

Long-Term Effectiveness and Safety of bictegravir/tenofovir alafenamide/emtricitabine in women living with HIV in Argentina

Ciencia Clínica - Poblaciones especiales

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Introducción. Women living with HIV (WLWH) have been historically underrepresented in both clinical and real-world studies, which has limited the availability of specific evidence and generated knowledge gaps regarding their response to antiretroviral therapy (ART). In this context, evaluating the long-term effectiveness, safety, and metabolic impact of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in WLWH is of particular relevance. **Materiales y métodos.** Subanalysis of the BICTARG study, a retrospective study conducted in Argentina between 2019 and 2024, including WLWH who switched to B/F/TAF. Over four years, we assessed virological outcome (virological suppression defined as HIV RNA < 50 copies/mL), adverse events, and metabolic parameters (total cholesterol, HDL, LDL, triglycerides, and fasting glucose). **Resultados.** Among 818 WLWH who switched to B/F/TAF, the median (IQR) age was 47 (41-53) years. At baseline, 78% had virologic suppression and median (IQR) CD4+ T-cell was 597 (393-840) cell/mm³. Half had at least one comorbidity; the most frequent were dyslipidemia (44.5%), osteopenia-osteoporosis (30.1%), obesity (26.6%), and hypertension (24.7%). The main reasons for switching were simplification (57%), prevention of toxicity (24%), and current toxicity (17%). Previous regimens included: 39% boosted protease inhibitors; 32% non-nucleoside reverse transcriptase inhibitors; and 23% integrase inhibitors. The median (IQR) prior to switching to B/F/TAF for total cholesterol, HDL, LDL, and triglycerides (mg/dL) was 193 (162-224), 53 (44-64), 112 (91-137), and 117 (85-166), respectively, and at 48 months was 206 (163-235), 55 (45-66), 119 (83-146), and 123 (99-187). Median (IQR) fasting glucose at baseline was 90 (84-97) mg/dL and 90 (89-94) mg/dL at 48 months. No statistically significant changes were observed in the metabolic parameters evaluated. Virological suppression rates at 12, 24, 36, and 48 months were 96%, 96%, 99%, and 100%, respectively. No virological failures occurred, and adverse events were reported in < 1%. **Conclusiones.** This subanalysis represents the first Argentine cohort exclusively composed of WLWH receiving B/F/TAF. In this population, B/F/TAF demonstrated durable virological suppression, a favorable safety profile, and a neutral metabolic impact over four years of follow-up.