O092
Oral Session
Hepatitis B treatment and management

EFFICACY AND SAFETY OF TENOFOVIR TREATMENT AT 240 WEEKS IN PATIENT WITH CHRONIC HBV INFECTION

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Objective: Tenofovir disoproxil fumarate (TDF) is an orally administered ester prodrug of tenofovir, a nucleotide reverse transcriptase inhibitor. In CHB, the efficacy of TDF against HBV has been evaluated in two large randomized, phase III clinical studies in hepatitis B e antigen (HBeAg)-negative or HBeAg-positive adults, with compensated liver function.The aim of the present study was to evaluate efficacy and safety of Tenofovir in patients with chronic hepatitis B both HBeAg positive and negative.

Methods: We enrolled 130 patients with CHB (95 male; 35 female; median age:52 years old; 80% Caucasian, 20% non-caucasian; 40% naive and 60% previously treated (80% with viral suppression while 20% with viral relapse); 84% HBeAg negative while 16% HBeAg positive) undergoing TDF 300mg/daily or according to Creatinine Clearence (CrCl measured on MRDR five variables formula). In those subjects we evaluated at the following time points T0,T1,T3,T6,T9 and there after every three months for at least 240 weeks the following parameters: HBV-DNA (RT-PCR), CrCl, Serum Creatinine, BUN, Transaminasis, Microalbuminuria, Phosphoremia. DXA test was performed three times during the study period.

Results: Viral suppression was reached in all switched patients within 3 months. No viral resistance or relapse were found during follow-up. 12 out 35 HBeAg positive patients had a seroconversion throughout 2 years of therapy. No statistical significant difference were found in Creatinine Clearence or Creatinin serum levels or BUN in all time points. 1 female patient had microalbuminauria due to kidney stones after 2 years treatment. Only three patients showed light changes in BMD. No change in phosphoremia occurred.

Conclusion: In conclusion TDF at 5 years treatment maintains effective suppression of HBV DNA with no evidences of viral relapse or resistance. Further it seems not to be associated with statistical significant change in BMD or renal function in patients with chronic hepatitis B throughout 5 years follow-up despite previous report.