HIV Non-Nuke Rilpivirine Less Likely Than Sustiva to Cause Vitamin D Drops

March 8, 2011 By Tim Horn

Sustiva (efavirenz) may have a greater negative effect on vitamin D levels than Tibotec Therapeutic's experimental non-nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine (TMC278), according to results of a Phase III clinical trial comparing the two drugs and reported on Tuesday, March 1, at the 18th Conference on Retroviruses and Opportunistic Infections (CROI) in Boston.

Though a large percentage of patients in both study groups had suboptimal vitamin D levels before starting treatment with either drug, the risk of experiencing severe vitamin D deficiency was significantly higher among those receiving Sustiva plus Truvada (tenofovir/emtricitabine) compared with rilpivirine plus Truvada.

Mild-to-moderate Vitamin D deficiency is common among people living with HIV, explained David Wohl, MD, of the University of North Carolina School of Medicine in prefacing his review of the data in Boston. Sustiva, an NNRTI frequently taken in combination with Truvada and used as Atripla, is known to reduce vitamin D levels in the body. In one clinical trial Wohl mentioned—Tibotec's MONET study—vitamin D levels increased in people living with HIV who switched from a Sustiva-containing ARV regimen to a drug combination based on Norvir (ritonavir)–boosted Prezista (darunavir).

Wohl added that vitamin D deficiency can contribute to a number of complications, including bone loss, muscle weakness, immune dysfunction, a reduction in the heart's ability to contract properly, high blood pressure, diabetes and cancer.

A combined analysis of two clinical trials of rilpivirine compared with Sustiva—ECHO and THRIVE—indicate both drugs are comparable in terms of keeping viral loads undetectable for a year among first-time treatment takers, though a higher number of virologic failures and a greater incidence of HIV resistance to second-line NNRTI Intelence (etravirine) were noted in those taking rilpivirine. At the same time, rilpivirine performed better than Sustiva in terms of tolerability and side effects, owing to the fact that rilpivirine is not associated with the same central nervous system problems as Sustiva-based therapy.

Wohl's group examined ECHO for changes in vitamin D levels among those receiving rilpivirine and Sustiva. The clinical trial enrolled 690 people living with HIV starting ARV treatment for the first time to receive either rilpivirine 25 milligrams (mg) with Truvada once a day or Sustiva (600 mg) plus Truvada once a day.

Optimal or sufficient vitamin D levels were defined as blood samples containing 30 nanograms per milliliter (ng/mL) of vitamin D. Insufficient levels, or mild deficiency, were vitamin D levels between 21 and 29 ng/mL. Deficient levels, or moderate deficiency, were vitamin D levels between 10 and 20 ng/dL. And severe deficiency was defined as a vitamin D level below 10 ng/dL.

Before beginning therapy, Wohl noted, 72 percent of the patients enrolled had suboptimal vitamin D levels. He also pointed out that 14 percent of those in the rilpivirine group and 12 percent of patients in the Sustiva group were taking vitamin D supplements during the study.

Twenty-four weeks into the trials, vitamin D levels dropped in both groups—by an average of 2 ng/dL in the rilpivirine group and 4 ng/dL in the Sustiva group. After the 24-week time point, vitamin D levels increased in both groups. However, where patients in the rilpivirine group tended to end the 48-week study with same vitamin D levels they had upon starting the trial, those in the Sustiva group averaged vitamin D levels about 2.5 ng/dL below their pre-treatment measurements.

Wohl also noted that more patients in the Sustiva group developed severe vitamin D deficiency during the study compared with those in the rilpivirine group. About 8 percent of those with insufficient or deficient vitamin D levels in the Sustiva group at the start of the trial went on to develop severe vitamin D deficiency. In the rilpivirine group, about 2 percent in the insufficient or deficient groups experienced severe vitamin D deficiency.

Looking only at those with deficient pre-treatment levels, 4 percent compared with 20 percent of patients in the rilpivirine and Sustiva groups, respectively, developed severe vitamin D deficiency.

In conclusion, Wohl explained, average vitamin D levels after 48 weeks of treatment remained unchanged with the use of rilpivirine plus Truvada, whereas there were statistically significant reductions in vitamin D levels associated with Sustiva. “The risk of progression to severe [vitamin D] deficiency was significantly higher with [Sustiva] than [rilpivirine],” he added.

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