

中文題目：慢性 B 型肝炎病人接受貝樂克治療 5 年後發生肝癌的發生率和預測因子  
英文題目：The incidence and predictors of hepatocellular carcinoma beyond year 5 of entecavir therapy in patients with chronic hepatitis B

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## ABSTRACT

**Background:** A previous study demonstrated that the hepatocellular carcinoma (HCC) risk decreases beyond year 5 of entecavir/tenofovir therapy in Caucasian chronic hepatitis B (CHB) patients.

**Aim:** To study the HCC incidence beyond year 5 of entecavir therapy in CHB patients and to determine the risk factors associated with late HCC development.

**Patients and Methods:** From January 2007 to 2012, a total of 1397 nucleos(t)ide analogues (NA)-naïve CHB patients without decompensated cirrhosis and HCC within the initial 12 months under entecavir monotherapy for > 12 months were enrolled in this study. The HCC incidence and predictors were compared within and beyond year 5 of entecavir therapy.

**Results:** The cumulative incidence of HCC at year 3, 5, 7, and 10 years are 4.0%, 9.35%, 13.83% and 16.31%, respectively. HCC have been diagnosed in 95/1397 (6.8%) patients within the first year 5 and 32/613 (5.2%) patients beyond year 5 of treatment. Of the 1397 patients, the yearly HCC incidence rate was 2.34% within 1-5 years and 1.39% within 5-10 years. Of the 890 CHB patients without cirrhosis, the yearly HCC incidence rate was 0.64% within 1-5 years and 0.17% within 5-10 years. Of the 507 CHB patients with cirrhosis, the yearly HCC incidence rate was 4.6% within 1-5 years and 2.41% within 5-10 years. There was no significant difference in factors at baseline and 12 months of treatment between patients who have been diagnosed with HCC within and beyond 5 years. At year 5 of treatment, multivariable analysis showed that FIB-4 index and AFP levels were the independent risk factors for HCC development beyond year 5.

**Conclusions:** The HCC risk seems to decrease beyond 5 years of entecavir monotherapy in CHB patients with and without cirrhosis. FIB-4 index and AFP levels at year 5 of treatment were useful markers to predict HCC development beyond year 5 of entecavir therapy.