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Double balloon catheter induction of labor in pregnant women with COVID-19 infection

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Abstract

Background To identify the effectiveness and safety induction using a double-balloon catheter in the setting of Coronavirus disease 2019 (COVID−19) infection.

Methods This retrospective study included 577 COVID−19-afected women who underwent induction of labor with a double balloon catheter or spontaneously started delivery between December 7, 2022, and June 20, 2023; 154 women underwent induction of labor (double balloon catheter, study group) and 423 women underwent spontaneous started delivery (control group). Maternal and neonatal outcomes and complications during labor were assessed and compared.

Results Duration of the first stage of labor and total labor in the study group were significantly shorter than those in the control group ($P<0.05$). There were no statistically significant differences between the two groups in terms of maternal delivery complications ($P>0.05$). The two groups did differ significantly in the occurrences of pregnancy induced hypertension and gestational diabetes mellitus ($P<0.05$). The neonatal prognosis was similar between the two groups ($P>0.05$). After adjusting for maternal age, body mass index, gestational age at delivery, gestational age at infection, gravidity, parity, oxytocin administration and failure of progress of labor, multivariate logistic regression analysis found that COVID−19-afected women who received the double balloon catheter were not associated with an increased risk of fetal distress, intrapartum fever and cesarean section ($P>0.05$).

Conclusions Double balloon catheter is an effective and safe method for labor induction in pregnant women with COVID−19 and is not associated with an increased risk of fetal distress, intrapartum fever and cesarean section.

Keywords COVID−19, SARS-CoV−2, Induction of labor, Double balloon catheter, Infection, Fetal distress

Introduction

Coronavirus disease 2019 (COVID−19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV−2), is the first pandemic of the century [1]. To date, COVID−19 is still ongoing with no known cure or vaccine to prevent infection, and we are faced with the prospect of co-existence with this virus until an effective treatment strategy is found. However, women continue to give birth in a setting where great uncertainty remains regarding the potential impact of COVID−19 infection on pregnancy. Although the knowledge gained from viral outbreaks is continuously evolving, management of labor and delivery in pregnant women with COVID−19 remains a big challenge for obstetricians [2].

Leading obstetric organizations and experts recommend that COVID−19 status alone is not contraindicated for vaginal delivery [3], and decisions regarding the type of delivery should be made based on the risk of

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complications as normal [4]. Notably, healthcare providers should be aware that there are certain interventions specific to pregnancy, such as induction of labor (IOL). As one of the most common obstetric procedures to promote successful vaginal delivery [5], IOL is inevitable during the pandemic. Options for IOL include pharmacologic and mechanical methods [6], among which balloon catheters from mechanical methods are the commonly used methods given the favorable safety profile [7] and positive satisfaction [8] compared with pharmacologic methods. The use of a double-balloon catheter is widely preferred in our obstetrics department at a maternity teaching hospital in China. However, no information is available about the effectiveness and safety of double-balloon catheter among COVID−19-afected women who are undergoing labor induction. To clarify this gap, we conducted this research and aimed to share our experience with IOL in pregnant women with COVID−19 and contribute to improving the quality of care provided to pregnant women with confirmed COVID−19.

Materials and methods

Study design

This study was performed at seven obstetrics departments affiliated with the Hefei Maternal and Child Health Care Hospital, Hefei, China between December 7, 2022, and June 20, 2023, which is the largest tertiary obstetrics and gynecology hospital in Anhui province, with 20,000 deliveries on average per year. Before December 6, 2022, universal COVID-19 screening was implemented for nearly two months in our region. On December 7, universal COVID-19 screening was canceled, except for symptomatic patients or individual requests. Owing to the retrospective design of the study, the need to obtain informed consent from eligible women was waived by Hefei Maternal and Child Health Care Hospital. This study was approved by the Institutional Ethics Committee of Hefei Maternal and Child Health Care Hospital.

The inclusion criteria were women with singleton pregnancies with laboratory-confirmed COVID-19 (as identified by reverse transcriptase-polymerase chain reaction assay of throat swab samples) in a cephalic presentation undergoing IOL with a double-balloon catheter or spontaneously started deliveries.

The exclusion criteria were multiple pregnancies, fetal malformation or intrauterine fetal death, previous cesarean delivery or uterine surgery, elective cesarean section, and a breech or transverse presentation. Women presenting with contradictions to double-balloon catheters, including premature rupture of membranes and vaginitis were excluded.

After delivery, the perineum was detected by an experienced obstetrician using the recommended bidigital vaginorectal examination. In the present study, no third-or fourth-degree perineal tears were discovered, and only first- and second-degree perineal tears with bleeding requiring suturing were recorded.

Demographic information was extracted from the medical files, including maternal age, body mass index (BMI), gestational age at delivery, gestational age at infection, gravidity, parity and complicated with pregnancy induced hypertension or gestational diabetes mellitus.

The primary outcomes were the maternal and neonatal outcomes. We recorded the rate of switching to cesarean section, failure of progress of labor and intrapartum fever among COVID−19-afected women who underwent IOL with a double-balloon catheter or spontaneously started delivery as the maternal outcomes. For the neonatal outcomes, the proportions of fetal distress, neonatal asphyxia, neonatal weight and neonatal intensive care unit (NICU) admission were also recorded.

Successful vaginal delivery after induction with a double-balloon catheter or spontaneous delivery was added as a secondary outcome. We collected delivery variables, including the duration of the first, second, third, and total stages of labor; the use of oxytocin (in cases such as regular contraction does not occur spontaneously after removal of the double balloon catheter or insufficient labor progression); and the incidence of operative vaginal delivery, perineal laceration, episiotomy, precipitate labor, placental abruption, and placental adhesion.

Clinical procedures

In the double-balloon catheter group, the device was applied in accordance with the manufacturer's instructions. A transcervical double-balloon catheter (Cook catheter, Type CVB-18 F, Shenzhen Yixinda Medical New Technology Co. Ltd., China) was inserted into the cervix by the obstetrician at 8pm on the first day, until the anterior balloon was placed above the internal cervical os and the second balloon was placed in the vagina. Both the uterine and vaginal balloons were alternately filled with saline to obtain a volume of 80mL per balloon.

Indications for removal of the double-balloon catheter include: (1) placement for 12 h, (2) rupture of membranes, (3) onset of labor, (4) intrauterine infection, (5) fetal distress, and (6) abnormal bleeding.

If spontaneous expulsion of the balloon did not occur, the double balloons catheter was removed after 12 h period and oxytocin infusion was commenced. Initially, 2.5 units of oxytocin were diluted in 500 ml of 5% saline, namely 0.5% concentration of oxytocin was administrated at four drops per minute, increasing by four drops every 15 min according to uterine contractions. A maximum rate of 40 drops per minute was kept for one hour. If regular contractions were not achieved, the oxytocin concentration was adjusted to 1%. Careful observation of

continuous fetal heart rate and uterine contraction patterns is used throughout established labor.

Definite

The first stage of labor refers to the period from regular uterine contractions until the cervix is fully dilated to 10 cm.

The second stage of labor is described as the time from the cervical dilation of 10 cm until the delivery of the fetus.

The third stage of labor is defined as the period between delivery of the baby and the placenta.

Precipitate labor is defined as the time from regular uterine contraction to fetal placental delivery to less than 3 h.

Intrapartum fever is defined as body temperature > 38 ℃.

Fetal distress is a pathophysiological condition in which the fetus suffers from insufficient oxygen supply. The clinical criteria includes: a nonreactive non stress test, which is one that lacks sufficient fetal heart rate variability, or presence of sinusoidal pattern; fetal tachycardia > 160 bpm or persistent fetal bradycardia < 110 bpm for > 10 min or < 80 bpm for > 3 min (without an increasing tendency); complicated with variable decelerations with a duration of > 60 s or repeated late decelerations.

The intrapartum criteria of category II non stress test refers to any of the following findings: fetal tachycardia (> 160 beats per minute for > 10 min), baseline fetal heart rate with absent or minimal (fluctuations from baseline over 10-minute period ≤ 5) or moderate variability (fluctuations from baseline over 10-minute period with 6 to 25 bpm), recurrent late decelerations with moderate variability (> 50% of contractions), variable decelerations with slow return to (or overshoots) baseline, prolonged decelerations (> 2 min but < 10 min) or no accelerations after fetal scalp stimulation.

The intrapartum criteria of category III non stress test refers to sinusoidal pattern or absent fetal heart rate variability with recurrent late decelerations or recurrent variable decelerations (> 50% of contractions) or fetal bradycardia (fetal heart beats < 110 bpm for > 10 min).

The type of perineal laceration is classified according to the classification of the American College of Obstetricians and Gynecologists (ACOG) [9]: First-degree tear involving only the perineal skin; second-degree tear is defined as injury to the perineum involving the perineal muscles but not the anal sphincter.

Pregnancy induced hypertension refers to systolic blood pressure ≥ 140mmHg and/or diastolic BP ≥ 90mmHg occurring at or after 20 gestational weeks without significant proteinuria.

Gestational diabetes mellitus refers to abnormal glucose intolerance of varying degrees, which is first diagnosed in the second or third trimester of pregnancy.

Failure of progress of labor occurs when fetal head size is excessive for the maternal pelvic size, resulting in "failure to progress" in labor. The diagnosis of failure of progress of labor is commonly made using indirect"proxy," such as failure of descent of the fetal head through the pelvis or arrest of dilatation of the cervix. Clinical signs including cervix edema, the presence of markedly caput-succedaneum, or presence of the ring of Bandl, have all been proposed for the diagnosis of failure to progress.

Statistical analysis

Statistical analyses were performed using SPSS version 13.0 statistical packages (SPSS Inc., Chicago, USA.). The counting variables are expressed by percentage. Continuous variables were expressed as mean and standard deviation (SD). Comparisons between two groups were analyzed using the t-test for continuous variables and the chi-square test for categorical variables as appropriate. Multivariate logistic regression analysis was conducted to identify the association between the double-balloon catheter and the various variables. Adjusted odds ratio (AOR) and 95% confidence intervals (CI) were used to quantify this association. Statistical significance was set at $P < 0.05$.

Results

Of the 577 eligible pregnant women in the study, 154 were in the double-balloon catheter group (study group, 107 underwent successful vaginal deliveries and 47 underwent switching to cesarean sections), the indications for cesarean birth was fetal distress (24 cases), intrapartum fever (13 cases) and failure to progress (10 cases). 423 were in the spontaneously started delivery group (control group, 363 with successful vaginal deliveries and 60 who switched to cesarean sections), the indications for cesarean birth was fetal distress (40 cases), intrapartum fever (13 cases) and failure to progress (7 cases). The majority of pregnant women with COVID−19 in our cohort were classified as mildly ill, and no severe illness was observed in any of them. Fever was the dominant clinical manifestation, accounting for 79.9% and 71.4% of those who underwent IOL and spontaneously started deliveries, respectively.

Patient characteristics of the study population are presented in Table 1. No clinically significant differences were found between the two groups in terms of maternal age or proportion of multiparity ($P > 0.05$). The mean gestational age at infection was significantly lower, whereas that at delivery was higher in the study group ($P < 0.05$). The percentage of women with their first child differed significantly between the groups ($P < 0.05$). Women in the double-balloon catheter group were more likely to

Table 1 Comparison of baseline characteristics of the two groups

Variables	Study group (*n* = 154)	Control group (*n* = 423)	t/χ2	*P* value
Maternal age (years)	29.6 ± 3.4	29.9 ± 3.9	0.83	0.405
BMI(kg/m2)	22 ± 2.9	21.3 ± 2.7	-2.76	0.006
Gestational age at infection (weeks)	26.8 ± 8.6	30.2 ± 8.8	4.19	< 0.001
Gestational age at delivery (weeks)	40 ± 0.9	39.3 ± 1.3	-6.85	< 0.001
Gravidity (n, %)			14.43	0.001
1	93(60.4)	199(47)		
2	26(16.9)	139(32.9)		
≥ 3	35(22.7)	85(20.1)		
Multiparity (n, %)	38(24.7)	129(30.5)	1.86	0.173
GDM (n, %)	34(22.1)	52(12.3)	8.52	0.004
PIH (n, %)	32(20.8)	21(5)	33.85	< 0.001

BMI, body mass index; GDM, gestational diabetes mellitus; PIH, pregnancy induced hypertension; data are expressed as mean ± SD or n (%); $P < 0.05$, considered statistically significant. Study group, COVID–19-afected participants who underwent induction of labor with a double-balloon catheter; control group, COVID–19-afected participants who spontaneously started delivery

Table 2 Comparison of maternal and neonatal outcomes of the two groups

Variables	Study group (*n* = 154)	Control group (*n* = 423)	t/χ2	*P* value
Cesarean delivery(n, %)	47(30.5)	60(14.2)	19.94	< 0.001
Failure to progress(n, %)	10(6.5)	7(1.7)	9.24	0.002
Intrapartum fever(n, %)	14(9.1)	22(5.2)	2.92	0.088
Fetal distress(n, %)	25(16.2)	40(9.5)	5.19	0.023
Asphyxia (n, %)	0(0)	4(0.9)		0.578[b]
NICU admission (n, %)	1(0.6)	14(3.3)		0.083[b]
Birth weight (g)	3410.6 ± 376.7	3314.3 ± 389.0	-2.65	0.008

NICU, neonatal intensive care unit; [b] Fisher's exact probability; data are expressed as mean ± SD or n (%); $P < 0.05$, considered statistically significant. Study group, COVID–19-afected participants who underwent induction of labor with a double-balloon catheter; control group, COVID–19-afected participants who spontaneously started delivery

complicate with pregnancy induced hypertension and gestational diabetes mellitus ($P < 0.05$). Additionally, the mean BMI values were significantly elevated in the study group ($P < 0.05$).

For the primary outcome (Table 2), we noted that COVID–19-afected women who underwent IOL with a double-balloon catheter were associated with a higher rate of cesarean deliveries ($P < 0.05$). In addition, the incidences of fetal distress and failure to progress were higher in the study group than in the control group ($P < 0.05$). In contrast, the percentage of intrapartum fever was similar between the two groups ($P > 0.05$). Neonatal outcomes, we demonstrated that the two groups did not differ

Table 3 Comparison of delivery-related variables in women with successful vaginal deliveries of the two groups

Variables	Study group (*n* = 107)	Control group (*n* = 363)	t/χ2	*P* value
Duration of first-stage labor (H)	5.3 ± 3.1	6.4 ± 4.1	2.59	0.001
Duration of second-stage labor (H)	0.7 ± 0.5	0.7 ± 0.5	-0.28	0.776
Duration of third-stage labor (H)	0.1 ± 0	0.1 ± 0	0.44	0.659
Duration of total labor(H)	6.1 ± 3.3	7.2 ± 4.3	2.46	0.014
Oxytocin administration(n, %)	89(83.2)	134(36.9)	105.07	< 0.001
Vaginal-operative delivery (n, %)	2(1.9)	12(3.3)	0.59	0.442
Episiotomy(n, %)	4(3.7)	28(7.7)	2.06	0.151
Perineal laceration(n, %)	94(87.9)	307(84.6)	0.71	0.4
Precipitate labour(n, %)	16(15)	64(17.6)	0.42	0.517
Placental adhesion(n, %)	5(3.2)	20(4.7)	0.6	0.439
Placental abruption(n, %)	0(0)	4(0.9)		0.578[b]

H, hour; [b] Fisher's exact probability; data are expressed as mean ± SD or n (%); $P < 0.05$, considered statistically significant. Study group: COVID–19-afected participants with successful vaginal delivery induced by double balloon catheter; control group: COVID–19-afected participants with successful vaginal delivery with spontaneously started delivery

Table 4 Multivariate logistic regression analysis of the association between induction with double-balloon catheter and intrapartum fever and fetal distress

Variables	AOR (95% CI)	*P* value
Intrapartum fever(n, %)	1.055(0.464–2.397)	0.898
Fetal distress(n, %)	1.655(0.856–2.201)	0.134

AOR, Adjusted odds ratio; CI, confidence interval; $P < 0.05$, was considered statistically significant

significantly in the occurrences of neonatal asphyxia and NICU admission ($P > 0.05$). The median birthweight of the newborns was significantly different between the two groups ($P < 0.05$); however, both values were within the normal range.

Regarding secondary outcomes (Table 3), we found that the duration of the first and total stages in the study group was significantly shorter than that in the control group ($P < 0.05$). No differences were observed in the durations of the second and third stages ($P > 0.05$). There were also no differences in the rates of operative vaginal delivery, perineal laceration, episiotomy, precipitate labor, placental abruption, or placental adhesion between the two groups ($P > 0.05$). Compared with the control group, women in the study group were more likely to require oxytocin infusion ($P < 0.05$).

Table 4 depicts the results of the multivariate logistic regression analysis of the relationship between double-balloon catheter induced labor, intrapartum fever, and fetal distress. After adjusting for maternal age, BMI, gestational age at delivery, gestational age at infection, gravidity, and parity, COVID–19-afected women who

underwent IOL with a double-balloon catheter were not associated with an increased risk of intrapartum fever and fetal distress (AOR = 1.055, 95%CI 0.464–2.397; AOR = 1.655, 95% CI 0.856–2.201, respectively, $P > 0.05$).

Table 5 depicts the results of the multivariate logistic regression analysis of the relationship between double-balloon catheter induced labor and cesarean section. After adjusting for maternal age, BMI, gestational age at delivery, gestational age at infection, gravidity, parity, oxytocin administration, fetal distress and failure to progress, COVID–19-afected women who underwent IOL with a double-balloon catheter were not associated with an increased risk of cesarean section (AOR=1.925, 95%CI 0.744–4.979, $P > 0.05$).

Table 5 Multivariate logistic regression analysis of the association between induction with double-balloon catheter and Cesarean section

Variables	AOR (95% CI)	*P* value
Cesarean section(n, %)	1.925(0.744–4.979)	0.177

AOR, Adjusted odds ratio; CI, confidence interval; $P < 0.05$, was considered statistically significant

Discussion

Our study found for the first time the effectiveness and safety of double-balloon catheter in COVID-19-afected women who have undergone IOL. Based on these results, we observed that the double-balloon catheter was a safe and effective method for COVID-19-afected women without increased risk of fetal distress, intrapartum fever and cesarean section.

The double-balloon catheter, which is recommended by the World Health Organization, is the most popular option for IOL [10]. Traditionally, the double-balloon catheter itself does not directly promote uterine contractions, and the subsequent use of oxytocin is often needed for most patients to trigger effective uterine contractions. The success rate of vaginal delivery of double-balloon catheters varies widely depending on differences in the heterogeneity of study participants and the length of catheter retention in situ [11, 12]. In our study, the prevalence of COVID–19-afected women who delivered vaginally with catheter insertion for up to 12 h was 69.5%, which was similar to that of another study with a successful vaginal delivery rate of 71.0% [12]. Additionally, there were no significant differences in the incidence of operative vaginal delivery, perineal laceration, episiotomy, precipitate labor, placental abruption, and placental adhesion. The duration of the first and total stages was statistically shorter in the double-balloon catheter group than in the spontaneous started delivery group, and the results of our study were consistent with those of previous reports that the average induction to delivery time was significantly shorter for the double balloon [13]. Together, our findings suggest that the double-balloon catheter is effective and does not increase maternal risk during IOL for COVID–19-afected women. However, it should be noted that these studies focused exclusively on the comparison between mechanical and pharmacological methods in uninfected pregnant women. Thus, further studies are warranted to investigate the outcomes of women with COVID–19 who delivered vaginally via IOL.

As a foreign body insertion into the uterus, whether the placement of a double-balloon catheter increases the risk of infection remains a topic of debate. The literature on this topic is extremely broad and conflicting. Evidence suggests that the incidence of chorioamnionitis was higher in the double-balloon group than in the pharmacologic method group [14], and a 10% overall risk of intrapartum maternal infection was identified in women with balloon catheters for cervical ripening [15]. In contrary, in other reports, no maternal or fetal infection was observed with the use of a transcervical balloon catheter [15–17]. It is well established that COVID–19 is characterized by the activation of cytokine storms. Thus, concerns have been raised regarding the possibility of increased risk of infection among COVID–19-afected women undergoing IOL with a double-balloon catheter. To the best of our knowledge, no data has yet shed light on this topic. The results of our study found no differences in the rate of intrapartum fever among women with SARS-CoV–2 infection in the double-balloon catheter group versus spontaneous started delivery groups; after adjustment for potential confounding factors, the relationship between double-balloon catheter and intrapartum fever has also not been discovered. Our data further confirm the favorable safety profile of a double-balloon catheter, supporting that a double-balloon catheter is a reasonable option for patients with SARS-CoV–2 infection.

It is generally known that SARS-CoV–2's cellular receptor, the angiotensin converting enzyme–2 receptor (ACE–2), and the transmembrane protease serine 2 enzyme (TMPRSS2), which allows the virus to pass into the cell, are localized predominantly at the maternal-fetal interface of the placenta [18]. Therefore, the incidence of placental infection is reported to be up to 12% [19]. In parallel, placental infection is associated with placental vascular disease, mainly manifesting as maternal vascular malperfusion, which was found in 63.6% of the cases [20]. Subsequently, pathological lesions in the placenta lead to a higher risks of fetal distress [21]. Consequently, this raises the question of whether IOL with transcervical balloons may put the fetus at an increased risk of fetal distress among COVID–19-afected women. To date, no studies have addressed this question. Based on clinical observations, the findings of our cohort demonstrated that pregnant COVID–19-afected women who

underwent induced labor with a double-balloon catheter appeared to have an increased likelihood of fetal distress. However, after multivariable logistic regression analysis, we did not determine a possible relationship between the double-balloon catheter and fetal distress.

Currently, numerous studies are focusing on efforts to identify whether IOL with a double-balloon catheter is associated with increased odds of cesarean section. A study demonstrated no difference in the rates of cesarean deliveries for non-reassuring fetal status between mechanical ripening with a double balloon catheter and pharmacological methods with a dinoprostone [22]. The similar finding was noted between double balloon catheter and vaginal prostaglandin [23]. Furthermore, double balloon catheter was found to be a good alternative to conventional pharmacological methods for cervical ripening and labour induction with greater safety and cost-effectiveness than prostaglandin E2 [7]. Interestingly, we were unable to find relevant data in the medical literature regarding IOL with a double-balloon catheter among COVID-19-afected women and cesarean delivery. In our study, after adjusting for other variables in the multivariate analysis, we have found that for COVID-19-afected women undergoing IOL, the double-balloon catheter was not associated with cesarean delivery. We believe these findings appear to be crucial for patient counseling and shared decision making, as adequately informed of the complete information regarding delivery outcomes could increase the frequency with which double-balloon catheter is accepted.

Regarding neonatal outcomes, we did not examine the differences between the two groups in terms of neonatal asphyxia and NICU admission. Although differences in neonatal weight in two groups were found, both values were within the normal range. Our results echo the existing evidence of a previous study in pregnant women without COVID–19 infection, concluding that both uterine hyperstimulation causing non-reassuring fetal heart rate and neonatal intensive care admissions were more frequent after pharmacological ripening than after mechanical ripening [7]. Therefore, our study provides extremely important implications in clinical practice, suggesting that the use of a double-balloon catheter for IOL is feasible and safe for newborns.

This study has several limitations. First, the results of the present study may be limited by its retrospective nature; second, this study was carried out in a single institution, which could lead to some selection bias; and finally, the choice of fetal distress as a measured outcome may be potentially influenced by clinicians. The reasons for fetal distress are multi-factorial, including the level of expertise in fetal heart rate interpretation of health providers, and it is therefore difficult to determine the complex relationship between all factors influencing fetal heart rate. However, this study also includes a number of strengths. The COVID-19 screening strategy has definite strengths; the precise timing of COVID-19 infection is ascertained, and we can rule out the confounding factor originating from the distribution of gestational age at COVID-19 infection by multivariable logistic regression analysis, which could strengthen the magnitude of the associations assessed. Furthermore, data from only one hospital is another robust strength, as it lowers the risk of differences in data processing and hospital practices, such as obstetricians' experience and guidelines regarding IOL, management of labor progression, and the use of oxytocin.

In conclusion, as the threat of COVID–19 has not disappeared, the safety of pregnant women and appropriate medical care remain of the highest importance. Within this context, empirical evidence of maternal and fetal outcomes of IOL is still lacking. Our study provides health professionals with important clinical investigation among COVID–19-afected women who gave birth undergoing IOL with a double-balloon catheter, and shows further evidence regarding the effectiveness and safety of IOL in this setting.

Abbreviations

COVID-19	Coronavirus disease 2019
SARS-CoV–2	Severe acute respiratory syndrome-coronavirus–2
IOL	Induction of labor
BMI	Body mass index
NICU	Neonatal intensive care unit
ACOG	American College of Obstetricians and Gynecologists
SD	Standard deviation
AOR	Adjusted odds ratio
CI	Confidence intervals
ACE2	Angiotensin-converting enzyme 2
TMPRSS2	Transmembrane protease serine 2 enzyme

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Author contributions
J Yi produced the initial full write-up of the manuscript; J Yi, XL Meng and Y Chen contributed to data collection and analysis; and J Yi and L Chen revised the final manuscript carefully.

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Data availability
The datasets used during the current study are available from 10.6084/m9.figshare.24953589.

Declarations

Ethics approval and consent to participate
This retrospective research was approved by Hefei Maternal and Child Health Care Hospital. Owing to the retrospective design of the study, the need to obtain informed consent from eligible women was waived by Hefei Maternal and Child Health Care Hospital.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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