Sequential treatment with entecavir and lamivudine results in rebound of hepatitis B virus

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A two-year trial of entecavir followed by lamivudine (LAM) in patients with chronic hepatitis B virus (HBV) infection resulted in a virologic rebound rate of 24% and 12% drug-resistance rate. Patients who continued on entecavir therapy throughout the study period had undetectable HBV DNA at the two-year endpoint. Details of this trial are published in the April issue of *Hepatology*, a journal published by Wiley-Blackwell on behalf of the American Association for the Study of Liver Diseases.

The World Health Organization (WHO) estimates that more than 2 billion people worldwide have been infected with HBV; roughly 360 million of these cases are chronic infection that could lead to liver cirrhosis and hepatocelluar carcinoma (liver cancer). LAM is the first oral antiviral agent available to treat chronic HBV infection by inhibiting disease progression. However, a 2007 study by Yuen et al. determined that long-term treatment with LAM is associated with a 76% drug-resistance rate after eight years. In recent years, studies have shown entecavir to be superior to LAM in reducing HBV DNA, with only a 1.2% drug-resistance rate after five years.

In the current trial, James Fung, M.D., and the team led by Professor Man-Fung Yuen, M.D., Ph.D., from The University of Hong Kong, investigated whether initial HBV DNA suppression by the more potent antiviral agent, entecavir, could be maintained by switching to LAM, a

less potent and lower-cost antiviral. The potential for drug-resistance and virological rebound with sequential therapy of the two antiviral therapies was also examined. "Most patients with chronic HBV require long-term antiviral treatment and some patients opt to start with LAM therapy for cost-saving reasons. Our aim was to determine the efficacy and drug-resistance profile of switching to LAM after initial entecavir treatment," said Dr. Fung.

Researchers recruited 50 patients with chronic HBV who were all initially treated with entecavir (0.5 mg) for at least six months prior to the start of the study. A normal alanine aminotransferase (ALT) level and undetectable HBV DNA were required for inclusion in the study. Participants were randomized into two arms with patients in the first arm continuing to receive 0.5 mg of entecavir daily and patients in the second arm switching to 100 mg LAM daily. Routine liver biochemistry, hepatitis B serological test, and HBV DNA measurements were performed at 0, 4, 12, 24, 48, 72, and 96 weeks.

Results showed that 100% of patients in the entecavir-only arm continued to have undetectable HBV DNA, while 24% of participants who switched to LAM experienced virological rebound. Researchers noted that virological rebound continues to increase over time as two patients showed an increased in HBV DNA at 96 weeks. Additionally, three patients (12%) developed LAM-resistance. "Prior HBV DNA suppression with entecavir did not offer any significant advantage to patients who switched to LAM," concluded Dr. Fung. "The potential cost-saving benefit of switching to LAM was not realized due to the development of resistance."

More information: "Randomized Trial of Lamivudine Versus Entecavir in Entecavir-Treated Patients with Undetectable HBV DNA: Outcome At 2 Years." James Fung, Ching-Lung Lai, John Yuen, Charles Cheng, Ringo Wu, Danny Ka-Ho Wong, Wai-Kay Seto, Ivan Fan-Ngai

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Hung, Man-Fung Yuen. Hepatology; Published Online: February 14, 2011 (DOI: 10.1002/hep.24192); Print Issue Date: April 2011.

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