AB002. Antiemetic use in pregnancy and the risk of major congenital malformations: a population-based cohort study

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Background: Antiemetics are commonly used to treat nausea and vomiting of pregnancy, but conflicting information exists regarding its safety to the fetus. We quantified the risk of major congenital malformations (MCM) associated with first-trimester exposure to antiemetics.

Methods: Using the Quebec Pregnancy Cohort [1998–2015], first-trimester doxylamine-pyridoxine, metoclopramide and ondansetron exposures were assessed for their association with MCM overall and organ-specific malformations. Generalized estimating equations models were used to estimate odds ratios (OR), adjusting for potential confounding variables (aOR).

Results: Over 14 years of follow-up, the prevalence of antiemetic use during pregnancy increased by 76%. Within our cohort, 45,623 pregnancies were exposed to doxylamine-pyridoxine, 958 to metoclopramide, and 31 to ondansetron during the first-trimester of pregnancy. The mean gestational age at the first prescription filled was 8.2 weeks for doxylamine-pyridoxine exposed group, 9.4 weeks for metoclopramide exposed group, and 10.2 weeks for ondansetron exposed group. The mean number of exposed days during the first-trimester was 27.4 days among doxylamine-pyridoxine exposed-group, 17.7 days for metoclopramide exposed-group, and 12.8 days for ondansetron exposed-group. Doxylamine-pyridoxine and metoclopramide use were associated with an increased risk of overall MCM (aOR, 1.07, 95% CI: 1.03–1.11; 3,945 exposed cases and aOR, 1.27, 95% CI: 1.03–1.57; 105 exposed cases, respectively). Doxylamine-pyridoxine exposure was associated with increased risk of nervous system (aOR, 1.25, 95% CI: 1.06–1.47; 225 exposed cases) and musculoskeletal system defects (aOR, 1.08, 95% CI: 1.02–1.14; 1,735 exposed cases). Metoclopramide exposure was associated with increased risk of genital organ defects (aOR, 2.26, 95% CI: 1.14–4.47; 10 exposed cases). No statistically significant association was found between first-trimester ondansetron exposure and the risk of overall MCM, however, we only had 31 exposed pregnancies in our cohort.

Conclusions: First-trimester doxylamine-pyridoxine and metoclopramide exposure were associated with significantly increased overall MCM risk. No statistically significant association was found between first-trimester ondansetron exposure and overall MCM risk.

Keywords: Doxylamine-pyridoxine; first-trimester of pregnancy exposure; major congenital malformations; metoclopramide; ondansetron

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