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Prospective and Randomized Comparison of Tenofovir and Entecavir in Hepatitis B Reactivation Prophylaxis in Patients Receiving Immunosuppressive Therapy

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INTRODUCTION: Current guidelines recommend the use of prophylactic nucleoside(t)ide analogs in the prevention of Hepatitis B virus(HBV) reactivation due to immunosuppressive(IS) treatments. There is no prospective randomized study evaluating the efficacy of tenofovir disoproxil fumarate(TDF) in this indication and the recommendations for its use are mainly based on the experiences in chronic HBV treatment. The aim of this study was to compare the efficacy of TDF and entecavir (ECV) in preventing HBV reactivation in patients receiving IS.

METHODS: Between 2014 and 2017, patients who were documented as HBsAg and/or Anti-HBc IgG positive through the screening before IS treatment and prescribed prophylactic antiviral(AV) treatment indication according to the guidelines, were prospectively included in the study. Patients receiving medication for chronic HBV, with hepatitis C, D and HIV infection were excluded. Patients were randomized into two groups. TDF (245mg/day) was initiated by the first and ECV (0.5mg/day) was initiated by the second group before IS. AV treatments were continued for 6-18 months after the IS, according to the HBV reactivation risk profile. The patients were followed up in three-month intervals and the rate of HBV reactivation and side effects of the drugs were compared.

RESULTS: The study included 120 patients (ECV:60, TDF:60 patients), mean age 58±12 years(23-85). There was no significant difference between the groups with respect to age and gender. HBsAg (ECV:51.7%, TDF:63.3%), Anti-HBcIgG (ECV:48.3%, TDF:36.7%), HBeAg (ECV:5%, TDF:3,3%), HBV DNA positivity (ECV:33.3%, TDF: 46.6%) and reactivation risk profiles (63.9% medium risk in both groups and 36.1% high risk) were similar. Whereas 41(68.3%) patients in the group EVC and 37(61.7%) patients in the group TDF completed their prophylactic AV treatments. Patients received immunosuppressive therapy for mean of 25.3 ± 17.4 (23.5 ± 16.3 in the ECV and 27.2 ± 18.4 in the TDF group) weeks. The duration of prophylactic AV treatment after IS treatment was 11.6 ± 2.8 months in the ECV and 11.2 ± 2.8 months in the TDF group (p = 0.47). The follow-up period after AV treatment was 12.8 ± 5.6 months in the ECV and 12.2 ± 4.4 months in the TDF group (p = 0.62). HBV reactivation was detected in neither of the groups during prophylactic treatment and after AV treatment was discontinued. In the group TDF, the treatment, during the fourth month, was discontinued due to severe itching and skin rashes in 1 patient. In the group ECV, 10 (16.7%) (mostly insomnia, headache and nausea in 2 patients), in the group TDF 14 (23.3%), (mostly insomnia in 4 patients, itching in 3 patients) drug-related side effects were observed in patients (p=0,31).

Discussion: ETC and TDF are effective drugs to prevent HBV reactivation in HBsAg and/or HBcIgG positive patients treated with IS, and there is no difference with respect to the risk of reactivation and side effects.

Keywords: Hepatitis B, Immunosuppressive therapy, Reactivation, Prophylaxis, Tenofovir, Entekavir