O0072

Pharmacovigilance analysis of the Vigibase on antidepressants-related withdrawal syndrome in adults and adolescents

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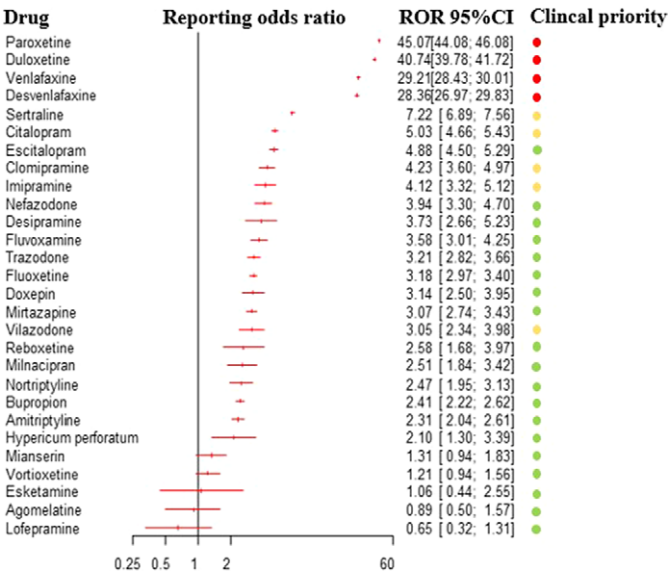
Introduction: Antidepressant discontinuation may cause withdrawal syndrome in some cases. However, evidence on this syndrome related to individual antidepressants is limited, as well as about individual risk factors for severe reactions.

Objectives: To ascertain whether each individual antidepressant is associated with an increased reporting of withdrawal syndrome as compared with other medications, and to examine clinical risk factors for severe reactions.

Methods: We conducted a pharmacovigilance study, with a case/non-case design. We included reports of antidepressant-related withdrawal syndrome from the VigiBase, the WHO global database of individual case safety reports of suspected adverse drug reactions. We performed a disproportionality analysis (calculating reporting odds ratio (ROR) and the Bayesian information component (IC)) of reports of antidepressant-related withdrawal syndrome, comparing antidepressants to all other drugs and to buprenorphine (as a positive control). Antidepressants with significant disproportionate reporting were ranked in terms of clinical priority. We compared serious versus non-serious reactions to determine clinical risk factors for severe reactions.

Results: Based on 31,688 reports of antidepressant-related withdrawal syndrome, we detected a disproportionate reporting for 23 antidepressants. The ROR for antidepressants altogether, compared to all other drugs, was 14.26 (95%CI:14.08-14.45), 17.01 for other antidepressants (95%CI:16.73-17.29), 13.65 for SSRIs (95% CI:13.41-13.90) and 2.8 for tricyclics (95%CI:2.59-3.02). Based on clinical priority ranking, the strongest signals were found for paroxetine, duloxetine, venlafaxine and desvenlafaxine (figure 1), being comparable to buprenorphine. Severe reactions were more frequently reported in males, adolescents, persons with multiple medications, and with longer treatment duration.

Image:



Conclusions: Antidepressants are associated with increased reporting of withdrawal syndrome compared with other medications, with differences between individual antidepressants. Clinicians should be aware of such differences, when prescribing and discontinuing these drugs, as well as of the risk to experience more severe withdrawal symptoms in specific cases.

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O0073

Pharmacovigilance analysis of the Vigibase on neonatal withdrawal syndrome following in utero exposure to antidepressants

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Introduction: Evidence on neonatal withdrawal syndrome following antidepressant intrauterine exposure is limited, particularly for antidepressants other than selective serotonin reuptake inhibitors (SSRIs).
Objectives: To ascertain whether maternal antidepressant treatment may be associated with withdrawal syndrome in neonates, investigating the comparative reporting between individual antidepressants and classes.
Methods: We performed a case/non-case pharmacovigilance study, searching reports of withdrawal syndrome in newborns in the VigiBase, the WHO database of suspected adverse drug reactions. Disproportionality analysis was performed, estimating reporting odds ratio (ROR) and the Bayesian information component (IC). Antidepressants were compared to all other medications, to methadone, and within each class of antidepressants (SSRIs, tricyclics (TCA) and other antidepressants). Antidepressants were ranked in terms of clinical priority, based on a semiquantitative score.
Results: We retrieved 406 reports of neonatal withdrawal syndrome in 379 neonates related to 15 antidepressants. Compared to all other drugs, disproportionate reporting was detected for antidepressants altogether (ROR: 6.18, 95%CI:5.45-7.01), for TCAs (10.55, 95%CI:8.02-13.88), other antidepressants (ROR: 5.90, 95% CI:4.74-7.36) and SSRIs (ROR: 4.68, 95%CI:4.04-5.42). All antidepressants showed a significant disproportionality, apart from bupropion (figure 1). We did not find any disproportionate reporting for any antidepressant compared to methadone. The clinical priority ranking showed moderate clinical priority for all antidepressants, with the exception four, that had a weak one (figure 1). Most frequently reported symptoms were respiratory symptoms (n=106), irritability/agitation (n=75), tremor (n=52) and feeding problems (n=40).
Image:

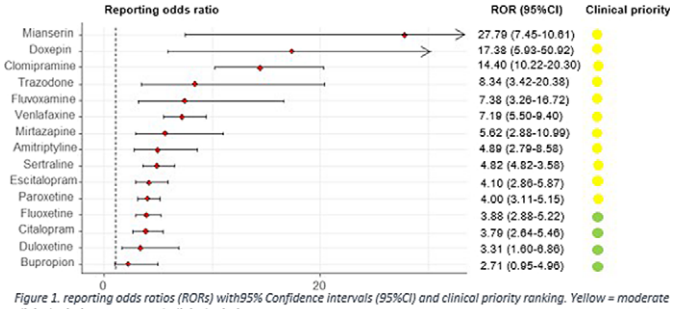

Figure 1. reporting odds ratios (RORs) with95% Confidence intervals (95%CI) and clinical priority ranking. Yellow = moderate clinical priority; green= weak clinical priority

Conclusions: Exposure to antidepressants in utero is associated with moderate signals of disproportionate reporting for neonatal withdrawal syndrome for most antidepressants. Clinicians should pay extra attention to neonates with antidepressant-treated mothers.

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Child and Adolescent Psychiatry

O0074

Claudin-5, occludin, zonulin and tricellulin levels of children with attention deficit/hyperactivity disorder

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