

LETTERS

PAROXETINE DURING PREGNANCY

Paroxetine is associated with malformation during pregnancy

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In their clinical review of the diagnosis and management of premenstrual disorders O'Brien and colleagues state¹: "Obviously, some patients may become pregnant while taking SSRIs [selective serotonin reuptake inhibitors] and these drugs have not been shown to be teratogenic" with a reference to an article reviewing the adverse effects of SSRIs in pregnancy.² This is incorrect and is inconsistent not only with the reference provided but also with both the label (black box warning and the pregnancy category D labelling) and the wider literature. Tuccori et al in fact state:

"Paroxetine has been associated with significant risks of major malformation, particularly cardiac defects, when used during pregnancy.

"Significant associations between maternal exposure to SSRIs and both persistent pulmonary hypertension of the newborn and a self-limiting neonatal behavioral syndrome have been reported in a number of recent original studies and meta-analyses."²

They correctly conclude: "The available evidence suggests that SSRIs and other serotonergic/noradrenergic antidepressants should be used with caution during pregnancy, with careful follow-up of infants exposed to these agents in utero."

Evidence shows SSRIs to be teratogenic in early pregnancy.³ Concerns about the effects on child development are emerging with a recent signal of a potential link with autistic spectrum disorder.^{4 5} This is important information for clinicians and patients to be aware of when use is in women of reproductive age. Women need to be warned of these potential adverse events when these medicines are prescribed.

Competing interests: DM and DH are expert witnesses for the plaintiff in cases involving Paxil and birth defects in the US. DM is also principal investigator in a New Zealand HRC funded randomised controlled trial of SSRI cessation in primary care. She is a member of the New Zealand Pharmaceutical and Therapeutic Products Advisory Committee.

- 1 O'Brien S, Rapkin A, Dennerstein L, Nevatte T. Diagnosis and management of premenstrual disorders. *BMJ* 2011;342:d2994. (3 June.)
- 2 Tuccori M, Testi A, Antonioli L, Fornai M, Montagnani S, Ghisu N, et al. Safety concerns associated with the use of serotonin reuptake inhibitors and other serotonergic/noradrenergic antidepressants during pregnancy: a review. *Clin Ther* 2009;31:1426-53.
- 3 Healy D, Mangin D, Mintzes B. The ethics of randomized placebo controlled trials of antidepressants with pregnant women. *Int J Risk Safety Med* 2010;22:7-16.
- 4 Pedersen LH, Henriksen TB, Olsen J. Fetal exposure to antidepressants and normal milestone development at 6 and 19 months of age. *Pediatrics* 2010;125:e600-8.
- 5 Croen LA, Grether JK, Yoshida CK, Odouli R, Hendrick V. Antidepressant use during pregnancy and childhood autism spectrum disorders. *Arch Gen Psychiatry* 2011. Published online 4 July. doi:10.1001/archgenpsychiatry.2011.73.

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