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## Adjustment of the spontaneous abortion rate following COVID-19 vaccination



We thank Dr Sun<sup>1</sup> for his comments regarding our calculation of the rate of spontaneous abortion in women who received a messenger RNA (mRNA) COVID-19 vaccine during pregnancy. In our study, 8 of the 124 women vaccinated in the first trimester, had a spontaneous abortion, yielding a rate of 6.5%.

Our study included women who received at least 1 dosage of an mRNA COVID-19 vaccine at any point during pregnancy from conception. We agree that selection bias was introduced by not accounting for the spontaneous abortion risk in the interim between conception and vaccination and by excluding those who had an early pregnancy loss in this time period. By excluding those who had an early pregnancy loss before vaccination, the spontaneous abortion rate was inherently lowered. To eliminate this bias, a cohort of pregnant women would need to be enrolled at conception and followed to determine the spontaneous abortion rate among those who elected to receive the vaccine and compare it with those who remained unvaccinated. This study design was not feasible at our center.

Although statistical modeling can be used to approximate the true population estimate, its utility is limited in studies, such as ours, with a small sample size and low absolute number of spontaneous abortions. To reduce selection bias, we could limit our calculation of the spontaneous abortion rate to women who were vaccinated at early gestational ages.<sup>2</sup> Another strategy would be to limit the analysis to women who were vaccinated at <8 weeks' gestation (when spontaneous abortion risk is highest). In that case, our rate becomes 7 of 74 (9.5%), which is similar to the rates reported in other studies on COVID-19 vaccination in pregnancy.<sup>3</sup>

We agree that the spontaneous abortion rate is dependent on the population and that additional larger, multicenter studies with a control group of unvaccinated women would be better

to evaluate this risk. The recent study by Kharbanda et al<sup>4</sup> is better designed to assess the association between COVID-19 vaccination and spontaneous abortion. We recognize the limitations of our study in determining and reporting the risk of spontaneous abortion. We look forward to future studies that will provide further information on the impact of COVID-19 vaccination on pregnancy outcomes. ■

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The authors report no conflict of interest.

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