Session: P-47. HIV: Treatment

Background. Black Americans are disproportionately impacted by HIV. The BRAAVE 2020 study, evaluated the safety and efficacy of switching to the guidelines-recommended single-tablet regimen bictegravir, emtricitabine, tenofovir alafenamide (B/F/TAF) in Black adults through week (W) 48.

Methods. Adults with HIV who self-identified as Black or African American and were virologically suppressed on 2 NRTIs plus a 3rd agent were randomized (2:1) to switch to open-label B/F/TAF once daily or stay on their baseline regimen (SBR). Prior virologic failure was allowed except failure on an INSTI. Prior resistance to NNRTIs, PIs and/or NRTIs was permitted except K65R/E/N, ≥3 thymidine analog mutations or T69-insertions. Primary INSTI-resistance was excluded. SBR participants switched to B/F/TAF at W24. Efficacy was assessed at the W24 (1° endpoint, noninferiority margin 6%) and at W48 as the proportion with HIV-1 RNA ≥ 50 c/mL by FDA Snapshot and by changes in CD4 count. Safety was assessed by adverse events (AE) and lab results.

Results. 495 were randomized and treated (B/F/TAF n=330, SBR n=165): 32% cis women, 2% transgender women, median age 49 y (range 18-79), 10% had pre-existing M184V/I mutation (Table 1), and 62% lived in the US South. At W24, 1% (2/328) on B/F/TAF vs 2% (3/165) on SBR had HIV-1 RNA ≥50 c/mL (difference -1.2%; 95% CI -4.8% to 0.9%) demonstrating noninferiority of B/F/TAF; 2 with pre-existing primary INSTI resistance were excluded from analysis. 163 assigned to SBR completed W24 and switched to B/F/TAF (SBR to B/F/TAF). At W48 1% (3/328) originally randomized to B/F/TAF and 0 SBR to B/F/TAF had HIV-1 RNA ≥ 50 c/mL (Table 2). The presence of baseline NRTI resistance did not affect the efficacy of B/F/TAF. No treatment emergent resistance was detected. The mean (SD) changes in CD4 were +7 cells/mm^3 (189) for B/F/TAF and -8 cells/mm^3 (159) for SBR to B/F/TAF. Median (IQR) weight increased 0.9 kg (-1.5, 4.1) and 0.6 kg (-1.0, 3.1) for B/F/TAF and SBR to B/F/TAF groups, respectively. Study drug-related AEs occurred in 10% of participants while on B/F/TAF; most were grade 1.

Table 1.

Table 1: Baseline characteristics

Characteristic	B/F/TAF (n=330)	SBR to B/F/TAF (n=165)
Age, y, median (range)	49 (18, 79)	49 (19, 70)
Sex at birth, % female	31	33
Gender identity, % cisgender	96	96
Hispanic or Latinx ethnicity, %	5	3
CD4 count, cells/μL	747 (570, 922)	758 (494, 969)
Median eGFR, mL/min (Q1, Q3)	110 (88, 132)	107 (86, 132)
Body-mass index, kg/m^2 median (Q1, Q3)	29 (26, 34)	29 (26, 34)
HIV/HBV Coinfected, %	5	2
Duration of HIV treatment, y median (Q1, Q3)	10 (6, 16)	11 (6, 18)
Baseline 3rd agent class, %		
INSTI	61	60
NNRTI	30	31
PI	9	9
Baseline NRTIs, %		
F/TAF	68	65
F/TDF	17	21
ABC/3TC	13	15
Baseline ARV resistance, %		
NRTI resistance	13	16
M184V/I	9	12
NNRTI resistance	21	19
PI resistance	11	15

Table 2.

Table 2: Switch to B/F/TAF Virologic Outcome at Week 48

	B/F/TAF (n=328)[a]	SBR to B/F/TAF (n=163)[b]
HIV-1 RNA <50 copies per mL	**310 (95%)**	**158 (97%)**
95% Confidence interval[c]	91.5% to 96.7%	93.0% to 99.0%
HIV-1 RNA ≥50 copies per mL	**3 (1%)**	**0**
95% Confidence interval[c]	0% to 3%	0 to 2%
HIV-1 RNA ≥50 copies per mL	2	0
Discontinued Due to Lack of Efficacy	0	0
Discontinued Due to Other Reasons	1	0
No Virologic Data and Last Available HIV-1 RNA <50 copies per mL	15 (5%)	5 (3%)
Discontinued Due to AE or Death[d]	8	1
Discontinued Due to Other Reasons[e]	7	3
Missing data but on Study Drug	0	1

a. 2 participants had primary INSTI mutations Y143C (n=1) and Q148K (n=1) detected in historical genotype and were excluded from the primary analysis, both continued on study and had HIV-1 RNA <50 copies/mL at Week 48.

b. 165 participants were randomized to SBR, 163 continued on study at Week 24 and switched to B/F/TAF.

c. Calculated based on Clopper-Pearson exact method

d. AEs: headache, nightmare, diarrhea, migraine (n=1 each); headache, hyperhidrosis (n=1), diarrhea, dry mouth, psychomotor hyperactivity, agitation, anxiety, insomnia (n=1), acute kidney injury (n=1, not related to study drug); abdominal distention, flatulence (n=1); subarachnoid hemorrhage (n=1, not related to study drug). Death due to gunshot wound (n=1, not related to study drug).

e. Other reasons: participant decision, investigator's discretion, lost to follow-up

Conclusion. Switching to B/F/TAF was highly effective for Black adults regardless of baseline regimen or pre-existing NRTI resistance and was associated with few treatment related AEs or discontinuations.

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1047. Weight change associated with switching to bictegravir/emtricitabine/tenofovir alafenamide in virally suppressed people with HIV

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Background. Integrase strand transfer inhibitor (INSTI) associated weight gain has been observed in a number of recent studies but with limited data on bictegravir. Here we examine weight change associated with the switch to co-formulated bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF).

Methods. We performed a retrospective analysis of consecutive PWH attending an academic outpatient clinic who received a prescription for B/F/TAF from 02/07/2018-02/07/2019 and had a baseline HIV RNA < 200 copies/mL prior to starting B/F/TAF. Baseline demographics and clinical parameters were obtained from chart review. Parameters of interest were collected for one year (at a minimum) before and one year after starting B/F/TAF. Linear mixed model analyses were conducted for PWH before/ after switch. Separate analyses were performed examining factors associated with ≥ 10% BMI increase versus < 10% increase.

Results. 156 PWH switching to B/F/TAF were identified, of whom 107 (69%) identified as men, 105 (67%) were African American. Median age was 49 years (IQR 35-57), weight 184 lb (IQR 153-208), and BMI 27.5 (IQR 23-32.3). At time of switch, 3% were underweight, 31% normal weight, 24% overweight, and 41% obese. 74% switched from INSTI-based regimen, 17% from NNRTI- and 16% from PI-based regimens. Of the INSTI, elvitegravir (54.3%) or dolutegravir (41.7%) were most frequently used. 50% were on TAF pre-switch with 28% on tenofovir disoproxil. The mixed model analysis indicated that there was not a significant shift in the mean BMI (P=0.2017) or BMI rate of change over time (P=0.792) after participants switched. 19.2% had ≥ 10% increase in BMI; and when compared to those with < 10% increase, younger age (42.8±13.8 vs. 48.9±13.2 years, P=0.036), switch from a non-PI based regimen (P=0.004), and switch from a TDF containing regimen (36.4% vs. 12.6%, P < 0.001) were associated with greater weight gain.

Conclusion. Overall, there were no significant changes in BMI between pre and post switch to B/F/TAF time periods; however the majority of PWH switched from an INSTI-based regimen. Analysis of PWH who experienced ≥ 10% increase compared to < 10% BMI increase, indicated that factors including younger age, switch from a non-PI containing regimen and switch from TDF were associated with greater weight gain.

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1048. Weight Gain after Initiation of Anti-Retroviral Therapy in Acute HIV-1.

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Background. Background: Excess weight gain with integrase strand transfer inhibitors (INSTIs) has been reported in some people with chronic HIV. In antiretroviral therapy (ART)-naïve people, greater weight gain over 18 months was reported with dolutegravir than other agents. We hypothesized that initiating an INSTI-based regimen during acute HIV infection (AHI) would result in more weight gain than a non-INSTI-based regimen, and INSTIs other than elvitegravir (EVG) would be associated with greater weight gain than EVG.

Methods. Methods: We performed a retrospective, observational, single center chart review analysis of adults with AHI (Feibig Stages 1-5) who were initiated on ART and followed for 48 (+/- 12) weeks. Changes in weight between people on INSTI- vs