

Category: Travail de recherche / Research work

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Title: Rotavirus Vaccine in Offspring Exposed to Tumour Necrosis Factor Inhibitors Does Not Increase Diarrhea-Associated Healthcare Events: Real-world Evidence to Guide Best Practices

Objective(s): Until recently, best practice guidelines recommended withholding rotavirus vaccine (a live vaccine) in offspring exposed in utero to any TNFi until 6 months of age due to fear of causing infection in immunosuppressed infants. As rotavirus is a common, severe form of gastroenteritis, particularly in unvaccinated infants, delaying vaccine administration until 6 months of age (instead of routine immunization starting at 2 months) may be associated with more diarrhea-associated morbidity. We compared risk of diarrhea-associated healthcare events in infants exposed in utero to TNFi according to rotavirus vaccine exposure in the first 6 months of life.

Method(s): Using MarketScan, we created a cohort of offspring born to mothers with chronic inflammatory diseases who received at least one prescription for TNFi during gestation between 2011 and 2021. Rotavirus vaccine exposure was based on ≥ 1 procedure billing code for RV5 and/or RV1 rotavirus vaccines and was classified as time-varying. Follow-up began at 2 months of life, when a child could theoretically receive their first vaccine. The first instance of diarrhea-associated healthcare use was defined via relevant ICD-9/10 diagnostic billing codes at hospitalizations and/or outpatient physician visits in the first 2-6 months of life. Cox proportional hazards models were used to estimate hazard ratios (HR) and 95% confidence intervals (CI) for diarrhea-associated healthcare use in infants exposed in utero to TNFi who received the rotavirus vaccine, compared with those TNFi-exposed infants who did not, within the first 2-6 months of life. Models were adjusted for maternal age, chronic inflammatory disease (e.g. rheumatoid arthritis, inflammatory bowel disease), medication use (i.e. corticosteroids, non-biologic immunomodulators), geographic region, year, and birth season (January-June vs July-December).

Result(s): A total of 3,089 offspring born to mothers with chronic inflammatory diseases were exposed to TNFi in utero. Of these, 2,241 (72.5%) received at least one dose of the vaccine within 2-6 months. Maternal characteristics, including systemic corticosteroid and non-biologic immunomodulator use, were similar between vaccinated and unvaccinated infants. The incidence rate of diarrhea-associated healthcare events in infants receiving the rotavirus vaccine was 8.8 (95% CI 5.8, 12.8) per 100 person-years versus 9.1 (6.9, 11.7) per 100 person-years in unvaccinated infants. Compared with no rotavirus vaccine administration within the first 2-6 months of life, receiving the rotavirus vaccine was not associated with an overall increased risk of diarrhea-associated healthcare events (adjusted HR 1.07; 95% CI 0.66, 1.74).

Conclusion(s): Our findings provide compelling evidence to recommend not delaying rotavirus vaccination in TNFi-exposed offspring.