PW01-259 - **PAROXETINE USE DURING PREGNANCY AND ADVERSE PREGNANCY OUTCOMES IN THE ABSENCE OF DETECTION BIAS**

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Objective: To quantify the prevalence of adverse pregnancy outcomes associated with gestational exposure to paroxetine before the FDA warnings on the risk of cardiac malformations in newborns associated with the use of paroxetine during gestation were issued in 2005.

Methods: Data on all pregnancies included in the Quebec Pregnancy Registry were analysed to estimate the prevalence of planned/spontaneous abortions and deliveries during 1998-2004, before the warnings were issued. All study outcomes including congenital malformations are physician-based, and made prospectively and routinely as part of health care management; exposure to paroxetine is based on automated prescription fillings. Trends in the frequency of gestational use of paroxetine during the study period were compared to the trends in the prevalence of cardiac malformations.

Results: Among the 109,344 eligible pregnancies, 1,612 (1.5%) were exposed to paroxetine. Amongst paroxetine users, 49% had a planned abortion, 7% a spontaneous abortion, and 44% a delivery. Amongst those who delivered, 3% had a baby with a cardiac malformation. The most prevalent cardiac malformations were atrial and ventricular septal defects (74%). During the study period, an increase in the prevalence of paroxetine use during pregnancy was correlated with an increase in the rate of cardiac malformations.

Conclusion: Paroxetine use during gestation is associated with an important risk of adverse pregnancy events above baseline rates. Before the warnings on paroxetine were issued, the increase in the prevalence of paroxetine use during pregnancy was already correlated with an increase in the rate of cardiac malformations, excluding the possibility of detection bias.

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