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Pregnancy and Perinatal Outcomes among COVID-19-Infected and Non-Infected Pregnant Women, Saudi Arabia: A Case-Control Study

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ABSTRACT

Background: *COVID-19 has been documented to affect pregnancy outcomes. Therefore, this study evaluated and compared pregnancy and perinatal outcomes, complications and risk factors among COVID-19 infected and non-infected Saudi pregnant women.* ***Methods:*** *A retrospective case-control study was conducted in Maternal and Children Hospital, Abha. One COVID-19 infected patient was matched with 2 uninfected patients (controls). Data were collected using a researchers-generated standardized report form. The t-test and Fisher test were used to compare groups. Logistic regression was used to determine the associations between exposure to COVID-19 and adverse maternal and neonatal outcomes.* ***Results:*** *We recorded data from 150 patients (50 cases and 100 controls). COVID-19 positive women had a significantly increased likelihood of developing complications and having poor maternal and neonatal outcomes. Among factors associated with poor maternal and neonatal outcomes among women with COVID, the cesarean section has the strongest association (aOR=20.1, CI 6.8-54.64), followed by preterm delivery (aOR=6.71, CI 2.27-19.87), and hypertension (aOR=6.55, CI 1.63-26.33), while Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) score had the weakest association (aOR=3.51, CI 1.11-11.16).* ***Conclusions:*** *COVID-19 was associated with poor maternal and neonatal outcomes. Therefore, there is a need to closely monitor pregnant women with COVID-19 and their babies during delivery and perinatal period to mitigate short-term and long-term health adverse effects.*

Keywords: COVID-19, Coronavirus disease, Maternal outcomes, Neonatal Outcomes, Pregnancy

INTRODUCTION

Severe Coronavirus disease (COVID-19) symptoms were commonly found in vulnerable people, including pregnant women [1]. Pregnant women with COVID-19 are more prone to be admitted to the Intensive Care Unit (ICU) with severe symptoms of COVID-19 [2]. The pregnancy makes women more vulnerable due to decreased immunity by pregnancy and newborns are also vulnerable due to their immature immune systems [2]. The viruses causing respiratory diseases, including SARS-CoV-2, have been found to severely affect pregnant women because pregnancy increases heart rate and stroke volume and reduces pulmonary residual capacity, which results in a higher risk of hypoxemia [3]. Fetal immunity has a lower cytolytic function than natural Fetal killer (NK) cells, lower intensity of antigen-specific antibody response, immature T-cells and fewer inflammatory mediators. All of these increase fetal susceptibility to infections [3]. In addition, viral infection can attack the placenta, impair its function, induce abortion or preterm labour/delivery, and lead to long-term neurodevelopmental sequelae [3,4].

As science reveals more about COVID-19, the potential risk of vertical transmission to the fetus/neonates have become a significant concern on top of reported worse clinical outcome in pregnant women infected with COVID-19 [4]. A review of 287 pregnant women from 6 different countries showed fewer adverse maternal and neonatal outcomes in pregnant women with COVID-19 compared to previous coronavirus outbreak infections in pregnancy. Vertical transmission was not reported, but its possibility was suggested in three neonates and they reported one neonatal death, one stillbirth and one abortion [3]. Another systematic review and meta-analysis of 3158 pregnant women found that women who were obese, hypertensive, or had a respiratory disorder were more likely to be symptomatic and have more complications when infected with SARS-CoV-2 [5].

A case-control study conducted on 261 pregnant women in 3 countries (Oman, Jordan and Irak) found more pregnancy complications in high-risk pregnant women than pregnant women with COVID-19 and healthy pregnant women. The common complications were: preeclampsia, virginal bleeding during pregnancy, preterm labour, premature rupture of membrane and low neonatal Apgar score. No severe neonatal adverse outcomes of COVID-19 were found in this study [6].

In Saudi Arabia, Al-Matary et al. found that the most common adverse pregnancy outcome was prematurity (15.5%), followed by Fetal distress (6.5%) and preeclampsia (2.0%) and one maternal death. They also found that the majority of pregnant women had mild or moderate disease symptoms and no evidence of possible vertical transmission of COVID-19 infection from mothers to their fetuses/neonates [7].

A study conducted in Qassim, Saudi Arabia, revealed that one-third of women missed their antenatal care appointments during the COVID-19 pandemic, fearing being infected with COVID-19 [8]. This may result in adverse outcomes associated with poor pregnancy follow-up not directly related to COVID-19.

Despite more studies being conducted to understand COVID-19 in pregnancy as science reveals more about SARS-CoV-19 and the COVID-19 pandemic, in Saudi Arabia, there is limited data on COVID-19 and its effect on pregnancies and neonates and the outcomes of COVID-19 in pregnancy and perinatal period have not been sufficiently studied. Therefore, this study will evaluate pregnancy and perinatal outcomes, complications and risk factors among COVID-19-infected and non-infected pregnant women who gave birth at Maternity & Children Hospital, Abha and Saudi Arabia.

MATERIALS AND METHODS

Study Design and Setting

A retrospective case-control study was conducted on pregnant patients at Maternity & Children Hospital, Abha, Saudi Arabia, from June 2020 to July 2021.

Study Population

The case group included all the pregnant patients diagnosed with COVID-19 during pregnancy and women who gave birth during the study period and with complete medical records for the current pregnancy. The control group included pregnant women not diagnosed with COVID-19 during pregnancy and women without COVID-19 who gave birth in the study settings during the study period and with complete medical records for the current pregnancy. Pregnant

women aged less than 18 years old, women who had pregnancy complications before infection with COVID-19 and pregnant women with missing data >10% in the antenatal or Intranatal Medical Records were excluded.

Procedure

The researcher collected data on demographic, clinical, treatment, maternal complications/outcomes, and fetal and neonatal complications/outcomes from the medical records. The confirmation of COVID-19 infection was based on positive results of quantitative real-time Reverse Transcription-Polymerase Chain Reaction (qRT-PCR) following the World Health Organization (WHO) guidelines.

For every COVID-19positive participant in the study, two COVID-19-negative pregnant women were added to create an unbiased sample of all pregnant women without a COVID-19 diagnosis.

Data were collected using a researchers-generated standardized report form that captures the participants' demographic, clinical characteristics, and pregnancy outcomes (i.e., maternal and neonatal outcomes). Data were collected by three trained medical students at King Khalid University.

Demographic data collected included age, parity, educational level, gravidity, Body Mass Index (BMI), and medical and obstetric morbidities. Data were collected by three trained medical students at King Khalid University. Clinical characteristics included; clinical presentation of COVID-19 infection, hospital admission, Intensive Care Unit admission, supplemental oxygen requirement >48 hours of $FiO_2 \geq 28\%$, and invasive mechanical ventilation requirement.

Participants' maternal outcomes included gestational age at delivery, preeclampsia, vaginal bleeding, premature rupture of membranes, preterm labour, placenta abruption, induction of labour, cesarean section, mode of delivery, intrauterine fetal dead, and maternal death.

Data about neonatal outcomes comprised signs of fetal distress, low Apgar score (<6), stillbirth, abnormal umbilical cord, birth weight, fetal asphyxia, neonatal death, Large for Gestational Age (LGA), Small for Gestational Age (SGA), birth weight, Neonatal Intensive Care Unit (NICU) admission, and length of hospital stay and any congenital malformation.

Statistical analysis

We performed descriptive and analytic statistics using Statistical Package for the Social Sciences SPSS 21(SPSS, Chicago, IL, USA). Data were presented as mean (standard deviation) for the quantitative and n (%) for the qualitative variables. The T-test, χ^2 test and Fisher test were used to compare groups. The normality of the distributions was tested using the Kolmogorov-Smirnov test. Logistic regression was used to determine the associations between exposure to COVID-19 and adverse maternal and neonatal outcomes. Analyses were adjusted for confounders, and the results were evaluated against a confidence interval of 95% and a P-value<0.05 for statistical significance.

Ethical considerations

Anonymity was assured by replacing personally identifiable information with codes and then cross-checking was done to identify and remedy inconsistencies at the time of data entry. All information gathered was kept securely in a database. Only the investigator of this project and the supervisor has access to the information kept in the database.

RESULTS

Data from 150 patients were recorded in the study. The patients' mean age was 29.16 ± 5.78 years old for the case group and 30.42 ± 6.16 for the control group. The BMI (Mean=31.2) of COVID-19-positive patients was significantly higher than the Body Mass Index (BMI) (29.1) of patients in the control group (p=0.003). The gestation age at delivery was higher for the control group (Mean=39.04 *vs*. Mean=36.72) (p=0.001). There were slight differences in other characteristics without statistical differences (Table 1).

Table 1 Backgrounds characteristic of the case and control

Variables	Case and Control	Mean	SD	p-value
Mother's Age	Corona Negative	29.16	5.78	0.221
	Corona Positive	30.42	6.16	
Gravida	Corona Negative	3.1	1.95	0.057
	Corona Positive	3.8	2.28	
Parity	Corona Negative	1.92	1.34	0.182
	Corona Positive	2.28	1.89	
BMI	Corona Negative	29.1	3.3	0.003
	Corona Positive	31.2	5.07	
Gestational age at Delivery in weeks	Corona Negative	39.04	1.75	<0.001
	Corona Positive	36.72	2.63	
BMI= Body Mass Index				

Comparing maternal morbidities between case and control groups, we found that the case group generally had more morbidity. The case group had more cases of hypertension (p=0.004) and preeclampsia (p=0.001) than the control group. Anaemia, diabetes mellitus, and vaginal bleeding are more prevalent among the COVID-19-positive pregnant women at 66.7%, 66.7% and 62.5%, respectively but the difference was not statistically significant (Table 2).

Table 2 Comparison of maternal morbidities between case and control groups

Variables		Control Group (n and %)		Case Group (n and %)		p-value
Hypertension >(140/90)	No	97	70.00%	42	30.00%	0.004
	Yes	3	27.30%	8	72.70%	
Diabetes mellitus	No	98	68.10%	46	31.90%	0.077
	Yes	2	33,3%	4	66.70%	
Anemia	No	99	67.30%	48	32.70%	0.258
	Yes	1	33.30%	2	66.70%	
Preeclampsia	No	98	69.00%	44	31.00%	0.01
	Yes	2	25.00%	6	75.00%	
Any vaginal bleeding	No	97	68.30%	45	31.70%	0.118
	Yes	3	37.50%	5	62.50%	

Table 3 Comparison of maternal clinical outcome during delivery between case and control groups

Variables		Control Group (n and %)		Case Group (n and %)		p-value
Excessive bleeding during delivery	No	99	69.20%	44	30.80%	0.031
	Yes	1	4.30%	0 6	85.70%	
Premature rupture of membrane	No	98	69.00%	44	31.00%	0.017
	Yes	2	25.00%	6	75.00%	
Induction of labor	No	94	67.60%	45	32.40%	0.507
	Yes	0 6	54.50%	5	45.50%	

Gestational weeks at delivery	≥ 37 weeks	92	74.20%	32	25.80%	<0.001
	≤ 36 weeks	0 8	30.80%	18	69.20%	
Mode of delivery	Normal	95	79.20%	25	20.80%	<0.001
	Cesarean section	5	16.70%	25	83.30%	
Maternal health status	Well	95	69.90%	41	30.10%	0.16
	Very sick	5	35.70%	9	64.30%	
Maternal death		-		1	100%	

The COVID-19 was more significantly associated with delivery at less gestational weeks (≤ 36 weeks) and cesarean sections (p<0.001), followed by premature rupture of membranes (=0.017), and excessive bleeding during delivery (p=0.031). Induction of labour was reported more in COVID-19 negative women (54.5%) but without a statistical significance. Only one maternal death was observed in the COVID positive cases however no such incident occurred in the COVID negative cases (Table 3).

Table 4 Comparison of maternal clinical management between case and control groups

Variables		Control Group (n and %)		Case Group (n and %)		p-value
ICU admission	No	99	70.70%	41	29.30%	<0.001
	Yes	1	10.00%	9	90.00%	
Need O_2 support	No	96	71.10%	39	28.90%	<0.001
	Yes	4	26.70%	11	73.30%	
Need mechanical ventilation	No	99	67.30%	48	32.70%	0.258
	Yes	1	33.30%	2	66.70%	
Hospital admission before delivery	No	96	91.40%	9	8.60%	<0.001
	Yes	4	8.90%	41	91.10%	
Referral to another hospital	No	100	68.50%	46	31.50%	0.01
	Yes	0	0.00%	4	100%	

Table 4 presents a comparison of clinical management between cases and control groups. COVID-19-positive pregnant patients were significantly more likely to be admitted to the Intensive Care Unit (<0.001), to need oxygen support (<0.001), to be admitted before delivery (<0.001), and to be referred to more equipped hospitals for treatments (p=0.001) than COVID-19 negative pregnant patients.

Table 5 Comparison of neonatal outcome between case and control groups

Variables		Control Group (n and %)		Case Group (n and %)		p-value
Birth status	**Alive**	**91**	**69.60%**	**42**	**30.40%**	0.189
	Stillbirth	3	37.50%	5	62.50%	
	IUFD	10	76.90%	3	23.10%	
Neonatal death	Yes	0	0.00%	4	0.01%	0.043
Birth weight	Normal Birth weight (≥ 2.5kg)	87	70.20%	37	29.80%	0.06
	Low birth weight (<2.5 kg)	13	50.00%	13	50.00%	

APGAR score	Less than 6	8	36.40%	14	63.60%	0.001
	More than 6	92	71.90%	36	28.10%	
Need ICU support	No	88	69.8%	38	30.20%	0.059
	Yes	12	50.00%	12	50.00%	
Congenital malformation	No	92	68.10%	43	31.90%	0.248
	Yes	8	53.30%	7	46.70%	
COVID Test	Positive	----	----	4	8%	
	Negative	----	-----	15	30%	
	Not done	100	100.00%	31	62.00%	
APGAR= Appearance (skin color), Pulse (heart rate), Grimace response (reflexes), and Activity (muscle tone); ICU= Intensive Care Unit; IUFD=Intrauterine Fetal Demise/Death; COVID=Coronavirus Disease						

Table 5 shows the comparison of neonatal outcomes between case and control groups. There was a statistically significant association between COVID-19 infection and low APGAR scores (p=0.001) and neonatal death (p=0.043). Newborns of COVID-19-positive women were more likely to have poor neonatal outcomes than newborns of COVID-19-negative women but the differences for other neonatal outcomes were not statistically significant.

Table 6 Logistic regression for the factors associated with poor maternal & neonatal outcomes among COVID- 19 positive pregnant women

Variables	aOR	95% CI		p-value
Maternal morbidities				
Hypertension				0.008
No	**Ref**			
Yes	6.55	1.63	26.33	
Gestational weeks at delivery				
≥ 37 weeks (Full term)	**Ref**			0.001
≤ 36 weeks (Preterm)	6.71	2.27	19.87	
Mode of delivery				
Normal and assisted	**Ref**			<0.001
Cesarean Delivery	20.1	6.8	54.64	
Premature rupture of membranes				
No	**Ref**			0.03
Yes	6.07	1.12	33.04	
APGAR score				
More than 6	**Ref**			0.03
Less than 6	3.51	1.11	11.16	
aOR: adjusted Odds Ratio, CI: Confidence interval, APGAR: Appearance (skin colour), Pulse (heart rate), Grimace response (reflexes), and Activity (muscle tone)				

All variables with P-Value<0.3 in the bivariate analysis were included in the logistic regression model. The adjusted or was reported in Table 6. Hypertension, gestational weeks at delivery, mode of delivery, premature rupture of membranes and APGAR scores were associated with poor maternal and neonatal outcomes among COVID-19-positive pregnant women. The cesarean section had the strongest association (aOR=20.1, CI: 6.8-54.64), followed by preterm delivery (aOR=6.71, CI: 2.27-19.87), and hypertension (aOR=6.55, CI: 1.63-26.33), while Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) score had the weakest association (aOR=3.51, CI: 1.11-11.16).

DISCUSSION

Our study evaluated pregnancy and perinatal outcomes and morbidities among COVID-19 infected and non-infected pregnant women. We also assessed risk factors for poor maternal and neonatal outcomes. In this case-control study, we found that COVID-19-positive women had a significantly increased likelihood of developing complications such as preterm delivery, hypertension, preeclampsia, premature rupture of membranes, undergoing cesarean section and experiencing Intensive Care Unit and pre-delivery admissions, Oxygen support and referrals to other hospitals. Newborns of COVID-19-positive women were more likely to have poor neonatal outcomes. Hypertension, gestational weeks at delivery, mode of delivery, premature rupture of membranes and Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) scores were associated with poor maternal and neonatal outcomes.

The gestational age at delivery was lower among COVID-19 positive women compared to COVID-negative women, explained by the significant association between COVID-19 and preterm delivery (≤ 36 weeks) found by this study. Other morbidities such as hypertension, preeclampsia, and premature rupture of membranes were also more prevalent in COVID-19 women than women without COVID-19 and are risk factors for preterm delivery, further explaining lower gestational age at delivery among COVID-19 positive women. These findings agree with another study conducted in 45 hospitals in Spain, which reported an increase in preterm deliveries and premature rupture of membranes among women with COVID-19 [9]. COVID-19 comorbidities, such as severe pneumonia and pregnancy complications, such as eclampsia and preeclampsia, increase the likelihood of pre-term delivery, either iatrogenic to save neonatal and maternal life or natural. Another study reported an increase (19%) of iatrogenic preterm delivery among symptomatic COVID-19 infected patients compared to asymptomatic patients (8.8%) [10]. Our study indicated that BMI was significantly higher among COVID-19-positive women, while the gestational age at delivery was lower. This might indicate the association between BMI and gestational age, as reported by another study by Kumarasinghe et al. who showed that overweight and obesity were risk factors for preterm delivery among COVID-19-positive women [11].

We found that COVID-19 was associated with increased maternal morbidities where hypertension was the most prevalent, followed by preeclampsia. Since preeclampsia is classified among the hypertensive disorders of pregnancy, gestational hypertension increase is expected to go along with preeclampsia increase, in addition to the fact that gestational hypertension can complicate preeclampsia and eclampsia. Similarly, another study conducted in the USA reported increased risks of hypertensive disorders and preeclampsia among COVID-19-positive pregnant women. However, that study contrasted our findings of preterm delivery association with COVID-19 because no association was found in that study [12]. While some previous studies have found a significant association between COVID-19 and diabetes during pregnancy, our study showed an increase in diabetes among COVID-19 positive women compared to COVID-19 negative women but without a statistically significant difference. Kurian et al. found that diabetes increased the odds of adverse maternal and neonatal outcomes [13].

A study carried out by Westgren, et al. found that COVID-19-positive women, during pregnancy and early the postpartum period were relatively at high risk of being admitted to the Intensive Care Unit and needing mechanical ventilation [14]. However, our study contrasted this finding of the significantly increased likelihood of requiring mechanical ventilation because we didn't find any significant difference between pregnant women with and without COVID-19. However, our findings were similar to Intensive Care Unit admissions and we found that pregnant women with COVID-19 were more likely to need oxygen support than women without COVID-19. Mechanical and biochemical changes caused by pregnancy affect lung function and capacity during pregnancy and when coupled with the impact of COVD-19 on the reparatory system, such as pneumonia, they all explain the association with oxygen support and Intensive Care Unit admission in the Intensive Care Unit are mostly the only hospital unit to be well equipped for providing respiratory support [15].

Our study indicated that more newborns of women with COVID-19 had poor neonatal outcomes than newborns of COVID-19 negative women, with the difference in low APGAR scores being the most significant. These findings might be due to increased complications and comorbidities among women with COVID-19, such as preterm delivery, premature rupture of membranes, hypertensive disorders, and other comorbidities, which themselves are associated with COVID-19 and risk factors for poor neonatal outcomes [16]. Our findings agree with other studies which reported the association between COVID-19 and poor neonatal outcomes, such as low birth weight, neonatal intensive care unit admissions, respiratory support and neonatal death [9,11,12,17].

Among the factors associated with poor maternal and neonatal outcomes among pregnant women with COVID-19, the cesarean section had the strongest association, followed by preterm delivery and hypertension (Table 6). Our findings are consistent with the study carried out in Sri Lanka and Bangladesh that found the caesarean section to be the highest among COVID-19-positive women [2,11]. Another study by Pierce-Williams, et al. revealed that cesarean sections increased with increased severity of symptoms among American COVID-19-positive pregnant patients [18]. Similar to our findings, Pierce-Williams, et al. found that 88% of women delivered preterm and 94% of them by cesarean section. All factors found in our study are already known risk factors for poor neonatal and maternal outcomes irrespective of COVID-19 presence. Therefore, since COVID-19 itself is associated with pregnancy complications such as preterm birth, preeclampsia, stillbirth, gestational diabetes, and neonatal death, it leads to more poor outcomes among women with COVID-19 than women without it [19].

Strength and Limitation of the Study

To our knowledge, this is the first study in the Asser region to explore the maternal and neonatal outcomes in COVID -19 positive pregnant women. Our study was retrospective which is prone to selection bias. In addition, our sample size was small, which could have caused over-and under-estimation, leading to inaccurate presence or absence of statistical significance of differences in variables between case and control groups. Future studies using prospective design and larger sample sizes are recommended.

CONCLUSION

This case-control study showed that COVID-19 was associated with poor maternal and neonatal outcomes. Compared to COVID-19 negative pregnant women, COVID-19 positive women had increased risks of overweight and obesity, maternal morbidities, and pregnancy complications. Low APGAR scores were more prevalent in newborns of COVID-19-positive women. Cesarean section, preterm delivery, and hypertension were the most risk factors associated with poor maternal and neonatal outcomes among COVID-19-positive women. This highlights the need for healthcare workers and the general population to be aware of the potential adverse effects of COVID-19 on pregnancy. Clinicians should pay extra attention and closely monitor pregnant women with COVID-19 and their babies during delivery and perinatal period to mitigate short-term and long-term health adverse effects.

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Author Contributions

Conceptualization, Bushra Saeed Fahran Alasmri, Methodology, Bushra Saeed Fahran Alasmri and Shamsun Nahar Khalil and Abdullah Alsabaani, Software, Bushra Saeed Fahran Alasmri, Amal Mohammed Alqahtani, Validation, Bushra Saeed Fahran Alasmri, Formal Analysis, Bushra Saeed Fahran Alasmri, Shamsun Nahar Khalil, and Abdullah Alsabaani, Investigation, Bushra Saeed Fahran Alasmri Shamsun Nahar Khalil, Mamdoh Eskandar, and Jameelah Ali Aboud, Resources, Bushra Saeed Fahran Alasmri and Jameelah Ali Aboud, Amal Mohammed Alqahtani, Data Curation, Bushra Saeed Fahran Alasmri, Jameelah Ali Aboud, Amal Mohammed Alqahtani, and Mamdoh Eskandar, Writing-Original draft preparation, Bushra Saeed Fahran Alasmri, Shamsun Nahar Khalil, Writing-Review and Editing, Shamsun Nahar Khalil, Abdullah Alsabaani and Mamdoh Eskandar and Jameelah Ali Aboud, Visualization, Bushra Saeed Fahran Alasmri and Shamsun Nahar Khalil, Supervision, Shamsun Nahar Khalil, Project administration, Bushra Saeed Fahran Alasmri and Jameelah Ali Aboud, Funding acquisition, Bushra Saeed Fahran Alasmri All authors have read and agreed to the published version of the manuscript.

Institutional Review Board Statement

The study was approved by the Ethics Committee of King Khalid University. The IBR number is #2002-1501.

Informed Consent Statement

This study was retrospective and data were extracted from the hospital registries. Therefore, no informed consent was required.

Data Availability Statement: The data presented in this study are available within the article.

Conflict of Interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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