Study Backs Early Hepatitis B Treatment—Even Without Liver Damage

Earlier HBV treatment with tenofovir alafenamide could help prevent progression to cirrhosis, liver cancer and other serious outcomes.

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In a major clinical trial across South Korea and Taiwan, researchers found that starting antiviral therapy for hepatitis B early—before signs of liver damage appear—significantly reduced the risk for liver cancer and other severe complications. These findings, published in The Lancet Gastroenterology & Hepatology, support updated treatment guidelines that primarily focus on viral load, not liver enzyme levels.

Over time, chronic hepatitis B virus (HBV) infection can lead to liver fibrosis, cirrhosis, hepatocellular carcinoma (the most common type of primary liver cancer) and the need for a liver transplant. But some people remain healthy for many years—or even a lifetime—without treatment. Hepatitis B treatment guidelines generally recommend starting antiviral therapy only when patients show signs of liver inflammation or damage, such as elevated levels of the liver enzyme alanine aminotransferase (ALT) or significant fibrosis. But a growing number of clinicians and advocates are calling for expanded treatment eligibility.

Young-Suk Lim, MD, of the University of Ulsan College of Medicine in South Korea, and colleagues analyzed the effectiveness of early treatment with daily tenofovir alafenamide (TAF). TAF is sold as Vemlidy for hepatitis B, and it is a component of some combination pills used to treat HIV, as the drug is active against both viruses. Specifically, the study authors asked whether prompt treatment could prevent serious liver-related clinical outcomes among people with a high HBV viral load in their blood, nearly normal liver enzyme levels and no apparent liver damage.

This analysis was part of a larger ongoing randomized, controlled trial called ATTENTION, taking place across 22 sites in South Korea and Taiwan (NCT03753074). From February 2019 to October 2023, a total of 734 people with chronic HBV between the ages of 40 and 80 were recruited into the study. They had a moderate to high HBV DNA viral load (between 4 and 8 log IU/mL), normal or slightly elevated ALT (below 70 U/L for men or below 50 U/L for women) and had not yet developed cirrhosis.

Of these, 369 were randomly assigned to receive TAF while 365 were placed in a control group and given no antivirals. The main endpoint was a composite of advanced liver-related outcomes including liver cancer, decompensation (loss of liver function), liver transplant or death from any cause.

Over a follow-up period of nearly 18 months, two people in the antiviral group reached the combined endpoint (both with liver cancer), compared with nine in the control group (seven cases of liver cancer, one decompensation and one death).

People who received prompt antiviral treatment had a much lower rate of serious liver-related problems, at just 0.33 cases per 100 person-years, compared to 1.57 per 100 person-years for those who didn't receive treatment—a 79% reduction in risk. Serious adverse events not related to liver disease occurred at similar rates in both groups (6% with treatment versus 7% without).

"The results of this interim analysis suggest that early treatment with tenofovir alafenamide reduces the risk of liver-related serious adverse events compared with observation in adults with non-cirrhotic chronic hepatitis B and moderate or high viremia but normal or mildly elevated ALT concentrations," wrote the researchers. "Although these findings await confirmation in planned future analyses, they suggest that existing guidelines could be expanded to allow early antiviral therapy in patients with a moderate or high HBV viral load, irrespective of ALT concentrations."

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