Twice-Daily Kaletra Possibly Better for Some Patients

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The results of an AIDS Clinical Trials Group (ACTG) study indicate that once-daily and twice-daily Kaletra® (lopinavir/ritonavir) are comparable in terms of viral load reductions over 48 weeks of treatment. However, statistical predictions discussed at the 14th Conference on Retroviruses and Opportunistic Infections also suggest that, among patients with high pre-treatment viral loads, the time to virologic failure may be shorter using once-daily Kaletra.

For people beginning HIV treatment for the first time, Kaletra-based treatment regimens are a popular option, dosed either once or twice a day. Once-daily dosing requires taking four tablets every 24 hours; twice-daily dosing involves taking two tablets every 12 hours.

A concern with all HIV treatment regimens is that people with high viral loads – generally defined as pre-treatment levels in excess of 100,000 – may face greater challenges keeping their viral loads undetectable compared to those with lower pre-treatment levels. Not only has this been an issue in the development of experimental agents, it has also been a key question in studies involving approved antiretrovirals, including clinical trials evaluating once-daily and twice-daily dosing options.

A focus of ACTG study 5073 was to determine if once- and twice-daily Kaletra work equally well, including patients who entered the trial with low and high viral loads. The study enrolled 408 HIV-positive patients, all of whom were new to antiretroviral treatment. All patients took Emtriva® (emtricitabine) with either Viread® (tenofovir) or Zerit® (stavudine).

The patients were randomized to one of three treatment groups. In the first group, patients took standard doses of twice-daily Kaletra. In the second group, patients took standard doses of once-daily Kaletra. In the third group, patients also received once-daily Kaletra, but as a component of "directly observed therapy" for 24 weeks, meaning that they took their daily doses under the direct supervision of healthcare workers for the first six months of the study (but without supervision for the last six months of the trial). Patients in the first two study groups took their medications without supervision.

Approximately 51% of the participants entered the study with viral loads of 100,000 or higher; 49% entered with viral loads below 100,000. The average viral load, among all patients enrolled, was 75,000. The average CD4 count was approximately 220.

After 48 weeks of treatment, a total of 87 virologic failures – meaning two consecutive viral loads above 200 – among the 402 patients were reported. Virologic failures were seen in 29/159 (18%)

of patients in the unsupervised twice-daily Kaletra group and 36/161 (22%) patients in the unsupervised once-daily Kaletra group. The difference between the two groups was not statistically significant, meaning that both groups responded equally well.

A notable difference was seen when comparing the once-daily and twice-daily Kaletra groups with respect to pre-treatment viral loads. The estimated probability of a sustained virologic response – a viral load below 200 – beyond 48 weeks of treatment among those with pre-treatment viral loads above 100,000 was 89% among those taking Kaletra twice a day, compared to an estimated probability of 76% among those taking once-daily Kaletra. The estimated difference of 13% between these two groups was statistically significant.

Looking at the study groups as a whole, irrespective of pre-treatment viral loads, the estimated probability of sustained virologic response beyond 48 weeks was 81% in the twice-daily Kaletra group and 78% in the once-daily Kaletra group. And among patients with pre-treatment viral loads below 100,000, there was no significant difference in the time to virologic failure between the once-daily and twice-daily Kaletra groups.

In conclusion the authors noted that, looking at the study as a whole, there were no differences in sustained virologic responses between the twice-daily and once-daily Kaletra groups. However, the large percentage of patients entering the study with viral loads above 100,000 allowed for the determination that the long-term risk of virologic failure is slightly higher for those with high viral loads taking the once-daily Kaletra-based regimen.

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