Tenofovir Is Safe and Effective for Hep B, Yields Little Bone Loss

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A new study has underscored previous findings that tenofovir is safe and effective for long-term treatment of hepatitis B virus (HBV), in particular for people with lamivudine resistance, and that it also leads to few kidney-related side effects and no clinically relevant bone loss, HIVandHepatitis.com reports. Researchers presented their data at the annual meeting of the American Association for the Study of Liver Disease (AASLD) in Boston. Meanwhile, a separate study showed only minimal evidence of bone loss in HBV patients taking tenofovir.

In a Phase IIIb study of Gilead Sciences' tenofovir, Scott Fung of Toronto General Hospital and his colleagues recruited 280 treatment-experienced hep B patients who were both hepatitis C- and HIV-negative and who had no pre-existing kidney function impairment. All of the patients were taking lamivudine when they started the study, had an HBV viral load of 1,000 or more and had documented lamivudine resistance.

Patients were randomly assigned to take either tenofovir or the antiretroviral Truvada (tenofovir/emtricitabine) for 96 weeks. The two arms had respective undetectable HBV DNA rates of 89 and 86 percent at the study's end. Kidney side effects were minimal, with no patients experiencing a significant serum creatinine increase, only 1 percent seeing a reduced serum phosphorus level below 2 milligrams per deciliter, and 3 percent experiencing a creatinine clearance below 50 milliliters per minute. None of the patients developed clinically relevant bone loss.

In another study, Upkar Gill of Cell and Molecular Science in London and colleges examined 122 hep B patients who took tenofovir for at least 48 weeks, plus a control arm of 48 hep B patients not on the drug. The doctors compared each person's bone mineral density with that of healthy adults, which is measured in T-scores. The average hip T-score for the tenofovir group was significantly lower than the control group's. T-scores for the lumbar spine and hip joint, however, were comparable between the two groups. The researchers found that patients experienced small declines in bone density after starting tenofovir, but that these changes soon leveled off and changed no further. Longer tenofovir use did not lead to increased bone loss. Furthermore, tenofovir did not appear to lead to changes in bone mineral density or bone biochemistry markers, and an apparent increase in serum alkaline phosphatase among those taking the drug was not statistically significant.

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