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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Session: P-47. HIV: Treatment

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.

Disclosures. **All Authors**: No reported disclosures

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

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Session: P-47. HIV: Treatment

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

non-INSTI regimens were compared, and in a subgroup analysis, EVG vs non-EVG and tenofovir alafenamide (TAF) vs non-TAF were compared. Chi-square, t-test, or Wilcoxon Rank Sum test were used, when appropriate.

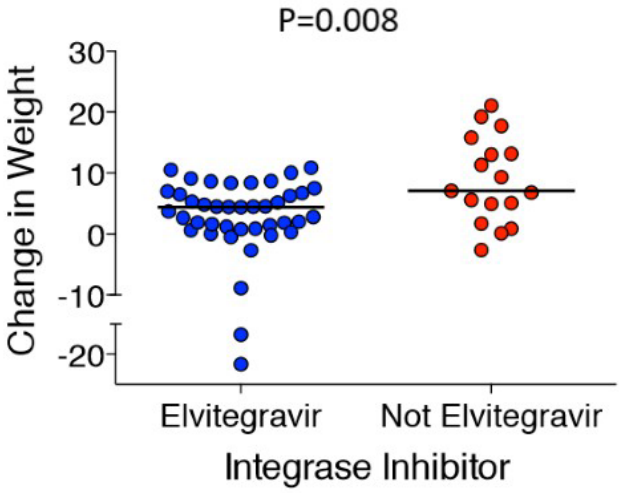
Results. Results: Baseline characteristics of the 61 participants are shown in Table 1. Overall median (IQR) weight change was 4.53 (1.22-8.36; within-group P< 0.0001) kg (Figure 1). Median weight change in 58 people initiated on INSTI was 4.66 (1.22-8.43; P< 0.0001) kg vs 1.64 (-3.08-6.57; P=0.75) kg in 3 people not on INSTI (between-group P= 0.33). Median weight change on EVG was 4.40 (0.91-6.71; P< 0.0001) kg vs 7.10 (4.97-13.15; P= 0.0001) kg for non-EVG INSTIs (between-group P= 0.008, Figure 2). Median weight change on TAF (n=33) was 2.66 (0.81-7.53; P= 0.002) kg vs 5.31 (3.72-9.34; P < 0.0001) kg in non-TAF (n=25) recipients (between-group P= 0.06). Lower baseline CD4$^+$ T cell count correlated with greater weight gain (P= 0.012). No association between weight gain and race (P= 0.930) or gender (P= 0.379) was noted.

Baseline characteristics and median weight change (kg) from baseline

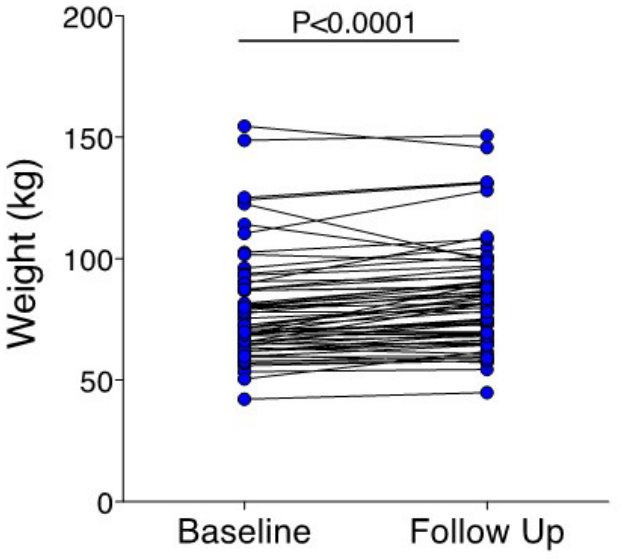
	Total	INSTI based regimen	Non-INSTI based regimen	Elvitegravir	Non Elvitegravir
No of participants	61	58	3	41	17
Race					
Black	25 (40.9)	24 (41.4)	1 (33.3)	15 (36.5)	9 (52.9)
White	35 (57.3)	33 (56.9)	2 (66.6)	25 (60.9)	8 (47.1)
Other	1 (1.6)	1 (1.7)	0 (0.0)	1 (2.4)	0 (0.0)
Ethnicity					
Hispanic	36 (59.0)	34 (58.6)	2 (66.7)	26 (63.4)	8 (47.1)
Non-Hispanic	25 (40.9)	24 (41.4)	1 (33.3)	15 (36.6)	9 (52.9)
Sex at Birth					
Male	49 (80.3)	46 (79.3)	3 (100.0)	34 (82.9)	12 (70.6)
Female	12 (19.7)	12 (20.7)	0 (0.0)	7 (17.1)	5 (29.4)
Baseline weight, kg					
	71.7(64.6-87.4)	72.7(64.7-87.5)	66.4(63.4-67.5)	75.4(64.9-90.7)	69.9(63.5-79.8)
Weight change, kg	4.53 (1.22-8.36)	4.66 (1.22-8.43)	1.64(-3.08-6.57)	4.40 (0.91-6.71)	7.10 (4.97-13.15)
Within arm p-value	P<0.0001	P<0.0001	P=0.75	P<0.0001	P=0.0001
Between-arm p-value		(P=0.33)		(P=0.008)	

Note: Data are presented as no (%) or median (IQR). The Elvitegravir and Non Elvitegravir subgroup analysis only includes patients in the INSTI based regimen

Weight change in elvitegravir vs non-elvitegravir integrase inhibitor regimen.



Overall weight gain seen over 48 weeks after initiation of antiretroviral therapy calculated using the Wilcoxon Rank Sum test.



Conclusion. People initiating ART during AHI gained weight over 48 weeks, with persons taking INSTIs gaining more weight, though this finding did not reach statistical significance due to small sample size. Amongst INSTI-treated persons, those not on EVG gained more weight than those on EVG. While the benefits of starting ART during AHI on immune system preservation and reservoir should not be underscored, risk and consequences of weight gain following ART initiation should be discussed when initiating ART during AHI.

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1049. Weight Gain in Persons Living with HIV (PLWH) Treated with Bictegravir Compared to Other Integrase Strand Transfer Inhibitors

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Session: P-47. HIV: Treatment

Background. Recent studies have given rise to the concern that some integrase strand transfer inhibitor (INSTI)-based antiretroviral therapy may lead to weight gain in PLWH. The objectives of this study were to compare the incidence of weight gain following initiation of bictegravir (BIC) compared to other INSTIs, and to assess whether any differences were associated with changes in metabolic indices.

Methods. Patients from the VA San Diego Healthcare System (VASDHS) were included in this retrospective cohort study if they were at least 18 years old and being treated for HIV with an INSTI that was started exclusively with FTC/TAF for at least 6 months. INSTI-containing regimens were excluded if initiated with non-FTC/TAF antiretroviral agents or if the patient was pregnant, using prescription weight loss drugs, or did not have weights recorded after the start of the studied regimen. The primary outcome was weight gain at 12 and 18 months after the start of the studied regimen. Secondary outcomes included changes in parameters used to define metabolic syndrome. Statistical analysis was performed using Mann-Whitney U, Chi-square, and Spearman's Rho tests.

Results. 560 patients with 809 instances of new INSTI prescriptions from VASDHS during November 2015 to October 2019 were reviewed for inclusion. Raltegravir-based regimens were excluded from analysis due to the limited number of eligible regimens. Study groups included group 1 (BIC, n=265), group 2 (elvitegravir/cobicistat, n=123), and group 3 (dolutegravir, n=35). There were no significant differences in baseline weight between groups. Median weight change at 12 months was 2.8 lbs. in group 1, 4.4 lbs. in group 2 (p=0.328 vs. group 1), and 5.3 lbs. in group 3 (p=0.133 vs. group 1). At 18 months, median weight change was 4.5 lbs. in group 1, 3.4 lbs. in group 2 (p=0.597 vs. group 1), and 7.7 lbs. in group 3 (p=0.585 vs. group 1). Within group 1, there was a significant increase in weight at 3, 6, 12, and 18 months compared to index date.

Conclusion. These results support the growing body of evidence associating INSTI use with weight gain, which was persistent over 18 months in all groups and in the context of a consistent FTC/TAF backbone in this study. No significant differences in magnitude of weight gain were observed between INSTIs.

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1050. Hepatitis C Infection amongst People who Inject Drugs (PWID): Injection Practices and Risk Factors

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Session: P-48. Hepatitis

Background. The rapidly progressing U.S. opioid epidemic has led to an increased prevalence of infections associated with injection drug use (IDU), such as Hepatitis C (HCV). Previous studies have identified a lack of screening, prevention, and treatment of HCV, which has contributed to an increase in HCV-related mortality. Transmission has been linked to unsafe injection practices. Our study aims to characterize risk factors associated with Hepatitis C (HCV) exposure amongst people who inject drugs (PWID) in Maine, a state heavily impacted by the opioid epidemic.

Methods. Data was obtained from a cross-sectional study of participants hospitalized with an IDU-associated infection at four hospitals in Maine identified as high-risk for HIV/HCV outbreaks. The Audio Computer-Assisted Self-Interview survey and medical record review were used to collect data. The components from the BIRSI 7-item score were used to assess the use of safe injection practices. HCV exposure was defined as HCV antibody positive and/or self-reported exposure. Analysis was performed using descriptive analyses and univariate regression modeling.

Results. Of the 101 participants enrolled, n=76 (75%) were identified as having exposure to HCV. Out of participants exposed to HCV, 57% reported homelessness (p=< 0.01). Participants exposed to HCV were more likely to have bacteremia during hospitalization (25%, p=.02). All participants unexposed to HCV perceived low likelihood of contracting HCV due to injecting (p=.01). Seventy-one percent of people exposed to HCV reported infrequent use alcohol pads prior to injecting (p=< 0.01) and 67% reported infrequent hand-washing (p=.09). Participants with a higher BIRSI-7 score had higher odds of exposure to HCV (OR=1.48, 95% CI 1.10-2.04).

Conclusion. The data obtained highlights significant relationships between HCV exposure and certain risk factors. Homelessness was found to be associated with HCV exposure, suggesting an opportunity for more targeted intervention within this subgroup of PWID. Unsafe injection practices as measured by the BIRSI-7 score were related to HCV exposure, indicating educational opportunities about safe injection