Yalda Afshar, Neil S. Silverman, Christina S. Han and Lawrence D. Platt*

Clinical guidance and perinatal care in the era of coronavirus disease 2019 (COVID-19)

https://doi.org/10.1515/jpm-2020-0400 Received August 23, 2020; accepted August 30, 2020; published online October 12, 2020

Abstract: Pregnant women may be at risk for more severe manifestations and sequelae of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). At this time, there remain significant evidence gaps to allow for comprehensive counseling of pregnant women and their families, specifically regarding the risks of gestational-age specific maternal outcomes and potential risks of intrauterine or peripartum viral transmission to the fetus or newborn. As maternal fetal medicine providers and consultants, we are uniquely positioned to mitigate the risks associated with maternal infection and to guide the care for infected pregnant women by being able to provide the most current evidencebased recommendations. Such care requires incorporating the rapidly evolving data regarding this virus and its impact on pregnancy, as well as taking a stand to advocate for best scientific and clinical practices to optimize both women's health and public health during this pandemic.

Keywords: COVID-19; maternal fetal medicine; obstetrics; perinatology; prenatal care; ultrasound; SARS-CoV-2.

Introduction

Coronavirus disease 2019 (COVID-19), caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was first described in China in December 2019 [1]. The spread of the virus in an essentially non-immune global population was unprecedented in recent

*Corresponding author: Lawrence D. Platt, MD, The Center for Fetal Medicine and Women's Ultrasound, Los Angeles, CA, USA; and Department of Obstetrics and Gynecology, Division of Maternal-Fetal Medicine, University of California Los Angeles, Los Angeles, CA 90048, USA, E-mail: ldplatt@gmail.com

Yalda Afshar, Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, University of California, Los Angeles, Los Angeles, CA, USA

Neil S. Silverman and Christina S. Han, Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, University of California, Los Angeles, Los Angeles, CA, USA; Center for Fetal Medicine and Women's Ultrasound, Los Angeles, CA, USA

history, and by March 11, 2020, the World Health Organization had declared the outbreak of COVID-19 infection a worldwide pandemic [2]. SARS-CoV-2 is highly contagious, with a reproduction number ranging from 2.0 to 5.7 [3, 4] and transmitted via respiratory droplets, with airborne transmission now viewed as representing a larger proportion of infectivity than previously hypothesized [5–9]. It remains undetermined if it can be passed through sexual intercourse or in vaginal secretions.

As has been documented with other viral respiratory illnesses, COVID-19 infection during pregnancy has been associated with higher morbidity and mortality compared to the non-pregnant state [10–14]. The pregnancy-specific course of COVID-19, however, remains incompletely characterized [15–18].

Effect of SARS-CoV-2 on pregnancy

To date, the majority of outcome data have been generally not demonstrated an increased risk of becoming infected with SARS-CoV-2 infection during pregnancy [19], though if infected, pregnant women appear to be at higher risk of morbidity [20, 21]. In the early phases of the pandemic, our knowledge regarding severe outcomes in pregnancy has been defined by case reports and small case series of the clinical courses of women infected during pregnancy [22, 23]. As with many newly-described diseases, especially infections, the early published literature (and we are only 8 months into this pandemic) tends to emphasize worse-case outcomes, which are more easily identified. These adverse outcomes include higher rates of preterm delivery, particularly among women with underlying medical comorbidities and obesity [15, 24–28].

The Center for Disease Control and Prevention (CDC) released its surveillance data regarding COVID-19 infection in June 2020 [20]. In their cohort of 326,335 laboratory-confirmed cases in women of reproductive age, 8207 women were pregnant, although data on pregnancy status was lacking in 72% of the total cohort. Among the pregnant patients, 32% had been hospitalized, compared to 6% of the non-pregnant cohort, although indications for admission were not reported. After adjusting for clinical

covariates, pregnant patients were found to be 1.5 times more likely (95% confidence interval [CI] 1.2-1.8) to be admitted to the intensive care unit and 1.7 times more likely (95% CI 1.2–2.4) to receive mechanical ventilation than the non-pregnant cohort, with no significant differences between the groups in COVID-related deaths. Despite the limitations of the data set, this report suggested that pregnant patients should be counseled on theoretically higher risks associated with disease, while they should continue following general recommendations for infection control for the prevention of COVID-19 [29].

Similar to non-pregnant populations, however, the majority of infected pregnant patients develop mild symptoms that do not require inpatient management and support [20]. Clinical symptoms associated with SARS-CoV-2 are thought to include fever, cough, sore throat, myalgia, and malaise, shortness of breath, gastrointestinal symptoms, and loss of taste or smell [26, 30, 31]. Of particular concern in the pregnant population is the cohort of asymptomatic but still infectious pregnant people, which was first reported in New York City as an additional risk for community transmission of SARS-CoV-2 [30, 32].

Additional larger and prospective cohorts are needed to gain better insight into risks and outcomes for this specific at-risk population. In an attempt to broaden our knowledge, a national prospective surveillance registry has been created which enables enrollment of COVID-19 infected pregnant patients at time of diagnosis, either by the provider or by the patient herself. This registry (the PRIORITY cohort) currently has over 1,100 subjects enrolled to date (https://priority.ucsf.edu/dashboard).

Call to action for maternal fetal medicine specialists during the COVID-19 pandemic

Maternal fetal medicine (MFM) subspecialists are centrally positioned to lead the way in providing clinical guidance, care, and recommendations for maintaining the health of the maternal-fetal dyad in this quickly changing environment as we learn more about COVID-19. Professional societies, such as the Society for Maternal-Fetal Medicine (SMFM), American Congress of Obstetricians and Gynecologists (ACOG), and International Society of Ultrasound in Obstetrics and Gynecology (ISUOG), are integral in the curation, generation and broad dissemination of evidence-based guidelines. MFM physicians must also continue to advocate for the elimination of inclusion of pregnant and lactating women in clinical studies to improve care and access of treatment options to this population [33].

SARS-CoV-2 testing and management

Many Labor and Delivery units in the United States have transitioned to universal testing of all admitted obstetrical patients; however, at this time recommendation for testing for SARS-CoV-2 relies on local testing availability, infection prevalence, and clinical judgments combined with symptoms [34]. Testing is generally by RT-PCR; however, this also varies by local availability. Deficits in test or staffing availability (or both) has led some localities to transition to protocols using COVID-19 antigen testing via oropharyngeal swabs, either at a collection site or self-collected and sent to a lab. The implicit acceptance here is a tradeoff of increased availability and lowered cost against decreases in sensitivity and specificity of the test [35].

Infection with SARS-CoV-2 currently is not an independent recommendation for delivery, unless dictated by routine obstetrical indications or maternal complications [36]. Medically-indicated preterm delivery for mechanicallyventilated women in the 3rd trimester has been reported, with improved ventilatory management achievable after delivery [24, 36, 37]. If preterm delivery is indicated, antenatal corticosteroids for fetal lung maturity should still be administered up until 33 6/7 weeks; this should be individualized in the late preterm period (34 0/7-36 6/7) [38]. Similarly, the administration of magnesium sulfate for fetal neuroprotection up to 31 6/7 weeks gestation is still indicated, unless specific maternal contraindications are present, and dosing may need to be modified in the setting of critically-ill patients with renal injury or pulmonary edema [36]. Due to an increased risk of thromboembolic events with COVID-19, prophylactic anticoagulation should be considered in the pregnant patient who is admitted for complications related to the viral infection. Both the ACOG and SMFM provide comprehensive recommendations for delivery planning in pregnant with COVID-19 [39].

For women who recover from COVID-19 infections, while data are currently limited regarding trimesterspecific impact of infection, increased risks of intervillous placental thrombosis have been described in the setting of pre-delivery infection [40]. Therefore, serial surveillance of fetal growth, especially during the third trimester, appears to be reasonable, as with other antenatal infections with potential fetal or placental impact, and is discussed with and offered to these patients in our practice.

Impact of the pandemic on outpatient high-risk prenatal care

Though many prenatal care providers have spaced out prenatal visits to incorporate only the essential "milestone"

visits, such as those including baseline labwork and exams, diabetes screening, and periodic surveillance of fetal growth and maternal health and well-being, interval in-person contacts and patient's self-surveillance at home will still be indicated. The availability and incorporation of telemedicine has increased dramatically during the COVID-19 pandemic, and has proved an important complement to necessary in-person patient visits, along with combined multi-disciplinary visits for routine and higher-risk pregnancy indications, and limiting antenatal fetal surveillance to what is safe and appropriate [41]. Telemedicine-based care for high-risk obstetric patients has also been described [42]. However, barriers to access of telemedicine should be assessed, including lack of access to technology or Internet, lack of privacy due to residential constraints, concerns about intimate partner violence, or presence of hearingimpairment (REF: Duzyj, Thornburg, Han. Aug 2020 [43]).

In our practices, an in-person visit is scheduled only after a negative screen for COVID-19 symptoms is obtained at the time of making the appointment. In a time when pregnant patients, along with the rest of the population are negotiating sometimes changeable local recommendations on limiting travel outside the home and maintaining social distancing, we have found that the possibility of combining and thereby limiting outside visits to medical settings to be welcomed and accepted by these patients. In addition, we have not encountered any resistance to symptom screening by patients at the time of scheduling a visit, or at the time they arrive for their appointment, before entering the formal office area.

Protections against COVID-19 in the outpatient obstetrical setting

Though it may have been initially associated with concern and even anxiety, we have strictly enforced a policy that limits the number of people in the office at any given time to a workable minimum, both for patients' partners and visitors, as well as among the clinical office staff. This policy was instituted early in the pandemic, when it became clear that risk mitigation could be enhanced and strengthened by decreasing the absolute number of people in clinical and waiting areas in the office. This was explained to patients at the time of scheduling and on practice websites as a critical aspect of public health recommendations to moderate the potential risk of disease spread, especially from asymptomatic individuals. These recommendations were initiated at a time when it became apparent that the spread of COVID-19 infection was becoming widespread in diverse communities, and was not limited to focal high-prevalence regions nationally. This policy eventually became adopted by the majority of obstetric practices in our area, for both general OB/GYN and MFM outpatient areas, and had already been adopted by almost all the large inpatient medical centers in our region.

Two types of MFM practices are represented by the authors of this document. For those of us in private academic practice, no primary obstetrical care is provided. All patients in this setting are referred by primary generalists, for indications of both fetal ultrasound surveillance and for comanagement of maternal and fetal medical complications, up to and, not uncommonly, beyond the end of the pregnancy. While consult referrals are rarely discouraged, in the time of the current pandemic, referring physicians have been informed that if a patient had undergone cell-free DNA screening with low-risk results returned, the usual referral for a first-trimester fetal evaluation could be deferred until the second trimester, especially if community transmission rates continued to increase or the patient wished to minimize office visits. We also work with the primary obstetrician to incorporate some aspects of a "routine" prenatal care visit into an MFM consultative office visit when it is compatible, allowing patients to minimize excursions to physician offices while the shelter-in-place policies remain in effect. This can easily include assessment and documentation of fetal well-being (including antenatal testing), recording vital signs, including weight, checking for signs or symptoms of preterm labor or preeclampsia, as well as drawing any prenatal labs, including those for prenatal genetic screening, that might coincide with an MFM office visit. Vaccinations, such as Tdap and influenza, as well as GBS screening can also be incorporated into these visits. For those in an academic practice or in a private practice that also provides global obstetrical care, the MFM and obstetrical prenatal care components can be similarly consolidated into in a single visit to minimize visits.

Risk mitigation against viral transmission was also incorporated into routine practices during the course of the typical clinical day. An "evaluation station" was set up outside the entrance to the office spaces, where all patients have their temperature checked and are asked about any possible COVID-19 symptoms before they are allowed to enter. All employees also undergo a similar procedure before entering the office. Patients are informed at the time of booking a visit that a mask or face covering is required for the entire duration of their appointment; signage to that effect is also prominently posted in the evaluation area. In order to optimize social distancing, patient appointments were spaced farther apart, with double booking permitted only for emergency indications. As previously noted, patients are also informed at the time of their booking that partner and other visitors may not accompany them into

the office. Use of FaceTime and other real-time audiovisual conferencing platforms is actively encouraged during all visits, and each exam room is equipped with a smartphone stand to allow a partner to actively share and participate in the visit. Rare exceptions are made for a partner to be present during an exam if consultation for a likely or known anomaly is part of the referral, either structural or genetic, and the couple is seen in one of the office's larger exam rooms to allow for appropriate distancing of all individuals.

As was our practice prior to the COVID-19 pandemic, we work closely with sonographers in our practices. While all patients are examined by scan by a physician during their visit, they may or not also have a preceding scan by a sonographer, depending on the patient schedule, the number of doctors in the office on a given day, or sonographer absence due to illness or other issues. As the pandemic progressed, the physicians and sonographers discussed the use of best-practice judgment in trying to limiting the time of contact with any individual patient, while still affording her a thorough and informative evaluation. Some have proposed that tele-sonography could be incorporated into prenatal diagnostic centers, with only sonographers physically present to scan and a physician remotely reading the images from a separate location. We strongly felt as a group that it would not be ethically acceptable to us to place a sonographer at potential risk of infection to avoid the physician from having the same degree of close patient contact, understanding that a 6-foot distance from the patient is unrealistic for an ultrasound exam.

To protect all persons performing ultrasounds equivalently, all physicians and sonographers in the office initially wore surgical masks and gloves during the day for all patient contacts as well as for work within an indoor office. These masks were provided to employees by the practice. Given the nature of outpatient MFM practice, N95 masks were not recommended or required, since none of our procedures would be viewed as aerosolizing, and discussion-only components of the visit could be performed in the setting of distancing. As the pandemic progressed in our region, with wider community spread, the use of face shields or protective goggles (not eyeglasses alone) was strongly recommended for all persons performing ultrasounds during the day, though they could be removed when not in close contact with patients. No special gowns were used. At the completion of each scan, the ultrasound room was completely cleaned including the exam table and ultrasound machine. The guidelines for scanning included above followed the guidelines of ISUOG and SMFM [18, 39].

Similar to pregnant patients, pregnant healthcare workers (HCW) should follow infectious disease risk mitigation strategies. At this time there are no data that support a recommendation that they stop working, though they may wish to consider limiting exposure to higher-risk procedures, especially in individuals with suspected or confirmed SARS-CoV-2 infection. Still, recommendations for practice in the current setting must be individualized to the individual HCW, considering their personal wishes, along with their work location and available resources in their region.

SARS-CoV-2 transmission during delivery and breastfeeding

There is some biological plausibility to the potential for in utero transmission of SARS-CoV-2 [44, 45]; however, to date there have not been consistent definitive data reported that describe the underlying mechanisms, the predictability, or the rate of intrauterine infection. Current data suggest that the risk of vertical transmission of SARS-CoV-2 remains low, regardless of mode of delivery [15, 19, 24, 41, 46-50]. A recent case report from France supports the possibility that intrauterine transmission can occur [45] . This report describes a patient admitted at 35.5 weeks gestation with significant respiratory symptoms and a diagnosis of COVID-19 infection by PCR; she was delivered by cesarean for a category three fetal heart rate tracing. RT-PCR detected both the E and S genes of SARS-CoV-2 from her nasopharyngeal swab and her blood, as well as from her vaginal swab, amniotic fluid obtained through intact membranes at the time of surgery, the placenta, and from neonatal blood. Viral load was highest in maternal blood and the placenta. Before this report, SARS-CoV-2 had not been identified in vaginal secretion samples [51, 52]. It is also unlikely that SARS-CoV-2 is transmitted through breastmilk [53, 54]. Currently, the American Academy of Pediatrics recommends that the mothers infected with SARS-CoV-2 breastfeed, ideally using expressed breastmilk, with proper hand-hygiene, washing of pumps and bottles, and wearing a mask [55].

Conclusions

Pregnant women may be at risk for more severe consequences of SARS-CoV-2 infection compared to nonpregnant adults, with more advanced maternal infection appearing to also increase the risk of adverse pregnancy outcomes. At this time, there remain significant gaps in evidence preventing comprehensive counseling for these women and their families, especially risks specific to infections in pregnancy, namely maternal morbidities and the potential for intrauterine or peripartum virus transmission. As maternal fetal medicine specialists, we are uniquely positioned to work toward attenuating the risk of infection in and guide the care of pregnant women infected with SARS-CoV-2 using evidence-based recommendations as they evolve. This mission requires collating the rapidly evolving body of literature for the obstetrical community and patients, and take a stand in risk mitigation during this pandemic. To state it in a Bayseian way familiar to epidemiologists, we need to be ready to always "update our priors" in this time of health crises, that is, always be willing to update and incorporate new knowledge into our existing beliefs [56].

Research funding: None declared.

Author contributions: All authors have responsibility for the entire content of this manuscript and approved its submission.

Competing interests: Authors state no conflict of interest.

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