COVID-19 Vaccination in Pregnant Women: Exploring Serious Adverse Events

Sir,

Pregnant women represent a high-risk population that is prone to developing severe forms of *SARS-CoV-2* infection. This infection in pregnancy leads to a higher risk of preeclampsia/eclampsia, maternal mortality, and fetal complications such as preterm labour, *etc*.[1] Hence, vaccination of this population group is needed in order to prevent such unfavourable outcomes. Information in regards to the safety of COVID-19 vaccination in pregnancy is still in the preliminary stages. Initial research regarding the safety of mRNA-based vaccines in pregnancy revealed 46 events of spontaneous abortions reported to the Vaccine Adverse Event Reporting System (VAERS) and 115 cases of pregnancy loss among 827 participants from the V-safe registry.[2] Thus, similar studies for the Johnson & Johnson/Janssen (J&J/Janssen) COVID-19 vaccine have become the need of the hour. According to the CDC, more than 13 million individuals have been vaccinated with Ad26.COV2.S vaccine. Out of these, thrombosis with thrombocytopenia syndrome (TTS) has been observed at a rate of 4 per million doses.[3] Although some researchers have debated certain risk factors such as Venous Thromboembolism amongst COVID-19 vaccines,[4,5] the latest CDC guidelines recommend the use of mRNA-based vaccines over adenoviral ones.[6]

A 25-year female, who was five weeks into pregnancy, presented with a 3-day history of increased vaginal bleeding. On further inquiry, it was revealed that 13 days ago, she had received Ad26.COV2.S vaccine. Past history was significant for iron deficiency anaemia. Examination revealed dark-red blood in the vaginal vault and an open cervical OS. Baseline investigations (complete blood count, comprehensive metabolic profile, and coagulation testing) were normal. A pelvic ultrasound revealed expulsion of products of conception as well as an incidental finding of iliac vein thrombosis in the right adnexa. There was no family history of blood clots or miscarriages. Initially, enoxaparin 40 mg BID was prescribed and she was counselled regarding bleeding side effects. Later on, a haematology consultation was done and after a detailed discussion with the patient, her medication was changed to dabigatran 150 mg BID. The patient was kept on regular follow-ups.

American College of Obstetrics and Gynaecology (ACOG) continues to strongly advocate for COVID-19 vaccination of pregnant women. On the other hand, CDC has not been able to precisely establish a risk-estimate regarding the proportion of spontaneous abortions after COVID-19 vaccination yet.[7] Hence, women who are pregnant or planning pregnancy should remain vigilant when receiving the vaccination. Furthermore, according to ACOG guidelines, mRNA-based COVID vaccines are recommended over the J&J/Janssen vaccine for pregnant and lactating women.[7] Since pregnancy is itself a hypercoagulable state, risk-estimation of TTS in pregnancy is of great significance. The data regarding the safety of the J&J/Janssen vaccine from the V-safe and VAERS registry in pregnancy is lacking as well. Therefore, we recommend opting for safer FDA-approved vaccines for which a thorough risk/benefit analysis has been conducted. Rapid review of any and every adverse event along with a comprehensive evaluation of data will ultimately help to achieve a better understanding of vaccine safety.

COMPETING INTEREST:

The authors declared no competing interest.

AUTHORS' CONTRIBUTION:

ST: Literature search, drafting of manuscript, and critical review.

MABH: Drafting of manuscript and critical review.

AS: Conceptualisation of idea.

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