Vemlidy Prevents Transmission of Hepatitis B From Mother to Infant

Two different studies found that Vemlidy was safe and effective for pregnant women and their infants.

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Vemlidy (tenofovir alafenamide, or TAF) was found to prevent transmission of hepatitis B virus (HBV) from mother to infant, based on two studies presented at the AASLD Liver Meeting Digital Experience.

HBV is commonly transmitted from mother to child. Transmission can be prevented by vaccinating the infant at birth, and further bolstered by the administration of hep B immunoglobulin, or injected antibodies. But when pregnant women have a high viral load, these precautions can be insufficient.

According to the World Health Organization, pregnant women having a high viral load should be given tenofovir from week 28 of pregnancy until delivery. This was based on research that found Viread (tenofovir disoproxil fumarate, or TDF) is safe and effective at preventing HBV transmission from mother to child.

Vemlidy is a newer formulation of tenofovir that is less toxic to the kidneys and bones compared to Viread. On the other hand, Vemlidy is also linked with higher blood lipid levels and a higher risk of weight gain. But little information in available on the safety and efficacy of Vemlidy administration during pregnancy as a means of preventing vertical transmission of hep B.

Calvin Q. Pan, MD, of NYU Langone Health in New York City, and colleagues ran a multicenter study that enrolled 71 mothers who were positive for hepatitis B 'e' antigen between December 2018 and May 2020. These women received Vemlidy during their second or third trimester to prevent vertical transmission. Their children were given hepatitis B immunoglobulin and multiple doses of the HBV vaccine at birth and at one and six months after birth.

Around 78% of the study population adhered to their daily antiviral regimen. The researchers found that 86% of mothers experienced a reduction in HBV viral load below 200,000 IU/mL at the time of delivery, with an average drop of 3.69 log IU/mL over the course of treatment, resulting in an average value of 4.09 log IU/mL at delivery.

All of the delivered infants tested negative for hepatitis B surface antigen (HBsAg), which is a sign of current infection. Despite two thirds of these babies being breastfed, none became infected.

The researchers found that the mothers and infants did not experience any severe adverse events, and no congenital defects were observed in the babies. These infants also met national standard measures for weight, height and head circumference. About 16% of the mothers had abnormal levels of the liver enzyme alanine transaminase (ALT).

“TAF therapy for highly viremic mothers was well tolerated and effectively prevented mother-to-child transmission of HBV,” the researchers said.

In another study, Qing-Lei Zeng, MD, of the The First Affiliated Hospital of Zhengzhou University, in China, and colleagues conducted a multicenter study including pregnant women with high levels of HBV DNA. These 232 women received Vemlidy or Viread from weeks 24 to 35 of pregnancy. Their babies were given hepatitis B immunoglobin at birth and doses of the HBV vaccine at birth and at months one and six.

Women in this study all completed their course of treatment. All the women had a drop in HBV DNA levels at the time of delivery, by about 3,000 IU/mL for those on Vemlidy and 2,500 UI/mL for those on Viread.

None of the infants born to these women, including those who were breastfed, tested positive for HBsAg at seven months. Further, they had no congenital defects and their physical and neurological measures were comparable to the World Health Organization’s standard and the national average in China.

Vemlidy was well tolerated, with no discontinuations because of adverse effects. Themost common adverse event was (19%). A few women had abnormal levels of ALT.

The researchers concluded that “TAF was safe for highly viremic pregnant women and their infants until 7 months, and reduced the mother-to-child rate of HBV to 0%.”

Click here to read the first study abstract from The Liver Meeting Digital Experience.

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