clarify the route of infection in SARS-CoV-2–positive neonates but there is no sufficient evidence to exclude the possibility of vertical transmission for COVID-19 based on the current available data.

Preeclampsia as an outcome was not observed in the included patients. In one systematic review with Seventeen observational studies with low to moderate risk of bias, reported on 2769 pregnant women with a positive SARS-CoV-2 PCR test and 13,807 with a negative test, higher odds for preeclampsia (OR 1.30; 95 % CI 1.09–1.54) [45].

Screening and testing pregnant patients for Covid-19 is a question often asked particularly in those admitted to hospital for any reason. Therefore, universal testing of pregnant patients presenting to the hospital should be strongly considered as an important measure to prevent in-hospital and community transmission of COVID-19. This strategy seems needed as more than two-thirds of identified pregnant women have no symptoms. It is interesting to note in the results that the pregnancy-related complications in asymptomatic was in stage A: 40 of 81 (49 %) vs stage C (severe disease) 4 of 81 (4.9 %). We hypothesize the explanation may be due to either the same size was not large enough, or the asymptomatic covid-19 patients may have others risk factors that we could not adjust for in this study.

The vaccination data was not collected for the study that started in May 2020. To explore perinatal outcomes in SARS-CoV-2–vaccinated pregnant women comparing with unvaccinated counterparts a systematic review conclusion reported no difference in the probability of having a small for gestational age fetus (OR 0.97, 95 % CI 0.85–1.09; p = 0.570) [48], while in another systematic review of 23 studies including 117,552 COVID-19 vaccinated pregnant people, almost exclusively with mRNA vaccines, there was no evidence of an increased risk of pregnancy related outcomes including miscarriage.

Preeclampsia, and the dependent outcome is (pregnancy-related complications or no complications) and the independent predictors as risk factors so the ability of having a small for gestational age fetus (OR 0.97, 95 % CI 0.85–1.09; p = 0.570).

More studies with larger sample sizes will be needed to confirm these results.

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