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## Pregnancy outcome following in utero exposure to bisphosphonates.

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### Abstract

**BACKGROUND AND AIM:** The safety of bisphosphonates in human pregnancy has not been well established. To characterize pregnancy outcome in women receiving bisphosphonates, we conducted a multi-centre, prospective cohort study with a comparison group. **METHODS:** Patients were recruited through 3 teratogen information centres in Canada and South Korea. We followed 21 women exposed to bisphosphonates during or <3 months before pregnancy, and 21 matched-comparison group women without exposure to known teratogens. Pregnancy/neonatal outcome data were collected by interview. The primary endpoint was neonatal outcome including major birth defects. The secondary endpoints included other pregnancy outcomes such as spontaneous abortions. **RESULTS:** Indication of the therapy was osteoporosis in all patients. There was no difference in the maternal demographics between the 2 groups. In the bisphosphonate group, there were 18 live births, 2 spontaneous abortions and 1 therapeutic abortion, which were not significantly different from the comparison group. The mean gestational age (mean $\pm$ SD) of the bisphosphonate group was 38.7 $\pm$ 1.9 weeks (comparison group: 39.3 $\pm$ 1.9 weeks; P=0.42), and the mean birth weight was 3.1 $\pm$ 0.3 kg (comparison group: 3.3 $\pm$ 0.5 kg; P=0.11). In the bisphosphonate group, there was a child diagnosed with Apert syndrome, an autosomal dominant acrocephalosyndactyly, with a fibroblast growth factor 2 mutation. **CONCLUSION:** Coupled with existing data in the literature, our findings suggest that preconceptional and first-trimester use of bisphosphonates may not pose substantial fetal risks.