

PREGNANT WOMEN BEING TREATED FOR DEPRESSION CAN HEAVE A COLLECTIVE SIGH OF RELIEF

If you are pregnant and suffering from depression, take your medication. Recent chilling evidence that taking the antidepressant paroxetine during pregnancy may increase the risk of heart defects appears to be unfounded, according to a newer and better designed study.

INITIAL PANIC WITH PAXIL

The panic started when GlaxoSmithKline, the manufacturers of paroxetine under the trade name Paxil, reviewed their databases and found a two-fold increased rate of heart defects among babies whose mothers had been prescribed the drug. But in a prescription database study like that one, it is impossible to tell who actually took their medication. *"Too often women stop their treatment abruptly when they find out they are pregnant, which can lead to a quick relapse of symptoms, possibly leading to adverse effects on the fetus,"* says Alicja D. Fishell, MD, FRCPC, an expert in women's health, psychiatry and pharmacology at the University of Toronto.

BETTER DESIGNED RESEARCH FINDS FEARS UNFOUNDED

To evaluate this potential risk more rigorously, Adrienne Einarson, RN, of the Motherisk Program at the Hospital for Sick Children in Toronto, and her team obtained health information on 1,174 babies born to mothers around the world who were taking paroxetine during the first trimester of their pregnancy, when the fetus's heart is developing. The outcomes of women taking paroxetine during pregnancy were then compared against the outcomes of an equal number of pregnant women who had not taken paroxetine and were not depressed.

They also evaluated 2,061 published cases of babies whose mothers took paroxetine during pregnancy and obtained more detailed information about the nature of each case.

The rate of heart defects was the same among women who had and had not taken paroxetine: 0.7%. This is on par with the general rate of heart defects in newborns. *"In every pregnancy, about 1 in 100 babies are*

going to have heart defects," says Einarson. *"That's nature."*

WHY THE DIFFERENCE?

Why the conflicting result? *"Regrettably, studies on first trimester exposure to paroxetine or other antidepressants have a high degree of heterogeneity when it comes to methods used,"* says Fishell. *"This leads to conflicting results, even if some of the studies' designs are similar. This is the largest prospective controlled study [conducted on this topic]."* It is also unique in that it directly confirmed at the time that the women in the paroxetine group were actually taking the drug and that the infants identified as having heart defects really had these defects. Other studies have relied on people's memories of past events.

"Because of this study's [rigorous] design and the fact that the results are so reassuring, it is a helpful tool in discussions with women and partners who are weighing the risk/benefit of treatment of severe depression or anxiety disorders with paroxetine during pregnancy," says Fishell.

That's Einarson's key goal. *"We do this research here at Motherisk so that people can make an evidence-based decision about whether they are going to take these drugs in pregnancy or not. That is the bottom line for us."*

The bottom line for pregnant women? *"There's no evidence to date that taking antidepressants in pregnancy increases the risk for birth defects, including heart defects,"* says Einarson. *"In fact, recently it's being found that being depressed during pregnancy and in the postpartum period may actually have its own adverse effects." ❧*

BY ALISON PALKHIVALA



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Ref.: Einarson A, Pistelli A, Desantis M, Malm H, Paulus WD, Panchaud A, Kennedy D, Einarson TR, Koren G. Evaluation of the risk of congenital cardiovascular defects associated with use of paroxetine during pregnancy. *American Journal of Psychiatry* 2008;165(6):749-752.