Another Study Finds No Heart Attack Risk From Abacavir

March 25, 2011

People taking abacavir (found in Ziagen, Epzicom and Trizivir) had no greater risk of having a heart attack than people not taking abacavir, according to an analysis of six AIDS Clinical Trials Group (ACTG) studies reported in the April 1 issue of Clinical Infectious Diseases. Though the studies predominantly involved people with low cardiovascular disease (CVD) risks, the ACTG analysis joins other reports in challenging the conclusions of studies suggesting that abacavir treatment increases the risk of CVD among people living with HIV.

Three major studies have now found an increased risk of heart attacks associated with abacavir. These include two cohort studies—the Data Collection on Adverse events of Anti-HIV Drugs (D:A:D) cohort and the French Agence Nationale de Recherches sur le SIDA (ANRS) cohort—and a study comparing delayed or interrupted treatment with continuous treatment, called Strategies for Management of Antiretroviral Therapy (SMART). The three studies have significantly different designs, populations and methods, yet all indicated at least some degree of increased heart attack risk among people taking abacavir.

Meanwhile, analyses conducted by ViiV Healthcare (formerly GlaxoSmithKline) and the U.S. Food and Drug Administration of multiple controlled clinical trials involving abacavir found no increased risk—they also failed to find any biological explanation or hint for why the other studies did. Though this has remained a controversy, current antiretroviral (ARV) guidelines recommend that people with high CVD risk factors do not use abacavir.

To add to the knowledge base on abacavir and cardiovascular disease risk, Heather Ribaudo, PhD, from the Department of Biostatistics at the Harvard School of Public Health in Boston, and her colleagues from the ACTG A5001/ALLRT Protocol Team, analyzed data on more than 5,000 HIV-positive people drawn from six ACTG studies.

Most of the participants were younger than 45, and most were male, though the cohort was racially diverse. One-year follow-up data was available for 92 percent of the participants, and six-year follow-up data was available for 22 percent.

Over the course of the study, there were 36 heart attacks, roughly two thirds of which occurred between the second and sixth year on ARV therapy.

Based on several different types of analysis, Ribaudo and her colleagues could find no additional heart attack risk in those taking abacavir. In fact, the only factor that predicted a heart attack were older age and traditional heart attack risk factors, such as smoking and a history of

cardiovascular disease.

No study of abacavir and heart attack risks is going to be perfect, and Ribaudo and her team acknowledge that their own analysis has limitations. For one thing, the total number of heart attacks was low, and it is possible that a difference might have emerged with larger numbers. Also, three of the studies directly randomized people to abacavir or another similar drug, while three did not randomize their treatments this way. This could also have affected the study outcomes. Finally, clinical trials such as those included in the ACTG analysis tend to exclude individuals with underlying health problems, such as high blood pressure or very high cholesterol or triglyceride levels. In other words, people in the ACTG studies may have been at a lower risk of a heart attack before starting abacavir, compared with those in the "real world" D:A:D and ANRS cohorts.

Nevertheless, the authors cite one potential strength not present in the studies that have thus far found an increased heart attack risk: The randomized ACTG trials were able to reduce the chance that people with higher heart attacks risks were preferentially put on abacavir, as was possibly done in the earlier cohort studies because providers at that time felt abacavir was more heart "friendly"—less likely to causes lipid increases, etc.—than other regimens. If this kind of "channeling" bias was in effect, it could go a long way toward explaining the increased heart attack risk found in those earlier studies.

"We found no evidence of an increased risk of [heart attack] or serious CVD associated with the use of abacavir as part of initial treatment over the first year of [ARV therapy] and the longer term that was consistent in [several types of analyses]," the authors conclude. "Classic CVD risk factors were the strongest predictors of [heart attacks] and serious CVD events and should be the main focus in assessing CVD risk among HIV-1 infected individuals."

Clarification: According to data from the ANRS study, reported at the 16th Conference on Retroviruses and Opportunistic Infections (CROI) in 2009, documented an association between abacavir use and an increased risk of heart attacks, additional data from the study—reported later that year at the 5th IAS Conference on the Pathogenesis, Treatment and Prevention of HIV—suggested that the link disappeared after filtering out patients using cocaine or IV drugs, also known to be risk factors for heart attacks.

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