JT SOUTHWESTERN NEWS

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Study finds that drugs used for treatment of influenza in pregnancy appear to be safe, UT Southwestern researchers conclude

DALLAS – April 29, 2010 – Tamiflu and two other drugs used to treat influenza appear safe for pregnant women and their babies, researchers at UT Southwestern Medical Center have found in a retrospective study of 239 cases of women who received the medications during pregnancy.

The study provides "reassuring safety data about commonly used medications," the researchers concluded in their study, which appears in the April issue of *Obstetrics and Gynecology*.

"A woman has to balance the benefits and potential risks of any medication taken during pregnancy. But with influenza, the added risks of complications from the disease in pregnancy need to be considered," said Dr. George Wendel, professor of obstetrics and gynecology at UT Southwestern and senior author of the study.

"This is the first large study that systematically looked at the safety of all these drugs in pregnancy," he said.

Researchers analyzed the medical records of 82,336 women who gave birth at Parkland Memorial Hospital from 2003 to 2008, a period that spanned five flu seasons. The investigators compared two groups of pregnant women: women without flu and women with flu who had received one of three oral medications marketed under the brands Tamiflu, Relenza and Flumadine. Of the women studied, 239 had flu and had been treated with one of the three medications.

The study showed no difference in the mothers' rates of preeclampsia, preterm birth, gestational diabetes, premature membrane rupture, fever during labor or prolonged hospital stay.

After birth, there was no difference in birth weight, need for intensive care, seizures or jaundice among the babies. There also was no significant difference in stillbirths or major or minor malformations that could be attributed to the medications, the study showed.

The only significant difference involved a bowel condition, necrotizing enterocolitis, often associated with prematurity. Two premature babies in the treatment group were born with this condition. Each of the mothers, however, received a different anti-flu drug, so the prematurity may have been the major common factor, said Dr. Laura Greer, assistant instructor of obstetrics and

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gynecology and lead author of the paper.

One limitation of study was that only 13 percent of the women with flu were treated during the first trimester, a critical time in fetal development. "Overall, this study provides important safety data to guide clinicians and patients in treating influenza in pregnancy," Dr. Greer said.

The data collection stopped a year before the pandemic H1N1 flu strain, or swine flu, became widespread. Tamiflu was used in 2009 to treat pandemic H1N1 infection, a type of influenza A; it is also effective in treating seasonal influenza A and B infection. The other two medications were more commonly used in earlier influenza seasons.

Other UT Southwestern obstetrics and gynecology researchers involved in the study were Dr. Jeanne Sheffield, associate professor; Dr. Vanessa Rogers, assistant professor; Dr. Scott Roberts, professor; and Dr. Donald McIntire, professor.

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