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Efficacy, durability, and tolerability of dolutegravir/lamivudine and dolutegravir/rilpivirine for the treatment of HIV in a real-world setting in Belgium

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Abstract
Objectives: A paradigm shift from three-drug regimens to two-drug regimens (2DRs) is currently taking place in real-world clinical practice. This study aimed to describe the efficacy, durability, and tolerability of dolutegravir (DTG)/lamivudine (3TC) and DTG/rilpivirine (RPV) in a real-world setting. Methods: This was a retrospective, observational, multicentre (ten centres in Belgium) study involving adult treatment-naïve and treatment-experienced people living with HIV on DTG/3TC or DTG/RPV between 1 January 2019 and 30 September 2020. The primary endpoint was rate of virological suppression (VS; plasma HIV-1 viral load [VL] <50 copies/ml) using an on-treatment analysis. Main secondary endpoints included the proportion of patients that experienced loss of VS (LVS; defined as two consecutive HIV-1 VLs of >200 copies/ml after initially achieving VS) and a resistance analysis at the time of LVS; rate, incidence, and reasons for discontinuation of treatment (stopping treatment or changing any component of the 2DR); and change in weight, along with the proportion of patients reporting a >10% weight gain. Ordinal logistic regression analysis examined associations between baseline variables and >10% on-treatment weight gain. Results: Overall, 948 patients were included, of whom 734 (77%) were on DTG/3TC and 214 (23%) were on DTG/RPV. Baseline characteristics included 54% aged ≥50 years, 31% female, 31% Black sub-Saharan African, 95% treatment-experienced, and 8% with HIV-1 VL ≥50 copies/ml. Through 48 weeks, the rate of VS for the overall cohort was 98.3% (99.1% with 3TC; 96.2% with RPV). LVS was observed in 0.5% (n = 5) of the overall population (n = 1 [3TC group], n = 4 [RPV group]). There were 40 treatment discontinuations (4.2%, n = 27 [3TC group]; n = 13 [RPV group]), corresponding to an incidence of 4.7 per 100 patient-years. The most common reason for discontinuation was an adverse event (1.4%), with neurotoxicity the most frequent (0.5%). Median on-treatment weight gain at week 48 was 1 kg (interquartile range [IQR] −1–3) overall, 1 kg (IQR −1–3) in the 3TC group, and 2 kg (IQR 0–4) in the RPV group. A >10% weight increase was observed in 6.3% of patients. Regression analysis showed that being on a tenofovir disoproxil fumarate-based regimen prior to 2DR initiation was the only variable associated with a >10% increase in weight from baseline (odds ratio 3.48; 95% confidence interval 1.13–10.68; p = 0.038). Conclusion: In this real-world analysis, the 2DRs analysed were effective, durable, and safe for both treatment-naïve and treatment-experienced patients. A slight increase in weight was associated with these regimens. © 2022 British HIV Association.

Author Keywords
dolutegravir/lamivudine; dolutegravir/rilpivirine; HIV; real-world data; virological suppression

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