Should patients stop taking Prozac when pregnant?

May 19 2017, by Anne Buist

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Women, and perhaps their doctors, may be concerned when they see reports of a study showing an association between taking fluoxetine, an antidepressant also known as Prozac, during pregnancy and birth defects

in children.

These findings aren't new. We've known for some time of an *association* between taking antidepressants (selective serotonin reuptake inhibitors or SSRIs, specifically fluoxetine and paroxetine) during pregnancy and a higher risk of birth malformation in babies.

But is a knee-jerk reaction to stop taking antidepressants when you discover you're pregnant warranted? It's important to take a step back – there are many factors to consider, one of which is that whether antidepressants themselves *cause* birth defects has never been proven. And stopping medication could lead the woman to relapse into depression, which can be a risk to the baby in itself.

What was the recent study?

Studies that have shown an association between antidepressants and birth defects have largely been observational. Observational studies, in this instance, mean those following women from early pregnancy to the postpartum period (immediately after birth), recording information related to their health and that of the fetus, and later, child.

The recent paper published in the *British Journal of Clinical Pharmacology* was a meta-analysis of such studies. This research method takes a number of similar studies (in this case 16 observational studies exploring fluoxetine use during pregnancy) and pools the results.

It concluded that taking fluoxetine in the first trimester of pregnancy increased the risk of birth defects in the child by 18%. These defects might include the child being born with spina bifida, or having an extra ureter (the duct though which urine passes from the kidney to the bladder).

More specifically, it found that heart-related defects increased by 36%. This included both septal defects (holes in the heart wall), many of which are minor and do not require intervention, and non-septal defects (such as malformations in a heart valve or vessels).

In terms of population-level risk, these percentage increases mean for every 100 women not on antidepressants who have babies with a defect, 118 women on antidepressants will have babies with a defect. And for every 100 women not on an antidepressant who have babies with a heart defect, 136 women on antidepressants will have babies with a heart defect.

This is a real increased risk, but it is a small increase considering the baseline risk is small. Across the general population, only eight per 1000 of all deliveries, which includes the babies of women on antidepressants, will be born with a heart defect.

Association isn't causation

It's important to note, however, that none of the studies in the meta-analysis were randomised controlled trials: where one group is randomly chosen to receive the drug being tested, while another group receives a placebo or different drug.

Such trials would be unethical in pregnant women. So we can only "test" for outcomes in children of women who take drugs during pregnancy by observing them. Then we can only conclude whether taking the drug was *associated* with an increased risk to the baby, rather than the drug having *caused* the risk.

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The observational studies on women and their babies cannot be considered equivalent in quality to randomised controlled trials. This is because we are not comparing two equivalent groups: women who take antidepressants and those who don't. We are observing women who have many differences, which can sometimes also be risk factors.

Women taking fluoxetine will be doing so due to poor mental health, which is often associated with other health issues, such as gestational diabetes. Some studies suggest gestational diabetes could lead to heart defects in the fetus. Poor mental health is also associated with higher levels of smoking, alcohol and illicit drug use, which are well known to

adversely impact fetal development.

Just by observing women over time, we can't know whether it was one of these other factors that caused a higher increase in risk, or the antidepressants. And not all the studies in the meta-analysis controlled for other risk factors.

Studies that controlled for alcohol use, for instance, showed a lower, 13% increase in heart malformations, compared to 31% in those that did not. And none of the studies controlled for the dose of the drug women were taking. It is likely the fetuses exposed to 80mg daily of fluoxetine are going to be at higher risk of birth defects than those exposed to 20mg daily.

The safest course of action

Deciding whether or not to continue on medication in pregnancy is always a balancing act: the risk to the mother of being off the medication, and the effects of her being unwell on the fetus, versus the risk of medication to the fetus.

Australian guidelines suggest women who have been well for a year or more, only ever had one episode of depression or anxiety, were never suicidal and kept functioning (going to work for instance) when unwell, could likely stop taking their antidepressants with little risk.

But for those with more serious, recurrent illnesses, there is no risk-free option. The likelihood the illness will recur when off medication is high, and this itself puts the fetus at risk.

Women who are unwell have poorer self-care and may be at risk of suicide. Infants born to women who were unwell in pregnancy are also more likely to have higher levels of the stress hormone cortisol at birth.

This continues throughout their lives and is a probable marker for a higher risk of their own mental health issues.

Prozac hardly used in pregnancy

Authors of the recent study noted fluoxetine was the most frequently prescribed medication in pregnant women. This may be true in other countries but is unlikely to be the case in Australia.

We have known for some time fluoxetine, as well as another SSRI paroxetine, has been linked with a small increased risk in birth defects. Fluoxetine has a long half-life, which means it stays longer in the system than other SSRIs, including in the baby after delivery. This makes it less attractive to use in pregnant women.

Australian guidelines advise a SSRI with a shorter half-life, and without the specific risk identified with fluoxetine, be prescribed for pregnant women.

Ideally, a woman will see her doctor when planning a pregnancy and, with her partner, will decide on the best options in their specific case. By reducing weight and stopping smoking, alcohol and illicit drugs, as well as deciding what to do about their antidepressant, women will ensure the risk to them and their babies is as low as possible.

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