SSC Subcommittee Project

Global registry of DIC in pregnancy

Subcommittee:
A joint project from: Women’s Issues in Thrombosis and Hemostasis and DIC Subcommittee

Person responsible (Chair / Principal Investigator):
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Description Abstract
Disseminated intravascular coagulation (DIC) is a serious complication of a serious obstetric complication that contributes to increased maternal morbidity and mortality. The rate of DIC during pregnancy varies globally. It is relatively low in developed countries (0.03%-0.35%), while the reported incidence is much higher (0.9%) in the developing world. The etiologies also differ among nations with placental abruption as a leading cause in the developed states in comparison to preeclampsia and intrauterine fetal death in the developing world. There are very few publications that provide an international or global perspective to the prevalence of DIC and the obstetrical complications, which are associated with it. Therefore, this project aims to develop a global registry of DIC cases during pregnancy, their clinical presentation, and recording maternal, as well as neonatal outcome.

Design and methodology

- Building an online registry that will collect all the available data on cases of DIC during pregnancy, globally. This registry will be managed through a joint venture of the Women’s Health and DIC SCC committees of the ISTH.
- ISTH REDCap will be used (the questionnaire is currently being developed)
- The registry will include information on
  - The epidemiologic characteristics of the patients
  - Clinical conditions that lead to the DIC
  - How it was diagnosed
  - Basic laboratory information
  - How it was treated
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- What was the outcome of the patient
- A previously developed questionnaire for DIC and Sepsis, conducted under the auspice of the DIC SSC, will be used as a foundation for this proposal.

- Participants: physicians, obstetricians and hematologist managing cases of DIC in pregnancy and/ or able to promote the use of this registry through their national professional societies.

**Data expected to collect, sample size and statistical analysis:**

DIC during pregnancy is not frequent (our study recorded 70 cases out of a total of 20,000 deliveries). Nevertheless, with a global effort, information regarding ~150 cases over a period of two-three years could be collected.

In light of the lack of a well-established data regarding the complications and clinical end point of patients with DIC during pregnancy, a proper sample size analysis is required. For this reason, a pilot study aiming to complete 50 questionnaires will be conducted. A sample size to provide sufficient power to characterize the clinical manifestations of the disease and its global diversity, will be calculated accordingly.

**Study population (Inclusion, exclusion, eligibility) (patient population; recruitment of participating institutions/physicians and subjects; minimum number needed; expected number):**

The study population will include all pregnant women who develop DIC, based on clinical definition of their attending physician. We will not exclude any patient unless there may be a question regarding the diagnosis of DIC. In such a case, the physician who reported the case will be consulted. All women will be eligible to be included in this study and any physician can submit a case to the registry.

Invitation to participate in this registry will be enhanced through:

1) ISTH newsletter
2) Various professional societies in thrombosis & hemostasis, maternal & fetal medicine, and obstetrics and gynecology.
3) International and national meetings on the subject and other related issues.
4) Personal communications of physicians from both SCCs (DIC and Women’s heath) via their centers.

**Expected timeline:**

Project stage/set up: 6 months
Launch: SCC meeting 2018
Duration: 3 to 5 years depending on the rate of recruitment- 2021
Finalization/analysis: analysis of the data after the completion of its collection
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Reporting: as a research paper(s) in the relevant journals

Expected outcomes (ie. publications):

We expect to publish several research papers regarding the global epidemiology of DIC in pregnancy, the diagnostic criteria and scores, and current treatment modalities and maternal outcome.

Additionally, we hope to be able to develop interventions to increase awareness and improve prevention and treatment of pregnant women who develop DIC.

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

The project will be based on web-based questionnaire that will be available through the ISTH web-site and any other international society who will be joining this venture.

The data collected will be kept in a registry, and will be analyzed following the completion of data collection.

The infrastructure needed include:

1) The ISTH secretary will maintain the website, and the link to the questionnaire.
2) Study investigators and collaborators will collect the cases
3) Statistical support to analyze the data (this will be covered by Department of Obstetrics at Ben Gurion University in Beer Sheva Israel)
4) A small budget ~ 1500$ will be required to cover expenses such as members lists of specific societies.

Possible references:


