

中文題目：貝樂克和惠立妥停藥時表面抗原小於 40 IU/mL 的病人 B 型肝炎病毒復發的發生率和相關因子

英文題目：Incidence and predictors associated with HBV relapse after cessation of entecavir or tenofovir in patients with HBsAg below 40 IU/mL

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**Background:** Our previous study demonstrated that hepatitis B surface antigen (HBsAg) less than 40 IU/ml at the end of treatment (EOT) was a predictor of sustained response after discontinuing NAs. In clinical practical, however, patients with such low HBsAg levels still have risks of hepatitis B virus (HBV) relapse.

**Aim:** To investigate the incidence and predictors associated with HBV relapse in patients with levels of EOT HBsAg  $\leq$  40 IU/mL after cessation of entecavir or tenofovir disoproxil fumarate (TDF) treatment.

**Methods:** This study recruited 112 patients with levels of HBsAg less than 40 IU/mL at EOT (62 entecavir and 50 TDF). All patients had post-treatment follow-up for at least 6 months. Post-treatment virological relapse was defined as a serum HBV DNA level greater than 2000 IU/mL, and clinical relapse was defined as an alanine aminotransferase (ALT) level greater than 80 U/L and a HBV DNA level greater than 2000 IU/mL.

**Results:** Of the 112 patients, the 5-year incidences of virological relapse, clinical relapse, and HBsAg loss were 31.3%, 21.5%, and 56.3%, respectively. Multivariate analysis showed that age, NA-experienced status, baseline HBcrAg and EOT HBsAg were associated independently with virological and clinical relapse. Baseline HBcrAg level of 3 log U/mL and EOT HBsAg level of 20 IU/mL were the optimal value for predicting HBV relapse. The 5-year virological relapse rates in patients with HBsAg at EOT  $\leq$  20 (n=61) and  $>$ 20 (n=51) IU/mL were 13.3% and 53.6% ( $p < 0.001$ ), and clinical relapse rates were 10.3% and 37.5%, respectively ( $p = 0.009$ ). The 5-year virological relapse rates in patients with baseline HBcrAg  $\leq$  3 (n=38) and  $>$ 3 (n=74) log U/mL were 13.4 and 40.8% ( $p = 0.008$ ), and clinical relapse rates were 2.6% and 31.5%, respectively ( $p = 0.003$ ). Rates of virologic and clinical relapse and HBsAg loss within 5 years were 4.2%, 0% and 81.6%, respectively in patients with a combination of baseline HBcrAg  $\leq$  3 log U/ml and EOT HBsAg level  $\leq$  20 IU/mL. No patients experienced hepatic decompensation when clinical relapse occurred with a timely retreatment.

**Conclusion:** A combination of baseline HBcrAg less than 3 log U/ml and EOT HBsAg level less than 20 IU/mL might reduce the risk of HBV relapse and guide treatment cessation in patients with CHB who achieved HBsAg  $\leq$ 40 IU/mL.