Conclusions: CU-HCC and REACH-B scores were significantly lower after 1-year of AVT and were maintained thereafter. CU-HCC and REACH-B scores after 1-year of AVT independently predicted the risk of HCC development in patients with CHB in whom AVT was initiated.

Keywords: Hepatocellular carcinoma, Chronic hepatitis B, Antiviral therapy, Risk prediction model

O-047

Improved Bone and Renal Safety at 1Year after Switching from TDF to TAF: In Chronic HepatitisB(CHB) Patients from East Asia

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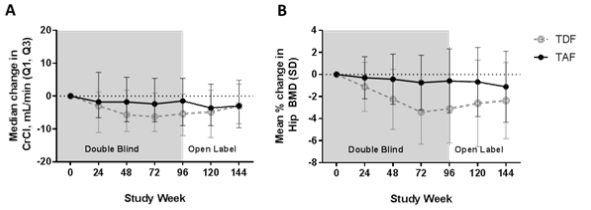
Aims: TAF has shown similar efficacy to TDF with less bone and renal effects in 2 large multinational Phase 3 studies after 96weeks(2 years) of double-blind (DB) treatment. Here we evaluated efficacy and safety, including bone and renal parameters, in the subset of patients from East Asia(EA) who completed 2years of DB treatment with TAF 25mg or TDF 300mg once daily and were switched to open label(OL) TAF 25mg once daily for 1year.

Methods: In 2 identically-designed studies, 1298 CHB patients who were HBeAgnegative (Study 108; N=425) or HBeAg-positive(Study 110; N=873) were randomized and treated. At Week96, 540(42%; TAF 360; TDF 180) patients including 240(18%; TAF 156; TDF 84) EA patients, had completed 2years of DB TAF or TDF treatment and been switched to OL TAF. Safety including bone(serial DXA scans of spine and hip) and renal(CrCl by Cockcroft-Gault [$eGFR_{CG}$]) parameters, viral suppression and biochemical response were assessed at Year 3.

Results: In EA patients on DB TDF switched to OL TAF(TDF®-TAF), $eGFR_{CG}$ improved at Year 3 vs. Year 2 (median [Q1, Q3] change = +3.0 [-3.0, +8.4] ml/min); and was stable in those continuing TAF(TAF®TAF)(figure). BMD also improved at Year 3 vs. Year 2 in TDF®TAF patients (mean[SD]% change: spine = +2.2%[3.48]; hi*P*=+0.7%[2.44]) while BMD changes were stable for TAF®TAF patients (figure). High rates of virologic control (HBV DNA<29IU/mL) were maintained in those on treatment at Year3 vs Year2(TDF®TAF 96% and 95% and TAF®TAF 90% and 93%); ALT normalization (AASLD criteria) increased in TDF®TAF patients and was similar to TAF®TAF patients at 1 year following switch(46% vs 42%; M=F).



Conclusions: EA patients switched to TAF after 2 years of TDF had improved bone and renal safety; virologic control was maintained and ALT normalization increased. The results in EA patients are comparable to those seen in the overall population.

Keywords: CHB, TDF, TAF, Switch

O-048

Safety and Efficacy at 1-Year after Switching from TDF to TAF in CHB Patients with Risk Factors for TDF Use

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Aims: Tenofovir alafenamide (TAF), a new prodrug of tenofovir (TFV), is now a preferred treatment in the 2017 EASL HBV Guidelines, and may be particularly useful in patients with risk factors for TDF associated renal and bone effects. We assessed the 1 year safety and efficacy in CHB patients with TDF risk factors who were switched from TDF to TAF.