Risk of Virologic Failure 40 Percent Higher Among Blacks vs. Whites

March 1, 2011 By Tim Horn

There is a 40 percent higher risk of virologic failure among blacks, compared with whites, starting HIV treatment for the first time, according to a new AIDS Clinical Trials Group (ACTG) analysis reported by Heather Ribaudo, PhD, of Harvard University School of Public Health on Monday, February 28, at the 18th Conference on Retroviruses and Opportunistic Infections (CROI) in Boston. Unfortunately, while one of the study's goals was to explore the many possible factors associated with this disparity, the researchers did not have key socioeconomic data to draw any firm conclusions.

Interestingly, blacks in the analysis had modestly higher CD4 cell counts after 96 weeks of treatment in the five clinical trials included in the analysis.

Several studies have found inferior virologic responses—viral loads that either fail to go undetectable or become detectable during follow-up periods—among U.S. and European minority groups, compared with whites. Ribaudo and her ACTG colleagues hypothesized that this may be associated with socioeconomic factors—such as education level, housing status and access to care—yet a number of studies designed to look at these possible barriers found no evidence for differences in treatment outcomes. In turn, Ribaudo's group looked at data from various ACTG studies to explore differences in treatment responses, along with factors associated with those differences between blacks and whites.

The researchers conducted an analysis of five large ACTG clinical trials, testing a variety of triple-drug antiretroviral (ARV) regimens being used as first-time therapy, conducted between 1998 and 2005. The primary goal of the analysis was a strict intent-to-treat review of virologic failure risk; virologic failure was defined as a viral load above 1,000 between weeks 16 and 24 in the studies, or a viral load above 200 after 24 weeks in the studies. The analysis involved all patients enrolled in the studies, regardless of whether or not they remained on treatment. Other goals included conducting an as-treated analysis—looking only at those who remained on treatment in the study—as well as examining the change in CD4 cell counts over the course of treatment.

Of the men enrolled in the studies, 1,202 were white and 820 were black. Of the women, 142 were white and 331 were black. The average age of the participants was 37 at the start of the trials, with pre-treatment viral loads averaging 100,000 copies. The white men tended to have higher CD4 counts upon starting treatment for the first time (244 cells versus 178 cells among black men), whereas women tended to have similar pre-treatment CD4 counts. Black men were also twice as likely to have a history of hepatitis C infection (17 percent versus 9 percent), whereas

rates of hepatitis C infection were similar among both groups of women (12 percent among whites and blacks).

Sexual contact was more likely to be the mode of HIV transmission in white men compared with black men (87 percent versus 75 percent), whereas sexual transmission was more likely to be the mode of transmission in black women compared with white women (82 percent versus 74 percent). Education levels also differed between the racial groups: 61 percent of the white men and 38 percent of the white women had education beyond high school, compared with 44 percent of black men and 29 percent of black women.

According to Ribaudo, blacks were 40 percent more likely to experience virologic failure of first-line ARV therapy in the studies compared with whites. “This finding was seen consistently across a range of [first-time] ARV regimens,” Ribaudo said.

The increased likelihood of virologic failure among blacks persisted even after taking into consideration a variety of pre-treatment risk factors—such as sex, disease status, other diseases/illnesses, mode of transmission, history of depression and alcohol use—and was documented in both the intent-to-treat and as-treated data reviews. However, lower age, higher pre-treatment viral loads, hepatitis C infection and self-reports of recent non-adherence were all associated with an increased risk of virologic failure. “There was some evidence associated with lower education and less satisfaction with support,” Ribaudo noted.

Yet despite the higher risk of virologic failure, blacks tended to experience somewhat higher CD4 cell gains in the studies—an increase of 33 CD4 cells after 96 weeks of treatment in the studies compared with whites. However, Ribaudo pointed out that it remains unclear that this modest difference is clinically meaningful.

In concluding her presentation, Ribaudo noted that the five-study analysis has a number of limitations.

First, it was primarily a U.S.-based population and can’t speak to racial differences in treatment responses documented in other countries.

Second, measures of adherence in the studies were simplistic, based on a patient-reported recalls of compliance in the four days before study visits—“Our analysis did not capture finer patterns of non-adherence,” Ribaudo said.

Third and perhaps most important, though the study was conducted to look for socioeconomic factors associated with virologic failure in the studies, the clinical trials collected only limited information regarding patients’ specific social factors. “Such information was only available for older studies,” Ribaudo added, “and were limited in their scope. There was no information regarding income, housing, access to care, etc.”

Finally, some of the regimens studied in the early clinical trials are no longer standard-of-care, though Ribaudo reminded delegates that the association between race and virologic failure was robust across regimens, even among the ARV drug combinations used today.

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