Sustiva vs. Kaletra? We Have a Likely Winner

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The U.S. Department of Health and Human Services (DHHS) currently recommends either Sustiva® (efavirenz) or Kaletra® (lopinavir plus ritonavir) – in combination with two nucleoside reverse transcriptase inhibitors (NRTIs) – for HIV-positive people starting treatment for the first time. But a central question has been lingering for several years: which of these medications is the most effective? Long-awaited study results, reported yesterday at the International AIDS Conference (IAC) in Toronto, may help settle this question once and for all.

The study (A5142) was conducted by the AIDS Clinical Trials Group and was reported at IAC by Sharon Riddler, MD, of the University of Pittsburgh. It actually compared three drug regimens taken for almost two years: Kaletra plus two NRTIs, Sustiva plus NRTIs, and Kaletra plus Sustiva (without any NRTIs).

A5142, with an enrollment of 757 treatment-naive patients, is the first large study to compare Kaletra to Sustiva – the reigning standard-of-care options in the United States for HIV-positive people starting treatment for the first time.

Across the board, all of the treatment regimens were reported to be effective by Dr. Riddler. Among the three treatment groups, approximately 83% had viral loads below 50 after 96 weeks of treatment.

However, there was one key difference between the treatment groups. The time to virologic failure – defined as a viral load that increased above 200 after being below this point during the study – was shorter in the Kaletra/NRTIs group than in the Sustiva/NRTIs group. The percentage of patients who experienced virologic failure by week 96 of the study was 33% in the Kaletra/NRTIs group, compared to 24% in the Sustiva/NRTIs group and 27% in the Kaletra/Sustiva group. The comparison between the Sustiva/NRTIs group and the Kaletra/NRTIs group was statistically significant, meaning that the difference most likely was not due to chance.

Dr. Riddler also explained that, at week 96 of the study, the percentages of patients with viral loads less than 50 was 83% in the Kaletra/Sustiva group, 89% in the Sustiva/NRTIs group, and 77% in the Kaletra/NRTIs group. Here also the difference between the Sustiva/NRTIs group and the Kaletra/NRTIs group was statistically significant.

When it came to CD4 count (T cell count) increases, however, the Kaletra/NRTIs group came out slightly ahead of the Sustiva/NRTIs group. After 96 weeks of treatment, CD4 counts increased by 285 cells in the Kaletra group, compared to an increase of 241 in the Sustiva group. This difference was also statistically significant.

The medications were equally well tolerated when measured by the number of study volunteers who had to stop their treatment due to side effects. However, some of the side effects associated with symptoms (e.g., nausea, diarrhea, and headache) and blood test abnormalities (e.g., increased triglyceride levels) were more common in the Kaletra/Sustiva group compared to the Kaletra/NRTIs or Sustiva/NRTIs groups.

Dr. Riddler pointed out that the A5142 study team has much more data to analyze from this study. Detailed information regarding side effects including metabolic changes (cholesterol, blood sugar, and lipodystrophy), adherence, and resistance testing will be reviewed in the next few months.

Until firm conclusions can be drawn, Dr. Riddler indicated that when a primary goal of therapy is to keep viral load undetectable for as long as possible to prolong the benefits of treatment and reduce the risk of drug resistance, Sustiva plus two NRTIs appears to be a better bet than Kaletra plus two NRTIs.

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