Tenofovir - pilot study finds good impact on lipids

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HIV infection causes the body to increase production of chemicals that trigger inflammation. Such inflammation is only partially reduced with anti-HIV therapy. Prolonged inflammation appears to cause unfavourable changes to many organ systems, including the cardiovascular system. In some surveys, a large proportion of HIV-positive people report that they smoke tobacco and some use illicit drugs such as cocaine. These substances increase the risk of damage to the heart and blood vessels.

In several clinical trials researchers have replaced the drug d4T (stavudine, Zerit) in participants’ regimens with tenofovir (Viread, and in Truvada and Atripla). This switch from d4T generally improved abnormal lipid levels in the blood. However, it was not clear why this improvement occurred. Was it because d4T was replaced by a less toxic drug or did tenofovir have lipid-lowering effects?

To try to answer these questions, American researchers conducted a pilot study called ACTG 5206. Their complex study design revealed that tenofovir can indeed lower lipid levels in the blood.

Study details

Prior to entering the study all participants were taking HAART and had abnormal lipid levels in their blood. On average, their viral load was below the 400-copy/ml mark.

The study design was complex: a randomized, double-blind, placebo-controlled cross-over trial. For the first 12 weeks, participants received either placebo or tenofovir. This was followed by a wash-out period of four weeks, when none received placebo or tenofovir. After this, people who had previously received tenofovir were given placebo and previous placebo users were given tenofovir. This latter part of the study—the cross-over period—lasted for 12 weeks.

Since this study included a cross-over design, only a relatively small number of people was needed for statistical analysis. Seventeen adults were recruited from several clinics across the United States—25% women and 75% men.

Results

Participants were taking a variety of treatments, some based on protease inhibitors and others based on non-nukes (NNRTIs). Thirteen people completed the study as follows:

- tenofovir then switched to placebo – 6 people
- placebo then switched to tenofovir – 7 people

Compared to placebo, levels of the following lipids fell in tenofovir users:

- bad cholesterol (LDL-c) – 17% decrease
- total cholesterol – 14% decrease

These differences between placebo and tenofovir users were statistically significant; that is, not likely due to chance alone.

Virologic suppression continued throughout the study. CD4+ cell counts did not increase significantly.
Side effects

No life-threatening effects occurred during the study. However, one participant developed seriously altered levels of phosphorus in the blood, perhaps related to exposure to tenofovir.

Tenofovir is processed by the kidneys; in rare cases, it can cause serious kidney damage. This can be detected by abnormal levels of the waste product creatinine in the blood. However, in the present study, changes in creatinine levels were generally not different when participants were taking placebo or tenofovir. This should not be surprising, as participants were exposed to tenofovir for a relatively short time.

ACTG 5206, while having a small number of participants, was of a robust study design. As a result, this pilot study clearly found that tenofovir can reduce levels of some lipids in the blood. While the results from ACTG 5206 are promising, long-term studies are needed to discover if tenofovir-containing regimens can have an impact on cardiovascular health.

—Sean R. Hosein

REFERENCE:


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