

was not included in the analysis of viral outcome (Table 2). One patient had cardiac arrest following missed dialysis, hyperkalemia and rectal hemorrhage from metastatic rectal cancer.

Table 1: Patient Demographics.

| | |
|---|--|
| Mean Age (Range) | 61.8 years (50-74) |
| Gender | Male: 90.5% (19/21) Female: 9.5% (2/21) |
| Race | African-American: 95.2% (20/21) Caucasian: 4.8% (1/21) |
| Comorbidities | Hypertension: 61.0% (13/21) Coronary artery disease: 19.0% (4/21) Diabetes Mellitus, Type 2: 19.0% (4/21) Chronic Kidney Disease: 28.6% (6/21) Cancer: 14.3% (3/21) Active Hepatitis B: 9.5% (2/21) Hepatitis C: 33% (7/21) Cirrhosis: 23.8% (5/21) Peptic Ulcer Disease: 19.0% (4/21) Lower GI Bleed: 14.3% (3/21) Seizure disorder: 14.3% (3/21) Peripheral Neuropathy or Radiculopathy: 28.6% (6/21) Dementia or Cognitive Impairment: 19.0% (4/21) Psychiatric Disorders: 47.6% (10/21) |
| Antiretroviral Therapy Regimen | Dolutegravir/Doravirine alone: 66.7% (14/21) Dolutegravir/Doravirine + Lamivudine: 14.3% (3/21) Dolutegravir/Doravirine + Emtricitabine: 4.8% (1/21) Dolutegravir/Doravirine + Tenofovir: 4.8% (1/21) Dolutegravir/Doravirine + Cobicistat-boosted Darunavir: 4.8% (1/21) Dolutegravir/Doravirine + Emtricitabine/Tenofovir: 4.8% (1/21) |
| Mean Duration of Follow-Up (Range) | 10 months (3-17) |

Figure 1: Reasons for Switching to Dolutegravir with Doravirine.

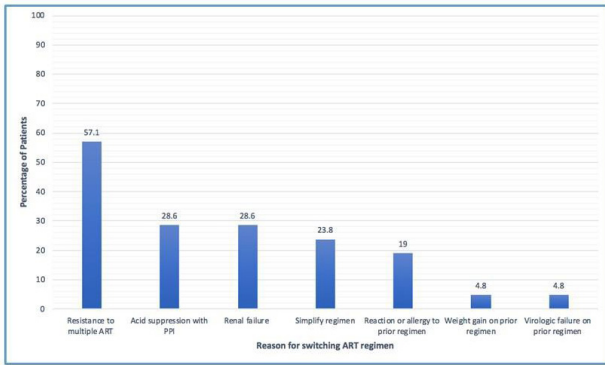


Table 2: Virologic Control Before and After Switching to Dolutegravir with Doravirine.

| | Virologic control in 12 months prior to switch (all patients) | Virologic control post-switch (>12 months follow-up) | Virologic control post-switch (all patients) |
|----------------------------------|---|--|--|
| Undetectable VL (<50), % (n) | 61.9% (13) | 66.7% (6) | 70% (14) |
| VL 50 to 200, % (n) | 14.3% (3) | 22.2% (2) | 15% (3)* |
| VL >200, % (n) | 14.3% (3) | 22.2% (2) | 10% (2) |
| No VL data, % (n) | 9.5% (2) | - | 5% (1) |
| Mean CD4 | 513 | 561 | 560 |
| CD4 <200 | 14.3% (3) | 22.2% (2) | 15% (3) |
| No CD4 data | 9.5% (2) | - | 15% (3) |
| Total number of persons included | 21 | 9 | 20 |

*One with preexisting V106A mutation

Conclusion. In an era of abundant ART options, we identified a subset of older PWH whose treatment options are defined by extensive comorbidities, viral resistance, and medication interactions or toxicities. Doravirine is attractive for this population as it can be used in renal impairment, moderate hepatic impairment, is unaffected by timing of meals, and (unlike rilpivirine) has no interaction with proton pump inhibitors. Dolutegravir is included in NRTI-sparing regimens that HHS guidelines suggest should be considered in older PWH, especially with CKD. We found that dolutegravir with doravirine is well tolerated, and achieves virologic

suppression in the majority of PWH, indicating this combination is useful when other ART options cannot be used.

Disclosures. All Authors: No reported disclosures

1010. Effective Management of HIV in Rural Georgia Using Telemedicine

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Session: P-47. HIV: Treatment

Background. The increasing incidence of HIV and lack of care in rural areas contributes to the ongoing epidemic. The dearth of specialized health services within remote communities and access of this population to available services poses a challenge to HIV care. Telemedicine (TM) is a potential tool to improve HIV care in these remote communities, but little is known about its effectiveness when compared to traditional (face-to-face) (F2F) care. The objective of this study is to examine the effectiveness of HIV care delivered through TM, and compare to F2F care.

Methods. This is a retrospective chart review of all HIV positive patients who attended either the F2F clinic (Augusta, GA) or the TM clinic (Dublin, GA) between May 2017 to April 2018. Data extracted included demographics, CD4 count, HIV PCR, co-morbidities, dates of clinic attendance, HIV resistance mutations and ART changes. Viral suppression and gain in CD4 counts were compared. T-test was conducted to test differences in characteristics and outcomes between the two groups.

Results. 385 cases were included in the study (52.5% black, 82% females, F2F=200, TM=185). Mean CD4 count in the TM group was statistically higher (643.9 cells/mm³) than the F2F group (596.3 cells/mm³) (p< 0.001). There was no statistically significant difference in mean HIV viral load (F2F= 416.8 cp/ml, TM=713.4 cp/ml, p=0.3) and rates of year-round viral control (F2F= 73% vs TM = 77% p= 0.54). 38 patients achieved viral suppression during the study period (F2F= 24, TM =14) with a mean change of -3.34 x 10⁴ vs -1.24 x 10⁴, respectively. The difference in mean change was not statistically significant by Snedacor's W Statistics. This indicates there was no significant difference between the two populations in terms of mean viral suppression among patients who were otherwise not suppressed before the study period.

Conclusion. To achieve an HIV cure, HIV care is required to extend to rural areas of the country and the world. Through delivery of care using TM, trained specialists can target communities with little or no health care. Moreover, use of TM achieves target outcome measures comparable to F2F clinics. Increase in the use of TM will improve the access to specialty HIV care and help achieve control of HIV in rural communities.

Disclosures. All Authors: No reported disclosures

1011. Efficacy and Safety of Doravirine in Treatment-Naïve Adults ≥50 Years Old With HIV-1

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Session: P-47. HIV: Treatment

Background. Nearly 50% of people living with HIV in the US are ≥50 years old. Older people are more likely to have late-stage HIV infection at diagnosis, greater risk for cardiovascular disease and certain cancers, and concurrent medications for common age-related conditions. Doravirine (DOR) is a next-generation NNRTI with activity against first-generation NNRTI-associated mutations, a neutral impact on lipids, and few drug-drug interactions with commonly used medications.

Methods. We compared Week 96 results from DOR Phase 2 and Phase 3 trials (P007, P018, and P021) in treatment-naïve adults ≥50 vs < 50 years old. 855 participants received DOR 100mg +2 NRTIs in P007 & P018 or fixed combination DOR/3TC/TDF in P021; 383 participants received ritonavir-boosted darunavir (DRV) +2 NRTIs in P018; and 472 received efavirenz (EFV) 600mg +FTC/TDF in P007 or fixed combination EFV/FTC/TDF in P021. Participants who took ≥1 dose of study drug were included; the Observed Failure approach was used for missing efficacy data. All analyses were done by descriptive statistics.

Results. Of 1710 participants, 187 (11%) were 50-70 (median 54) years old at study entry. Baseline characteristics and treatment outcomes are summarized below for participants < 50 vs ≥50 years old. The older cohort had more women, more participants with AIDS, and lower median CD4+ T-cell counts than the younger cohort, whereas baseline HIV-1 RNA was similar between age cohorts. Hypertension and use of analgesics were more common in older participants. In each treatment group, the older cohort had a higher proportion of participants with HIV-1 RNA < 50 copies/mL at week 96 and fewer discontinuations due to lack of efficacy than the younger cohort. Mean change in CD4+ T-cell count was similar between age cohorts in the DOR and DRV groups and was lower for older participants in the EFV group. Rates of drug-related AEs and serious drug-related AEs were similar between age cohorts across all treatment groups. Discontinuations due to drug-related AEs were similar between age cohorts in the DOR group and were slightly higher for older participants in the DRV and EFV groups.

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 | | | | | | |
| Withdrawn 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 |
| Withdrawn due to AE, % | 2.4 | 3.0 | 7.6 | 4.0 | 6.5 | 12.5 |
| Withdrawn 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-world 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/mm ³ (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 (%) | 36 (12) |
| Dual NRTI+INSTI, n (%) | 174 (57) |
| PI+INSTI, n (%) | 8 (3) |
| NNRTI+INSTI, n (%) | 3 (1) |
| Other, 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+ ≥2 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

^aTotal 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