Treatment Interruptions “Particularly Hazardous” for Those Coinfected With Hep B

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Interrupting antiretroviral (ARV) therapy may be “particularly hazardous” for people living with HIV and chronic hepatitis B virus (HBV) infection, according to data from the Strategies for the Management of Antiretroviral Therapy (SMART) study published online by the journal AIDS. Increases in HBV viral load and accelerated immune deficiency were documented among coinfected individuals partaking in structured drug holidays in the study.

A number of medications used to treat HIV—tenofovir (found in Viread, Truvada and Atripla), emtricitabine (found in Emtriva, Truvada and Atripla) and lamivudine (found in Epivir, Combivir and Trizivir)—are also active against HBV, making them ideal agents to be used by people coinfected with both viruses. About 10 percent of the HIV-infected population worldwide is infected with HBV.

Like HIV, long-term antiviral therapy is often required to prevent HBV from reproducing and causing irreversible liver damage. Also like HIV, there are lingering concerns regarding discontinuing treatment, even temporarily, in those infected with HBV. For example, rebounds in HBV viral load after discontinuing treatment can lead to potentially dangerous flares in liver enzymes and, occasionally, permanent liver damage (hepatic decompensation) in both HBV-monoinfected and HIV/HBV-coinfected patients.

SMART enrolled more than 5,000 HIV-positive patients—132 of whom were coinfected with HBV—who had CD4 counts above 350 cells and were either on treatment or had not yet started therapy. The patients were randomized to one of two groups: 1.) a continuous treatment group, in which treatment would be continued indefinitely; or 2.) an episodic treatment group, in which treatment would be delayed or discontinued until the CD4 count falls below 250 cells, followed by treatment until the CD4 count is back above 350 cells, followed by another treatment discontinuation until the CD4 count again falls below 250 cells (and so on).

CD4 cell-guided episodic treatment was associated with higher rates of opportunistic infections, non-AIDS diseases and death compared with continuous therapy, according to data first reported more than four years ago.

Post-study results focusing specifically on those coinfected with HIV and HBV are set to be published in AIDS by Gregory Dore, MD, PhD, of the University of New South Wales in Sydney and his SMART colleagues. Seventy-two participants coinfected with HIV and HBV were randomized to the episodic treatment group, and 62 were randomized to the continuous treatment group.

HBV viral load rebounded by more than 1 log in about 32 percent of those in the episodic treatment group, compared with 3 percent of those in the continuous treatment group. Thirteen coinfected patients experienced HBV viral load rebounds in excess of 3 log, 12 of whom were in the episodic treatment group.

Hepatic flares—defined as increases in the ALT liver enzyme to levels above 200 units per milliliter (U/mL)—were uncommon among patients in the episodic treatment group, occurring in one patient with an HBV viral load rebound of greater than 1 log and one patient with an HBV viral load rebound of less than 1 log. What's more, there were no cases of hepatic decompensation in either study group.

"Although ALT data collection was only undertaken retrospectively and available in a minority of participants," the authors write, "the low rate of hepatic flare even in those with significant HBV DNA rebound is somewhat reassuring."

The time to reinitiate therapy in the episodic treatment group was faster among the HBV-positive patients compared with those not coinfected with HBV in SMART, indicating that CD4 cell counts fall more rapidly among patients living with both HIV and HBV once treatment is discontinued. Whereas patients in the episodic treatment group not infected with HBV (or hepatitis C virus) spent about 17.8 months off ARV therapy, those coinfected with HBV spent, on average, 7.5 months off ARVs before having to restart therapy.

In conclusion, the authors reiterated that interrupting therapy among coinfected participants in the SMART study was associated with frequent HBV viral load rebound and more rapid and higher rates of ARV reinitiation. "Such outcomes," they add, "indicate that [ARV therapy] interruption may be particularly hazardous for this subpopulation of HIV-infected individuals."

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