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## Fetal outcome following roxithromycin exposure in early pregnancy.

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### Abstract

**OBJECTIVE:** Because very little information exists on the fetal safety of roxithromycin, we aimed to extend the knowledge on fetal outcome in pregnant women who were exposed to roxithromycin in early pregnancy.

**METHODS:** Twenty pregnant women inadvertently exposed to roxithromycin during early pregnancy were identified and prospectively followed-up. For comparison, 170 pregnant women matched by age and gravidity, not being exposed to any potential teratogenic agent during pregnancy, were recruited as controls. All gestations were confirmed by ultrasound examination, and participants were followed-up until delivery. Newborns were examined by a neonatologist. **RESULTS:** Of 20 pregnant women exposed to roxithromycin during early pregnancy, information was obtained from 17 cases. The median dose of roxithromycin to which pregnant women were exposed was 300 mg/day (range 300-450 mg/day) and exposure occurred at a mean of 4.0 (range 2.8-17.6) weeks. Mean gestational age at delivery was 39.2 weeks in the exposed group and 39.4 in the controls ( $p = 0.6$ ). Birth weight of babies exposed in utero to roxithromycin was not different to controls. We did not observe any major malformation in the exposed group whereas three (1.8%) occurred in the control group. **CONCLUSIONS:** Despite the limitations of the study due to the small sample size, roxithromycin appears not to be a major teratogen.