

Anti-Inflammatories for Asthma May Be Teratogenic

BY ROBERT FINN
San Francisco Bureau

MONTEREY, CALIF. — Women who take anti-inflammatories for asthma during the first trimester of pregnancy have an elevated risk of giving birth to an infant with anorectal atresia, according to results of a multicenter, case-control study of more than 7,000 women.

Anti-inflammatory use was not associated with any other birth defects, nor was the use of bronchodilators, Shao Lin, Ph.D., and colleagues at the New York State Department of Health reported in a poster presentation at the annual meeting of the Teratology Society.

The multicenter case-control study was part of the National Birth Defects Prevention Study, which collects data from 10 regions in the United States.

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The investigators included women exposed to asthma medications at least once during a critical period defined as from 1 month prior to pregnancy to the end of the third pregnancy month. They focused on babies born between 1997 and 2003 with one of seven birth defects: diaphragmatic hernia, esophageal atresia, intestinal atresia, anorectal atresia, neural tube defects, omphalocele, and limb reduction.

In all, the investigators identified 2,248 infants with birth defects born to mothers taking asthma medications. They compared them with 4,986 nonmalformed, live-born infants identified by birth certificates or birth hospitals.

After adjusting for age, body mass index, parity, race/ethnicity, education, alcohol use, smoking, gender, folic acid use, fever, cocaine use, and the use of seven different vasoactive medications, the investigators found no significantly increased risks of birth defects associated with maternal bronchodilator use.

Maternal anti-inflammatory use, on the other hand, was associated with a statistically significant 2.6-fold increase in the risk of anorectal atresia. There were no other statistically significant associations between anti-inflammatory use and birth defects.

The investigators acknowledged that their study could not determine whether it was the anti-inflammatories or the asthma itself that was the causal agent. The use of asthma medications during the entire critical period could be an indication of especially severe asthma. They wrote that further studies would be needed to separate the effects of asthma from the effects of asthma treatment.

The risk of a rectal atresia was significantly elevated when the mother used anti-inflammatories during the entire critical period from 1 month prior to conception to the end of the third month.

They also found a dose-response relationship because the risk was higher in those who used the drugs throughout the critical period compared with those who used anti-inflammatory drugs infrequently.

The investigators concluded that using asthma medications during the critical period of pregnancy carried no increased risk of isolated neural tube defects, omphalocele, or limb reduction.

In an interview, Gerald Briggs, B.Pharm., a pharmacist clinical specialist

at the Women's Pavilion, Miller Children's Hospital, Long Beach, Calif., commented on Dr. Lin's study. "While a dose-response relationship is important for determining causation, the timing of the exposure also is critical," he said. "Saying that some subjects used the drugs 'infrequently' is very subjective. What if some of the 'infrequent' users avoided the critical time (weeks 6-7) for causing anorectal atresia? That would reduce or eliminate the argument for a dose response. Moreover, at

least three different classes of anti-inflammatory drugs were grouped together."

Given these concerns, Mr. Briggs said, "I completely agree with the investigators that the study could only raise a hypothesis that requires further study. I would be reluctant to recommend that physicians change the way they counsel women with asthma until more information is available."

Dr. Lin disclosed no conflicts of interest associated with the study. ■



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