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Commentary

Real world data speak a different language about the outcome of pregnancies undergoing SARS-CoV-2 vaccinations

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Letter to the Editor

We read with interest the review article by Leik et al. about the antibody response, placenta antibody transmission; and adverse events to anti-SARS-CoV-2 vaccines in pregnant females [1]. It was found that the most common side effects to anti-SARS-CoV-2 vaccines are injection site discomfort, tiredness, and migraine, that spike-1 (S1), spike-2 (S2), or receptor-binding domain (RBD) antibody production is higher after the second than the first dose of the vaccine, and that longer latency between vaccination and birth are associated with increased fetal IgG antibody titers and reduced antigen transmission [1]. It was concluded that mRNA-based anti-SARS-CoV-2 vaccines are safe for pregnant females and their unborn fetus [1]. The study is appealing but raises concerns that should be discussed.

We disagree with the conclusions that "anti-SARS-CoV-2 vaccinations are primarily safe for expectant mothers" and that "there is no evidence that COVID-19 vaccinations affect gestation". We also disagree with the opinion that pregnant females only experience discomfort at the injection site, tiredness, migraine, shivers, malaise, rash, or vomiting as stated in the section about side effects to SARS-CoV-2 vaccines [1]. On the contrary, there is increasing evidence that anti-SARS-CoV-2 vaccinations are not free of side effects, that the spectrum of side effects is much broader than propagated, and that these side effects can be even severe or fatal in single cases as has been reported from several studies published as per the end of April 2022 (Table 1) [2]. In an evaluation of the vaccine adverse event reporting system (VAERS) database, vaginal bleeding, preterm term delivery (<37w), spontaneous abortion <20w, stillbirth (>20w), birth defects, and maternal death during pregnancy have been reported in quite a number of patients [2]. These severe side effects occurred with the brands Biontech Pfizer vaccine (BPV), Moderna vaccine (MOV), and Johnson & Johnson vaccine (JJV) [2]. In a study comparing triple with double vaccinated pregnant females it was found that the prevalence of postpartal haemorrhage was significantly higher among the triple vaccinated compared to the double vaccinated females [3]. Two weeks after having received the JJV, a 30 years-old female in the 27th week of gestation, developed Guillain-Barre syndrome (GBS), subtype facial diplegia and dysphagia, with complete recovery within 4 weeks after administration of intravenous immunoglobulins (IVIG) [4]. In a retrospective cohort study of 2305 pregnant females undergoing anti-SARS-CoV-2 vaccination during pregnancy, it turned out that females vaccinated in the second trimester were more likely to have preterm birth [5]. A 31yo gravida 2, para 1, with a past medical history of immune thrombocytopenia (ITP) experienced a relapse of ITP in her 8th week of gestation after having received the first dose of the BPV four weeks before [6]. Despite a declining thrombocyte count she received the second dose and the thrombocyte count further declined [6].

The statement "After 14 days of receiving the BPV 0.18% of expectant mothers had COVID-19 infection, while 0.51% acquired COVID-19 infection within 2 weeks of vaccination" is unclear and requires clarification. Do the authors mean that some females had COVID-19 prior to vaccination?

Overall, the interesting study has some limitations that call the results and their interpretation into question. Clarifying these weaknesses would strengthen the conclusions and could enhance the study. The representation that anti-SARS-CoV-2 vaccines are safe for pregnant females contradicts real world figures.

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No funding was received.

Ethics approval

Ethics approval was in accordance with ethical guidelines. The study was approved by the institutional review board.

Abbreviations: RBD, Receptor binding domain; BPV, Biontech Pfizer vaccine; ITP, Iimmune thrombocytopenia; IVIGs, Iintravenous immunoglobulins; JJV, Johnson & Johnson vaccine; MOV, Moderna vaccine; VAERS, Vvaccine adverse event reporting system.

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Table 1
Side effects to SARS-CoV-2 vaccines in pregnant females reported as per the end of April 2022.

Side effect	Vaccine brand	Outcome	NOP	Reference
Spontaneous abortion (<20w)	BPV, MOV, JJV	death	828	[2]
Vaginal bleeding	BPV, MOV, JJV	favourable	101	[2]
Preterm delivery (<37w)	BPV, MOV, JJV	nr	76	[2]
Stillbirth (>20w)	BPV, MOV, JJV	death	62	[2]
Placental abnormalities	BPV, MOV, JJV	mr	35	[2]
Birth defects	BPV, MOV, JJV	nr	33	[2]
Premature membrane rupture	BPV, MPV	nr	25	[2]
Neonatal death	BPV, MOV, JJV	death	12	[2]
Maternal death	BPV, MOV	death	8	[2]
Facial diplegia	JJV	CR	1	[4]
Relapse of ITP	BPV	CR	1	[6]

BPV: Biontech Pfizer vaccine, CR: complete recovery, ITP: immune thrombocytopenia, JJV: Johnson and Johnson vaccine, MOV: Moderna vaccine, NOP: number of patients, nr: not reported.

Consent to participate

Consent to participate was obtained from the patient.

Consent for publication

was obtained from the patient.

Availability of data

All data are available from the corresponding author.

Code availability

Not applicable.

Author contribution

JF. Design, literature search, discussion, first draft, final approval. FS: literature search, discussion, final approval.

Registration of research studies

N/a.

Guarantor

N/a.

Declaration of competing interest

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.'

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