COVID-19 Vaccination, Pregnant Woman, and Adverse Effects: Comment

Sir,

We would like to comment on the article "COVID-19 Vaccination in Pregnant Women: Exploring Serious Adverse Events".[1] A 25-year woman who was five weeks pregnant appeared with a three-day history of increasing vaginal bleeding, according to Tariq *et al*.[1] Further investigation found that she had received the Ad26.COV2.S vaccine 13 days prior. Iron deficiency anaemia was important in the past.[2] According to Tariq *et al*., since pregnancy is already a hypercoagulable state, estimating the risk of thrombosis with thrombocytopenia syndrome (TTS) during pregnancy is extremely important. The V-safe and VAERS registry data on the J&J / Janssen vaccine's safety during pregnancy are also inadequate. Choosing safer FDA-approved vaccines that have undergone a comprehensive risk / benefit study is advised to choose by Tariq *et al*.[1] In the end, a thorough analysis of the data and a prompt examination of every adverse event will contribute to a greater knowledge of the safety of vaccines.

The relationship might not be exactly what the report states. An intriguing clinical puzzle is the prevalence of adverse responses following a COVID-19 vaccination. Case-specific data may be presented in articles, but it is impossible to pinpoint exactly how confounding variables influence results. The optimal course of action may not be easy to decide. The objective of the current study is to learn more about the impacts of COVID-19 vaccination aversion, which stands out as being highly unusual. Due to a dearth of clinical data describing the physiological and immunological status of COVID-19 vaccine recipients before injection, it may be challenging to establish the precise cause of a vaccination reaction. It can be challenging to show that a particular confusing circumstance does not exist.

Comorbidities are rarely mentioned in clinical records, even when they exist. Due to a lack of knowledge, determining the specific patho-immuno-pharmacological relationship can be difficult at times. It can be difficult to comprehend how concurrent medical issues influence clinical outcomes. The least important factor is genetics.[2] It is difficult to obtain additional information when none of the study's conclusions can be supported by existing evidence. There may be a need for additional research that takes into account additional factors.

COMPETING INTEREST:
The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:
RM, VW: Conception and design of the work, acquisition, analysis, interpretation of data, drafting of the work, and critical revision for important intellectual content.

Both authors approved the final version of the manuscript to be published.

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Received: February 17, 2023; Revised: July 22, 2024; Accepted: July 23, 2024
DOI: https://doi.org/10.29271/jcpsp.2024.09.1135

AUTHOR'S REPLY

I appreciate the opportunity to address the points raised regarding my article on the potential adverse effects of the Johnson & Johnson (J&J) COVID-19 vaccine in pregnant women.

The J&J COVID-19 vaccine, also known as the Ad26.COV2.S vaccine, has not been recommended for pregnant women according to the latest guidelines of the Centres for Disease Control and Prevention (CDC) in the United States due to limited data on its safety during pregnancy.[1,2] This recommendation underscores the necessity for a cautious approach when considering vaccination options for such high-risk populations.

While clinical trials for the J&J vaccine did not specifically include pregnant women, data from animal studies have raised concerns about the potential risks of the vaccine during pregnancy. In particular, these studies have suggested that the vaccine may cause harm to the developing placenta, potentially leading to pregnancy complications.[3,4] This highlights the need for extensive human data to fully understand the implications of administering this vaccine to pregnant women.

It is crucial to consider that COVID-19 vaccines, when compared to influenza vaccines, are associated with a significant increase in adverse events with all proportional reporting ratios of >2.0. These adverse events include menstrual abnormalities, miscar-

riages, foetal chromosomal abnormalities, foetal malformations, foetal cystic hygromas, foetal cardiac disorders, foetal arrhythmias, foetal cardiac arrest, foetal vascular mal-perfusions, foetal growth abnormalities, foetal abnormal surveillance, foetal placental thrombosis, low amniotic fluid, and foetal death / stillbirth, all with p-values significantly lower than 0.05.[5] This is not only statistically significant but also clinically alarming and has now been proven using correlating autopsy findings.[6] These autopsy findings are crucial, revealing significant pathological changes that correlate with the adverse events reported. Such findings emphasise the need for careful consideration and further investigation into the vaccine's safety profile, especially for vulnerable populations such as pregnant women.

The response to my article seems to underestimate the gravity of the potential adverse effects and the lack of comprehensive data on the J&J vaccine's safety during pregnancy. Given the significant risks associated with pregnancy itself being a hypercoagulable state, it is imperative to follow the recommendations from authoritative bodies such as the CDC and the American College of Obstetricians and Gynaecologists (ACOG).[1,7]

In my previous work, including the article "Challenges of COVID-19 Vaccination Delivery in Pakistan," I have consistently advocated for vaccination and have been pro-vaccine from the very first day.[8] My advocacy is rooted in the understanding that vaccines are a critical tool in combating and even eradicating infectious diseases, provided they are backed by robust safety and efficacy data.

Furthermore, it is essential to acknowledge the emerging evidence suggesting that genetic predispositions can significantly impact individual responses to vaccines. Comprehensive research that includes genetic, environmental, and other risk factors is essential to developing a holistic understanding of vaccine safety in pregnant women.

In conclusion, the safety of the J&J COVID-19 vaccine in pregnant women remains an area requiring significant research. Until more robust data is available, it is critical to follow established guidelines that prioritise the safety of this vulnerable population. Rigorous research and years of testing are essential to establish comprehensive safety data before implementing widespread use of any vaccine.

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