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Media Contacts:
Renee Tessman, rtessman@aan.com, (612) 928-6137
M.A. Rosko, mrosko@aan.com, (612) 928-6169

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Abstract Title: Fetal Antiseizure Medication Effects on Neuropsychological Outcomes at Age 3 Years in the MONEAD Study

Press Release Title: Do Epilepsy Medications Taken During Pregnancy Affect Child's Development?

Authors: Kimford Meador¹, Morris Cohen², David Loring³, Carrie Brown⁴, Chelsea Robalino⁴, Page Pennell⁵

¹Neurology, Stanford University, ²Pediatric Neuropsychology International, ³Emory University, ⁴Emmes, ⁵Brigham and Women's Hospital

Objective: To examine the neurodevelopmental effects of fetal antiseizure medication (ASM) exposures on age 3-year-old neuropsychological outcomes.

Background: Adverse neurodevelopmental effects of ASM exposures remain uncertain for many ASMs. Teratogens act in an exposure-dependent manner, but clearance changes occur during pregnancy for many ASMs so that dose-dependent effects may not accurately reflect actual fetal ASM exposure.

Design/Methods: The Maternal Outcomes and Neurodevelopmental Effects of Antiepileptic Drugs (MONEAD) study is a prospective, observational, multi-center investigation of pregnancy outcomes. Women with epilepsy (WWE) and healthy women (HW) were enrolled during pregnancy. The primary outcome for children at age 3 was a Verbal Index score calculated by averaging the Differential Ability Scales-II (DAS-II) Naming Vocabulary and Verbal Comprehension subtests, Preschool Language Scale-5 Expressive Communication and Auditory Comprehension subscales and Peabody Picture Vocabulary Test-4. Children of WWE vs. HW were compared using ANCOVA. Association with maximum ASM blood levels (ABLs) in the 3rd trimester was assessed with multiple linear regression. Models were adjusted for maternal IQ, education and ASM group (ABL model only).

Results: At enrollment, most pregnant WWE were on monotherapy (74%) which were primarily lamotrigine (LTG, 43%) or levetiracetam (LEV, 37%). Dual therapy LTG+LEV was the most prevalent polytherapy (44%). Age 3 Verbal Index scores did not differ for children of WWE (n=275, LS Mean (95% CI)= 103.4 (102.1, 104.6)) vs HW (n=77, 102.7 (100.2, 105.1)) in adjusted analyses. ASM exposure effects were not seen for maximum 3rd trimester ABLs (n=251, adjusted parameter estimate (95% CI)= -1.2 (-6.2, 3.8)). In secondary analyses of DAS-II Non-Verbal Index and General Conceptual Ability scores, children of WWE and HW did not differ, nor did the ASM exposure effects in children of WWE.

Conclusions: In these preliminary analyses, neurodevelopmental outcomes did not differ between children of WWE vs. HW, and exposure-dependent ASM effects were not seen.

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