

Study explores use of ADHD medications during pregnancy and risk of birth defects

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Adults, including women of reproductive age, are increasingly being prescribed medications to treat Attention Deficit Hyperactivity Disorder (ADHD) but little evidence has been available about whether exposure to these drugs during early pregnancy may increase the risk of birth defects. A new study conducted by investigators from Brigham and Women's Hospital (BWH) in collaboration with investigators in the five Nordic countries leverages data from multiple large cohorts to define and quantify what, if any, increased risk may be posed by taking the most commonly used ADHD medications. The team found that one medication, methylphenidate, increased risk of heart defects by a small amount while another medication, amphetamines, did not. Their findings are published this week in *JAMA Psychiatry*.

"Our findings suggest a small increase in the risk of cardiac malformations associated with first-trimester exposure to <u>methylphenidate</u>, but not to <u>amphetamines</u>," said corresponding author Krista Huybrechts, PhD, of the BWH Division of Pharmacoepidemiology and Pharmacoeconomics. "This information may be important to patients and their physicians as they weigh the risks and benefits of alternative treatment strategies for attention deficit hyperactivity disorder."

This study is the first to publish from the International Pregnancy Safety Study (InPreSS) consortium, which seeks to provide the best available human data on the safety of prescription medications during pregnancy by combining large-scale data from several countries using the highest



possible methodological standards. Animal studies of very high doses of amphetamines had suggested a potential risk of increased <u>heart defects</u> and other <u>birth defects</u>, but data regarding safety in human offspring had been limited. The new work makes use of data from 1.8 million pregnancies in the U.S. Among the women in this cohort, more than 2,700 filled a prescription for methylphenidate during their first trimester of pregnancy, and more than 5,500 filled one for amphetamines. The team validated their findings by also examining data from a cohort of 2.5 million pregnancies from Nordic registries.

Overall, based on both populations, the team found a 28 percent increased risk of heart malformations after first-trimester exposure to methylphenidate. This increase corresponds to three additional infants born with <u>congenital heart defects</u> for every 1,000 women treated with methylphenidate during the first trimester of pregnancy. No association was observed for methylphenidate and <u>congenital birth defects</u> overall, or for amphetamines and any congenital or heart defect.

"Our study markedly expands the evidence base regarding the safety of methylphenidate use in pregnancy," said Huybrechts. "Although the absolute risk is small, it is nevertheless important evidence to consider when treating young women of reproductive age and pregnant women."

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