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Anti-herpes drug reduces need for Caesarean sections in infected women

DALLAS – July 11, 2006 – Giving an anti-viral drug to pregnant women who have a history of genital herpes significantly lowers the rate of Caesarean sections needed to protect the infant from becoming infected with the virus, researchers at UT Southwestern Medical Center have found.

The UT Southwestern study is the first large-scale confirmation that the drug valacyclovir hydrochloride (Valtrex) is effective in the last month of pregnancy, the researchers said. The study appears in this month's issue of the journal *Obstetrics and Gynecology*.

"I think this will help immensely in giving doctors stronger evidence in using this treatment," said Dr. Jeanne Sheffield, assistant professor of obstetrics and gynecology at UT Southwestern and lead author of the study. "Besides reducing the number of herpes outbreaks at birth, we also dropped the numbers of women without symptoms who were shedding the virus into the birth canal."

Herpes, one of the most common sexually transmitted viral infections, causes periods of genital sores, followed by months or years of dormancy. It can't be cured, although the number and severity of outbreaks can be reduced through medication. Many women of reproductive age are unaware that they have the virus.

In rare cases, infants can catch herpes simplex virus from the birth canal or genital region of the mother during birth, even when the mother isn't showing symptoms. Current medical protocol is to offer C-sections to all women with active genital herpes lesions at the time of delivery. Nonetheless, 70 percent of neonatal herpes cases occur in infants of women who asymptomatically shed the virus near delivery, according to the researchers.

"The whole goal of this study was to reduce active genital herpes lesions at delivery that require a Caesarean delivery to prevent neonatal herpes," Dr. Sheffield said.

The UT Southwestern study, which involved 338 pregnant women with a history of genital herpes, was a randomized, double-blind trial, with neither the doctors nor the women knowing who was getting the medication.

Twenty-eight women had C-sections because of active herpes lesions. Seven of the 170 women (MORE)

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in the valacyclovir group, or 4 percent, had the operation, while 21 of the 168 women in the placebo group, or 13 percent, had C-sections. The 69 percent reduction in the rate of clinical herpes simplex virus at the time of delivery was statistically significant, the researchers said.

None of the babies in either group were born with herpes. There also were no differences in complications between the valacyclovir and placebo groups.

"This work is a good example of a well-designed study that is of sufficient size to help clinicians and patients have confidence in the efficacy and safety of anti-viral suppression in late pregnancy," said Dr. George Wendel, professor of obstetrics and gynecology and senior author of the study.

Other UT Southwestern researchers involved in the study were Dr. Vanessa Laibl, assistant professor of obstetrics and gynecology; Dr. Scott Roberts, associate professor of obstetrics and gynecology; and Dr. Pablo Sanchez, professor of pediatrics.

The work was supported in part by GlaxoSmithKline.

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