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Astemizole use in pregnancy

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To the Editor:

In the October 1996 issue of the Journal, Pastuszak et al. (J Allergy Clin Immunol 1996;98:748-50) reported on the safety of astemizole use in pregnancy. A comparison was made between 114 women who had taken astemizole during pregnancy and 114 women, matched for age and smoking and alcohol use, who had not been exposed to this drug. Pregnancy outcomes were similar, including two major birth defects in each group. Although this is interesting and important data, the study's methods and conclusions would appear to require some clarification.

From a strictly experimental point of view, to answer questions regarding the safety of a drug's use in pregnancy, one would design a prospective, double-blind, placebo-controlled study. Such a study would be difficult to support on ethical grounds, and thus information regarding the safety of medications during pregnancy must be sought from "unintentional" drug exposures. The investigation reported here is described as a "prospective, controlled, observational study" in which subjects were enrolled after being "counseled by two Teratogen Information Services."

We believe several questions need to be answered. What information were the women

given regarding the safety of astemizole use in pregnancy? Were they advised to stop taking the drug or that it was safe to continue? If the women were not told to discontinue astemizole and were then followed up to assess the potential adverse effects of the drug, was informed consent obtained? Furthermore, although it is reassuring that there was not an increased rate of adverse pregnancy outcomes in the 114 women taking astemizole (relative risk = 1.0), from the data presented, we calculate the upper value of the 95% confidence interval of astemizole's relative risk to be 7.5. Thus the sample size in this study is too small to uncover what may be a substantial increase in relatively rare events such as birth defects. As such, the authors' definitive conclusions that the "study suggests that astemizole can be used safely during pregnancy" and that "pregnant women with allergic conditions should not be told to discontinue effective H₁ blockers" do not seem justified by the data. Until further information (albeit difficult to obtain) becomes available, we believe it is still prudent to minimize the use of all medications during pregnancy and, when medications are necessary, to choose those with more definitive safety records.¹

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Reference

TOP

1. National Asthma Education Program. Management of asthma during pregnancy. National Institutes of Health, National Heart, Lung, and Blood Institute. September 1993. NIH Publication No. 93-3279.

Articles with References to this Article

TOP

This article is referenced by these articles:

IgE-mediated anaphylaxis caused by bites of the pigeon tick *Argas reflexus*: Cloning and expression of the major allergen Arg r 1

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Christiane Hilger, Jean-Claude Bessot, Nicolas Hutt, Fabienne Grigioni, Frédéric de Blay, Gabrielle Pauli, François Hentges

ABSTRACT

FULL TEXT