I BEST OF THE WEEK (29 ago – 04 set 2022)

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Safety of COVID-19 vaccines in pregnancy: a Canadian National Vaccine Safety (CANVAS) network cohort study

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Abstract

Background: Pregnant individuals have been receiving COVID-19 vaccines following pre-authorisation clinical trials in non-pregnant people. This study aimed to determine the frequency and nature of significant health events among pregnant females after COVID-19 vaccination, compared with unvaccinated pregnant controls and vaccinated non-pregnant individuals.

Methods: We did an observational cohort study, set in seven Canadian provinces and territories including Ontario, Quebec, British Columbia, Alberta, Nova Scotia, Yukon, and Prince Edward Island. Eligibility criteria for vaccinated individuals were a first dose of a COVID-19 vaccine within the previous 7 days; an active email address and telephone number; ability to communicate in English or French; and residence in the aforementioned provinces or territories. Study participants were pregnant and non-pregnant females aged 15-49 years. Individuals were able to participate as controls if they were unvaccinated and fulfilled the other criteria. Data were collected primarily by self-reported survey after both vaccine doses, with telephone follow-up for those reporting any medically attended event. Participants reported significant health events (new or worsening of a health event sufficient to cause work or school absenteeism, medical consultation, or prevent daily activities) occurring within 7 days of vaccination or within the past 7 days for unvaccinated individuals. We employed multivariable logistic regression to examine significant health events associated with mRNA vaccines, adjusting for age group, previous SARS-CoV-2 infection, and trimester, as appropriate.

Findings: As of Nov 4, 2021, 191 360 women aged 15-49 years with known pregnancy status had completed the first vaccine dose survey and 94 937 had completed the second dose survey. 180 388 received one dose and 94 262 received a second dose of an mRNA vaccine, with 5597 pregnant participants receiving dose one and 3108 receiving dose two, and 174 765 non-pregnant participants receiving dose one and 91 131 receiving dose two. Of 6179 included unvaccinated control participants, 339 were pregnant and 5840 were not pregnant. Overall, 226 (4·0%) of 5597 vaccinated pregnant females reported a significant health event after dose one of an mRNA vaccine, and 227 (7·3%) of 3108 after dose two, compared with 11 (3·2%) of 339 pregnant unvaccinated females. Pregnant vaccinated females had an increased odds of a significant health event within 7 days of the vaccine after dose two of mRNA-1273 (adjusted odds ratio [aOR] 4·4 [95% CI 2·4-8·3]) compared with pregnant unvaccinated controls within the past 7 days, but not after dose one of mRNA-1273 or any dose of BNT162b2. Pregnant vaccinated females had decreased odds of a significant health event compared with non-pregnant vaccinated females after both dose one (aOR 0·63 [95% CI 0·55-0·72]) and dose two (aOR 0·62 [0·54-0·71]) of any mRNA vaccination. There were no significant differences in any analyses when restricted to events which led to medical attention.

Interpretation: COVID-19 mRNA vaccines have a good safety profile in pregnancy. These data can be used to appropriately inform pregnant people regarding reactogenicity of COVID-19 vaccines during pregnancy, and should be considered alongside effectiveness and immunogenicity data to make appropriate recommendations about best use of COVID-19 vaccines in pregnancy.