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The impact of the mode of delivery on the prognosis of pregnant women with COVID-19: a multicentre observational study

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ABSTRACT

Objective. The aim of this study was to assess the maternal and foetal outcomes in pregnant women with COVID-19 infection at birth and the impact of the mode of delivery on the prognosis of these patients.
Materials and Methods. This is a multicentre observational study including pregnant women delivering while infected with COVID-19 from January 2021 to June 2022 in 3 regions in the south of Tunisia. To assess the impact of the mode of delivery among patients included, they were divided into 2 groups: Group 1 included patients who had caesarean delivery. Group 2 included patients who had vaginal delivery.
The maternal and foetal outcomes were compared between the 2 groups. Multivariable logistic regression was performed to assess the association between the mode of delivery and maternal and foetal adverse outcomes.
Results. We included 201 patients: 129 caesarean deliveries and 72 vaginal deliveries. Demographic parameters and the severity of COVID-19 signs before delivery were comparable in both groups. We noted higher rates of increased need for oxygen, maternal complications, and intensive care unit referral in the caesarean group ($p < 0.001$). Caesarean birth was significantly associated with the risk of clinical deterioration (aOR 12.9, 95%CI 4.89-34.4, $p < 0.001$), maternal death (aOR 3.84, 95%CI 0.839 -17.5, $p = 0.042$), and an increased risk of neonatal intensive care unit admission (aOR = 3.72; 95%CI: 1.63-8.48, with $p = 0.001$).
Conclusions. Caesarean delivery may worsen the prognosis of pregnant women with COVID-19. It was also associated with adverse foetal outcomes.

INTRODUCTION

The infection of COVID-19 during pregnancy can lead to severe maternal outcomes with high rates of morbidity and mortality, particularly when the infection occurs at the end of pregnancy because of the peripartum physiological changes [1].
Caesarean delivery can be indicated for foetal distress caused by maternal hypoxemia or severe and complicated preeclampsia associated with COVID-19, or for obstetrical reasons [2]. It can also be discussed for maternal saving in the case of severe ARDS or other life-threatening complications, according to the severity of the disease and the term of pregnancy [3]. Nevertheless, several studies reported that COVID-19 status alone was a common indication for caesarean delivery early in the pandemic [4]. For others, caesarean delivery was indicated to either prevent vertical transmission or to protect the health care team [5]. However, the prognosis of caesarean delivery patients may be deteriorating because this mode of delivery is associated with increased bleeding and thromboembolic events, in addition to immunodepression caused by the surgery [6]. Moreover, opting for vaginal delivery and accepting labour in patients with COVID-19 seems to be safe and was recommended by several scientific societies [7, 8]. Although, recent studies assessed the impact of COVID-19 clinical manifestations on the mode of delivery [9], there are still little data about the consequences of the mode of delivery on maternal and perinatal outcomes of infected parturients [10, 11].
This study aimed to assess the maternal and foetal outcomes in pregnant women with SARS-CoV-2 infection at birth and the impact of the mode of delivery on the prognosis of these patients.

MATERIALS AND METHODS

Study design

After obtaining patients' oral consent and local ethics committee approval, a multicentre observational cohort study was conducted to determine the impact of the mode of delivery on the prognosis of pregnant women with COVID-19.

Study setting

This study was conducted in the period lasting from January 2021 to July 2022, at 4 level 2 or level 3 maternity hospitals throughout the south of Tunisia. Four hospitals participated in this study: the Hedi Chaker University Hospital in Sfax, the Habib Bourguiba University Hospital in Medenine, the COVID-19 national military hospital in Sfax, and the regional Hospital of Tataouine.

Study population with selection criteria

Women with singleton completed pregnancies and a positive reverse transcriptase-polymerase chain reaction (RT-PCR) test result for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and who delivered within the next 5 days were included in the study. We did not include patients aged less than 18 years, as well as individuals declining to consent or not being able to consent for themselves. We did not include parturients who were hospitalised for COVID-19 but had negative rt-PCR at the moment of birth. We excluded the cases of foetal loss defined as spontaneous antepartum foetal death < 14 WG and cases of late miscarriage 14-24 WG. Patients whose management did not adhere to the standard protocol were also excluded.

Data collection

We collected data about:

- Patients' characteristics: age, body mass index (BMI), term of pregnancy, previous co-morbidities, and vaccination status.
- Clinical and biological data before delivery: clinical signs and the severity of COVID-19 syndrome; the need for O_2, the incidence of preeclampsia, anaemia, and cytolysis, as well as radiographic and biological findings.
- The maternal outcomes after delivery: a clinical deterioration was defined by an increased need for O_2 supplementation after delivery, or referral to ICU, and maternal complications (ARDS, postpartum haemorrhage, thromboembolic events, septic shock, and pregnancy-related complications including retro-placental hematoma; HELLP syndrome, and acute fatty liver of pregnancy). For severe COVID-19 requiring advanced oxygen support or intensive care before delivery, clinical deterioration is defined by the incidence of a severe complication or death.
- Maternal follow-up and prognosis: the length of stay in the COVID-19 unit or ICU and final outcome (recovery, surviving with a post-COVID syndrome or death).

- Neonatal outcomes considered were neonatal ICU (NICU) admission, rates of prematurity, and SARS-CoV-2 perinatal transmission.

Study size

The sample size determination was based on data from preliminary results of the 36 first patients enrolled in this study (10 vaginal deliveries and 26 caesarean deliveries). The incidence of clinical deterioration was 10% in the vaginal delivery group and 34.6% in the caesarean delivery group. So, we determined that a study sample of 70 patients in each group is required for 95% confidence level and 5% margin of error.

Bias

All patients enrolled in this study had the same management protocol. We verified that the clinical management of COVID-19 in the different hospitals participating in this study adheres to the INAES (Instance nationale de l'évaluation et de l'accréditation en santé) guidelines for COVID-19 patients [12]. Obstetric management was standardized for all enrolled patients. The timing and mode of delivery in all participating hospitals were determined primarily on the basis of obstetric indications.

Statistical analysis

To assess the impact of the mode of delivery among pregnant women who tested positive at the moment of birth on the prognosis of the patients, they were divided into 2 groups:

- Group 1: patients who gave birth by caesarean section.
- Group 2: patients who had a vaginal delivery.

Then, statistical analyses were achieved using the SPSS 23.0 (SPSS, Chicago, IL, USA) statistical package. Continuous variables were presented as means value ± standard deviation in the case of Gaussian distribution and as medians in the case of non-Gaussian distribution.

We distinguished two groups according to the mode of delivery among positive pregnant women. The comparison between groups was achieved by Student's t-test and Chi^2 test for continuous variables and categorical variables, respectively. The Fisher exact test was used when the Chi^2 test was not applicable. The Mann-Whitney U test was used for non-parametric continuous variables. Multivariable logistic regression was performed to assess the association between mode of delivery and maternal clinical deterioration after delivery adjusting for maternal age, body mass index, comorbidities, need for oxygen supplementation at admission, nulliparity, and prematurity. The significance threshold was set at $p < 0.05$.

Ethical approval

The approval of the Hedi Chaker University Hospital Local Ethics Committee was obtained under reference CPP 0239/2020 before beginning the study.

RESULTS

Of 212 patients participating in the study, 201 were included. Eleven patients were excluded: four for foetal loss (< 14 WG), five for late miscarriage (14-24 WG), and two for receiving Tocilizumab. The 201 patients included were recruited mainly from

Table 1. *Demographic and prepartum parameters.*

	Group 1 Caesarean delivery n = 129	Group 2 Vaginal delivery n = 72	P-value
Age (years)	31.04 ± 5.9	30.7 ± 5.9	0.308
Age > 35	41	15	0.066
BMI (kg/m²)	28.6 ± 3.6	28.04 ± 3.6	0.299
BMI > 30 Kg/m²	49	24	0.308
With co-morbidities (ASA > II)	21	6	0.083
Term at delivery (WG)	36.18 ± 3.2	36.08 ± 3.5	0.847
Primiparous	34	22	0.316
Multiparity (≥ 2)	95	50	
Vaccinated (yes/no)	42/87	30/42	0.128

3 regions in the south of Tunisia: Sfax (n = 137), Medenine (n = 38), and Tataouine (n = 14). Seven patients, recruited from the COVID-19 national military Hospital, were from other regions. In our study, caesarean section was the mode of delivery for 129 patients (64%) and vaginal delivery was noted for 72 patients (36%).

Demographic data such as age, BMI, comorbidities, term of pregnancy, parity, and vaccination status were comparable in both groups (**Table 1**).

Of 201 pregnant patients included, 5 presented with severe COVID-19 symptoms requiring ICU admission and advanced oxygen support before delivery. Four of them underwent caesarean delivery and only one had a vaginal preterm delivery. No patient with severe COVID-19 died before delivery. Asymptomatic COVID-19 was seen in 18 patients (13.9%) in the caesarean delivery group *versus* 22 patients (30.5%) in the vaginal delivery group with p = 0.005. One hundred fifty-six patients presented with minor and mild COVID-19 symptoms. Forty-nine patients delivered vaginally and 107 by caesarean delivery. Among the 129 patients who had a caesarean delivery, the main indications were obstetrical indication (38.7%), foetal distress (37.3%), maternal lifesaving (12.4%), and severe preeclampsia (3.8%). However, 10 patients (7.8%) underwent caesarean delivery without any indication. The severity of COVID-19 and the need for oxygen supplementation before delivery were comparable between the 2 groups (**Table 2**). For the 5 patients needing intensive care referral before delivery, we noted no death before delivery and all of them died after delivery. Clinical deterioration after delivery was noted in five patients (6.9%) from the vaginal delivery group *versus* 64 (49.6%) from the caesarean delivery group with p < 0.001. The rates of increased need for oxygen after delivery, ICU referral, and postpartum complications were significantly higher in the caesarean delivery group with p < 0.001 (**Table 3**).

In the ICU, the need for mechanical ventilation, catecholamine, and maternal deaths were higher in the caesarean group (**Table 3**). After adjustment for potential confounding factors, caesarean birth was significantly associated with clinical deterioration (aOR 12.9 and 95%CI 4.89-34.4 with p < 0.001). It was also associated with maternal death (aOR 3.84, 95%CI 0.839-17.5 with p = 0.042).

Premature birth was more frequent in the caesarean group (37 patients) in comparison with the vaginal delivery group (12 patients) with p = 0.04. Neonatal intensive care unit admission was noted in 8 newborns (11.1%) in the vaginal delivery group *versus* 41 newborns (31.7%) in the caesarean delivery group with p = 0.001. After adjustment for confounding factors, caesarean birth was associated with an increased risk of NICU admission (aOR 3.72, 95%CI 1.63-8.48, with p = 0.001).

Table 2. *Maternal data before delivery.*

	Group 1 Caesarean delivery n = 129	Group 2 Vaginal delivery n = 72	P-value
Asymptomatic (%)	18 (13.9%)	22 (30.5%)	**0.005**
Cough	78	42	0.378
Fever	67	34	0.308
Headache or asthenia	59	30	0.334
Dyspnoea	39	17	0.232
Digestive signs (nausea, vomiting, diarrhoea...)	23	10	0.312
Others: (Sore throat or rhinorrhoea, anosmia and ageusia)	19	4	0.059
Pre-eclampsia	29	9	0.083
Anaemia < 10g/dL	22	10	0.344
Cytolysis (> 3×)	20	4	**0.043**
Thrombopenia < 50,000	2	1	0.425
Radiological signs > 50% (yes/no)	11/16	2/2	0.060
O_2 needed < 6L/min	42	20	
O_2 needed 6-15L/min	12	0	0.065
O_2 needed > 15 L/min*	4	1	
Referral to ICU before delivery	4	1	0.411

*Need for advanced O_2 support (Optiflow or CPAP).

Vertical transmission was seen in 5 newborns (2.48%) and breastfeeding in 151 patients (75.1%) with no significant differences between the two groups (**Table 3**).

DISCUSSION

Our study showed that caesarean section delivery worsened the prognosis of pregnant women with COVID-19 at birth. It was significantly associated with the risk of clinical deterioration after delivery (aOR 12.9, 95%CI 4.89-34.4, $p < 0.001$) and maternal death (aOR 3.84, 95%CI 0.839- 17.5, $p = 0.042$), as well as increased risk of neonatal intensive care unit admission (aOR 3.72, 95%CI 1.63- 8.48, with $p = 0.001$). Early in the pandemic, caesarean section was a very common practice [13, 14] with COVID-19 status alone being a common indication [4]. Some physicians thought that a caesarean would avoid an emergency caesarean section under general anaesthesia and tracheal intubation [15], which is risky for the pregnant woman [16]. Moreover, there was a debate on the risk of vertical transmission in vaginal delivery [5, 17]. Nevertheless, even if an enhanced recovery program after a caesarean section reduces the risks of postpartum complications and improves maternal outcomes [18], the physiological stress induced by surgery is known to increase the rate of complications in infected pregnant women [19, 20]. In our study, we noted that the referral to ICU was not only due to clinical deterioration of COVID-19 signs but also to obstetrical complications like postpartum haemorrhage [21] or HELLP syndrome [22]. Our results were comparable with previous studies in the literature [23-25]. A Spanish study [22] reported that COVID-19-infected women (with mild symptoms) undergoing caesarean delivery may have been at higher risk of adverse outcomes, but after adjusting for confounding factors, caesarean birth remained independently associated with an increased risk of clinical deterioration (aOR 13.4, 95%CI 1.5-121.9, $p=0.02$).

An Italian retrospective study [24], published earlier in the pandemic, showed the safety of vaginal delivery and the low risk of intrapartum SARS-CoV-2 transmission to the newborn. In another

Table 3. *Maternal and neonatal outcomes after delivery.*

	Group 1 Caesarean delivery n = 129	Group 2 Vaginal delivery n = 72	P-value
Clinical deterioration (%)	64 (49.6%)	5 (6.9%)	**< 0.001**
Increased need for O_2 after delivery (yes/no)	53	3	**< 0.001**
O_2 needed < 6L/min	36	16	
O_2 needed 6-15L/min	16	2	**0.024**
O_2 needed > 15 L/min or Optiflow	26	2	
Postpartum referral to ICU	40	2	**< 0.001**
Complications (yes/no)	56	5	**<0.001**
ARDS	28	1	
Postpartum haemorrhage	11	2	
Thromboembolic events	5	1	**< 0.001**
Septic shock	4	1	
Pregnancy related complication	11	2	
CPAP after delivery	26	2	**< 0.001**
Need for intubation > 24 h	16	2	**0.016**
Catecholamine > 24 h	17	2	**0.011**
Length of hospital stay (days)	8.4 ± 6	3.8 ± 0.7	**< 0.001**
Maternal death	13	2	**0.048**
Severe prematurity: delivery < 28 WG	1	4	0.087
Premature delivery: 28-34 WG	37	12	**0.04**
Vertical transmission	3	2	0.589
breastfeeding	94	57	0.207
Admission in neonatal ICU	41	8	**0.001**
Neonatal deaths and stillbirth	10	1	**0.050**

study [25], vaginal delivery rates were high and associated with favourable outcomes, with no cases of vertical transmission. These findings are comparable with our results. The main clinical implication is that the mode of delivery among SARS-CoV-2-infected mothers should be based on obstetric indications and COVID-19 alone should never be an indication for caesarean delivery [26].

The risk of perinatal death in pregnancies with COVID-19 infection was reported, and it was mainly related to prematurity [27]. The severity of COVID-19 symptoms, particularly when there was a need for high oxygen flow and advanced oxygen support, was independently associated with adverse foetal outcomes [28]. This category of pregnancies may need emergent caesarean delivery for foetal distress or for maternal life-saving to face severe hypoxemia due to ARDS [29]. Including this category of patients explains the high rates of caesarean delivery in our study in comparison with previous Italian study [30], but may present a selection bias. To overcome this bias, we gave a specific definition of maternal clinical deterioration after delivery, particularly for these patients.

In our pregnant population, the incidence of vaccination was insufficient, and our patients remained hesitant. They still adopt a prudential lifestyle to avoid infection [31], although the vaccination benefits were proven in a previous study [32]. The vaccination rate was comparable in both groups, and we suggest that it doesn't affect the main outcomes of this study.

The main limitation of the study is that we recruited pregnant women with COVID-19 for a long time (more than one year). In this period, new variants appeared, and different waves occurred (mainly delta wave and omicron wave) and we have no idea about the variants in our population [33]. In this period, vaccination was generalized in our population, which may be implicated in reducing the severity of symptoms and impacting the mode of delivery [32]. We should also mention that there are some disparities in the capacity and experience of the healthcare teams of the hospitals participating in the study, which can impact maternal and foetal outcomes after delivery. Limitations include the lack of sufficient information to seek vertical transmissions like additional amniotic fluid, cord blood, and placenta samples [34]. The follow-up after delivery was limited to only 1 month. However, long-term surveillance seems to be necessary to detect more adverse effects of COVID-19.

CONCLUSIONS

Caesarean section delivery was associated with higher rates of postpartum clinical deterioration, complications, and maternal deaths. We also noted poor foetal outcomes in the caesarean delivery group. So, the mode of delivery among SARS-CoV-2-infected mothers should be based on obstetric indications and the severity of COVID-19 symptoms. COVID-19 alone should never be an indication for caesarean delivery. Vaginal delivery was safe and appropriate in mild forms and was associated with better maternal and foetal outcomes with no additional risk of vertical transmission.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contribution

A.J.: Conceptualization, investigation, methodology, writing – review & editing. M.K.: Writing – original draft. O.B: Data curation, formal analysis, investigation. F.M.: Investigation. K.C., K.K.: Supervision, validation, visualization.

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Study registration

N/A.

Disclosure of interests

The authors declare that they have no conflict of interests.

Ethical approval

Obtained from the HCUH (Local Ethics Committee).

Informed consent

Obtained from all parturients included in the study.

Data sharing

Data are available under reasonable request to the corresponding author.

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