

## Validation of the Easl 2017 Clinical Practice Guidelines Criteria for Switching HBV Patients LONG-TERM Treated with Tdf to Etv or Taf

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### Abstract Text

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**Background:** The 2017 EASL Clinical Practice Guidelines recommend Tenofovir Alafenamide (TAF) or Entecavir (ETV) instead of Tenofovir Disoproxil (TDF) in chronic HBV patients older than 60 years, or with bone disease or with renal disease. Aim of the study was to define the proportion of CHB patients currently treated with TDF in two European centers that should be switched to TAF to prevent or minimize bone and renal toxicities.

**Methods:** All consecutive chronic HBV patients on TDF before 31 Dec 2017 were enrolled in a cross-sectional study at the control blood sample, between Jan and 1<sup>st</sup> May 2018. GFR was assessed by Cockcroft-Gault formula; last spine DEXA scans, Vit D, and PTH levels were used.

**Results:** 565 patients were enrolled: 62 (18-91) years-old, 92% Caucasian, 92% HBeAg negative, 77% genotype D, 75% males, 40% cirrhotics, 33% arterial hypertension, 10% diabetes, BMI 25 (16-46) kg/m<sup>2</sup>, 95% undetectable HBV DNA, 91% normal ALT, 53% previously exposed to Lamivudine or Adefovir. They were treated by TDF for 96 (3-149) months, 33% on a reduced daily dose: 9% *ab initio* (90% NUC-exposed) and 24% after 33 (1-103) months of TDF (69% NUC-exposed), following a GFR decrease in 65% and hyperphosphaturia appearance in 35%. Out of 258 NUC-naïve subjects who started TDF 245 mg/day, 42 (16%) have reduced dose after 38 (1-101) months due to GFR in 69%. Over the entire enrolled population, 21% had GFR <60 mL/min (77% already on a reduced TDF dose), 19% low serum phosphate, 6% increased albuminuria, 6% moderate dipstick proteinuria. 4% had Vit D <15 ng/ml, 20% elevated PTH, 13% osteoporosis and 62% on Vit D supplementation from 49 (1-221) months. By applying the EASL 2017 criteria, 55% were >60 years, 17% had osteoporosis or were steroid-treated, and 36% had renal disease. Overall, 66% had at least one criterion, 8% all three criteria, 12% age and bone criteria and 10% bone and renal criteria. 28% met both the age and renal criteria.

**Conclusion:** A significant proportion of CHB patients on long-term TDF in a real-life setting fulfills the EASL 2017 recommendations to switch to ETV or TAF. Besides, TDF dose reductions due to renal alterations are required in many of these patients.

### Disclosures

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Maria Buti – Gilead: Speaking and Teaching

Pietro Lampertico – Gilead: Speaking and Teaching; BMS: Speaking and Teaching; ROCHE: Speaking and Teaching; GSK: Speaking and Teaching; Janssen: Speaking and Teaching; Abbvie: Speaking and Teaching; MSD: Speaking and Teaching; Arbutus: Advisory Committee or Review Panel; Arrowhead: Advisory Committee or Review Panel

The following people have nothing to disclose: Alessandro Loglio, Luisa Roade, Marta Borghi, Roberta Soffredini, Floriana Facchetti, Dhanai Di Paolo, Maria DEL MAR Riveiro Barciela, David Tabernero

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