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ORIGINAL ARTICLE

Maternal and Perinatal Outcomes of Pregnant Women with SARS-CoV-2 infection: a single center experience

Short title: SARS-CoV-2 infection in pregnancy

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ABSTRACT

Background: The aim of this study was to evaluate maternal and perinatal outcomes of pregnant women affected by COVID-19 during the first pandemic wave in a third level university hospital of southern Italy.

Methods: This was a single-center, cohort study on SARS-CoV-2 in pregnancy. Pregnant women with laboratory-confirmed SARS-COV-2 from August 1, 2020 to January 1, 2021 from University of Naples Federico II were included in the study. A confirmed case of COVID-19 was defined as a positive result on real-time reverse-transcriptase-polymerase-chain-reaction (RT-PCR) assay of nasal and pharyngeal swab specimens. The primary outcome was the incidence preterm birth.

Results: 249 singleton pregnancies, positive to SARS-COV-2 at RT-PCR nasal and pharyngeal swab, were included in the study. Mean gestational age at diagnosis was 31.0 ± 6.7 weeks, with 2.4% of women being diagnosed in the first, 14.1% in the second and 83.5% in the third trimester of pregnancy. The vast majority of the women received therapy with low molecular weight heparin (88.8%). 47 women (18.9%) required oxygen therapy. The rate of admission to the maternal intensive care unit was 2.8%. There was one case of maternal death, accounting for a maternal mortality rate of 0.4%. Out of the 249 ended pregnancies, we reported two spontaneous abortions and two stillbirths. Among the 245 live-born babies, no neonatal deaths were recorded. All babies were tested negative at RT-PCR nasal and pharyngeal swab. The incidence of preterm delivery before 37 weeks was 10%.

Conclusion: SARS-COV-2 infection in pregnant women during the first pandemic wave in the South of Italy was associated with relative low rates of maternal and perinatal adverse outcome.

INTRODUCTION

The spread of COVID-19 in the last two years has had incalculable consequences [1,2]. Initially, a lockdown was imposed by the government and all non-urgent medical treatments were stopped and postponed, while healthcare resources were reallocated to face this unprecedented health crisis. Guidelines and advices were soon released by experts and subspecialty societies to direct obstetrical and gynecological management [3-15]. Interestingly, during the lockdown period, a significant decrease in admissions to the emergency units was also found for obstetric–gynecological conditions [16-21], and even for important tests, such as invasive prenatal diagnosis, a drop in the number of procedures was noted [22], clearly showing that pregnant women were more concerned than others of contracting the infection and suffering from the COVID-19 disease [23,24]. Moreover, reproductive medicine had to cease treatment unless for fertility preservation due to oncologic reasons, with consequences also on fertility and natality rates, opening a debate on the urgency to reduce time to pregnancy in women with poor prognosis [25-29]. Very soon, it appeared clear that pregnant women should have been considered a population at increased risk for severe forms of infection and therefore adverse maternal and perinatal outcomes [30-37]. One of the most dangerous complications of COVID-19 is pneumonia, which during pregnancy can have even more serious consequences due to the reduced lung excursion capacity [38,39]. Furthermore, it was questioned how to diagnose and monitor lung involvement in pregnant women, since computed tomography (CT) scan raises the risk of fetal damage due to ionizing radiations, and therefore lung ultrasound has been largely proposed in this subset of the population, as a fast and easy procedure with apparently no risk for the fetus [40-45].

Italy was one of the first countries in Europe to be hit, initially in the northern regions, but few months later also the southern were reached by the pandemic wave. In this scenario, it is of striking importance to address the consequences of SARS-CoV-2 infection both on maternal and on fetal-neonatal health, and more data are needed also to help the management of future cases. The aim of this study was to evaluate maternal and perinatal outcomes of pregnant women affected by COVID-19 during the first pandemic wave in a third level university hospital of southern Italy.

MATERIALS and METHODS

Study design and participants

This was a single-center, retrospective cohort study on SARS-CoV-2 in pregnancy. Clinical records and compiled data of all consecutive pregnant women with laboratory-confirmed SARS-CoV-2 from August 1, 2020 to January 1, 2021 from our institution (University of Naples Federico II) were included in a dedicated merged database.

Data before August 1, 2020 were excluded for two reasons: first of all, data were partially included in our prior multicenter WAPM collaboration, where University of Naples was the coordinator center [33]. In addition, before August 1, 2020 the vast majority of patients were screened only in case of recent exposure history, or in case of clinical symptoms or signs. After August 1, 2020 a policy of universal screening at the time of triage was applied [46]. COVID-19 was diagnosed on the basis of The World Health Organization (WHO) interim guidance [47]. A confirmed case of COVID-19 was defined as a positive result on real-time reverse-transcriptase-polymerase-chain-reaction (RT-PCR) assay of nasal and pharyngeal swab specimens [1,2]. Data on recent exposure history, clinical symptoms or signs, laboratory findings, maternal and perinatal outcomes were collected. Screening of neonates born from mothers infected by SARS-CoV-2 was performed with daily swabs during the 72h of routine hospital neonatal stay.

Outcomes

The primary outcome was incidence of preterm birth at less than 37 weeks of gestations. Secondary outcomes were maternal admission to intensive care unit (ICU), maternal death, perinatal death, cesarean delivery, admission to neonatal ICU (NICU), and vertical transmission confirmed at neonate RT-PCR assay.

Study definitions

Abortion was defined as pregnancy loss before 22 weeks of gestations. Stillbirth was defined as intrauterine fetal death after 22 weeks of gestation. Neonatal death was defined as death of a live-born infant within the first 28 days of life. Perinatal death was defined as either stillbirth or neonatal death. Preterm birth was defined as delivery before 37 weeks of gestation. Fever was defined as an axillary temperature of 37.5 °C or higher.

Statistical analysis

Standard descriptive statistics (median with range, mean ± SD and frequencies with percentages) were used to describe the features of cases.

RESULTS

Characteristics of the included women

During the study period, 263 singleton pregnancies, positive to SARS-CoV-2 at RT-PCR nasal and pharyngeal swab, were referred to our center. We did not have any twin pregnancy affected by SARS-CoV-2 infection during the first pandemic wave. Of them, 249 ended the pregnancy and were included in the study. The 14 women with an ongoing pregnancy were excluded from the study.

Mean gestational age at diagnosis was 34.2 ± 6.9 weeks, with 2.4% of women being diagnosed in the first, 14.1% in the second and 83.4% in the third trimester of pregnancy. The most common symptom at the time of triage was cough (27.7%), while anosmia was present in 28 women (11.2%). The vast majority of the women received therapy with low molecular weight heparin (LMWH) (88.8%) (Table 1). None of the included women were vaccinated against SARS-CoV-2, because the vaccine was not available yet at that time.

Maternal and perinatal outcomes

47 women (18.9%) required oxygen therapy. There were three cases of intubation, and the rate of admission to ICU was 2.8%. There was one case of maternal death, accounting for a maternal mortality rate of 0.4%. The death occurred in a 34-year-old pregnant woman at 17 weeks of gestation. The woman presented with fever, shortness of breath, and thrombocytopenia with platelet count of 900 per cubic millimeter. The patient was therefore admitted to ICU, where developed multiorgan failure. Out of the 249 ended pregnancies, we reported two spontaneous abortion and two stillbirths. Among the 245 live-born babies, no neonatal deaths were recorded. Of them 15 (6.1%) were admitted to NICU. All babies were tested negative at RT-PCR nasal and pharyngeal swab. The incidence of preterm delivery before 37 weeks was 10% (Table 2).

DISCUSSION

Main findings

The rate of preterm birth in our cohort was 10%. Furthermore, the study showed that in pregnancies complicated by SARS-CoV-2 infection during the first pandemic wave in the South of Italy, the risk of maternal mortality was low (0.4%), as well as the rate of perinatal mortality (0.8%), and about 2.8% of the women required admission to ICU. . The risk of vertical transmission was negligible, with no cases confirmed positive after the delivery.

Strength and limitations

Strength of our study is represented by the universal policy screening methods which allowed to recognize all infected pregnant women according to the WHO criteria. Limitations are given by the single center design and the overall small sample size. Moreover, we did not perform a statistical analysis comparing our results to healthy pregnant women or other COVID-19 affected cohorts, but limited to describe the phenomenon in our main regional university hospital.

Implications

The burden of SARS-CoV-2 infection during pregnancy raises the importance of viral screenings, and the need for protection of this population during seasonal viral infections or viral epidemics.

Historically, during the past influenza pandemic in the 20th century, there was increased risk for miscarriage and preterm birth, especially for women suffering from pneumonia [48]. Moreover, during seasonal influenza, the rate of visits for acute respiratory disease were significantly higher for pregnant women compared to non-pregnant [49]. Also, fetal defects have been associated to hyperthermia during the first trimester, and Central Nervous System (CNS) disease if this happens during more advanced gestational ages [50]. Furthermore, Zika virus infection during pregnancy has been associated to brain or eye defects when it affects pregnant women in the first trimester but also to preterm birth and low birth weight during the second or third trimester [51].

Looking to SARS-CoV-2, another Italian study reported similar rates for asymptomatic pregnant women (57.6%) with lower rates of fever and cough (18.1% and 10.6%, respectively). Also, the rates of therapies administered were different: in particular, antibiotic use (24.1%) and LMWH (55.3%) were less commonly used in their population. Finally, our rates of cesarean delivery were sharply higher compared to them (29.15%), and there is a difference in the finding of neonatal positivity, given that we did not find any compared to their 2% [52].

Our population came mostly from women tested positive for SARS-CoV-2 at the time of triage using a policy of universal screening with RT-PCR nasal and pharyngeal swab. Therefore, the percentage of asymptomatic women in the study was high (58.6%). The WAPM working group on COVID-19 in pregnancy [33] published a large multicenter study including 388 pregnant women from 72 different centers in 22 different countries in Europe, the USA, South America, Asia and Australia, enrolled between 1 February 2020 and 30 April 2020. The included participants came mostly from women referred for suspected COVID-19, due to symptoms or exposure, and consequently tested with RT-PCR nasal and pharyngeal swab. Therefore, the percentage of asymptomatic women was lower (24.2%), and the maternal and perinatal outcomes worse (Table 3). Indeed, the presence of symptoms raises the risks of complications [53].Our study did not report any cases of suspected vertical transmission and all live-born babies tested negative after delivery at RT-PCR test on nasopharyngeal swab. The possibility of mother-fetal vertical transmission of SARS-COV-2 is still unclear [54-56-51]. Testing for SARS-CoV-2 presence by reverse transcriptase PCR has repeatedly failed to identify the presence of the viral genome in maternal and neonatal specimens including placenta, umbilical cord blood, amniotic fluid or amniotic swab, maternal blood, vaginal secretions and breastmilk [34,57]. The WAPM study [33] reported one case of suspected vertical transmission, with a neonate tested positive soon after birth. The newborn was asymptomatic and had negative RT-PCR test after 14 days of life. Another mother-fetal vertical transmission case of COVID-19 occurred in a pregnant woman with rectal and stool maternal swab positive for COVID-19 as reported by Carosso et al. [58]. The authors concluded that SARS-COV-2 can enter the neonatal nasopharynx and potentially trigger neonatal infection. In a meta-analysis of 300 deliveries from mother with COVID-19 infection, only 9 newborns tested positive for SARS-COV-2 with an average pooled

incidence of vertical transmission of 16 per 1,000 newborns (95% confidence interval 3.40 to 73.11) [59]. However, only one of the nine newborns were symptomatic at birth.

The different mortality rate in the different studies may be explained by the study location, e.g. low- vs high-income countries, and by the study design, e.g. study inclusion criteria [60-64]. In the WAPM study, the maternal mortality rate was reported to be 0.8% [33]. In a study conducted at the University of Washington, authors found that pregnant women who had an infection with COVID-19 were 3.5 times more likely to be hospitalized because of the virus, and that mortality rates in pregnant women were 13 times higher than people of similar ages who had the disease [62].

This evidence raised the question of the importance of COVID-19 vaccine in pregnant women even in absence of level-1 data on safety of vaccine in this population [65-67]. However, since the introduction of vaccinal programs against SARS-CoV-2 infection, pregnant women demonstrated that the anxiety of contracting the infection was not higher than the anxiety of possible adverse events linked to the novel mRNA-based vaccines, with low percentages of acceptance worldwide [68-82]. Indeed, so far reassuring data have been released and published on the importance of vaccine against SARS-CoV-2 during pregnancy, given that antibodies generate a robust humoral immunity in pregnant and lactating women and were also transferred to fetus and neonates through cord blood and breast milk [83-85]. Moreover, vaccination has been seen to not increase the risk of adverse maternal-fetal and perinatal adverse outcomes [86-88]. At the moment we are facing another pandemic wave, with overcrowding of hospitals even more than what happened during previous waves, due to the increased infectiveness of the omicron-variant. In such a scenario, it is of fundamental importance that women get the vaccination and eventually the booster dose during pregnancy, to avoid the risk of worse infection and hospitalization. In the meantime, more data are still needed on SARS-CoV-2 during pregnancy, to uncover the mechanisms through which it determines adverse maternal and fetal-neonatal outcomes and counteract its action.

CONCLUSION

The rate of preterm birth in SARS-COV-2 affected pregnant women during the first pandemic wave was 10%, with negligible risk of vertical transmission, and overall low rate of maternal and perinatal adverse outcomes. Further studies are needed to increase the knowledge of SARS-CoV-2 consequences on maternal and fetal-neonatal health.Vaccine against SARS-CoV-2 should be strongly counselled among pregnant women, given that the pandemic has not ended and protection is still needed, also for eventually future waves.

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TABLES

Table 1. Characteristics of the included women.

Table 2. Maternal and perinatal outcomes.

Table 3. Maternal and perinatal outcomes comparing our cohort with the WAPM cohort study.

table 1

	N = 249
Demographics	
Age (years) Mean ± SD	31.0 ± 6.7
Healthcare workers n (%)	10 (4.0%)
Smoking n (%)	45 (18.1%)
Nulliparous n (%)	124 (49.8%)
Chronic disease pre-existing pregnancy n (%)*	105 (42.2%)
Obesity n (%)**	31 (12.4%)
Gestational age at infection (weeks) Mean ± SD	34.2 ± 6.9
Infection in the first trimester of pregnancy n (%)	6 (2.4%)
Infection in the second trimester of pregnancy n (%)	35 (14.1%)
Infection in the third trimester of pregnancy n (%)	208 (83.5%)
Flu vaccine	1 (0.4%)
Symptoms	
Fever n (%)	70 (28.1%)
Cough n (%)	69 (27.7%)
Rhinorrhea n (%)	8 (3.2%)
Anosmia n (%)	28 (11.2%)
Shortness of breath n (%)	18 (7.2%)
Diarrhea n (%)	1 (0.4%)
Conjunctivitis n (%)	2 (0.8%)
Asymptomatic n (%)	146 (58.6%)
Pharmacologic Treatments	
Hydroxychloroquine n (%)	6 (2.4%)
Any antibiotics n (%)	77 (30.9%)
Azithromycin n (%)	48 (19.3%)
Antiviral drug - **Any** - **Oseltamivir n (%)** - **Lopinavir/Ritonavir n (%)** - **Darunavir/Ritonavir n (%)** - **Remdesivir n (%)**	 28 (11.2%) 3 (1.2%) 9 (3.6%) 1 (0.4%) 12 (4.8%)
LMWH n (%)* **	221 (88.8%)
Steroids n (%)	77 (30.9%)

*Data are presented as number (percentage) or as mean ± standard deviation (SD). * including diabetes, hypertension, or asthma; ** defined as body mass index of 30 or greater; ***anticoagulants were used as prophylactic regimen.LMWH, Low molecular weight heparin.*

Table 2

	N = 249
MATERNAL OUTCOMES	
Use of oxygen, any type	47 (18.9%)
Admission to ICU n (%)	7 (2.8%)
CPAP n (%)	24 (9.6%)
Intubation n (%)	3 (1.2%)
Maternal death n (%)	1 (0.4%)
PERINATAL OUTCOMES	
Stillbirth n (%)	2 (0.8%)
Neonatal death n (%)	0
Admission to NICU n (%)	15 (6.1%)
Birth weight (grams) Mean ± SD	3098 ± 567
Preterm birth n (%)	25 (10.0%)
Gestational age at delivery Mean ± SD	38.2 ± 4.0
Cesarean delivery n (%)	213 (85.5%)
Possible vertical transmission n (%)	0

Data are presented as number (percentage) or as mean ± standard deviation (SD). CPAP, Continuous Positive Airway Pressure; ICU, intensive care unit; NICU, neonatal intensive care unit.

Table 3

MATERNAL OUTCOMES		
	Napoli study	**WAPM study (14)**
Asymptomatic n (%)	146/249 (58.6%)	94/388 (24.2%)
Use of oxygen, any type	47/249 (18.9%)	Not reported
Admission to ICU n (%)	7/249 (2.8%)	43/388 (11.1%)
CPAP n (%)	24/249 (9.6%)	Not reported
Intubation n (%)	3/249 (1.2%)	25/388 (6.4%)
Maternal death n (%)	1/249 (0.4%)	3/388 (0.8%)
PERINATAL OUTCOMES		
Stillbirth n (%)	2/249 (0.8%)	6/265 (2.7%)
Neonatal death n (%)	0/249	5/250 (2.0%)
Admission to NICU n (%)	15 (6.1%)	69/250 (27.6%)
Birth weight (grams) Mean ± SD	3098 ± 567	2921 ± 772
Preterm birth n (%)	25/249 (10.0%)	70/265 (26.4%)
Gestational age at delivery Mean ± SD	38.2 ± 4.0	37.2 ± 3.9
Cesarean delivery n (%)	213/249 (85.5%)	136/250 (54.4%)
Possible vertical transmission n (%)	0 /249	1/250 (0.4%)

Data are presented as number (percentage) or as mean ± standard deviation (SD.) CPAP, Continuous Positive Airway Pressure; ICU, intensive care unit; NICU, neonatal intensive care unit.