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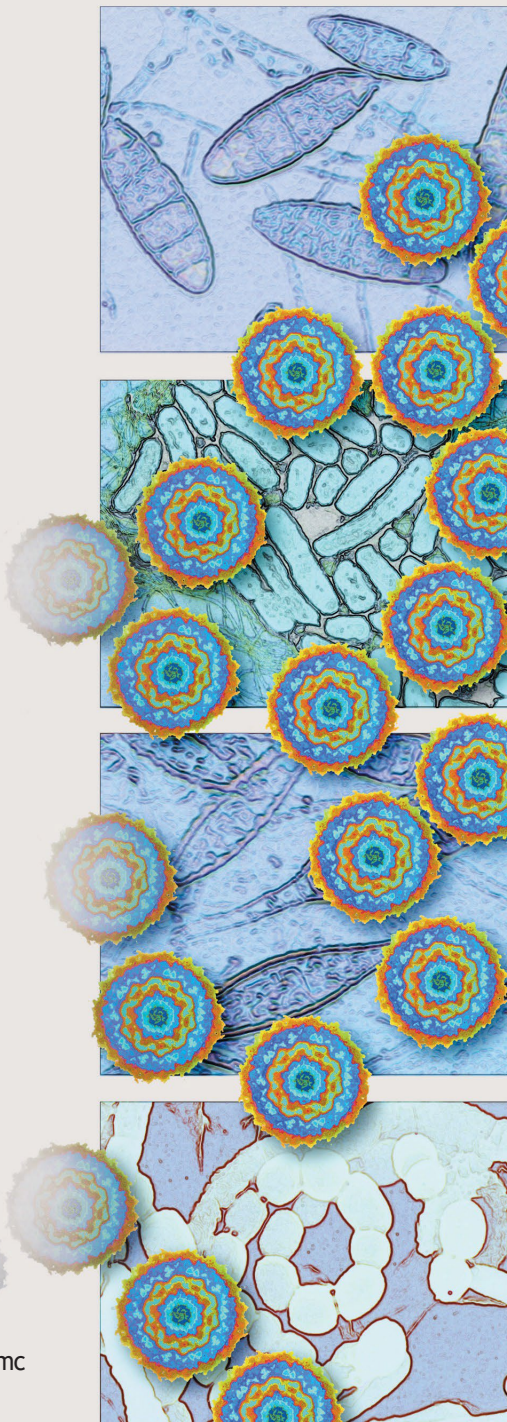

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P-043. CHANGES IN PATIENT-REPORTED NEUROPSYCHOLOGICAL OUTCOMES IN VIROLOGICALLY SUPPRESSED PERSONS WITH HIV SWITCHING TO DTG/3TC OR BIC/FTC/TAF: A SUBSTUDY OF THE PASO-DOBLE RANDOMIZED CLINICAL TRIAL

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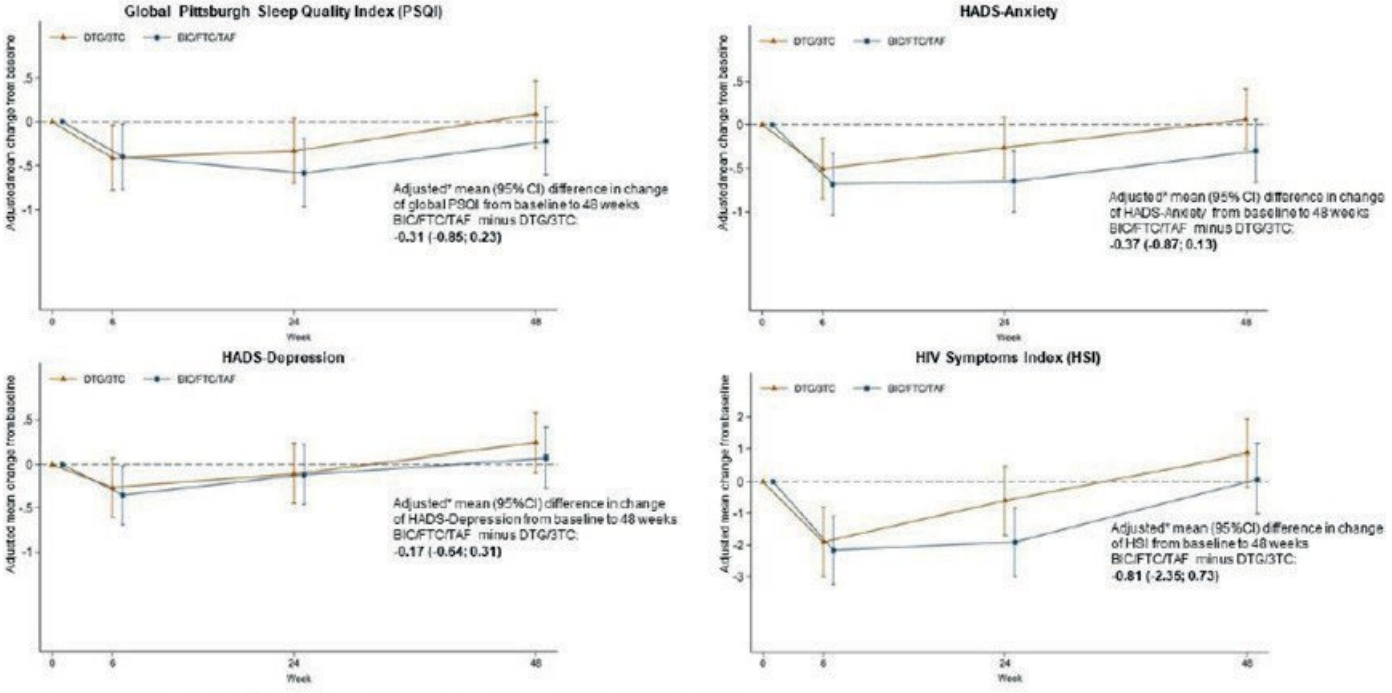
Introduction: PASO-DOBLE (ClinicalTrials.gov NCT04884139) demonstrated that DTG/3TC was noninferior and produced less weight gain than BIC/FTC/TAF in virologically suppressed persons with HIV (PWH). Second-generation integrase inhibitors have been associated with adverse neuropsychological effects, which may be difficult to detect. Patient-reported outcomes measures (PROMs) capture subjective perception of health through questionnaires. We used PROMs assessing neuropsychological symptoms in PWH from PASO-DOBLE.

Methods: Clinically stable, virologically suppressed PWH on regimens containing ≥ 1 pill/day, boosters, or drugs with cumulative toxicity such as efavirenz or TDF were randomized (1:1) to switch stratifying by TAF in the regimen discontinued and sex. Pittsburgh Sleep Quality Index (PSQI), Hospital Anxiety and Depression Scale (HADS), and HIV Symptoms Index (HSI) were assessed at baseline, 6, 24, and 48 weeks. Increasing scores in the evaluated PROMs represent a subjective worsening of health status. Clinically relevant thresholds were: PSQI > 5 (poor sleep), and HADS-Anxiety/ HADS-Depression > 8 (mild) or > 11 (moderate). Differences from baseline within each arm and between arms were assessed.

Results: Between 14-July-2021 and 24-March-2023, 553 PWH initiated DTG/3TC (n = 277) or BIC/FTC/TAF (n = 276), including 155 (28%)

Figure 1. Mean adjusted* changes from baseline in Pittsburgh Sleep Quality Index (PSQI), Hospital Anxiety and Depression Scale (HADS), and HIV Symptoms Index (HSI) validated tools



*Adjusted for presence of TAF in previous regimen, sex, age, race, and baseline PROMs values

with TAF in previous regimen and 147 (27%) women. At baseline, > 50% had poor sleep, nearly 25% anxiety, and approximately 10% depression (Table). Adjusted (presence of TAF in previous regimen, sex, age, race, and baseline PROMs values) mean changes in PROMs from baseline are shown in Figure 1. Within each arm, there were significant decreases from baseline in global PSQI, HADS-Anxiety, and total HSI scores at 6 weeks, but differences disappeared at 48 weeks. Between arms, there were no differences in changes from baseline in PROMs or in the proportions of participants above clinically relevant thresholds at the different time points evaluated.

Conclusions: Sleep quality and anxiety were very common in this clinically stable cohort. PROMs initially improved after switching to either arm, therefore diluting the neuropsychological symptoms relative to the pre-switch status. There were no differences between arms in changes in neuropsychological PROMs from baseline.