

Does dosing of drug for mom make a difference for baby's risk of cleft lip, palate?

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Taking a higher dose of topiramate during the first three months of pregnancy may increase a baby's risk of cleft lip or cleft palate more than when taking a lower dose, according to a study published in the December 27, 2017, online issue of *Neurology*, the medical journal of the American Academy of Neurology.

Topiramate is prescribed to prevent seizures in people with [epilepsy](#). It is also used to prevent migraine headaches or treat bipolar disorder. In combination with phentermine, it may be prescribed for weight loss.

"While topiramate is not recommended for pregnant [women](#), unplanned pregnancies are common, so it's important to fully examine any possible risk," said Sonia Hernandez-Diaz, MD, DrPH, of the Harvard T.H. Chan School of Public Health in Boston. "Our study found that when [pregnant women](#) took topiramate during the first trimester, baby's risk of [cleft lip](#) or palate was three times greater than if mom was not taking the drug. The risk was higher when the mother took high doses of the drug than when she took lower doses."

For the study, researchers looked at Medicaid data and identified nearly 1.4 million women who gave birth to live [babies](#) over a 10-year period. Women who filled a prescription for topiramate during their first three months of pregnancy were compared with women who did not fill a prescription for any anti-seizure drug. They were also compared to women who filled a prescription for lamotrigine, another drug used to reduce seizures in epilepsy. There were 2,425 pregnancies in the

topiramate group, 2,796 in the lamotrigine group, and more than 1.3 million in the group not taking anti-seizure drugs. Researchers then looked at how many women in each group gave birth to a baby diagnosed with [cleft lip](#) or [cleft palate](#).

Researchers found that among the more than 1.3 million pregnancies in the group not taking anti-seizure drugs, 1,501 babies had cleft lip or cleft palate which translates to a risk of 1.1 per 1,000. For the 2,425 babies born to mothers who filled a prescription for topiramate during the first trimester of pregnancy, the risk of cleft lip or cleft palate was 4.1 per 1,000. The risk was 1.5 per 1,000 in the babies born to the 2,796 women taking lamotrigine.

Compared to the group not taking anti-seizure medications, women with epilepsy on topiramate had an eight times greater risk of giving birth to a baby with cleft lip or cleft palate, while the women taking the drug for other conditions had a 50 percent higher risk. Women with epilepsy took a higher dose of the [drug](#) than those with other conditions. The average daily dose for women with epilepsy was 200 milligrams, while the average for women without epilepsy was 100 milligrams. Additionally, the risk of cleft lip or cleft palate for those taking more than 100 milligrams for any reason was five times greater than those not taking anti-seizure drugs, while those taking less than 100 milligrams had a 60 percent greater risk than those not taking anti-seizure drugs. Results were similar when women taking topiramate were compared with those taking lamotrigine.

"Our results suggest that women with epilepsy on topiramate have the highest relative [risk](#) of giving birth to a baby with cleft lip or cleft palate, likely due to the higher doses of topiramate when used for controlling seizures," said Hernandez-Diaz. "The best course may be to avoid prescribing high doses of topiramate to women of childbearing age unless the benefits clearly outweigh the risks."

A limitation of the study is that [topiramate](#) doses were not randomly assigned to patients and therefore women on high doses may be different from those on low doses for reasons incompletely measured by the investigators, such as severity of epilepsy.

More information: Sonia Hernandez-Diaz et al, Topiramate use early in pregnancy and the risk of oral clefts, *Neurology* (2017).

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