



THE BODY PRO

The HIV/AIDS Resource for Healthcare Professionals

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BI-WEEKLY PROFESSIONALS UPDATE • June 10, 2004

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IN THE NEWS

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Week-On, Week-Off HAART Shows Promise in Pilot Study

A seven-day-on, seven-day-off approach to antiretroviral therapy may hold promise in HIV-infected patients, particularly for those in regions with limited access to antiretrovirals, according to a study by Mark Dybul, M.D., and colleagues from the National Institute of Allergy and Infectious Diseases. The proof-of-concept study involved eight patients who entered the study after a minimum of six months on successful combination antiretroviral therapy. The researchers found that a once-daily, short-cycle structured intermittent therapy regimen consisting of ddI (didanosine, Videx), EFV (efavirenz, Sustiva) and 3TC (lamivudine, Epivir) maintained undetectable viral load levels in seven of eight patients for 60 to 84 weeks. (The eighth patient withdrew from the study for “personal reasons,” according to the study authors.) No significant changes were observed in patient CD4 count or emerging resistance mutations during the study period. The findings were published in the June 1 issue of the *Journal of Infectious Diseases*.

Twice-Daily Nelfinavir Formulation Reaches Market

A 625-mg tablet formulation of nelfinavir (Viracept) is now available, more than a year after the dosage received approval from the U.S. Food and Drug Administration. The new formulation will decrease the typical pill burden associated with nelfinavir from five to two tablets per day, although a potential for increased incidence of diarrhea is possible with this larger dose.

High Prevalence of Drug Resistance Found in New Study

HIV drug resistance mutations among HIV-infected, treatment-naïve patients are more likely to be found in specific populations, according to a U.S. study published in the June 15 issue of the *Journal of Infectious Diseases*. The 10-city study discovered that resistance mutations were more likely to be found among whites (13%), men who have sex with men (12%), or subjects whose sexual partner was taking antiretroviral medications (15%). Overall, 8.3% of the diverse group of 1,082 study subjects, most of whom were chronically infected, had major protease or reverse transcriptase mutations.

ASK YOUR COLLEAGUES

Q: Is there any justification in using IDV 400 mg three times daily with twice-daily ZDV/3TC? I'm a pharmacist who has received a prescription for an incarcerated patient whose treating physicians — who have limited HIV experience — are simply represcribing this regimen, which was handed down from the patient's previous prison.

BENJAMIN YOUNG, M.D., *Attending Physician at Rose Medical Center in Denver, Colo. and a Clinical Instructor at the University of Colorado Health Sciences Center.*

The combination of thrice-daily unboosted IDV (indinavir, Crixivan) 400 mg with ZDV [zidovudine, Retrovir]/3TC is highly unusual and does not utilize the FDA-approved dose of 800 mg three times daily. As such, I would have to consider whether the IDV dose was intended by the prescribing physician or if this was a prescribing error.

Additionally, given the availability of easier-to-take and more potent combinations, I would not recommend this four- or five-times-daily regimen for initial treatment. I would have to have a compelling reason to support the selection of this regimen and dose. Instead I would recommend any of a number of highly recommended alternatives as spelled out in the Department of Health's treatment guidelines.

Q: I've read that ddI and TDF should not be coadministered in a first-line regimen with EFV. Do you concur? Is 3TC + EFV + TDF a better bet?

BENJAMIN YOUNG, M.D. The combination of ddI and TDF (tenofovir, Viread) has received a fair amount of attention in recent

months for several reasons. First, since both drugs can be dosed once daily, the combo was a potential nucleoside backbone for other once-daily treatments. However, it was discovered that TDF significantly raises ddI levels, which has led to reduction of the ddI dose from 400 to 250 mg a day when taken with TDF (for patients who weigh more than 60 kg).

All data on the ddI + TDF combination have come from the analysis of treatment-experienced patients. When dosed at the previous standard (400 mg), ddI + TDF was shown to cause significantly more toxicity and treatment discontinuation. (I authored this study for the CDC's HOPS collaborative and presented the data at the EACS meeting last fall in Warsaw.) By contrast, the lower-dose ddI + TDF combinations appear to be much better tolerated and relatively safe.

The real issue to your question, though, is the use of ddI + TDF as part of first-line therapy for HIV. Here, I can't make a strong endorsement for a ddI + EFV + TDF combination. That's not to say that that the regimen might not work, but rather that it has not been studied (to my knowledge) in therapy-naïve patients. This is because we have a number of other well-studied NRTI combinations, with long-term safety and effectiveness data — 3TC + ZDV and 3TC + TDF, for example (though FTC [emtricitabine, Emtriva] can likely substitute for 3TC). Both of these combinations are endorsed by recent U.S. treatment guidelines. To this extent, the combo of 3TC + EFV + TDF, as you've mentioned, is one of the recommended regimens, provided that your patient has not acquired NNRTI-resistant virus. This regimen has been extensively studied in the important Gilead 903 clinical trial; see The Body Pro's conference coverage for more details.



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