

Pregnancy outcomes following gabapentin use: Results of a prospective comparative cohort study

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Background: Gabapentin (Neurontin^{*}) is an antiepileptic drug designed to treat partial seizures and is a γ -aminobutyric acid (GABA) analog that differs both structurally and pharmacologically from other classes of antiepileptic drugs (AEDs). However, despite the increasing number of patients receiving gabapentin for other indications, there is only limited information regarding the safety of this medication when used during pregnancy.

Objectives:

- 1. Determine whether first trimester use of gabapentin is associated with an increased risk for major malformations;
- 2. examine rates of spontaneous abortions (SA), therapeutic abortions (TA), stillbirths, mean birth-weight and gestational age at delivery;
- 3. Examine rates of Poor Neonatal Adaptation Syndrome (PNAS) following late pregnancy exposure.

Methods: The study design was prospective, where women were included who initially contacted services in 6 countries between 5-8 weeks and compared to a comparison group of women exposed to non-teratogens., collected in a similar fashion.

Results: We have data on (n=223) pregnancy outcomes exposed to gabapentin and (n=223) unexposed pregnancies. The rates of major malformations were similar in both groups (p=0.845). There was a higher rate of preterm births; (p=0.019) and low birth weight <2500 grams (p=0.033) in the gabapentin group. Among infants who were exposed to gabapentin up until delivery, 23/61 (38%) were admitted to either the Neonatal intensive care unit (NICU) or Special Care Nursery (SCN) for observation and/or treatment, versus 6/201(2.9%) live births in the comparison group (P<0.001). There were two cases of possible PNAS, in neonates exposed to gabapentin close to delivery, compared to none in the comparison group, although it must be noted that these infants were concomitantly exposed to other psychotropic drugs. Among the women who took gabapentin, the major indications were pain n=90 (43%) and epilepsy n=71 (34%); the remainder were for other indications, mostly psychiatric.

Conclusion: Our results suggest that although this sample size is not large enough to make any definitive conclusions, gabapentin use in pregnancy does not appear to increase the risk for major malformations. This finding and the increased risk for low birth weight and preterm birth requires further investigation.

Biography

Adrienne Einarson RN, retired from her position at The Mother risk Program at The Hospital for Sick Children, in Jan 2011 after 21 years of service, 14 years as the Assistant Director, but is continuing her involvement as a consultant. She remains an active member of the team and continues to supervise trainee's involvement in research. Her main research interests are in psychiatry and the safety of psychopharmacologic drugs in pregnancy. Other research interests include perception of risk, determinants of decision-making, attitudes and practices and knowledge transfer and translation. To date, she has published 181 papers in the peer reviewed literature and has collaborated on several book chapters and other projects in this field.

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