Early Viread and Infant Vaccination Prevents Mother-to-Child Transmission of Hepatitis B

Even without HBV immunoglobulin, no infants acquired hepatitis B from mothers with a high viral load.

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A simplified regimen of Viread (tenofovir disoproxil fumarate) for pregnant women plus infant vaccination for hepatitis B virus (HBV) eliminated vertical transmission even without the use of HBV immunoglobulin, or antibody therapy, according to findings presented at the AASLD Liver Meeting.

Without any intervention, the risk of HBV transmission from mothers with a high viral load to their infants during pregnancy and delivery ranges from 70% to 90%, according to the World Health Organization (WHO). For prevention, U.S. and WHO guidelines recommend Viread starting around seven months of gestation for pregnant women with an HBV viral load above 200,000, along with HBV vaccination (active immunization) and HBV immunoglobulin (passive immunization) for infants. However, HBV immunoglobulin is costly and may be unavailable or in short supply in lower-income nations.

Calvin Pan, MD, of New York University Langone Health, and colleagues assessed whether early Viread plus infant vaccination, without HBV immunoglobulin, could ward off vertical transmission of the virus.

The randomized trial included 280 hepatitis B “e” antigen (HBeAg) positive women with HBV DNA levels above 200,000 enrolled at seven centers in China. Women who also had hepatitis A, C, D or E; HIV; or a sexually transmitted infection were excluded. Those with preexisting kidney problems were also excluded (as tenofovir can cause kidney toxicity) as were those with decompensated liver disease or liver cancer.

Women in the experimental arm started Viread between week 14 and week 16 of gestation, while those in the control arm received the antiviral from week 28. At the time of delivery, women in the experimental group had been receiving Viread for 23 weeks while those in the control group had been on treatment for 11 weeks.

All the infants were given their first HBV vaccine dose within 12 hours of being born and additional doses at weeks 4 and 24. Infants born to mothers in the control group—but not those in the experimental group—were also given HBV immunoglobulin.

A total of 265 women (average age 28 years) completed the study, with 269 infants born.

At 28 weeks after birth, the mother-to-child HBV transmission rate was 0% in both the experimental and control arms. Women in the experimental group had a lower median HBV DNA level at delivery—and more fell below the 200,000 cutoff—compared with those in the control group who took Viread for a shorter duration. There were no significant differences in the rates of serious maternal adverse events or congenital defects among the infants in either group.

Viread initiated at week 16 of gestation for highly viremic mothers combined with infant vaccination achieved a 100% success rate in this study, Pan reported. There were no safety concerns for mothers or infants during the 28-week postpartum follow-up period.

“[O]ur trial provides convincing evidence for using maternal [Viread] therapy to replace infants’ [HBV immunoglobulin] as a new strategy,” the researchers concluded. “This approach can help resource-limited countries overcome the barriers to the inaccessibility of [HBV immunoglobulin] and scale up the global elimination of HBV infection.”

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