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COVID19 during pregnancy: a systematic review of reported cases.

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Title:
COVID19 during pregnancy: a systematic review of reported cases.

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Condensation:
Outcomes for mothers and neonates with COVID-19, described in the literature, have been favorable, but almost all had preterm cesarean delivery for reasons which are unclear.

Short title: Delivery of pregnancies with COVID-19

AJOG at a Glance:
A. Why was this study conducted?
COVID-19 is pandemic and will affect a large number of pregnant patients in the near future. Preliminary experience suggests that the outcome is often favorable, but it is unclear how and when these patients have been delivered.

B. What are the key findings?
The median gestational age was 36.5 weeks (IQR 35-38), with 15 cases of preterm birth (39%); cesarean delivery was reported in 96% of the cases but the indications were not clearly described.

C. What does this study add to what is already known?
Most patients with COVID-19 illness thus far have been delivered preterm by cesarean, in some cases electively. Whether this is warranted or not remains to be established.
Abstract:

- Objective: to conduct a systematic review of the outcomes reported for pregnant patients with COVID-19.
- Data sources: we searched electronically Pubmed, Cinahl, Scopus using combination of keywords “Coronavirus and/or pregnancy”; “COVID and/or pregnancy”; “COVID disease and/or pregnancy”; “COVID pneumonia and/or pregnancy. There were no restriction of languages in order to collect as much cases as possible.
- Study eligibility criteria: all pregnant women, with a COVID-19 diagnosed with acid nucleic test, with reported data about pregnancy and, in case of delivery, reported outcomes.
- Study appraisal and synthesis methods: all the studies included have been evaluated according the tool for evaluating the methodological quality of case reports and case series described by Murad et al.
- Results: 6 studies including 51 women were eligible for the systematic review. Three pregnancies were ongoing at the time of the report; of the remaining 48, 46 were delivered with a cesarean section and 2 vaginally; there was 1 stillbirth and 1 neonatal death.
- Conclusions: although vertical transmission of SARS-Cov2 has been excluded thus far and the outcome for mothers and fetuses has been generally good, the high rate of preterm cesarean delivery is a reason for concern. These interventions were typically elective, and it is reasonable to question whether they were warranted or not. COVID-19 associated with respiratory insufficiency in late pregnancies certainly creates a complex clinical scenario.

Keywords: COVID19, SARS-CoV-2, Coronavirus pneumonia in pregnant women, neonatal outcomes in COVID 19, vertical transmission novel coronavirus, Viral pneumonia, preterm birth, fetal death, stillbirth, cesarean section
On the 12th March 2020, the World and Health Organization announced the new Coronavirus outbreak pandemic, on the basis of more than 20,000 confirmed cases and almost 1,000 deaths in Europe. At the end of last December 2019, a cluster of cases of pneumonia of unknown cause was first reported in Wuhan, Hubei Province, China. At the beginning of January 2020, a novel Coronavirus was identified as the etiologic agent by Chinese authorities, called 2019-nCoV. Other coronavirus infections include the common cold (HCoV 229E, NL63, OC43 and HKU1), Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). A study reviewed the epidemiologic, clinical, laboratory, and radiological features, as well as treatment and clinical outcomes, of patients with laboratory-confirmed COVID-19 pneumonia. The presence of COVID-19 in a pregnant patient raises concerns, as other types of coronaviruses were frequently associated with adverse outcomes. Professional organizations have rapidly published preliminary documents providing advice on diagnosis and management. However, the scientific literature on the subject is scanty.

Objective

Our aim was to collect and review the available information about the impact of COVID 19 on mother and fetuses and to focus upon time and mode of delivery, and we conducted a systematic review of the available literature in English and Chinese languages.

Methods

The following electronic databases were screened from 14th March until 16th March 2020 in order to detect eligible papers: PubMed, Scopus and Cinahl. The search terms for retrieving articles related with the theme of interest were: “Coronavirus and/ or pregnancy”; “COVID and/or pregnancy”; “COVID disease and/or pregnancy”; “COVID pneumonia and/or pregnancy.”
Criteria for study selection

Reports included in the present review consisted of case series, case reports and retrospective studies. No randomized controlled trials (RCT) were found. Only reports describing management of pregnancies complicated by COVID-19 infection were included in this systematic review. We registered this review on PROSPERO. We did not provide contacts with the corresponding authors because the time constraints and the importance to have immediate results.

Assessment of risk of bias

Two study investigators (ANDG and RR) independently conducted the primary literature research using the main search terms. The same study investigators (ANDG and RR) independently reviewed the data collection forms in a second screening time, when the studies not conforming to the pre-established eligibility and inclusion criteria were excluded. At the third review time, the remaining reports were further analyzed for compatibility. In case of any disagreement between the examiners after independent evaluation, consensus was reached by re-evaluation and discussion with more experienced author (GS). The remaining studies were finally introduced into the final review step of qualitative synthesis.

Data quality assessment

Two independent examiners (ANDG, RR) applied the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) for the data extraction and quality assessment. The examiners (ANDG, RR) independently assessed the methodologies of the studies according the tool for evaluating the methodological quality of case reports and case series described by Murad et al. This tool considers 4 domains: selection, ascertainment, causality and reporting and provides 8 questions to aid quality score. (Table 1) If all of the domains were satisfied, the study would be classified as ‘good quality’; if three of the domains were satisfied, the
study would be classified as ‘fair quality’. If only two or one of the domains were satisfied, the study would be classified as ‘poor quality’.

Data extraction and synthesis

A total of 205 articles were found through the research engines (PubMed, Cinahl, Scopus), with publication dates from 1969 to 2020. The selection process followed the PRISMA workflow. We excluded 180 papers for these reasons: animal studies (165), the abstract was not available (3), the contents were not related to the topic of our review, or not provided any significant information (12). To collect as much cases as possible, no restriction on language (Chinese and English) was applied in the selection of articles. We included only studies in which the diagnosis was based on the criteria provided by the New Coronavirus Pneumonia Prevention and Control Program (4th edition and subsequent) published by the National Health Commission of China. After deletion of duplicates, thus, a total of 12 references were selected; 6 full text articles were excluded because data were not comparable. We subsequently reviewed the 6 articles describing clinical presentation, pathogenesis, macroscopic and histopathological aspects, natural history, diagnosis and treatment. Therefore, we selected all reported cases aged up to 20 years and analyzed the following aspects: clinical features, symptoms, associated diseases, fetal characteristics, time of delivery, type of delivery and follow-up. Two study investigators (ANDG and RR) independently reviewed the data collection forms to verify data accuracy.

Results

A total of six studies were eventually selected for analysis (Figure 1, Table 2) From a methodological point of view, only one study fulfilled all of the domains and three were classified of fair quality. Two studies were judged to be of poor quality because the selection criteria of the cases were unclear. The majority of the papers did not report follow-up of the women.
We found a total of 51 cases of pregnancies with COVID-19 illness. In 50 patients the diagnosis of COVID-19 was confirmed by quantitative Reverse transcriptase-polymerase chain reaction (qRT-PCR) on samples from the respiratory tract. In one patient\textsuperscript{16} diagnosis was based on clinical symptoms and a chest CT scan typical for viral interstitial pneumonia. Because the exclusion of other diseases, that could cause fever and lung infection, the local Center for Disease Control (CDC) then registered her as a confirmed 2019-nCoV case.

Median maternal age was 30 years (IQR 27.5-33). Median gestational age at diagnosis was 36 weeks (IQR 35-37.5). Of 48 patients that were delivered, the median gestational age was 36.5 weeks (IQR 35-38), and overall 15 (39\%) were delivered prior to 37 weeks. The interval between symptoms onset and delivery described in 22 cases,\textsuperscript{6, 7, 8, 16} ranged between 1 and 7 days (median 2, IQR 1-4). Symptoms appeared after delivery in 3 cases.\textsuperscript{16} Symptoms at onset of COVID-19 infection were reported for 35 pregnant women (69\%), and they were similar to those described in non-pregnant patients (table3):\textsuperscript{2}

- 17 (48\%) pregnant women presented with fever at admission;
- 16 (46\%) women indicated dry cough (considered alone or in association with other symptoms);
- 8 patients had fever only in the postpartum period;

Less frequent symptoms included: sore throat (5 cases); dyspnea (4); fatigue (3), myalgia (3), malaise (2), diarrhea (2); cholecystitis (2).

No pregestational comorbidities such as hypertension, diabetes, or cardiovascular disease were reported. There was one case of gestational hypertension at 27 weeks, and a case of pre-eclampsia at 31 gestational weeks; in both cases after the diagnosis of COVID 19 occurred. There was also one case of influenza at admission in hospital for respiratory difficulties, in addition to COVID 19 during pregnancy.\textsuperscript{6} Four patients had had a previous cesarean section, one a previous stillbirth, and there was one case of placenta praevia\textsuperscript{7}
We found no cases of infection during the first trimester of pregnancy; 2 cases of infection in the second trimester and 49 cases in the third trimester. The two second trimester and one third trimester (33 weeks) cases were reported as ongoing. Of the remaining 48 women, 2 had a spontaneous vaginal delivery: one at 34 weeks and 2 days (in this case, diagnosis of COVID-19 was done only after delivery) and at 31 weeks (this was a case of twin pregnancy). The remaining 46 patients underwent cesarean delivery. The indications to the caesareans were not clearly reported in all cases. Available data is reported in table 4. It is noteworthy that premature rupture of the membranes occurred in at least 26% of patients (9/34).

One patient, 30 years old, with no comorbidities, was diagnosed with COVID-19 disease at 34 gestational weeks and developed severe pneumonia. Her conditions worsened during hospitalization, requiring intensive care unit (ICU) admission with multiple organ dysfunction syndrome (MODS) associated with acute respiratory distress syndrome (ARDS) requiring intubation and mechanical ventilation, acute hepatic failure, acute renal failure and septic shock. A intrauterine fetal demise occurred in this case. This patient, at the time of publication of the original work, was still in the support of Extracorporeal Membrane Oxygenation (ECMO). For another patient is described admission to ICU after delivery for developing severe pneumonia and because the worsening of general condition; she was discharged at the time of publication of the original paper. Not all studies report data for the radiologic tests performed in pregnant women: among 51 cases of COVID-19 infection during pregnancy, for only 22 patients is reported a chest CT confirmatory for typical signs of viral infection, one case was negative and one case had chest X-rays positive for pneumonia. Data from laboratory tests are not complete for all cases. Authors report increased concentrations of alanine aminotransferase (ALT) and aspartate aminotransferase (AST), for two patients.

One fetal death occurred in a patient critically ill. The remaining 48 neonates (one set of twins) were in good condition at the time of birth. Unfortunately not all reviewed studies reported 5-min Apgar score. In all cases neonatal throat swab samples were collected immediately after delivery.
within 72 hours after birth and were negative with the exception of one infant that however was only tested 36 hours after birth. One neonate was delivered by cesarean section at 34 weeks and 5 days, adequate for gestational age (AGA), admitted to intensive neonate care unit (NICU) 30 minutes after delivery due to shortness of breath and moaning, developed thrombocytopenia, liver dysfunction, multiple organ failure and died 9 days after delivery. The authors stated that, although a throat swab in this neonate was negative for COVID-19 disease, a perinatal infection cannot be excluded. Admission to the intensive neonate care unit in the remaining infants was not clearly described.

Comment

Principal finding

Thus far, pregnant patients with COVID-19 illness have been almost invariably delivered by cesarean section, and frequently before term gestation. This is a reason for concern, as the COVID-19 pandemic is spreading around the world and most likely many pregnant women will be affected. However, one may question whether the choices made by the obstetricians thus far were modified. In most cases, the indication for the operation was not clearly stated, and it is certainly possible that the decision was influenced by the understandable anxiety towards the potential consequences of a new viral infection. Indeed, in our analysis of the available literature, the outcome has been generally favorable for both mothers and fetuses, although a word of caution is necessary. Of 51 cases we have analyzed, at least one mother was severely compromised, and in general follow-up data were scanty. We confirm that there is no evidence of vertical transmission, but previous experience with infections, caused by similar pathogens, such as SARS and MERS, indicates that vertical transmission is not the exclusive cause of fetal morbidity and mortality. Out of 48 fetuses that were delivered, there was one stillbirth in a severely compromised mother, and there was also one neonatal death that may not be independent from the infection. At present, the available evidence does not provide insight as to these patients require or not a different
approach from a standard one. It would be important that in the near future studies around the
implications of COVID-19 in pregnancy contain thorough information about both the maternal and
fetal conditions at the time of delivery, as well as the rational behind obstetric interventions.

Strength and limitations
The main strength of our analysis is that we have provided thus far the largest series on pregnancies
with COVID-19 illness. The main weakness is that the available literature around the obstetric
implications of COVID-19 is limited, both in numbers and quality. The justification behind our
study is that the spread of the disease dictates the need to rapidly evaluate and discuss the evidence
that has been generated.

Clinical implications
Authorities and Professional Societies, such as the Italian Health Council, the English Royal
College of Obstetricians and Gynecologists, and the Society of Maternal Fetal Medicine have
taken the stance that COVID-19 is not a contraindication to vaginal delivery. This appears
reasonable, in light of the absence of vertical transmission and of the outcome that in the
preliminary experience has been generally good. However, thus far, virtually all patients have
undergone elective cesarean delivery soon after the diagnosis. Whether this contributed to the
favorable results that were observed seems unlikely, but cannot be excluded with certainty. In non-
pregnant patients COVID-19 illness spans along a wide spectrum of severity. The majority of
patients, particularly those of young age, are asymptomatic or anyhow have no respiratory
compromise. In these cases, standard obstetric care seems sufficient, with the only caveat, that fetal
distress was described in almost 20% of cases. Whether this was related to maternal compromise or
not is not known, but it seems reasonable to provide continuous fetal monitoring in labor. In a
minority of patients (1 case in our series of 51) severe compromise will be present. In such a cases,
after fetal viability, cesarean delivery may be life-saving for both the mother and neonate. The most difficult scenario is certainly the intermediate case, a patient with compensated respiratory insufficiency, that may deteriorate in the following days. In preterm pregnancies, balancing the pros and cons of a conservative management versus expediting the delivery is difficult, as well as deciding the optimal mode to deliver a mother on the presence of hypoxia. The issue of obstetric complications is also relevant. The high rate of premature delivery in our review appears to be mostly the consequence of elective interventions. However, COVID-19 illness seems to be associated with spontaneous preterm birth as well, as in our review preterm labour was reported in at least 6/48 cases and premature rupture of the membranes in 9/34.

**Conclusion**

The available data on COVID-19 illness in pregnant patients do not provide a clear conclusion into the clinical implications for mother and fetus. The outcome thus far described is favorable, but fetal and maternal risks should be underestimated. Although preterm delivery was mostly the consequence of elective interventions, a trend towards spontaneous prematurity is present. It is essential that future studies provide more detailed information on maternal and fetal conditions, as well as the rationale for obstetric interventions. Experience, thus far, is limited to patients that developed the disease in late gestation and were delivered shortly after the diagnosis. The fetal consequences of long standing infections occurring in early gestation are unknown.

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Table 1. Table tool used for the evaluation of the methodological quality of case reports and case series.13

| Domains   | Leading explanatory questions |
|-----------|-------------------------------|
| Selection | 1. Does the patient(s) represent (s) the whole experience of the investigator (centre) or is the selection method unclear to the extent that other patients with similar presentation may not have been reported? |
|           | 2. Was the exposure adequately ascertained? |
|           | 3. Was the outcome adequately ascertained? |
| Ascertainment | 4. Were other alternative causes that may explain the observation ruled out? |
| Causality | 5. Was there a challenge/rechallenge phenomenon? |
|           | 6. Was there a dose-response effect? |
|           | 7. Was follow-up long enough for outcomes to occur? |
| Reporting | 8. Is the case(s) described with sufficient details to allow other investigators to replicate the research or to allow practitioners make inferences related to their own practice? |

Table 2. List of studies included in the analysis

| First author, year | Judgement* | Cases | Type of study | Setting |
|--------------------|------------|-------|---------------|---------|
| Huijun Chen et al6 | GOOD       | 9     | Retrospective | Department of Gynaecology and Obstetrics, Zhongnan Hospital of Wuhan University, Wuhan, Hubei, |
| Study Authors          | Study Design | Study Size | Setting                                                                 |
|-----------------------|--------------|------------|-------------------------------------------------------------------------|
| Yangli Liu et al      | FAIR         | 13         | Retrospective Hospital of Sun Yat-sen University, Guangzhou, Guangdong 510080, China. |
| Chen Shuo et al        | POOR         | 3          | Retrospective Department of Obstetrics and Gynecology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430022, China. |
| Zhang Lu et al         | FAIR         | 16         | Retrospective with control group Department of Obstetrics, The Central Hospital of Qianjiang City, Qianjiang 433199, China. |
| Huaping Zhu et al      | FAIR         | 9          | Retrospective Department of Neonatology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430022, China |
| Yang Li et al          | POOR         | 1          | Retrospective The First Affiliated Hospital, College of Medicine, Zhejiang University, Hangzhou, China |

* Using the tool described by Murad et al. 13

**Table 3.** Reported symptoms at diagnosis

**Della Gatta et al:** Delivery of pregnancies with COVID-19
| Onset symptoms | Reported only for 35/51, often in combination (%) |
|---------------|-----------------------------------------------|
| Dry cough     | 16/35 (45.7)                                  |
| Fever admission | 17/35 (48.6)                               |
| Postpartum fever | 8/35 (22.9)                                |
| Myalgias      | 3/35 (8.6)                                   |
| Malaise       | 2/35 (5.7)                                   |
| Dyspnoea      | 4/35 (11.4)                                  |
| Sore throat   | 5/35 (14.3)                                  |
| Diarrhoea     | 2/35 (5.7)                                   |
| Fatigue       | 3/35 (8.6)                                   |
| Cholecistites | 2/35 (5.7)                                   |

**Table 4.** Indications to cesarean section in 34 cases

| Indication           | Cases (%) |
|----------------------|-----------|
| COVID-19 pneumonia   | 19 (55.9) |
| PROM                 | 9 (26.5)  |
| Fetal distress       | 6 (17.6)  |
| Preterm labour       | 4 (11.8)  |
| Previous caesarean   | 3 (8.8)   |
| Previous stillbirth  | 2 (5.9)   |
| Pregnancy at term    | 2 (5.9)   |
### Table:

| Condition                               | Frequency |
|-----------------------------------------|-----------|
| Elevated liver enzymes                 | 1 (2.9)   |
| Preeclampsia                           | 1 (2.9)   |
| Previa Placenta                        | 1 (2.9)   |
| Abruptio Placenta                      | 1 (2.9)   |
| Multiple Organ Dysfunction Syndrome    | 1 (2.9)   |
| Oligohydramnios                        | 1 (2.9)   |
| Psychosocial factors                   | 1 (2.9)   |

### Figure legends

#### Figure 1

Search strategy flow chart
Record identified through searching in 3 databases (Pubmed, Cinahl, Scopus) 
N=205

Records after deletion of duplicates 
N=192

Records screened by title and abstract 
N=192

Records excluded 
N=180
Reasons: Animal studies (165); abstracts not available (3), contents not related to the topic of our review or not provided any significant information (12)

Full text article assessed for eligibility 
N=12

Full text article excluded n=6
Reasons: data not comparable, lack of details

Studies included in qualitative synthesis 
N=6