Diclectin May Not Impair Child's Brain Function

BY SHARON WORCESTER
Southeast Bureau

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 at the meeting.

In a prospective, randomized, double-blind study, they examined 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.

Groups did not differ significantly 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.

"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is a generic form of the drug Bendectin, which was marketed in the United States until 1983 when it was voluntarily withdrawn by its manufacturer, Merrell Dow Pharmaceuticals Inc., following a series of lawsuits claiming the drug caused birth defects. The company won every case and numerous studies have confirmed the drug's safety. Duchesnay Inc. is seeking FDA clearance to market the drug here. ■

Brain Damage Common After a Decade of SLE

VIENNA — Over one-quarter of a cohort of childhood-onset systemic lupus erythematosus patients had evidence of irreversible brain damage, Vibke Lilleby, M.D., reported at the annual European congress of rheumatology.

Her 71-patient series with childhood-onset SLE had a mean age of 13 years at symptom onset and a 11-year disease duration. The brain showed irreversible damage in 28% of cases. Irreversible renal damage and musculoskeletal damage were each present in 13%, according to Dr. Lilleby of the University of Oslo.

Mean SLE International Collaborating Clinics/American College of Rheumatology Damage Index—a validated measure of nonreversible organ damage—was 1.3.

The high rate of irreversible brain and other organ damage in this cohort is a byproduct of the greatly improved long-term prognosis for childhood-onset SLE during the past 4 decades. Patients who in former years would have had a poor life expectancy are today surviving much longer, with an associated increase in multiorgan morbidity due to the disease process itself or to its treatment, she explained at the congress, sponsored by the European League Against Rheumatism.

—Bruce Jancin

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