

Table 2. Linear Regression for the Difference of DI scores (post – pre), n =376.

Variable	Estimate	95% CI	p-value
Intercept (ref: 51 years old and Black/AA)	0.38	(0.01, 0.75)	0.05
Age	0.00	(0.00, 0.01)	0.13
White	-0.17	(-0.36, 0.02)	0.08
Other race (Hispanic/Latino, Asian, Native Hawaiian/Other Pacific Islander)	0.05	(-0.18, 0.29)	0.66
Viral suppression (Yes)	-0.17	(-0.38, 0.04)	0.11
Dolutegravir-based ART (Yes)	-0.18	(-0.50, 0.15)	0.28
Efavirenz-based ART (Yes)	0.00	(-0.34, 0.34)	1.00
NNRTI-based ART (Yes)	0.23	(-0.11, 0.57)	0.19
PI-based ART (Yes)	-0.03	(-0.37, 0.32)	0.89
Interactions between the patient's ART and Cardiovascular Meds at Baseline (Yes)	-1.42	(-1.64, -1.19)	<.0001
Interactions between the patient's ART and Hyperglycemic Meds at Baseline (Yes)	0.02	(-0.23, 0.28)	0.85
Interactions between the patient's ART and Anti-inflammatory Meds at Baseline (Yes)	-1.90	(-2.14, -1.65)	<.0001
Interactions between the patient's ART and Pain Meds at Baseline (Yes)	-1.49	(-1.85, -1.13)	<.0001
Interactions between the patient's ART and Antifungals at Baseline (Yes)	-1.05	(-1.38, -0.72)	<.0001
Interactions between the patient's ART and Hormonal Therapies at Baseline (Yes)	-0.82	(-1.16, -0.48)	<.0001
Interactions between the patient's ART and Neurologic and Psychiatric Meds at Baseline (Yes)	-1.52	(-1.72, -1.32)	<.0001
Interactions between the patient's ART and Gastrointestinal and Urologic Meds at Baseline (Yes)	-1.51	(-1.79, -1.24)	<.0001
Interactions between the patient's ART and Polyvalent Supplements at Baseline (Yes)	-0.02	(-0.21, 0.17)	0.82
Interactions between the patient's ART and Other Meds at Baseline (Yes)	-0.86	(-1.27, -0.45)	<.0001

Conclusion. Switching ART to BIC/FTC/TAF can reduce the incidence of DIs among treatment-experienced PWH who are receiving CMs for a broad range of comorbid conditions.

Disclosures. Jason J. Schafer, PharmD, MPH, Gilead (Research Grant or Support)/Merck (Grant/Research Support, Advisor or Review Panel member)/ViiV (Advisor or Review Panel member) Elizabeth Sherman, PharmD, Gilead (Grant/Research Support) Jennifer Cocohoba, PharmD, AAHIVP, BCPS, ViiV (Grant/Research Support)

1045. Treatment-Related Physical, Emotional, and Psychosocial Challenges and their Impact on Indicators of Quality of Life

Patricia De Los Rios, MSc¹; Brent Allan, MS²; Chinyere Okoli, PharmD, MSc, DIP¹; Benjamin Young, MD, PhD³; Erika Castellanos, n/a³; Garry Brough, BA Joint Hons in French/Italian⁴; Anton Eremin, MD⁵; Giulio Maria Corbelli, PhD⁶; Marvelous Muchenje, BSW, MSc, in Global Health⁷; MARTA MC BRITTON, n/a⁷; Nicolas Van de Velde, PhD¹; ¹ViiV Healthcare, Toronto, ON, Canada; ²International AIDS Society, Melbourne, Victoria, Australia; ³Global Action for Trans* Equality, Mijdrecht, Utrecht, Netherlands; ⁴Positively UK, London, England, United Kingdom; ⁵Moscow Regional AIDS Center, Moscow, Moskva, Russia; ⁶EATG NGO, Rome, Lombardia, Italy; ⁷Instituto Cultural Barong, São Paulo, São Paulo, Brazil

Session: P-47. HIV: Treatment

Background. Despite effectiveness of antiretroviral therapy (ART), some people living with HIV (PLHIV) still face barriers to daily oral ART adherence, including inconvenient scheduling, food requirements, adverse effects, and privacy concerns. We characterized treatment-related physical, emotional, and psychosocial challenges among PLHIV from 25 countries.

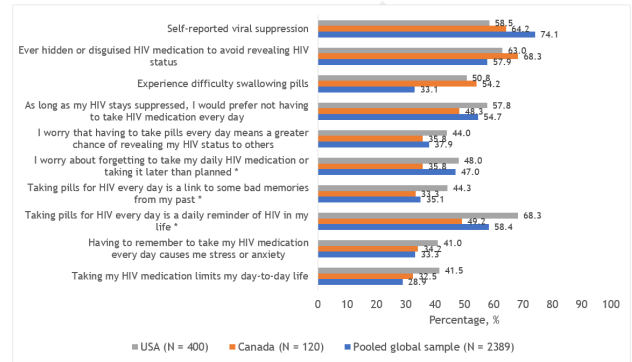
Methods. 2389 PLHIV adults on ART were surveyed in the 2019 Positive Perspectives Study, a standardized, self-reported survey of HIV patients aged 18-84 years on treatment. Data were collected on ART-related perceptions and behaviors. Descriptive and multivariable analyses were performed.

Results. Most participants were male (67.9%), aged < 50 years (70.7%), and reported viral suppression (74.1%). ART-related challenges included cueing of bad memories (58.4%), disguising HIV pills (57.9%), stress (33.3%), and difficulty swallowing pills (33.1%). Privacy and emotional challenges were generally similar between the USA and Canada (Figure 1). In the pooled sample, those who felt limited by their ART had higher odds of reporting suboptimal overall health (AOR 1.90, 95%CI:1.57-2.29), treatment dissatisfaction (AOR 2.21, 95%CI:1.82-2.69), and suboptimal adherence (AOR 1.90, 95%CI:1.57-2.29). Difficulty swallowing, any side effects, and privacy concerns were associated with increased odds of suboptimal overall health (AOR 2.10, 1.88, and 1.43, respectively) and suboptimal adherence (AOR 2.51, 1.50, and 1.87, respectively); all P< 0.05; results for other outcomes are in Figure 2. Overall, 12.6% (302/2389) had shared their HIV status solely with their primary HIV provider, whereas 6.8% (163/2389) “always” shared their HIV status. Only 52.0% were comfortable discussing ART-related privacy concerns with providers, although 29.0% overall missed ≥1 ART dose in the past month from privacy concerns. Overall, 54.7%

preferred a nondaily regimen if their HIV stays suppressed, while 72.3% were open to ART with fewer therapies.

Figure 1

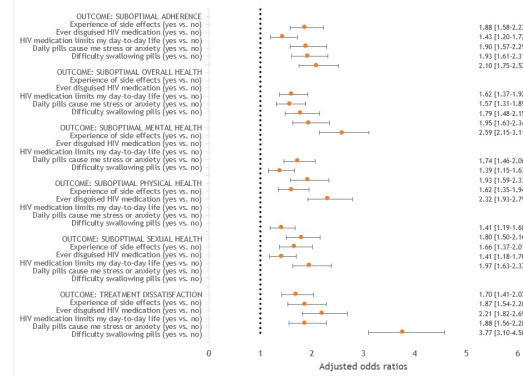
Figure 1. Percentage of people living with HIV aged ≥18 years from 25 countries who reported various physical and psychosocial challenges with their treatment, Positive Perspectives Study, 2019.



Asterisks (*) indicate statistically significant differences between the USA and Canada at P<0.05 using Chi squared tests.

Figure 2

Figure 2. Adjusted odds ratios of the relationship between various treatment challenges and poor health and treatment dissatisfaction outcomes among people living with HIV aged ≥18 years from 25 countries, Positive Perspectives Study, 2019.



All analyses were adjusted for age, gender, race, education, region, and duration of disease. Suboptimal adherence was defined as a report of ≥1 reason for which the respondent missed ART doses ≥5 times within the past month.

Conclusion. This study identified several challenges with ART among PLHIV, underscoring the need for increased flexibility of ART delivery to meet diverse patient needs. Addressing these needs may improve overall health outcomes for more PLHIV on therapy.

Disclosures. Patricia De Los Rios, MSc, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee) Chinyere Okoli, PharmD, MSc, DIP, ViiV Healthcare (Employee) Benjamin Young, MD, PhD, ViiV Healthcare (Employee) Garry Brough, BA Joint Hons in French/Italian, ViiV Healthcare (Employee, Independent Contractor, Other Financial or Material Support, Speakers Fees and Honoraria) Anton Eremin, MD, ViiV Healthcare (Advisor or Review Panel member) Marvelous Muchenje, BSW, MSc, in Global Health, ViiV Healthcare Canada (Employee) Nicolas Van de Velde, PhD, GlaxoSmithKline (Shareholder)ViiV Healthcare (Employee)

1046. Week 48 Outcomes from the BRAAVE 2020 Study: A Randomized Switch to B/F/TAF in African American Adults with HIV

Debbie Hagins, MD¹; Princy Kumar, MD²; Michael Saag, MD³; Anson K. Wurapa, MD⁴; Indira Brar, MD⁵; Daniel Berger, MD⁶; Olayemi Osiyemi, MD⁷; Corri Lynn Hileman, MD⁸; Moti Ramgopal, MD FACP FIDSA⁹; Cheryl McDonald, MD¹⁰; Christiana Blair, MS¹¹; Kristen Andreatta, MSc¹²; Sean E. Collins, MD, MS¹³; Diana M. Brainard, MD¹⁴; Hal Martin, MD, MPH¹⁵; ¹Coastal District Care Clinic, Savannah, Georgia; ²Georgetown University School of Medicine, Washington, DC; ³University of Alabama at Birmingham, Birmingham, AL; ⁴Infectious Disease Specialists of Atlanta, Atlanta, GA; ⁵Henry Ford Hospital, Detroit, Michigan; ⁶Northstar Medical Center, Chicago, Illinois; ⁷Triple O Research Institute PA, West Palm Beach, Florida; ⁸Case Western Reserve University School of Medicine, Cleveland, Ohio; ⁹Midway Research Center, Ft. Pierce, FL; ¹⁰Tarrant County Infectious Disease Associate, Fort Worth, TX; ¹¹Gilead Sciences Inc., Foster City, California; ¹²Gilead Sciences, Inc, Foster City, California; ¹³Gilead Sciences, Foster City, California

Background. Black Americans are disproportionately impacted by HIV. The BRAAVE 2020 study, evaluated the safety and efficacy of switching to the guideline-recommended single-tablet regimen bicitegravir, 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 (1st 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/mm³ (189) for B/F/TAF and -8 cells/mm³ (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 3 rd agent class, %		
INSTI	61	60
NNRTI	30	31
PI	9	9
Baseline NRTIs, %		
F/TAF	68	65
F/DF	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, night sweats, 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.

Disclosures. Debbie Hagins, MD, Gilead Sciences Inc. (Consultant, Grant/Research Support, Scientific Research Study Investigator, Advisor or Review Panel member) Janssen (Grant/Research Support) Merck (Consultant, Grant/Research Support, Advisor or Review Panel member) Viiv Healthcare (Consultant, Grant/

Research Support, Advisor or Review Panel member) Princy Kumar, MD, Gilead Sciences Inc. (Scientific Research Study Investigator) Michael Saag, MD, Gilead Sciences Inc. (Consultant, Grant/Research Support, Scientific Research Study Investigator) Merck (Consultant, Grant/Research Support) Proteus (Grant/Research Support) Viiv Healthcare (Consultant, Grant/Research Support) Anson K. Wurapa, MD, Gilead Sciences Inc. (Grant/Research Support, Scientific Research Study Investigator, Advisor or Review Panel member) GlaxoSmithKline (Grant/Research Support) Janssen (Grant/Research Support, Advisor or Review Panel member) Pfizer (Grant/Research Support) Indira Brar, MD, Gilead (Speaker's Bureau) Janssen (Speaker's Bureau) Viiv (Speaker's Bureau) Daniel Berger, MD, Gilead Sciences Inc. (Scientific Research Study Investigator) Olayemi Osiyemi, M.D., GlaxoSmithKline (Advisor or Review Panel member, Speaker's Bureau) Viiv Healthcare (Advisor or Review Panel member, Speaker's Bureau) Corrylynn Hileman, MD, Gilead Sciences Inc. (Consultant, Scientific Research Study Investigator) Moti Ramgopal, MD FACP FIDSA, AbbVie (Speaker's Bureau) Allergan (Speaker's Bureau) Gilead Sciences Inc. (Consultant, Scientific Research Study Investigator, Speaker's Bureau) Janssen (Speaker's Bureau) Merck (Consultant) Viiv Healthcare (Consultant) Cheryl McDonald, MD, Gilead Sciences Inc. (Grant/Research Support, Scientific Research Study Investigator, Speaker's Bureau) Janssen (Grant/Research Support) Merck (Grant/Research Support, Speaker's Bureau) Viiv Healthcare (Grant/Research Support) Christiana Blair, MS, Gilead Sciences (Employee, Shareholder) Kristen Andreata, MSc, Gilead Sciences (Employee, Shareholder) Sean E. Collins, MD, MS, Gilead Sciences (Employee) Diana M. Brainard, MD, Gilead Sciences (Employee) Hal Martin, MD, MPH, Gilead Sciences Inc. (Employee, Shareholder)

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

Daniel Vo, MD¹; Charles W. Goss, PhD²; Qinghua Lian, MS²; Jane A. O'Halloran, MD, PhD³; ¹Washington University, Saint Louis, Missouri; ²Washington University in St. Louis, St. Louis, Missouri; ³Washington University in St. Louis, Missouri

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

Harmanpreet Kaur, MD¹; Netanya S. Utay, MD²; Jordan Lake, MD³; Roberto Arduino, MD²; Miao Hongyu, MS, PhD⁴; ¹UT Health McGovern Medical School, Houston, Texas; ²UT Health Science Center, Houston, TX; ³University of Texas Health Science Center at Houston, Houston, TX; ⁴University of Texas Health Science Center, Houston, Texas

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