Switch for a long-term success

OC67 REASONS FOR DISCONTINUATION OF SINGLE-TABLET REGIMEN RILPIVIRINE/EMTRICITABINE/TENOFOVIR ALAFENAMIDE (RPV/FTC/TAF) IN THE ERA OF 2ND-GENERATION INSTIS

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Background The triple regimen of RPV/FTC/TAF was recommended in the past both as initial and switch strategies in people living with HIV (PWH) and largely adopted in clinical practice due to its safety, tolerability, efficacy and convenience. We report on the durability of this single tablet regimen and the reasons for treatment discontinuation (TD) in the INSTI era.

Methods Retrospective and observational study in PWH consecutively enrolled on RPV/FTC/TAF in 6 large HIV clinics, in Northern Italy. The primary composite endpoint was TD defined as any reason of discontinuation (including virological failure (VF), as confirmed HIV RNA >50 copies/mL or any values followed by a switch). Survival analysis with Kaplan-Meier estimator was used to assess the probability of treatment discontinuation over time.

Results A total of 2658 PWH were included in the study, 75% were males, 45% heterosexual, 36% MSM, and 80% were born in Italy. Median nadir (IQR) CD4 count was 308 (183-453) cells/ml and 20% had AIDS. At study entry, median age (IQR) was 48 (40-45) years, median CD4 count (IQR) was 660 (481-870) cells/ml and 68% had received 3 or less treatment lines. Overall, 82% of PWH had switched from other effective regimens (NNRTI-, PI- and INSTI-based triple options in 86%, 3% and 2.4%, respectively). A total of 1497 (56.3%) of subjects discontinued this regimen. The major reasons for stopping were simplification to 2-drug regimens (51.5%), drug interactions (16%), toxicity (5.6 %), lost to follow-up (4.6%), side effects (3.2%) and pregnancy (2.6%), while VF occurred in 4.4% of individuals. A total of 2.3% of individuals died during the follow-up. Among those who discontinued, 57.4% were switched to 2-drug INSTI-based regimens (i.e. DTG/3TC, DTG/RPV and CABO/RPV LA for 49.7%, 33% and 9.1%, respectively), while the remaining subjects mostly switched to 3-drug INSTI-based regimens (27%). For those continuing on RPV/FTC/TAF, median (IQR) follow-up since this regimen initiation was 6 (5-7) years.

Conclusions RPV/FTC/TAF demonstrated a high virological efficacy and durability as switch strategy in real life. TD was largely driven by simplification to 2-drug regimens or shift to a regimen with a higher barrier to resistance, while virological failure was infrequent.

OC68 CLINICAL OUTCOMES IN PWH SWITCHING FROM ORAL COMBINATIONS WITH DOLUTEGRAVIR (DTG) + LAMIVUDINE (3TC) OR RILPIVIRINE (RPV) TO BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE (B/F/TAF): DATA FROM THE ITALIAN ICONA FOUNDATION COHORT (OPTIMIZE-BIC ANALYSIS)

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Background Data on the effectiveness and durability of B/F/TAF in people with HIV (PWH) switching from DTG-based two-drug oral regimens (2DR) are limited. We aimed to characterize treatment-experienced PWH switching from DTG-based 2DR to B/F/TAF and to evaluate virological, immunological, and metabolic outcomes.

Methods OPTIMIZE-BIC (GS-IT-380-7670) is a retrospective analysis including PWH from the ICONA cohort who switched from DTG+3TC or DTG+RPV (single- or multi-tablet regimens) to B/F/TAF, between Jul-2019 and Apr-2025, regardless of HIV-RNA at switch. We included only PWH with ≥1 HIV-RNA measurement post-switch. Participants were stratified by HIV-RNA at switch: <50 copies/ml (uVL) or ≥50 copies/ml (dVL). The primary endpoint was virological suppression (HIV-RNA <50 copies/ml) at the last follow-up. Secondary endpoints included time to: -virological failure (VF, 2 consecutive HIV-RNA >50 or single >1000 copies/ml followed by ART-change) among uVL; -virological suppression (VS) among dVL; -treatment discontinuation (TD) for any reason and for toxicity. Changes in CD4 count, CD4/CD8 ratio, liver enzymes, and lipid profile were assessed. Kaplan–Meier methods and mixed linear regression models were used.

Results Eighty-three PWH were included; median age 48 years (IQR 38–58), 69.9% male, and median ART exposure of 7.7 years (IQR 3.6–11.4). At switch, 47 (56.6%) were in the uVL group and 36 (43.4%) in the dVL group (table 1). After a median follow-up of 1.4 years (IQR 0.6–2.6), overall 74/83 PWH (89.2%, 95%CI 80.4–94.9) had HIV-RNA <50 copies/mL at last observation.

In the dVL group, 83.3% (95%CI 67.2–93.6) had HIV-RNA <50 cps/ml at last assessment. Median time to suppression was 3.5 months (95%CI 2.8–5.3), with 81.8% (95%CI 67.2–92.6) of PWH reaching VS by 1-year (figure 1A).