Earlier Maternal Hepatitis B Treatment Curbs Vertical Transmission

Starting tenofovir at 16 weeks along with infant vaccination was just as effective as standard care including HBV immune globulin.

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A new clinical trial offers promising news for hepatitis B prevention, especially in low-resource settings: Maternal antiviral treatment with tenofovir starting at 16 weeks of pregnancy, paired with infant vaccination, was just as effective at preventing mother-to-child transmission as standard care, according to findings published in JAMA.

Hepatitis B virus (HBV) is a blood-borne pathogen that is readily transmitted from mother to child during gestation or delivery. Typically, pregnant women with a high HBV viral load are started on antivirals at 28 weeks into pregnancy to prevent vertical transmission. At birth, the newborn is given the first HBV vaccine dose as well as HBV immune globulin (HBIG) to boost immunity. But HBIG is expensive and not always available.

Calvin Pan, MD, of Guangzhou Medical University in China, and colleagues therefore conducted a study to assess the effectiveness of an alternative treatment plan for mother-child pairs (NCT03476083). The research team assessed whether administering tenofovir disoproxil fumarate (TDF; Viread) sooner to pregnant women with a high viral load and giving infants the first HBV vaccine dose but not HBIG would be comparable to standard care in preventing vertical transmission. World Health Organization guidelines recommend tenofovir for all pregnant women who test positive for hepatitis B surface antigen (HBsAg) when HBV DNA testing is unavailable.

Between June 2018 and February 2021, the researchers enrolled 280 pregnant women with hepatitis B at seven hospitals in China. The average age was 28 years, and the mean duration of gestation was 16 weeks. The mothers had HBV DNA levels greater than 200,000. They were randomized to receive standard care or earlier tenofovir with no HBIG for the infant.

About 95% of the women completed the study. Among all live-born infants, the rate of mother-to-child HBV transmission was very low. Just one infant in the early-treatment group showed signs of infection, compared to none in the standard-care group (0.76% versus 0%). When looking only at those who completed the full treatment protocol, there were zero cases of vertical transmission in either group. The difference in transmission rates between the two groups was small—well within the study's margin for showing that the early treatment approach was just as effective as standard

care.

The one infant tested positive for HBsAg but had undetectable HBV DNA at birth. This child was lost to follow-up and could not be tested later for chronic hepatitis B. Given the undetectable viral load at birth, “the likelihood of this infant developing chronic HBV infection was probably below 20%,” the authors noted. In a previous study, Pan and colleagues found that none of the 94 newborns with undetectable HBV DNA at birth developed chronic hepatitis B at 28 weeks, despite the fact that 6% were HBsAg-positive at birth.

As for safety, congenital defects and malformations occurred less often in the early-treatment group compared with the standard-care group (2.3% versus 6.3%). The researchers noted that a global registry found that women who received tenofovir during pregnancy had a birth defect rate comparable to that of the general population (2.6% versus 2.7%).

“Among pregnant women with HBV and high levels of viremia, TDF beginning at gestational week 16 combined with HBV vaccination for infants was noninferior to the standard care of TDF beginning at gestational week 28 combined with HBIG and HBV vaccination for infants,” the researchers concluded. “These results support beginning TDF at gestational week 16 combined with infant HBV vaccine to prevent MTCT of HBV in geographic areas where HBIG is not available.”

In their discussion, the authors noted that in earlier study that administered tenofovir to mothers starting at 24 weeks, 1.5% of infants developed chronic hepatitis B, suggesting that a shorter duration of treatment before delivery might be inadequate for controlling viremia, especially given the global preterm birth rate of around 12%.

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