

**Ericson A et al.** Delivery outcome after the use of antidepressants in early pregnancy. *Eur J Clin Pharmacol* 55, 503-08, 1999

Type of study	Population-based retrospective cohort
Where	Sweden
When	1995-1997
Characteristics of the cohort	Newborns whose mothers reported use of antidepressants in early pregnancy, identified in the Swedish Medical Birth Registry
Characteristics of the treated diseases	Not indicated
Exposure definition	Intake in early pregnancy
Ascertainment of drug exposure	Nation-wide medical birth registry. Information on drug use reported by pregnant women at their first visit to the antenatal clinic (usually at week 10-12, 6% before the end of week 9 after last menstrual period, 86% before the end of week 14 and 92% before the end of week 16). Information on the drugs used stored in the registry as Anatomical Therapeutic Chemical Classification codes, sometimes but not always supplemented with data on dosage and timing of drug use
Size of the studied cohort	Exposed to the studied drugs: - 969 women identified (531 selective serotonin re-uptake inhibitor-SSRI drugs (375 citalopram), 423 other antidepressants, 15 both) - 980 infants (533 SSRI, 432 other antidepressants, 15 both) Reference group: 281.728 infants
Exposed cohort	Newborns exposed to the studied drugs
Control cohort	All infants, born in the general population during the study period
Malformations definition	Not indicated
Delivery outcome/malformations ascertainment	Medical Birth Registry and Registry of Congenital Malformations (this registry identifies some further malformed infants never recorded with a malformation diagnosis in the Medical Birth Registry and can also specify the type of diagnosis in greater detail)
Prevalence of malformations among control offspring	Not indicated, but used to compute the expected number of malformation in the exposed
Analysis	- The observed number of each variable (multiple births, short gestational duration, low birthweight, perinatal mortality, congenital malformations) compared with the expected number, calculated from all births after stratification for year of birth, maternal age, parity, smoking habits during early pregnancy - OR and 95% CI were estimated using the Mantel-Haenszel technique and risk ratios based on observed/expected numbers, the latter calculated after stratification
Strengths	- Nation-wide population based study - The drug information was retrieved prospectively, data not affected by delivery outcome - Multiple sources for malformation identification reduced the risk of ascertainment bias - Information on other concomitant drugs use - The first and largest study about citalopram
Weaknesses	- Drug use reported by pregnant women (studied drugs may have been used but not recorded) - Some birth defects may not be included because they appear later after birth - Not indicated if information on maternal drug use was available at the time of paediatrician's examination - Dosage and timing of drug use often poorly specified - Incomplete information on reproductive end points (in e: abortions)

Main results

Based on this database, the use of antidepressants in early pregnancy does not seem to carry any significant risk for the infant that is detectable during the newborn period. No increase was seen in congenital abnormalities, observable in the perinatal period