Switching From Viread to Vemlidy Keeps Hepatitis B Suppressed for Two Years

People who switched showed improvement in markers of kidney and bone health but also rise in lipid levels.

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People with chronic hepatitis B who switched from Viread (tenofovir disiproxil fumarate, or TDF) to Vemlidy (tenofovir alafenamide, or TAF) maintained viral suppression for 96 weeks and showed evidence of improved kidney and bone safety, according to a report last week at the Digital International Liver Congress.

Nucleoside/nucleotide analogues such as tenofovir can suppress hepatitis B virus (HBV) indefinitely, but they usually do not lead to a cure. Ongoing treatment is usually necessary and therefore long-term safety is a concern. Viread, one of the most effective antivirals for hep B, is generally safe, but it can contribute to kidney problems and bone loss in susceptible people. Vemlidy is a newer formulation that is easier on the kidneys and bones but associated with more blood lipid abnormalities.

Pietro Lampertico, MD, PhD, of the University of Milan, presented final results from an international Phase III trial of people with hepatitis B who switched from Viread to Vemlidy (ClinicalTrials.gov number NCT02979613).

The study included 488 people who had undetectable HBV viral load for at least a year while taking Viread. About 75% were men, most were Asian and the average age was 51. Just over two thirds were hepatitis B 'e' antigen negative. At study entry, they had been taking Viread for a median of about four years. Around 15% had cirrhosis, about 10% had preexisting osteoporosis (bone loss) and about 12% had abnormal blood lipids. People with preexisting kidney function impairment were excluded.

The study participants were randomly assigned to either switch to Vemlidy or stay on Viread. After 48 weeks, everyone received Vemlidy and they were followed for an additional 48 weeks.

As previously reported, both medications proved highly effective at 48 weeks. Only one person in

each group had a detectable HBV viral load, showing that Vemlidy is noninferior to, or at least as good as, Viread. What's more, those who switched saw improvement in creatinine clearance and other markers of kidney function as well as increased bone density at the hip and spine. Both drugs were well tolerated, and the frequency of side effects was low and similar in the two groups.

Lampertico presented longer-term follow-up results at 96 weeks. At that point, almost all participants in both groups were still on treatment. Again, viral suppression rates remained high: 95% in the group that switched to Vemlidy at the start of the study and 94% in the group that switched at 48 weeks. Just one person in each group (0.4%) had detectable HBV DNA during follow-up, and neither of them developed drug resistance.

As expected, hepatitis B surface antigen (HBsAg) loss and hepatitis B surface antibody seroconversion—considered a functional cure—were rare in both groups.

ALT liver enzyme levels continued to improve in both groups, but more so in the one that switched to Vemlidy at 48 weeks. At 96 weeks, 80% of people in the initial switch group and 86% in the delayed switch group had normal ALT.

Treatment continued to be well tolerated at 96 weeks. No one in either group experienced severe drug-related side effects or serious adverse events, and only one person (in the initial switch group) stopped treatment due to adverse events.

Looking at blood lipids, total cholesterol, harmful LDL cholesterol and triglyceride levels increased during the first 48 weeks in the group that initially switched to Vemlidy but remained stable in the group that stayed on Viread. During the second period, those who switched at 48 weeks also saw an increase while those who switched initially maintained stable levels. The researchers noted that Vemlidy probably does not raise lipid levels itself, but rather those who switch no longer benefit from Viread's lipid-lowering effect.

With regard to kidney function, creatinine clearance initially improved in the group that switched to Vemlidy at the study's outset but declined slightly in the group that stayed on Viread during the first 48 weeks of the study. During the second period, those in the initial Vemlidy group saw little further change while those who switched to Vemlidy at 48 weeks saw an improvement.

Similarly, during the first 48 weeks, bone mineral density at the hip and spine increased in the group that initially switched to Vemlidy but decreased slightly in the group that stayed on Viread. During the second period, those who switched at 48 weeks also saw an increase—especially at the spine—while those who switched at the study's outset had continued improvement.

In summary, the researchers concluded, switching from Viread to Vemlidy maintained HBV viral suppression for almost two years and was safe and well tolerated.

These findings suggest that, because both medications work equally well, the choice might be guided by which side effects are of greater concern for a particular individual.

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