Study Finds No Link in OC Exposure, Birth Defects

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ST. PETE BEACH, FLA. — Periconceptional exposure to oral contraceptives was not associated with increased risk of adverse fetal outcomes in a recent prospective study.

None of the 45 woman who were exposed to oral contraceptives during the periconceptional period and were followed until after delivery gave birth to an infant with congenital malformations, compared with 6 of 225 controls.

The difference in the congenital malformation rate between the exposed group and control group was not significant, according to H.K. Ahn, M.D., and colleagues of the Motherisk Program at Sungkyunkwan University, Seoul, South Korea, during a poster presentation at the annual meeting of the Teratology Society.

The groups were also similar in regard to mean gestational age at delivery (39 weeks in both groups) and birth weight (3,257g in the exposed group, and 3,268g in the controls), the investigators said.

Women who were in the exposed group took oral contraceptives that contained either combined ethinyl estradiol and progesterone, or high-dose progesterone.

Although some earlier studies suggested a link between oral contraceptive use during pregnancy and increased risk of birth defects, later studies—including the current study—have failed to reproduce these findings.

"Exposure to oral contraceptives, including high doses of progesterone … did not increase adverse fetal outcomes," the investigators said. ■

Neurocognition Is Unimpaired By Diclectin

ST. PETE BEACH, FLA. — Diclectin used for nausea and vomiting of pregnancy does not appear to affect the later neurocognitive development of children who are exposed to the drug in utero, Irena Nulman, M.D., and her colleagues at the Hospital for Sick Children, Toronto, reported at the annual meeting of the Teratology Society.

The drug, available in Canada but not in the United States at this time, has proved safe in terms of fetal dysmorphology, but its effects on the developing central nervous system have been unclear, the investigators reported in a poster presentation at the meeting.

In a prospective, randomized, double-blind study, they compared the children's neurocognitive development and measures of child behavior and language development. The study included 42 mother-child pairs exposed to nausea and vomiting of pregnancy (NVP) and diclectin, 37 pairs exposed to NVP but not to pharmacotherapy, and 25 pairs not exposed to NVP.

No significant differences were found among groups in any of these measures. Children in all groups had scores in the normal range on total indexes of IQ and on measures of temperament, behavior, and language. For example, performance IQ scores were a mean of 119.76 in the NVP/diclectin-exposed group, 111.75 in the NVP-only group, and 110.08 in the unexposed group.

NVP affects 70%-80% of pregnant women and can lead to hyperemesis gravidarum, the investigators noted.

"Exposure to diclectin does not adversely affect child long-term full-scale IQ. … When indicated, diclectin therapy should be instituted to prevent hyperemesis gravid[ar]um and improve pregnant women's life style," they concluded.

Diclectin, manufactured by Duchesnay Inc., is a generic form of the drug Bendectin, which was marketed in the United States until 1983 when it was voluntarily withdrawn by its manufacturer, Merrell Dow Pharmaceuticals Inc., following a series of lawsuits claiming the drug caused birth defects. Although the company won every case and numerous studies have confirmed the drug's safety, the drug was never put back on the U.S. market. Duchesnay Inc. is currently attempting to gain Food and Drug Administration clearance to market diclectin in the United States.

—Sharon Worcester