SSC Subcommittee Project/Collaborative Project

NAME OF PROJECT- International Registry on Pregnancy and COVID-19 Associated Coagulopathy (COV-PREG-COAG)

Subcommittee - **ISTH Women's Health Issues in Thrombosis and Hemostasis**

Person responsible:

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Description Abstract:

Novel coronavirus (SARS-CoV-2), previously known as 2019-nCoV, which causes COVID-19, has affected 2,000,269 cases with 130,398 deaths worldwide. This is a respiratory illness, the symptoms of which usually include cough, high temperature and shortness of breath, and while short-term data based on small case-series suggests that pregnant individuals are not at higher risk of illness than the non-pregnant population, little is known about the impact COVID-19 will have on affected pregnancies and their maternal and fetal/neonatal outcomes.

Abnormal coagulation parameters were associated with poor prognosis in COVID-19 patients including elevated D-dimer, prolonged PT and abnormal platelet counts (thrombocytopenia or count elevation). Furthermore, DIC and an increased risk of VTE were also reported in severe disease. Anticoagulant therapy with LMWH was associated with a better prognosis in severely ill patients who meet sepsis-induced coagulopathy criteria or had a markedly elevated D-dimer. The extent and frequency of coagulation abnormalities in COVID-19 during pregnancy are currently unknown. Increased maternal mortality and poor obstetric outcomes have been demonstrated in association with other coronaviruses such as SARS and MERS13-15. This has not been evaluated with SARS-CoV-2. The use and safety of antiviral therapies in the context of COVID-19 and pregnancy is also unknown. Similarly, there are questions with respect to the risk of VTE in a COVID-19 affected pregnancy, the use of LMWH, the effects of corticosteroids use for acceleration of fetal lung maturity and the use and safety of antiviral therapies in the context of COVID-19 and pregnancy.

Knowledge of clinical and laboratory parameters with prognostic utility can be extremely valuable in managing pregnant women with COVID-19; determining the best treatment options, balancing maternal and fetal/neonatal risks and benefits, and avoiding unnecessary interventions. Further understanding of the incidence of COVID-19-related coagulopathy on maternal and fetal outcomes would likewise be of value to help guide treatment recommendations.

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Objectives

1- To examine coagulopathy in COVID-19 affected pregnancies and their potential link to disease severity
2- To examine VTE events in COVID-19 affected pregnancies and their potential link to disease severity
3- To study the hemostatic parameters in women with COVID-19, during each trimester of pregnancy
4- To study the hemostatic parameters in women with COVID-19, during the postpartum period
5- To assess the effects of COVID-19 related coagulopathy on maternal and fetal/neonatal outcomes
6- To evaluate the use/effects of therapies such as LMWH, Steroids for acceleration of fetal lung maturity, antibiotics, and antivirals

Design and methodology:

This is a prospective international registry study. A structured survey will be available online and will be distributed to ISTH members and will be open for participation by physicians//health care providers worldwide. We will ask physicians to enter anonymized information relating to patient with COVID-19 associated coagulopathy during pregnancy or postpartum period. The survey questionnaire includes

1- The type of coagulopathies seen in COVID-19 affected pregnancies and how they relate to the disease severity
2- The values of hemostatic parameters seen in pregnant women with COVID-19 during the first, second, and third trimesters
3- The values of hemostatic parameters seen in pregnant women with COVID-19 during the postpartum period
4- The effects of COVID-19 related coagulopathy during pregnancy on maternal and fetal/neonatal outcomes
5- To establish if there is a relationship between specific hemostatic parameters and maternal mortality and/or morbidity (ICU admission, iatrogenic delivery, haemorrhage, thrombosis)
6- The frequency and type of blood product transfusion
7- Therapies given: LMWH, steroids for acceleration of fetal lung maturity, antibiotics, and antivirals and whether any of these have effects on COVID-19 related coagulopathy or VTE

The physicians can choose not to participate or can withdraw at any time during the survey simply by not submitting it.

Inclusion Criteria**:** The study population will consist of pregnant individuals with a confirmed COVID-19 infection.

Expected timeline:

The survey will remain open from 2020 to 2023. Once the survey is closed, we will begin to analyze the data. At that time, no more responses will be collected.

The registry is available here https://redcap.isth.org/surveys/?s=4JPX9W98RH

Finalization/analysis:

Statistical analysis will involve descriptive statistics (mean, standard deviation, median, and range) for continuous variables while noncomparative statistics (count and percentage distribution) for categorical variables.

Expected outcomes:

Information on the incidence of COVID-19-related coagulopathy, risk and incidence of VTE and of treatment/ prophylaxis and the effect on maternal and fetal outcomes would be of value to help guide treatment recommendations. We also plan to publish the results as an original article in a peer-review journal.

Description of project set/up and management, needed infrastructure and resources (summary):

The project will utilize ISTH REDCap web application to contrast the questionnaire. A link will be available through the ISTH website and other international societies to help recruitment and data collection. Information on the registry call for participation will be sent out vis ISTH newsletter and will be posted on various social media platforms. The infrastructure needed include:

1) The education program coordinator will support and maintain the website, and the link to the questionnaire.

2) Project leads will examine the data, share with collaborators and will analyze using appropriate statistics

3) Manuscript will be coauthored by project leads and collaborators. Participants will be included subject to submission of information/ contribution to the success of the registry

Possible references:

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