

## Platform Session V: Epidemiology and Clinical Studies

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Few epidemiologic studies have investigated the safety of the antidepressant venlafaxine (Effexor®) during pregnancy. To examine whether use of venlafaxine during pregnancy is associated with any specific birth defect or class of defects, we analyzed data from the National Birth Defects Prevention Study (NBDPS), a multi-site population-based case-control study. We included mothers of children with birth defects (cases) and mothers of unaffected children (controls) for birth years 1997-2005 who completed the maternal interview and reported no other antidepressant use or prepregnancy diabetes. Exposure was defined as any venlafaxine use from 1 month preconception through month 3 of pregnancy. We calculated adjusted odds ratios (aOR) and 95% confidence intervals (CI) for the 29 birth defect categories with at least 400 interviewed case mothers, controlling for maternal age, race/ethnicity, obesity, education, parity, tobacco use, and folic acid use. Among the 6,661 control mothers, 7 (0.11%) reported any use of venlafaxine from 1 month preconception through month 3 of pregnancy; among the 16,241 case mothers included, 55 (0.34%) reported any use of venlafaxine. Statistically significant adjusted associations were found for cleft palate (4 exposed cases, aOR 4.2 [95% CI 1.2-14.5]), limb defects (3 exposed cases, aOR 4.3 [95% CI 1.1-16.8]), gastroschisis (4 exposed cases, aOR 11.5 [95% CI 2.9-45.3]), and heart defects (33 exposed cases, aOR 4.2 [95% CI 1.8-9.4]). Our data suggest associations between prenatal use of venlafaxine and some birth defects, but sample sizes were small. Because we examined a large number of birth defects categories, we would expect at least one category to be significant by chance. Additional studies are needed to confirm these results.

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Introduction: Early epidemiologic studies reported inconsistent associations between occupational exposure to organic solvents during pregnancy and congenital heart defects (CHD). Data from the National Birth Defects Prevention Study (NBDPS), an ongoing, population-based case-control study, were used to examine the association between 31 CHD subtypes in children and maternal occupational exposure to six chlorinated solvents - carbon tetrachloride, chloroform, methylene chloride, perchloroethylene, trichloroethane, and trichloroethylene, three aromatic solvents - benzene, toluene, and xylene, and Stoddard solvent from the month before conception through the end of the first trimester (B1-P3). Methods: Mothers of cases with CHD and live-born infants without birth defects who participated in the NBDPS between 1997 and 2002 and reported working outside the home during pregnancy were eligible for this study. Industrial hygienists determined whether each mother-job was exposed to a solvent. Potential confounders included in multivariable logistic regression models were maternal age, race-ethnicity, education, smoking during B1-P3, and folic acid supplement use during B1-P3. Results: There were 3,121 CHD case mothers and 2,951 control mothers available for analysis. Overall 8.1% of control mothers and 9.5% of case mothers were exposed to any organic solvent. Considering all heart defects combined, there were no statistically significant associations with any of the six chlorinated solvents, three aromatic solvents, or Stoddard solvent. Left ventricular outflow tract obstruction defects were associated with benzene (OR=2.54; 95% CI=1.04-6.35), an association driven by aortic stenosis (OR=5.48; 95% CI=1.52-19.75). Right ventricular outflow tract obstruction (RVOTO) defects were associated with Stoddard solvent (OR=1.74; 95% CI=1.06-2.85), an association driven by pulmonary valve stenosis (OR=1.86; 95% CI=1.07-3.22). RVOTO defects were also associated with carbon tetrachloride (OR=3.47; 95% CI=1.02-11.76), perchloroethylene (OR=1.61; 95% CI=1.03-2.49), and trichloroethane (OR=1.63; 95% CI=1.07-2.19). Discussion: There is limited evidence of an association between exposure to organic solvents and CHD. The few significant associations, although noteworthy, should be interpreted with caution. To date, this is the largest epidemiologic study of maternal occupational exposure to organic solvents and CHD.



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