

## Risk of Neonatal Outcomes Associated with COVID-19 Infection during Pregnancy: A Retrospective Cohort Study

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### Abstract

**Background:** Since its announcement as a pandemic, COVID-19 has been shown to be associated with more severe outcomes among pregnant women. Infected mothers may develop Intrauterine Growth Retardation (IUGR), stillbirth, premature labor, and Disseminated Intravascular Coagulation when carrying a child (DIC). The present study aimed to estimate the risk of severe COVID-19 and its correlation with adverse neonatal outcomes among pregnant women.

**Methods:** This was a population-based, retrospective cohort study of all pregnancies with a live birth or fetal death in Mashhad, Iran, from February 20, 2020, to June 21, 2020, on 460 patients who tested positive for COVID-19. The assessed neonatal outcomes included preterm birth, IUGR, stillbirth, severe neonatal asphyxia, and neonatal death. Modified Poisson and multinomial logistic regression models were used to derive relative risk estimates.

**Results:** 460 patients identified with COVID-19 during pregnancy were assessed in the study. Overall, the most prevalent complication was preterm birth, with a total of 119 (25.9) cases. In multivariable analysis, the risk of preterm labor, low birth weight, severe neonatal asphyxia, ICU-admitted mother, the length of hospitalization > 7 days and IUGR were significantly increased in the Stillbirth. The risk of global preterm birth had also significantly increased in the Stillbirth group compared to the other group (91.7% versus 23.7%, aOR = 3.66, 95% CI [8.85- 165.87],  $p < 0.001$ ).

**Conclusion:** Along with the possibility of more severe COVID-19 infection among pregnant women, five complicated outcomes were described in the present study, including preterm birth, IUGR, stillbirth, severe neonatal asphyxia, and neonatal deaths as risk factors of COVID-19 infection in pregnancy.

**Key Words:** COVID-19 Infection, Neonatal Outcomes, Retrospective Cohort Study, Pregnancy.

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## 1-INTRODUCTION

Three deadly outbreaks have been associated with the Coronaviridae family; Severe Acute Respiratory Syndrome (SARS), the Middle East Respiratory Syndrome coronavirus (MERS), and the most recent one, the Coronavirus Disease 2019 (COVID-19) (1).

COVID-19 is transmitted through droplets. Moreover, studies have shown that the recent lineage is more contagious than the earlier types; as from March 11, 2020, COVID-19 has been declared a pandemic and is the most deadly outbreak since 1918 (2, 3). More than 230 countries have reported COVID-19 cases at this time. Iran experienced its first case of COVID-19 on February 19, 2020, and with over seven million infected cases, it is ranked as the seventeenth most affected country by COVID-19 (4).

In previous Coronavirus pandemics, women were at a high risk of developing a serious illness. Similarly, certain groups are at higher risk for a more severe COVID-19 outcome, namely, pregnant women. Physiological changes in pregnant women (e.g., decreased lung expansion, increased heart rate, decreased residual capacity, and vasodilation in the lung resulting in edematous mucous membranes) may place them at an increased risk of developing pneumonia and acute lung injury. In addition, certain immunologic changes in pregnant women protect the fetus from the mother's immune responses. This further weakens the mother's immune system, placing her at risk of infection (3). Symptoms in this group are mostly fever, cough, and elevated CRP (1).

Several adverse outcomes threaten the fetus and the mother due to the possibility of vertical or peripartum transmission of the virus. These outcomes could be discussed in two stages: the fetal and the neonatal stages. Once carrying the fetus,

an infected mother could experience Intrauterine Growth Retardation (IUGR), stillbirth, preterm labor, and Disseminated Intravascular Coagulation (DIC).

Some systematic reviews and meta-analyses evaluating the pregnancy outcomes in women with confirmed SARS-CoV-2 infection have described that low birth weight (LBW) and PTB were more observed in pregnant women with COVID-19 than in pregnant women without COVID-19 (3, 5). However, other recent systematic reviews have not confirmed this correlation (6, 7).

Moreover, in the case of neonates, COVID-19 could result in dysbiosis due to the separation of an infected mother and her newborn. These outcomes have been attributed to the increased expression of the SARS-CoV-2 receptor, ACE2, in the uterus (8).

Given the significance of developing COVID-19 in a pregnant woman and that obstetric outcomes in COVID-19 are yet to be established, the present study aimed to examine the incidence of stillbirth and preterm delivery in COVID-19.

## 2- MATERIALS AND METHODS

### 2-1. Design and sampling

This was a descriptive prospective study on pregnant women confirmed for COVID-19 referring to Imam Reza hospital in Mashhad, Iran.

The study was conducted from February 20, 2020, to June 21, 2020. All patients were asked to fill in a consent form before the study and were allowed to terminate their cooperation at any time. Imam Reza hospital was the only referral hospital for patients with symptoms of coronavirus in the northeast of Iran from the beginning of the coronavirus pandemic, and all the pregnant women with signs and symptoms of Covid-19 or those with a positive test for the virus, though being asymptomatic, were referred to this center for delivery.

### 2-1-1. Inclusion and Exclusion Criteria

The study sample was selected by screening all the pregnant women (whether symptomatic or asymptomatic) and confirming the suspected patients by the use of real-time reverse transcription-polymerase chain reaction (RT-PCR) test or high-resolution computed tomography (HRCT). RT PCR test was performed on throat swab samples. The non-COVID patients were excluded from the study, and the confirmed ones were followed up to the delivery.

### 2-2. Procedure

The clinical status and the pregnancy outcomes of the patients were observed and recorded in data collection sheets. Neonatal outcomes included miscarriage, preterm birth, IUGR, respiratory distress, stillbirth, severe neonatal asphyxia, and neonatal death. miscarriage was defined as a spontaneous pregnancy loss before 20 weeks of gestation, Preterm birth was defined as any birth before 37th completed weeks of gestation (9), intrauterine growth retardation (IUGR) a fetal weight less than 10% of the predicted for gestational age (10) , and stillbirth as the fetal death at  $\geq$  20 weeks of gestation or with a birth weight of  $\geq$  350 grams (11), and severe neonatal asphyxia Apgar 0-3 according to Apgar score at 5 min (12).

To estimate the conception date, Information about gestational age at birth, birth date, or fetal birth was used. All women were categorized in one of the trimesters of pregnancy, according to the estimated conception date and COVID-19 laboratory test date. The 1st trimester was from the moment of conception and up to 13 weeks, the second trimester was from 14 to 28 weeks of pregnancy, and the third trimester was defined as gestational weeks of 29 to 40. The patients were excluded from the analyses if the date of their

positive coronavirus test was before the conception date or after the delivery. Perinatal death in an infant following live birth is indicated at the time birth records are submitted to the vital statistics system, usually within 2–3 days of birth.

### 2-3. Data analysis

The data were analyzed using SPSS ver. 25. Descriptive statistics determined that the numerical variables had a normal distribution. Chi-square tests were used to analyze categorical variables.  $P < 0.05$  was considered statistically significant. Modified Poisson and multinomial logistic regression models were used to derive relative risk estimates.

## 3-RESULTS

In the present study, a total of 460 COVID-19 patients were evaluated. In 260 women, the pregnancy was terminated and in the rest of them the pregnancy was going on. The mean age of pregnant mothers with covid-19 was  $30.81 \pm 6.22$  and their BMI was  $26.2 \pm 5.07$ . The length of hospitalization in the Corvid-19 ward was  $6.10 \pm 6.49$  days. 116 (25.2%) of these patients were admitted to ICU.

The mean gestational age (GA) of the fetuses at the time of the disease was  $29.67 \pm 6.30$  weeks. 160 (61.3%) of the patients gave birth by cesarean section. 120 cases (26.1%) were hospitalized in the neonatal ward due to fetal complications in the newborns after delivery. 17 (3.1%) of them were IUGR. Finally, 24 (5.2%) fetuses were stillbirths, and 2(.4 %) babies died after hospitalization within 28 days. Overall, the frequency of births by Cesarean section was 61.3% ( $n = 160$ ) amongst the pregnant women with COVID-19 infection. Maternal morbidities and adverse obstetrical outcomes of women according to stillbirth are presented in **Tables 1** and **2**.

**Table-1:** Maternal and neonatal characteristics according to COVID-19 diagnosis

variables	Minimum	Maximum	Mean	Std. Deviation
Age of mother(year)	15	46	30.81	6.225
BMI	17.72	44.79	28.2110	5.07093
The length of hospitalization(day)	0	57	6.10	6.497
GA(week)	4.00	41.00	29.6771	8.30642
APGAR 1	.00	10.00	7.1765	3.10495
APGAR 5	.00	10.00	8.2193	3.34568
Weigh in sonography(gram)	.00	4174.00	1818.1807	957.51535
Weight neonatal(gram)	350.00	4380.00	2909.4522	810.58984

**Table-2:** The complicated neonatal outcomes among the study participants

Neonatal outcome	Variables	
	Frequency	Percentage
Preterm birth	119	25.9
pregnancy at <37 weeks of gestation	69	15.1
28<pregnancy <32 weeks of gestation	20	4.3
22<pregnancy <28 weeks of gestation	23	5.0
pregnancy ≥22 weeks of gestation	5	1.1
Cesarean section	160	61.3
IUGR	17	3.7
Stillbirth	24	5.2
Severe neonatal asphyxia	7	1.5
Neonatal death	2	.4
Low birth weight	53	11.5
mother in ICU	116	25.2
Mother death	26	5.7

Five complicated outcomes were described in the present study for the pregnancies, including preterm birth, IUGR, stillbirth, severe neonatal asphyxia, and neonatal deaths (**Table 3**). According to the results of multivariable analysis, the risk of Preterm labor, Low Birth weight, severe neonatal asphyxia, ICU-admitted mother, the length of hospitalization > 7 days and IUGR were significantly increased in the Stillbirth group compared to the other group. Overall, the most prevalent complication was preterm birth, with a total of 119 (25.9%) cases. Multivariable analysis indicated that the risk of global preterm birth had significantly increased in the Stillbirth group compared to the other group (91.7% versus 23.7%, aOR = 3.66, 95% CI [8.85-165.87], p<0.001). The risk of Still birth

and neonatal death was significantly higher in the second trimester (50.0% versus 2.5%, aOR = 5.21, 95% CI [.001 - .027], p < 0.001) and in 28<pregnancy <32 weeks of gestation, the risk of stillbirth was 16.7% (aOR = 3.74, 95% CI [.004- .139], p < 0.05). The risk of Still birth and neonatal death was significantly higher in low birth weight neonates (66.7% versus 15.9%, aOR = 2.36, 95% CI [4.370 – 25.75], p < 0.001).

In total, 460 pregnant women with COVID-19 Infection were investigated. In the ICU admission group, both the risk of medically induced preterm birth (aOR = 1.15, 95% CI [.137 - .721], p < 0.001), and the risk of the length of hospitalization > 7 days (aOR = 1.75, 95% CI [1.35- 7.46], p < 0.001) were greatly increased.

**Table-3:** Risk of neonatal outcomes associated with COVID-19 infection during pregnancy

Maternal complications	Stillbirth & neonatal death		multinomial logistic regression		
	Yes, N (%)	No, N (%)	OR	CI (95 %)	P
Preterm labor	22 (91.7%)	97 (23.7%)	3.66	8.85 - 165.87	0.000
32< weeks of gestation <37	5 (20.8%)	64 (14.8%)	-2.580	0.014 - 0.399	0.076
28< weeks of gestation< 32	4 (16.7%)	16 (3.7%)	-3.744	0.004 - 0.139	0.024
22 <weeks of gestation <28	12 (50.0%)	11 (2.5%)	-5.21	0.001 - 0.027	0.005
pregnancy terminations ≥22 weeks of gestation	1 (4.2%)	4 (.9%)	-3.77	0.002 - 0.317	0.024
Low Birth weight	16 (66.7%)	69 (15.9%)	2.36	4.370 – 25.75	0.000
severe neonatal asphyxia	2 (8.3%)	5 (1.1%)	2.56	1.43 – 42.57	0.017
ICU-admitted mother	12 (50.0%)	104 (23.9%)	-1.15	0.137 - 0.721	0.006
The length of hospitalization > 7 days	11 (47.8%)	87 (22.4%)	1.75	1.35- 7.46	0.001
Mother death	3 (12.5%)	23 (5.3%)	-0.940	0.109- 1.406	0.150
IUGR	6 (25.5%)	11 (2.5%)	2.439	4.27 – 38.63	0.000
Age of mother <18	1 (4.3%)	16 (3.7%)	0.044	0.013- 84.576	0.985
40< Age of mother	4 (17.4%)	109 (25.3%)	1.201	0.021- 4.360	0.378
BMI> 25	4 (28.6%)	71 (31.7%)	-.713	0.072- 3.41	0.467

#### 4- DISCUSSION

In this prospective study, we aimed to evaluate the prenatal outcomes in patients with confirmed Covid-19. According to our findings, the rate of preterm labor was 25.9 in covid-19 patients. Similar to our study, previous studies have shown that Severe SARS-CoV-2 infection, compared to a mild illness, has been associated with higher rates of low birth weight, and preterm birth (13-15). Kuriloff et al. reported 23.5% preterm labor in their study which is the same as the percentage found in our study (16). Meanwhile, the rate of premature birth in a completely healthy pregnant woman without any infection is about 11% (17). Our study, further, showed that among the neonatal outcomes, preterm and stillbirth were significantly more frequent among the ICU-admitted patients. According to our policy in our country, intubated pregnant mothers with critical conditions after 32-34 weeks, in case of refractory hypoxemic respiratory failure or, a worsening critical condition, termination of pregnancy is recommended. Also, termination may be

advised in hospitalized pregnant mothers after 32-34 weeks who have pneumonia but are not intubated, and the general condition of the mother is getting worse; this could have affected our results (18).

Although extensive research has been carried out on the obstetrics outcome of COVID-19, what is not yet clear is the actual relationship between preterm labor and SARS-CoV-2. Most studies have not identified gestational age and it is also not obvious whether the preterm labor was spontaneous or iatrogenic (19).

Smith et al. collected information on pregnancy outcomes of 5893 women from 77 countries and concluded that severe Covid 19 in late pregnancy increased the rate of preterm birth due to preterm cesarean section. It also increased spontaneous preterm labor. However, severe infection before 20 weeks did not increase the risk of preterm labor and mild or moderate infection had minimal risk in late pregnancy (20).

It seems that medical or obstetric indications in the third trimester are

logical reasons for termination in pregnant women with severe SARS-CoV-2 infection. But it is not clear that the infection in the first or second trimester is associated with a following preterm birth (21). In our study, most preterm labors happened between ages 32 to 37 (15%) of pregnancy, this result is in line with those of previous studies. However, the rate of preterm birth among the ICU-admitted patients was 30.2%, while literature has shown a range from 6.1% to 55.56% (22, 23).

The rate of miscarriage in our study was 1.1% that was not more than that in a normal population. The abortion rate had been reported to be higher in some studies (24, 25) but more recent studies have not confirmed it. Cosma et al., for instance, performed a case control study on 225 pregnant women in the first trimester and concluded that severe acute respiratory syndrome coronavirus 2 infection does not affect the rate of abortion (26).

Intrauterine Growth Restriction (IUGR) is a condition that occurs in up to 10% of pregnancies (27). In our study, 17 cases (3.7%) developed fetal growth restriction and it seems that infection with COVID-19 has not affected the growth of the fetus. Contrary to our finding, Hamidi et al. concluded that severe COVID-19 infection leads to adverse neonatal outcomes such as higher admission to the neonatal intensive care unit and IUGR (28). Although early epidemiological studies had shown that SARS-CoV-2 infection increased the risk of fetal growth restriction, recent studies do not confirm this correlation (29, 30).

The rate of stillbirth in our study was 5.2% which was higher in patients admitted to the ICU section. The association between SARS-CoV-2 infection and stillbirth is less consistent. Yeonsong Jeong and Min-A Kim analyzed the data of 69 studies including 1,606,543 pregnant women with confirmed COVID-19 and found that the

risk of stillbirth was higher among patients with infection compared to patients without infection (31). In contrast, one systematic review has shown that the rates of stillbirths and neonatal deaths are relatively low (32). According to a recent report by the Centers for Disease Control and Prevention (CDC), as a result of the circulation of the delta variant in the United States, the relative risk of stillbirth in pregnant women with covid-19 increased significantly, from 1.47 prior to delta dominance to 4.04 during delta dominance (33). In our study, a mother's age over 40 increased the probability of infant death by 1.20%, and the ICU-admission of a mother and the mother's condition getting worse raised the probability of stillbirth for 1.72 times. Also, premature babies were 3.66 times more likely to die, as compared to term babies.

In agreement with previous studies, the authors observed a higher rate of cesarean section among patients with covid-19 (61%). Other studies have, similarly, revealed the same results showing that 60%–80% of babies were born by cesarean delivery (34-36) However, according to the American College of Obstetricians and Gynecologists, COVID-19 status alone is not an indication for cesarean delivery, and cesarean delivery should be performed based on obstetric (fetal or maternal) indications (37).

Furthermore, this study showed that the APGAR scores at minutes 1 and 5 in babies whose mothers were infected with COVID-19 were not different from those of the normal population. These results are in accordance with the findings of recent studies indicating that there were no significant differences in terms of APGAR score in women with COVID-19 and healthy pregnant women (38, 39).

Finally, 26.1% of newborns in our study were admitted in the NICU, while the admission rate of infants in study by

Kuriloff et al. was 50.9% (16). Nevertheless, in the review of 10,996 cases in 15 countries, conducted by Figueiro-Filho, Yudin, and Farine, only 20% of infants were reported to be hospitalized (40).

#### **4-1. LIMITATIONS AND STRENGTHS**

One of the primary strengths of this study is the unusually large sample size for a single-center study conducted in accordance with standards and management protocols. With the inclusion of a severely ill group and the control group, it was possible to examine the influence of increasing severity of COVID-19 on study results for the first time. By utilizing this data, obstetricians will be able to provide more nuanced advice regarding vaccination and treatment of severe COVID-19 as a significant factor resulting in unfavorable pregnancy outcomes.

Our study had some limitations; the SARS-CoV-2 genotypes were not analyzed, although new strains of the virus were identified throughout the research period. There may be a shortcoming in the study as a result of this. The prevalence of infections in the first and second trimesters of pregnancy and their impact on pregnancy outcomes have rarely been documented, which makes it difficult to gather relevant data and draw conclusions about the population as a whole.

#### **5- CONCLUSION**

Five complicated outcomes were described in the present study, including preterm birth, IUGR, stillbirth, severe neonatal asphyxia, and neonatal deaths; and our study found that a more severe outcome among pregnant patients with COVID-19 was associated with preterm birth, stillbirth. Severe disease of the mother and admission to the neonatal ward increases the probability of fetal and neonatal complications. So, it is important

to recognize and treat severe cases of COVID-19 infection as early as possible.

#### **6-ETHICAL CONSIDERATIONS**

This study was approved by the Ethics Committee of the Mashhad University of Medical Sciences with the approval code of IIR.MUMS.REC.1399.214. The consent form was obtained from all participants.

#### **7-Acknowledgments**

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#### **8-Conflict of interest**

None.

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