Prenatal exposure to phentermine-topiramate lower under safety program

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Under the Risk Evaluation and Mitigation Strategy (REMS), prenatal

exposure to phentermine-topiramate is lower than topiramate and other antiobesity medications (AOMs), according to a study published online March 21 in the *Annals of Internal Medicine*.

Noting that the U.S. Food and Drug Administration approval of phentermine-topiramate for obesity required a REMS to prevent prenatal exposure, Amir Sarayani, Pharm.D., M.P.H., Ph.D., from the University of Florida in Gainesville, and colleagues conducted a retrospective cohort study involving females aged 12 to 55 years to examine the rate of prenatal exposure, contraceptive use, and pregnancy testing with phentermine-topiramate compared to topiramate or other AOMs. Overall, 156,280 treatment episodes were included.

The researchers found that at treatment initiation, the adjusted prevalence of pregnancy was 0.9 versus 1.6 per 1,000 episodes for phentermine-topiramate versus topiramate (prevalence ratio, 0.54). For phentermine-topiramate versus topiramate, the incidence rate of conception during treatment was 9.1 versus 15.0 per 1,000 person-years (rate ratio, 0.61). Compared with AOMs, for phentermine-topiramate, both outcomes were similarly lower. Prenatal exposure was slightly lower in topiramate versus AOM users. In all cohorts, approximately 20 percent of patients had at least 50 percent of treatment days covered by contraceptives. Furthermore, ≤5 percent of patients had pregnancy tests before treatment, but this was more common among phentermine-topiramate users.

"Potential exposures were detected, suggesting the need for further clinical vigilance and risk mitigation," the authors write.

More information: Amir Sarayani et al, Assessment of the Risk Evaluation and Mitigation Strategy (REMS) for Phentermine–Topiramate to Prevent Exposure During Pregnancy, *Annals of Internal Medicine* (2023). DOI: 10.7326/M22-1743