

# Telbivudine – a Promising New Antiviral Agent in Patients with Chronic Hepatitis B

Andrea CIOBANU, MD

Cardiology and Internal Medicine Department, University Hospital of Bucharest, Bucharest, Romania

**C**hronic hepatitis B progression to cirrhosis and hepatocellular carcinoma is associated with persistent HBV (“hepatitis B virus”) replication. In order to diminish these end-stage complications, the main treatment target is to suppress HBV replication using antiviral therapy.

Numerous types of antiviral agents are available nowadays. Yet, there are not enough clinical data regarding the most effective and safety choice of treatment for the long term management of these patients.

Several preclinical and clinical studies showed that telbivudine has strong and specific antiHVB activity. More powerful and consistent data was then needed, in order to validate telbivudine’s efficacy, tolerability and safety.

1370 patients with HBeAg-positive or HBeAg-negative chronic hepatitis B were enrolled in the present study, in 20 countries. They were randomized to receive 600 mg of telbivudine or 100 mg of lamivudine once daily. The primary efficacy end point was to demonstrate the noninferiority of telbivudine to lamivudine regarding the therapeutic response (decreasing

the HBV DNA levels, as recommended by the current guidelines). The secondary end points included histological response, changes in serum HBV DNA levels, HBe Ag responses and normalization of the serum alanin aminotransferase levels.

Telbivudine was significantly superior to lamivudine concerning all the primary and secondary end points, among HBeAg-positive patients, at week 52 of follow-up. Telbivudine has also demonstrated its noninferiority to lamivudine among HBeAg-negative patients.

The number of serious adverse events was lower in telbivudine group than that in lamivudine group (18 versus 33 patients; 2.6% versus 4.8% respectively).

To summarize, the present study compared the efficacy and safety of telbivudine with the most widely prescribed anti-hepatitis B agent worldwide, lamivudine. Telbivudine’s characteristics have not yet been compared in clinical studies to those of other recently approved antiviral agents, such as entecavir. However, these clinical results are in favor of telbivudine as a powerful choice of treatment in patients with chronic hepatitis B.

---

*Comment on the paper:*

Lai CL, Gane E, Liaw YF, et al. – Telbivudine versus lamivudine in patients with chronic hepatitis B. *N Engl J Med* 2007; 357:2576-2588