

459 Salmeterol Use and Pregnancy Outcome: A Prospective Multi-Center Study

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There are limited data on the safety of the long-acting B_2 -agonist, salmeterol, when used during pregnancy. Between 1998 and 2001, The Organization of Teratology Information Services (OTIS), as part of an ongoing multi-center prospective cohort study of asthma medications in pregnancy, enrolled 126 pregnant women who used salmeterol. Ninety percent of these subjects used the drug in the first trimester while 77% continued use of the drug into the third trimester. We compared outcomes of these pregnancies to those of 91 asthmatic women who used only short-acting beta-agonists and 115 non-asthmatic women, all of whom were prospectively enrolled through the OTIS study. Maternal characteristics were similar among the three groups, including ethnic and maternal age distribution, pregnancy history, gestational age at time of enrollment, proportion of smokers, and number of subjects lost-to-follow-up (7.4% of the total sample). There were no significant differences among the groups in rates of spontaneous abortion, premature delivery, or preeclampsia. There were no significant differences among the groups in mean birth weight, length or head circumference of full-term infants, nor were there significant differences in the proportion of infants noted to be small for gestational age. Similar rates of major malformations were reported in all three groups (4.7%, 3.9% and 1.9% respectively) and all were within the range expected in the general population. Malformations reported in the salmeterol group included 1 case of bicuspid aorta with penoscrotal fusion, 1 case of bilateral and 3 cases of unilateral inguinal hernia. Although approximately 75% of the women in the salmeterol group also used an inhaled steroid medication, controlling for steroid use did not significantly affect the results. Furthermore, a symptom-based severity measure taken at up to four points during pregnancy, although consistently higher on the average in the salmeterol group compared to the short-acting beta-agonist group, was not significantly related to any endpoint measured. These data, although preliminary, suggest that salmeterol is not a major human teratogen.
