Dovato Works Well as a Rapid HIV Treatment Option

Two-drug combo of dolutegravir and lamivudine suppresses HIV in newly diagnosed people.

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A two-drug combination of dolutegravir and lamivudine can be a good option for newly diagnosed people starting rapid HIV treatment, according to study results presented at the 11th International Conference on HIV Sciences (IAS 2021).

In an effort to improve treatment convenience and minimize side effects, researchers have aimed to simplify antiretroviral therapy as much as possible while still maintaining viral suppression. One way to do this is reducing the number of drugs in a regimen.

Dolutegravir (sold alone as Tivicay), a potent integrase inhibitor with a high barrier to resistance, is most commonly used in two-drug therapy. The Dovato (dolutegravir/lamivudine) single-tablet regimen is approved for people switching therapy with stable viral suppression for at least six months and for those just starting treatment. The TANGO study showed that Dovato works well as a switch option, while the GEMINI 1 and GEMINI 2 trials showed that it is as effective for initial therapy.

In the Phase III STAT trial, Charlotte-Paige Rolle, MD, MPH of the Orlando immunology Center, and colleagues evaluated the effectiveness of Dovato for newly diagnosed people in a test-and-treat setting. Studies have shown that rapid treatment soon after diagnosis—ideally the same day—leads to improved retention in care and faster viral suppression.

Guidelines recommend that people should be tested for drug resistance mutations and hepatitis B virus (HBV) coinfection before starting Dovato. The lamivudine in Dovato is active against HBV as well as HIV, but people with coinfection should receive two drugs that work against HBV (typically tenofovir disoproxil fumarate or tenofovir alafenamide plus lamivudine or emtricitabine) to prevent drug resistance.

This study enrolled 131 newly diagnosed people at 16 sites in the United States. A quarter entered the trial the day they were diagnosed with HIV. More than 90% were men, the median age was 31, half were white, 47% were Black and 29% were Latino. About 40% had a high viral load over 100,000 copies, including 8% with a very high level over 1,000,000.

The participants were tested for drug resistance, HBV and kidney function at study entry, but they were started on Dovato within 14 days of HIV diagnosis, before these laboratory results were available. Treatment was modified if the tests later indicated dolutegravir or lamivudine resistance, HBV coinfection or impaired kidney function. One person was found to have HIV with pre-existing lamivudine resistance, and seven (5%) had hepatitis B.

As previously reported, and now published in the journal AIDS, an analysis at 24 weeks showed that 78% of all participants who started treatment (including those with missing data) had an undetectable viral load below 50, rising to 92% of those with available data, regardless of whether they stayed on Dovato or switched to another regimen.

At IAS 2021, Rolle reported updated results at 48 weeks, at which point 18 participants (14%) had withdrawn from the study and 10 had modified their regimen. With this longer follow-up, 82% of all participants had an undetectable viral load; most of those without viral suppression had dropped out and their data were missing. Among those with available data, 97% of those still on Dovato or on any regimen maintained viral suppression. Even most people who started treatment with a very high viral load above 500,000 or 1,000,000 reached an undetectable level.

Three of the seven people with hepatitis B underwent resistance testing, and the researchers saw no evidence of treatment-emergent HBV drug resistance at the time treatment was modified. Most added or switched to a regimen containing tenofovir alafenamide and emtricitabine.

Treatment was safe and well tolerated with few moderate or severe drug-related side effects (less than 2%). Only one person stopped Dovato due to adverse events.

“These data demonstrate the feasibility, good safety profile and high barrier to resistance of [Dovato] as a first-line regimen in a test-and-treat setting,” the researchers concluded. “Therapy adjustments for baseline resistance or HBV coinfection [occurred] safely via routine clinical care as needed.”

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