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Clinical outcomes after cessation of potent antiviral treatment in chronic hepatitis B patients

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INTRODUCTION: The aims of the present study were to assess the rates of hepatitis B virus (HBV) reactivation and to identify the predictors of relapse in CHB who discontinued entecavir (ETV) or tenofovir disoproxil fumarate (TDF) therapy.

METHODS: Between January 2015 and January 2017, 36 non-cirrhotic chronic hepatitis B (CHB) patients who had received TDF or ETV for ≥ 5 years (serum HBV DNA negative for ≥ 2 years, a liver stiffness <9 kPa using FibroScan) discontinued nucleoside/nucleotide analogues (NAs) therapy, were prospectively followed. After cessation of NAs therapy, the patients were followed up every month in the first year and then every 3-months along with standard laboratory tests including serum alanine aminotransferase (ALT), HBsAg and HBV DNA measurements. Serum HBsAg quantification was carried out at treatment discontinuation and every 3 months using the Roche Diagnostic Elecsys Kit. Relapse was defined as an episode of serum ALT elevation $>2 \times$ upper limit of normal and HBV DNA ≥ 20.000 IU/mL in two consecutive measurements that were at least 1 month apart after stopping NAs therapy. The median off treatment follow up duration was 26 months.

RESULTS: NAs treatment was discontinued in 36 patients (median age: 53 years; 25 males/11 females). At the treatment cessation, 32 patients had TDF and 4 patients had ETV therapy. CHB patients had been treated with NAs for a median duration of 77 months. Twenty-six patients had previously received other anti-HBV treatments for CHB, while 10 patients had no treatment. During the follow-up period, no patient died, developed jaundice or liver decompensation due to HBV reactivation. Relapse was occurred in 9 patients; 6 of them had relapsed in the first 6 months. The cumulative relapse rates were 2,8% at 3 months, 16,7% at 6 months, 22,1% at 12 months and 26,1% at 24 months, respectively. No significant differences in terms of HBV reactivation including age, gender, the duration of NA treatment, type of antiviral therapy, baseline serum ALT and HBV DNA levels, histological activity index and a liver stiffness and at the end of treatment quantitative HBsAg levels among patients with/without HBV reactivation. HBsAg quantitative values decrease in all patients. The ratio of CHB patients with HBsAg <100 IU / ml were 0%, 8,6%, 12% and 23,5% at the treatment cessation, at 6 months, at 12 months and at 24 months, respectively. One patient had experienced HBsAg loss after treatment cessation.

CONCLUSION: The present study showed that long-term ETV/TDF therapy with can be safely discontinued in non-cirrhotic CHB patients. HBsAg loss was rarely observed. This is probably associated with being CHB patients infected with genotype D in Turkey.

Keywords: Reactivation rates, Treatment cessation, Chronic hepatitis B (CHB), HBsAg quantification

Off-treatment serum HBsAg, HBV DNA kinetics of the non relapsers patients

