Conclusion. DOR is a beneficial option for adults ≥50 years old, given its similar efficacy and favorable safety profile compared to younger adults.

Doravirine Phase 2 and Phase 3 Trials in Treatment-Naïve Adults

Doravirine Phase 2 and Phase 3 Trials in Treatment-Naïve Adults						
	Age <50 years			Age ≥50 years		
	DOR	DRV	EFV	DOR	DRV	EFV
	(N = 754)	(N = 337)	(N = 432)	(N = 101)	(N = 46)	(N = 40)
Baseline Characteristics						
Age, median (range)	31 (18, 49)	32 (18, 49)	30 (18, 49)	54 (50, 70)	55 (50, 69)	53 (50, 69)
Female, %	14.9	13.4	11.3	19.8	26.1	27.5
AIDS diagnosis, %	9.3	8.6	12.0	15.8	17.4	20.0
CD4+ T-cells/mm^3, median (range)	415.5 (19, 1822)	400 (19, 1303)	394.5 (19, 1452)	354 (20, 1399)	363.5 (28, 1195)	379 (44, 906)
HIV-1 RNA $\log_{10}$ c/mL, median (range)	4.4 (2.0, 6.5)	4.4 (2.4, 6.5)	4.5 (2.7, 6.4)	4.4 (2.8, 5.8)	4.3 (3.0, 5.6)	4.5 (2.6, 6.7)
Hypertension, %	6.8	5.6	4.6	33.7	23.9	32.5
Analgesic use, %	39.8	34.7	36.3	46.5	41.3	62.5
Efficacy* and Safety Outcomes, Week 96						
Withdrew due to lack of efficacy, %	6.7	8.9	5.5	1.0	4.3	0.0
HIV-1 RNA <50 c/mL, %	81.9	76.3	85.3	85.5	80.6	92.6
Mean change in CD4+ T-cells/mm^3	230.4	208.2	228.5	234.6	194.7	165.0
Drug-related AE, %	32.1	32.3	64.6	34.7	30.4	50.0
Serious AE, %	5.7	6.8	7.9	15.8	21.7	22.5
Serious & drug-related AE, %	0.3	0.3	1.4	0.0	0.0	2.5
Withdrew due to AE, %	2.4	3.0	7.6	4.0	6.5	12.5
Withdrew due to drug-related AE, %	1.9	1.8	6.9	1.0	4.3	10.0
*Efficacy analyses did not include the Phase 2 study (P007) due to differences in study design.						

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1012. Efficacy, safety and tolerability of switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in HIV-1 infected virologically-suppressed older adults in a real-world setting

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Session: P-47. HIV: Treatment

Background. Approximately 50% of people living with HIV (PLWH) in the United States are ≥50 years old. Efforts are ongoing to identify antiretrovirals associated with fewer drug-drug interactions (DDIs) and long-term side effects in this group. Clinical trials of B/F/TAF demonstrated favorable efficacy and safety in older adults, however, data from real-word settings are needed to validate these results.

Methods. This retrospective analysis evaluated records from PLWH aged ≥ 50 years at the Orlando Immunology Center who were switched to B/F/TAF between 2/7/2018 and 5/31/2019. Eligible patients had baseline HIV-1 RNA< 50 copies/mL and were followed for 48 weeks post-switch. The primary endpoint was maintenance of HIV-1 RNA< 50 copies/mL at week 48. The impact of switching to B/F/TAF on DDIs, adverse events (AEs) and safety parameters were analyzed throughout the study.

Results. 306 patients met inclusion criteria. 62 (20%) were female, 126 (41%) were non-white, median age was 58 years (range [r] 50-81), median duration of HIV infection was 19.5 years (r 2-40), median number of chronic co-morbid conditions was 5 (r 0-20), and median number of baseline concomitant medications was 4 (r 0-23). 159 (52%) patients were switched from regimens containing ritonavir or cobicistat. The most commonly documented reason for switch was simplification (Table 1). At Week 48, 287 (94%) patients maintained an HIV-1 RNA< 50 copies/ml and 19 (6%) had an HIV-1 RNA between 50-200 copies/mL (Figure 1). 1 patient discontinued due to lack of efficacy. A total of 123 potential DDIs were identified in 104 (34%) patients taking a boosting agent or rilpivirine at baseline (Table 2). At Week 48, there was a significant median decline in total cholesterol (15.5 mg/dL, 95% confidence interval [CI]: 9.5; 21.5), LDL cholesterol (9.5 mg/dL, 95% CI: 4; 15.5) and triglycerides (20 mg/dL, 95% CI: 9.5; 32.5), and median weight increased by 2.5 pounds (95% CI: 1.5; 3.5). Treatment-related AEs occurred in 33 (11%) patients (all Grade 1-2) and led to 7 (2%) discontinuations.

Table 1-Baseline demographic and clinical characteristics

Characteristic	N=306
Median Age (range)	58 (50, 81)
Sex	
Male, n (%)	244 (80)
Female, n (%)	62 (20)
Race/Ethnicity	
Caucasian, n (%)	172 (56)
Black, n (%)	45 (15)
Hispanic, n (%)	77 (25)
Asian, n (%)	4 (1)
Other, n (%)	8 (3)
Median BMI (range)	27.9 (17.9, 48.3)
Median Weight, pounds (range)	183 (110, 320)
Median Baseline CD4⁺ cell count, cells/mm³ (range)	658 (58, 2302)
Co-Infection	
HBV, n (%)	11 (4)
HCV, n (%)	6 (2)
Median number of chronic comorbid conditions (range)	5 (0, 20)
Median number of concomitant medications (range)	4 (0, 23)
Median duration of HIV infection, years (range)	19.5 (2, 40)
Median number of ARV regimens prior to switch (range)	4 (1, 11)
Median time of documented virologic suppression prior to switch, years (range)	11 (1, 27)
Prior ARV Experience	
>2 NRTIs, n (%)	251 (82)
≥1 NNRTI, n (%)	218 (71)
≥2 PIs, n (%)	77 (25)
1 INSTI, n (%)	153 (50)
>1 INSTI, n (%)	57 (19)
Regimen prior to switch	
Dual NRTI+NNRTI, n (%)	69 (22)
Dual NRTI+PI, n (n%)	36 (12)
Dual NRTI+INSTI, n (%)	174 (57)
PI+INSTI, n (n%)	8 (3)
NNRTI+INSTI, n (%)	3 (1)
Other, n (n%)	16 (5)
Rationale for switch to B/F/TAF	
Simplification, n (%)	109 (36)
DDI avoidance, n (%)	84 (28)
TDF to TAF switch	62 (20)
Comorbidities, n (%)	25 (8)
Side Effects, n (%)	23 (7)
Other, n (%)	3 (1)
Historical genotypic resistance available, n (%)	**83 (27)**
≥1 NRTI RAM, n (%)	26 (31)
≥1 NNRTI RAM, n (%)	26 (31)
≥1 PI RAM, n (%)	29 (35)
≥1 INSTI RAM, n (%)	2 (2)
Pattern of NRTI RAMs[a]	
None, n (%)	57 (67)
M184V/I alone, n (%)	8 (9)
M184V/I+ 1 NRTI RAM, n (%)	3 (4)
M184V/I + > 1 NRTI RAM, n (%)	6 (7)

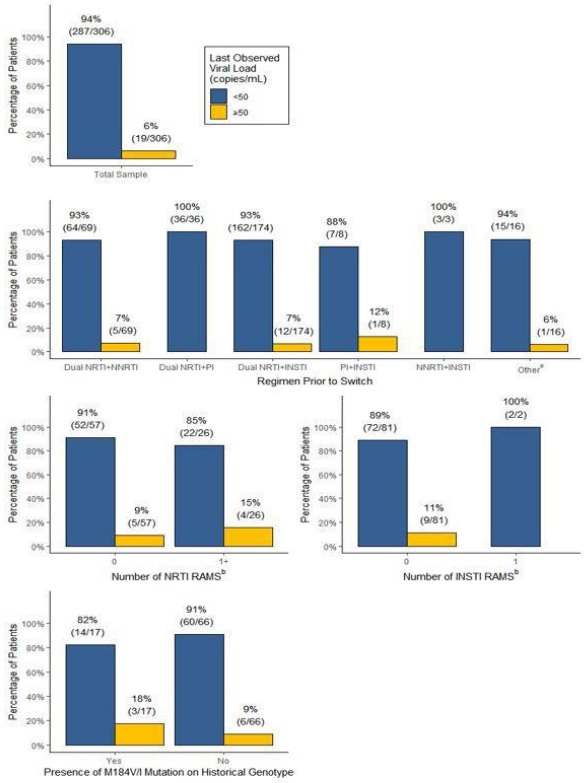
Abbreviations. BMI, Body Mass Index; HBV, hepatitis B; HCV, hepatitis C; ARV, antiretroviral; PI, protease inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; INSTI, integrase strand transfer inhibitor; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; DDI, drug-drug interaction; TDF, tenofovir disoproxil fumarate; RAMs, resistance associated mutations
[a]Total with available historical genotypes used as denominator

Table 2-Avoidance of Drug-Drug Interactions (DDIs) following switch to B/F/TAF

Baseline ARV	Concomitant Medication	DDI resolution following switch to B/F/TAF Total N (%)
Ritonavir or cobicistat containing regimen	Statins	73 (24)
Ritonavir or cobicistat containing regimen	PDE5 inhibitors	21 (7)
Ritonavir or cobicistat containing regimen	Factor Xa inhibitors	2 (0.6)
Ritonavir or cobicistat containing regimen	P2Y12 inhibitors	4 (1.3)
Ritonavir or cobicistat containing regimen	Warfarin	1 0.3)
Ritonavir or cobicistat containing regimen	Inhaled or intranasal steroids	13 (4)
Ritonavir or cobicistat containing regimen	HCV NS3/4A protease inhibitor	1 (0.3)
Rilpivirine	PPIs	5 (1.2)
Rilpivirine	H2 blockers	3 (1)

Abbreviations. B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; ARV, antiretroviral; PDE5, phosphodiesterase type 5; PPI, proton pump inhibitor; H2, histamine type 2

Figure 1-Subgroup analysis of virologic outcomes at Week 48



Abbreviations. NRTI, nucleoside reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; INSTI, integrase strand transfer inhibitor; RAMs, resistance associated mutations
[a]Other includes regimens with 3 antiretroviral drug classes
[b]Total with available historical genotypes used as denominator

Conclusion. In this real-world cohort, switching to B/F/TAF was associated with maintenance of virologic control, improvement in lipid parameters, and avoidance of DDIs in a large proportion of patients. These data support use of B/F/TAF as a treatment option in older PLWH.

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1013. Enhanced Oral Health Care Services for PLWHA - Midlands Region, South Carolina

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Session: P-47. HIV: Treatment

Background. An estimated 58- 64 % of people living with HIV/AIDS (PLWHA) do not receive regular dental care and this gap may be attributed to barriers related to cost, access to dental care, logistical issues, indifference to or fear of dental care.[1,2] The Immunology Center at Prisma- University of South Carolina, School of Medicine is a Ryan White funded Part B Program that provides care to > 2400 PLWHA. Based on the perceived barriers, an enhanced oral health care program was implemented in 2018, wherein patients in need of dental care and meeting inclusion criteria are referred to contracted local general dentistry and specialty practices.

Enhancements. Dedicated Dental Services Coordinator (DSC)
Facilitated transport to and from the dental clinic
Annual budget of $2700 per patient
Access to dental specialties (oral and maxillofacial surgery)
Restorative services (crowns, dentures and root canals)

Program Goals. The ultimate goal of the oral health care program is to provide biannual dental prophylaxis and expanded restorative services to PLWHA.

Inclusion criteria for referrals.
1 Virological suppression over 6 months. (HIV Viral Load < 200 c/mL)
2 Adherence with HIV clinic appointments.

Midlands Region, South Carolina

Methods. The DSC completes the following: monitoring of referrals, patient compliance to program inclusion criteria, linkage to dental care, payments for dental services, and coordination with case management.

Results. Between 2018 and 2019, 535 patients were referred to the oral health care program. Almost 75% 399 completed at least one dental clinic visit. The average number of visits for patients from their enrollment date (2018-2019 to December 2019 was 1.56, with an average of 8.08 services, and 1.13 prophylaxis visits with their oral health care provider. Patients were predominantly African American and male but were spread across a wide age spectrum and 8 counties. Nearly 94% of patients remained virologically suppressed during their oral health care treatment.

Table 1: 2018-2019 Program Summary of Oral Health Care

Table 1: *2018-2019 Program Summary of Oral Health Care*

Total Enrollment	399
Average Number of Visits	1.56
Average Number of Services	8.08
Average Number of Prophylaxis Visits	1.13

Table 2 & Figure 1: Oral Health Care Patients by Age Group, Figure 2: Oral Health Care Patient by Gender

Table 2 & Figure 1: *Oral Health Care Patients by Age Group*

Age Category (years)	Number	Percentage (%)
17 and younger	1	0.3%
18-24	7	1.8%
25-39	95	23.8%
40-59	218	54.6%
60-Plus	78	19.5%

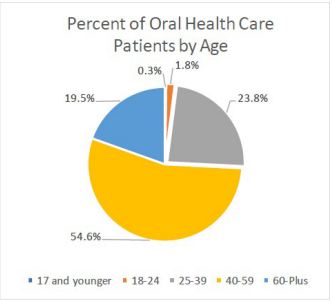

Figure 2: *Oral Health Care Patient by Gender*