Telbivudine Appears Safe in Pregnancy

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BOSTON – Limited use of the antiviral drug telbivudine is safe and effective for pregnant women with active hepatitis B virus infection and reduces perinatal transmission of the virus to their infants, Dr. Calvin Pan reported at the meeting.

In the first open-label case-control trial investigating the safety and efficacy of telbivudine during the second to third trimester of pregnancy, the synthetic nucleoside analogue led to significant increases in rates of complete virologic response and normalization of alanine aminotransferase (ALT) levels in treated versus untreated pregnant women with hepatitis B virus (HBV) infection, reported Dr. Pan of Mount Sinai School of Medicine in New York.

Additionally, there were no congenital defects identified up to 28 weeks post partum in the infants born to treated mothers. Dr. Pan and his colleagues at the Second Affiliated Hospital of the Southeast University in Nanjing, China, where the study was conducted, enrolled 88 pregnant women who screened positive for hepatitis B virus antigen (HBsAg) between gestational weeks 12 and 23 and who had serum HBV DNA levels of greater than 106 copies/mL and elevated ALT levels up to 10 times the upper limit of normal (40 IU/mL). Of the 88 patients, 53 opted to take telbivudine, and the remaining 35 served as the study’s control arm, he said.

Women in the treatment arm received 600 mg/day of telbivudine beginning sometime between 20 and 32 weeks’ gestation and continuing until a minimum of 4 weeks post partum, and infants born to women in both groups received hepatitis B immunoglobulin within 24 hours of birth and the HBV vaccine at birth, 1 month, and 6 months.

The mean duration of telbivudine treatment was 15.5 weeks, and all of the women who took the drug remained in the study through at least postpartum week 4, compared with 92% of the controls, said Dr. Pan. Physical and laboratory examinations were conducted at baseline, at some time during delivery, and at 4 weeks post partum, he said, noting that a second study looked at infant outcomes through 28 weeks.

At the time of delivery and 4 weeks post partum, a complete virologic response was observed in 53% and 62% of the treated patients, respectively, while no patients in the control arm achieved a complete virologic response at either time point, Dr. Pan reported.

“Both the control arm and the telbivudine arm had HBV DNA of approximately 8 logs. At the first time point, this was reduced substantially [to 2.35 log10 copies/mL] in the mothers in the treatment arm.”

With respect to ALT levels, 77% of the treatment group achieved normalization compared with 29% of the control group, Dr. Pan said. Also, the levels of HBeAg dropped by 98% in the treatment group, which was a significantly greater decrease than the 60% drop observed in the control group; the latter was likely the result of natural viral clearance, he noted.

An evaluation of newborn outcomes showed no congenital deformities nor any differences in gestational age, infant height and weight, or Apgar scores between the two groups, said Dr. Pan. Significantly fewer babies born to telbivudine-treated mothers versus untreated mothers had detectable HBsAg or detectable levels of HBV DNA at birth (4% vs. 23%).

Telbivudine appeared to be well tolerated as there were no adverse event–related treatment discontinuations, said Dr. Pan. Also, none of the patients experienced virologic breakthrough.

Despite concerns regarding antiviral treatment during pregnancy because of the potential risks to the fetus, the findings from the current study suggest that limited treatment with telbivudine can improve maternal and child outcomes, Dr. Pan concluded.

The study was funded by the Chinese Department of Health with no commercial support. Dr. Pan said he had no relevant financial disclosures.

DRUGS, PREGNANCY, AND LACTATION

Treatment of Genital Herpes Simplex

Genital infections with herpes simplex virus (both HSV-1 and HSV-2) are among the most common sexually transmitted diseases. Although the true incidence of the infection in women is unknown, data from one large national study suggested that 2% of women are treated for genital herpes annually greater than 6% of women are likely to contract the virus each year (Obstet. Gynecol. 2007;109:1489-98).

Treatment with antiviral drugs is indicated in pregnancy because both herpes types can infect the fetus (rarely) and newborn (commonly), resulting in significant morbidity and mortality. Primary infections have a higher risk of perinatal transmission than does recurrent infection.

Primary infection close to delivery has the highest risk for fetal and neonatal complications. Intrauterine infection, although rare, can result in abortions or stillbirths, skin scars, ophthalmic complications (chorioretinitis, microphthalmia), and brain damage. In addition to death, neonatal infection may involve the skin, eyes, mouth, and central nervous system.

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