

Pregnancy outcome following maternal exposure to pregabalin may call for concern

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Abstract

Objective: To investigate pregnancy outcomes following maternal use of pregabalin.

Methods: This multicenter, observational prospective cohort study compared pregnancy outcomes in women exposed to pregabalin with those of matched controls (not exposed to any medications known to be teratogenic or to any antiepileptic drugs). Teratology Information Services systematically collected data between 2004 and 2013.

Results: Data were collected from 164 exposed pregnancies and 656 controls. A significantly higher major birth defect rate in the pregabalin group was observed after exclusion of chromosomal aberration syndromes, and when cases with exposure during first trimester of pregnancy were analyzed separately (7/116 [6.0%] vs 12/580 [2.1%]; odds ratio 3.0, 95% confidence interval 1.2–7.9, $p = 0.03$). The rate of live births was lower in the pregabalin group (71.9% vs 85.2%, $p = 0.001$), primarily due to a higher rate of both elective (9.8% vs 5.0%, $p = 0.02$) and medically indicated (5.5% vs 1.8%, $p = 0.008$) pregnancy terminations. In the Cox proportional cause specific hazards model, pregabalin exposure was not associated with a significantly higher risk of spontaneous abortion.

Conclusions: This study demonstrated a signal for increased risk of major birth defects after first trimester exposure to pregabalin. However, several limitations such as the small sample size, differences across groups in maternal conditions, and concomitant medication exposure exclude definitive conclusions, so these results call for confirmation through independent studies.

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