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1. Background

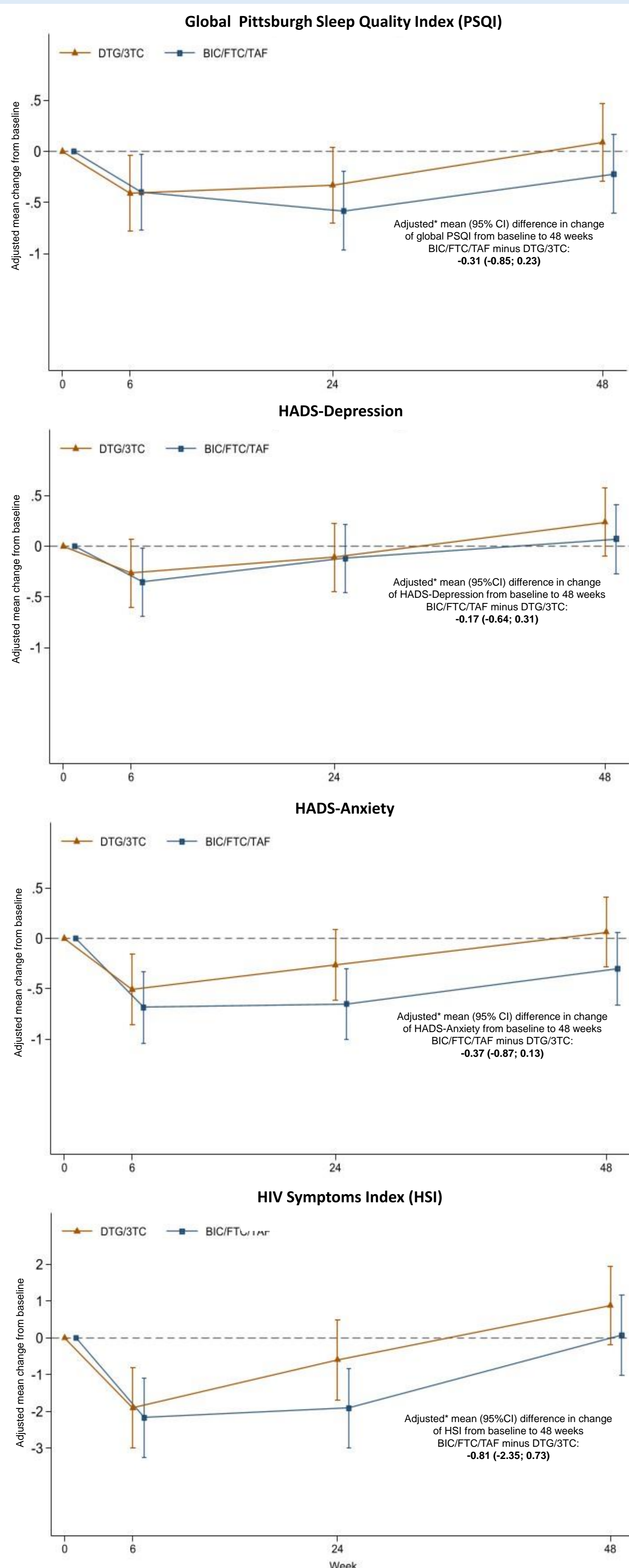
PASO-DOBLE (ClinicalTrials.gov NCT04884139) demonstrated that DTG/3TC was noninferior and produced less weight gain than BIC/FTC/TAF in virologically suppressed persons with HIV (PWH). Second-generation integrase inhibitors have been associated with adverse neuropsychological effects, which may be difficult 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.

2. Methods: Entry criteria & Patient Reported Outcomes (PROMs)

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.

4. Results: Mean adjusted* changes from baseline in PSQI, Hospital Anxiety and Depression Scale (HADS), and HSI tools



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

3. Results: Patient Reported Outcomes (PROMs) at baseline

	DTG/3TC (n=277)	BIC/FTC/TAF (n=276)	P-value
Global Pittsburgh Sleep Quality Index (PSQI)			
Mean (standard deviation)	6.3 (3.5)	5.5 (3.5)	0.011
Proportions (95%CI) of scores >5 (poor sleep)	61.9 (55.3-68.2)	55.1 (48.4-61.7)	0.141
HADS-Anxiety			
Mean (standard deviation)	5.4 (3.7)	5.3 (3.9)	0.695
Proportions (95%CI) of scores >8 (mild anxiety)	24.2 (19.2-29.7)	24.4 (19.4-29.9)	0.959
Proportions (95%CI) of scores >11 (moderate anxiety)	9.9 (6.6-14.1)	9.1 (6.0-13.1)	0.750
HADS-Depression			
Mean (standard deviation)	3.2 (3.1)	3.6 (3.6)	0.173
Proportions (95%CI) of scores >8 (mild depression)	9.6 (6.4-13.7)	12.4 (8.7-16.8)	0.301
Proportions (95%CI) of scores >11 (moderate depression)	3.0 (1.3-5.7)	6.9 (4.2-10.6)	0.033
HIV Symptoms Index (HSI)			
Mean total scores (standard deviation)	13.9 (11.5)	12.5 (11.5)	0.158

5. Conclusions

Poor sleep quality and anxiety were very common in this clinically stable cohort.

There was an initial transient improvement in patient-reported neuropsychological outcomes after switching to DTG/3TC or BIC/FTC/TAF, but at 48 weeks there were no differences within or between arms.