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Articles

Topiramate in pregnancy

Preliminary experience from the UK Epilepsy and Pregnancy Register

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ABSTRACT

Objectives: Topiramate (Topamax®) is licensed to be used, either in monotherapy or as adjunctive treatment, for generalized tonic clonic seizures or partial seizures with or without secondary generalization and for prevention of migraine. The safety of topiramate in human pregnancy is largely unknown. Here we report on our experience of pregnancies exposed to topiramate.

Methods: This study is part of a prospective, observational, registration and follow-up study. Suitable cases are women with epilepsy who become pregnant while taking topiramate either singly or along with other antiepileptic drugs (AEDs), and who are referred before outcome of the pregnancy is known. The main outcome measure is the major congenital malformation (MCM) rate. Secondary outcomes include risk of specific MCM, minor malformation rate, birthweight, and gestational age at delivery.

Results: Full outcome data are available on 203 pregnancies. Of these, 178 resulted in live birth; 16 had an MCM (9.0%; 95% CI 5.6% to 14.1%). Three MCMs were observed in 70 monotherapy exposures (4.8%; 95% CI 1.7% to 13.3%) and 13 in cases exposed to topiramate as part of a polytherapy regimen (11.2%; 95% CI 6.7% to 18.2%). Four of the MCMs were oral clefts (2.2%; 95% CI 0.9% to 5.6%). Four cases of hypospadias were reported (5.1%; 95% CI 0.2% to 10.1%) among 78 known live male births of which two were classified as major malformations.

Conclusions: The number of outcomes of human pregnancies exposed to topiramate is low, but the major congenital malformation rate for topiramate polytherapy raises some concerns. Overall, the rate of oral clefts observed was 11 times the background rate. Although the present data provide new information, they should be interpreted with caution due to the sample size and wide confidence intervals.

Responses to this article

María-Luisa Martínez-Frías

Topiramate in pregnancy: Preliminary experience from the UK
Epilepsy and Pregnancy Register

Neurology published online November 7, 2008

[Full Text](#)

John Craig, MRCP

Reply from the authors

Neurology published online November 7, 2008

[Full Text](#)

Articles citing this article

Newer-Generation Antiepileptic Drugs and the Risk of Major Birth
Defects

JAMA May 18, 2011 305:1996–2002

[Abstract](#) [Full Text](#) [Full Text \(PDF\)](#)

Can our understanding of epigenetics assist with primary prevention of congenital defects?

J. Med. Genet. February 1, 2010 47:73-80

[Abstract](#) [Full Text](#) [Full Text \(PDF\)](#)

Treating women with juvenile myoclonic epilepsy

PN October 1, 2009 9:268-277

[Abstract](#) [Full Text](#) [Full Text \(PDF\)](#)

TOPIRAMATE IN PREGNANCY: PRELIMINARY EXPERIENCE FROM THE UK EPILEPSY AND PREGNANCY REGISTER

Neurology June 9, 2009 72:2054-2055

[Full Text](#) [Full Text \(PDF\)](#)

Changing trends in antiepileptic drug prescribing in girls of child-bearing potential

Arch. Dis. Child. June 1, 2009 94:443-447

[Abstract](#) [Full Text](#) [Full Text \(PDF\)](#)

Topiramate Use During Pregnancy and Risk for Birth Defects

JWatch Neurology October 7, 2008 2008:1

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Topiramate: Another Concern About Teratogenicity

JWatch Psychiatry August 18, 2008 2008:6

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Topiramate: Another Concern About Teratogenicity

JWatch Pediatrics August 13, 2008 2008:5

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