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

Short title: Mode of delivery in COVID-19 infection

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Abstract

Objective: The aim of this study was to assess the maternal and fetal outcomes in pregnant women with COVID-19 infection at birth and the impact of the mode of delivery on the prognosis of these patients.

Material and Methods: This is a multicenter 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 cesarean delivery.
- Group 2: included patients who had vaginal delivery.

The maternal and fetal outcomes were compared between the 2 groups. Multivariable logistic regression was performed to assess the association between the mode of delivery and maternal and fetal adverse outcomes.

Results: We included 201 patients: 129 cesarean 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 cesarean group ($p < 0.001$). Cesarean 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: Cesarean delivery may worsen the prognosis of pregnant women with COVID-19. It was also associated with adverse fetal outcomes.

Keywords: cesarean section; vaginal delivery; COVID-19; maternal outcomes; fetal 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].

Cesarean delivery can be indicated for fetal 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 cesarean delivery early in the pandemic [4]. For others, cesarean delivery was indicated to either prevent vertical transmission or to protect the health care team [5]. However, the prognosis of cesarean 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 labor 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 fetal 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

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

b. 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.

c. 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 hospitalized for COVID-19 but had negative rt-PCR at the moment of birth. We excluded the cases of fetal loss defined as spontaneous antepartum fetal death < 14 WG and cases of late miscarriage 14–24 WG. Patients whose management did not adhere to the standard protocol were also excluded.

d. 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 O₂, the incidence of preeclampsia, anemia, and cytolysis, as well as radiographic and biological findings.
- The maternal outcomes after delivery: a clinical deterioration was defined by an increased need for O₂ supplementation after delivery, or referral to ICU, and maternal complications (ARDS, postpartum hemorrhage, 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.

e. 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 cesarean deliveries). The incidence of clinical deterioration was 10% in the vaginal delivery group and 34.6% in the cesarean 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.

f. 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.

g. 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 cesarean 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 \pm 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 Chi2 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 $p < 0.05$.

h. 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 fetal loss (< 14 WG), five for late miscarriage (14-24 WG), and two for receiving Tocilizumab. The 201 patients included were recruited mainly from 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, cesarean 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 cesarean 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 cesarean 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 cesarean delivery. Among the 129 patients who had a cesarean delivery, the main indications were: obstetrical indication (38.7%), fetal distress (37.3%), maternal life-saving (12.4%), and severe preeclampsia (3.8%). However, 10 patients (7.8%) underwent cesarean 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 cesarean 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 cesarean delivery group with $p < 0.001$ (table 3). In the ICU, the need for mechanical ventilation, catecholamine, and maternal deaths were higher in the cesarean group (table 3). After adjustment for potential confounding factors, cesarean birth was significantly associated with clinical deterioration (aOR=12.9 and 95% confidence interval was 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 cesarean 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 cesarean delivery group with $p = 0.001$. After adjustment for confounding factors, cesarean birth was associated with an increased risk of NICU admission (aOR=3.72; 95%CI: 1.63 – 8.48, with $p = 0.001$).

Vertical transmission was seen in 5 newborns (2.48%) and breastfeeding in 151 patients (75.1%) with no significant differences between the two groups (table3).

Discussion

Our study showed that cesarean 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, cesarean section was a very common practice [13, 14] with COVID-19 status alone being a common indication [4]. Some physicians thought that a cesarean would avoid an emergency cesarean section under general anesthesia 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 cesarean 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 hemorrhage [21] or HELLP syndrome [22]. Our results were comparable with previous studies in the literature [23, 24, and 25]. A Spanish study [22] reported that COVID-19-infected women (with mild symptoms) undergoing cesarean delivery may have been at higher risk of adverse outcomes, but after adjusting for confounding factors, cesarean birth remained independently associated with an increased risk of clinical deterioration (adjusted odds ratio, 13.4; 95% CI, 1.5-121.9; P = .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 study [25], vaginal delivery rates were high and associated with favorable 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 cesarean 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 fetal outcomes [28]. This category of pregnancies may need emergent cesarean delivery for fetal distress or for maternal life-saving to face severe hypoxemia due to ARDS [29]. Including this category of patients explains the high rates of cesarean 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 fetal 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.

Conclusion

Cesarean section delivery was associated with higher rates of postpartum clinical deterioration, complications, and maternal deaths. We also noted poor fetal outcomes in the cesarean 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 cesarean delivery. Vaginal delivery was safe and appropriate in mild forms and was associated with better maternal and fetal outcomes with no additional risk of vertical transmission.

- **Authors' contribution:**
 - A.J : Conceptualization, Investigation, Methodology, review & editing
 - M.K: original draft, Writing
 - O.B: Data curation, Formal Analysis and Investigation
 - F.M Investigation
 - K.C: Supervision, Validation, Visualization
 - K.K: Supervision, Validation, Visualization
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Table 1: Demographic and prepartum parameters.

	Group 1 Cesarean group 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/m ²)	28.6 ± 3.6	28.04 ± 3.6	0.299
BMI >30 Kg/m ²	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 (> or = 2)	95	50	
Vaccinated (yes/no)	42/87	30/42	0.128

Table 2: Maternal data before delivery:

	Group 1 Cesarean group 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
Dyspnea	39	17	0.232

Digestive signs (nausea, vomiting, diarrhea,..)	23	10	0.312
Others: (Sore throat or rhinorrhoea, anosmia and ageusia)	19	4	0.059
Pre-eclampsia	29	9	0.083
Anemia <10g/dL	22	10	0.344
Cytolysis (>3×)	20	4	0.043
Thrombopenia<50000	2	1	0.425
Radiological signs > 50% (yes/no)	11/16	2/2	0.060
O2 needed < 6L/min	42	20	0.065
O2 needed 6-15L/min	12	0	
O2 needed > 15 L/min: Need for advanced O2 support (Optiflow or CPAP)	4	1	
Referral to ICU before delivery	4	1	0.411

Table 3: Maternal and neonatal outcomes after delivery.

	Group 1 Cesarean group N= 129	Group 2 Vaginal delivery N= 72	P value
Clinical deterioration (%)	64 (49.6%)	5 (6.9%)	<0.001
Increased need for O2 after delivery (yes/no)	53	3	<0.001
O2 needed < 6L/min	36	16	0.024
O2 needed 6-15L/min	16	2	
O2 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	<0.001
Postpartum hemorrhage	11	2	
Thromboembolic events	5	1	
Septic shock	4	1	
Pregnancy related complication	11	2	
CPAP after delivery	26	2	<0.001
Need for intubation >24h	16	2	0.016
Catecholamine >24h	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

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