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887. Implementation of Long-acting Injectable Cabotegravir/Rilpivirine for HIV-1 Treatment at a Ryan White-funded Clinic in the U.S. South
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Session: P-51. HIV: Treatment

Background. In January 2021, the first ever long-acting injectable (LAI) antiretroviral therapy (ART), cabotegravir/rilpivirine (CAB/RPV), was approved for maintenance HIV-1 treatment in select patients with virologic suppression. LAI-ART has the potential to improve ART adherence, reduce HIV stigma, and promote equity in care outcomes, however, implementation in real-world settings has yet to be evaluated.

Methods. We launched a pilot LAI-ART program at the largest Ryan White-funded HIV clinic in the Southeast. From 4/14/21 to 5/14/21, providers referred interested and willing to switch to LAI-CAB/RPV who met screening criteria. Our interdisciplinary LAI team (Clinician-Pharmacy-Nursing) verified clinical eligibility (HIV-1 < 200 c/ml ≤ 4 months and no history of virologic failure, resistance to either drug, or chronic HBV infection) and pursued medication access for 28-day oral lead-in and monthly injectable CAB/RPV. We describe demographic and clinical variables of referred PWH and early outcomes in accessing LAI-ART.

Results. Among 42 referrals, median age was 40.5 (Q1-Q3, 32-52) years, 83% were men, and 76% Black. Payor source distribution was 26% Private, 19% Medicare, 10% Medicaid, and 45% ADAP. At the time of referral, median CD4 count was 583 (Q1-Q3, 422-742) cells/mm^3 and median sustained HIV-1 RNA < 200 c/ml was 1427 (Q1-Q3, 961-2534) days. A total of 35 patients (74%) met clinical eligibility for LAI-CAB/RPV, including 4 patients who required a transition off proton pump inhibitor therapy to accommodate oral RPV. Ineligible PWH were excluded due to evidence of CAB/RPV, including 4 patients who required a transition off proton pump inhibitor (PPI) (n=1). The table summarizes the process of pursuing LAI-ART access for the initial 10 enrollees by insurance status.

Table: Summary of medication access pursuit for patients enrolled in long-acting injectable LAI(CAB/RPV) program paid for by Ryan White-HIV

| Patient | Insurance | Presence of CAB/RPV prescription | Informed consent for LAI-ART | F/TDF prescribed | Time since last adherence failure (days) | Current LAI treatment | Current LAI treatment days
|---------|-----------|----------------------------------|------------------------------|----------------|----------------------------------------|----------------------|---------------------|
| 1       | Approved  | Yes                               | Yes                          | No             | 10                                     | DTG/FTC/AIDS         | 10      |
| 2       | Approved  | Yes                               | Yes                          | No             | 20                                     | DTG/FTC/AIDS         | 20      |
| 3       | Approved  | Yes                               | Yes                          | No             | 30                                     | DTG/FTC/AIDS         | 30      |
| 4       | Approved  | Yes                               | Yes                          | No             | 40                                     | DTG/FTC/AIDS         | 40      |
| 5       | Approved  | Yes                               | Yes                          | No             | 50                                     | DTG/FTC/AIDS         | 50      |
| 6       | Approved  | Yes                               | Yes                          | No             | 60                                     | DTG/FTC/AIDS         | 60      |
| 7       | Approved  | Yes                               | Yes                          | No             | 70                                     | DTG/FTC/AIDS         | 70      |
| 8       | Approved  | Yes                               | Yes                          | No             | 80                                     | DTG/FTC/AIDS         | 80      |
| 9       | Approved  | Yes                               | Yes                          | No             | 90                                     | DTG/FTC/AIDS         | 90      |
| 10      | Approved  | Yes                               | Yes                          | No             | 100                                    | DTG/FTC/AIDS         | 100     |

Conclusion. Our experience implementing LAI-ART at a Ryan White-funded HIV clinic in the South of the US has been challenged by substantial human resource capital to attain drug, delayed therapy initiation due to insurance denials, and patient ineligibility primarily due to concern for potential RPV resistance. These barriers may perpetuate disparities in ART access and virologic suppression among PWH and need to be urgently addressed so that LAI-ART can be offered equitably.

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889. Early Discontinuations and Adverse Events Among Treatment-Naïve Patients Initiating Integrase Inhibitors in a Real-world Setting
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Session: P-51. HIV: Treatment

Background. Cohort studies suggest higher rates of discontinuations (DCs) and adverse events (AEs) with integrase inhibitors (INSTIs) than is reported in clinical trials. Here, we assess DC of different INSTIs in combination with one of two tenofovir prodrugs in the first year following initiation defined as “early DC” in a real-world cohort of treatment-naive patients.

Methods. This analysis evaluated treatment-naive patients at a single center initiating raltegravir (RAL), elvitegravir/cobicistat (EVG/c), dolutegravir (DTG) or bictegravir (BIC) in combination with emtricitabine/tenofovir alafenamide (FTAF) or emtricitabine/tenofovir disoproxil fumarate (FTDF) from 1/2016-10/2020. Eligible patients had a minimum follow-up of 1 year. The primary endpoint was incidence of early INSTI DC. Secondary endpoints included AEs and risk factors for early INSTI DC and treatment-related AEs.

Results. 331 patients were included. Median age was 32 years, 89% were male, 43% were non-White, 8% started RAL-based therapy, 46% started EVG/c-based

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therapy, 22% started DTG-based therapy and 24% started BIC/TAF. 36 discontinued INSTI-based therapy early yielding an incidence rate of 0.17 DCs per person-years (PPY) among RAL patients, 0.14 DCs PPY among EVG/c patients, 0.22 DCs PPY among DTG patients, and 0.02 DCs PPY among BIC patients, p=0.006. Treatment-related AEs occurred in 27% of RAL patients, 42% of EVG/c patients, 50% of DTG patients, and 3% of BIC patients; p=0.607, and were responsible for early DC rates of 0.022 in 3 EVG/c patients and 0.075 in 5 DTG patients. No treatment-related early DCs occurred among RAL or BIC patients. No evaluated factor was significantly associated with early INSTI DC, however DTG use was significantly associated with treatment-related AEs (aOR 3.6, 95% confidence interval: [1.20; 10.82]).

Table 1. Risk factors for early integrase inhibitor discontinuation and treatment-related adverse events

| Risk Factor | Odds Ratio (95% CI) |
|-------------|---------------------|
| Age > 50    | 1.5 (1.1; 2.1)      |
| Male sex    | 1.2 (0.8; 1.7)      |
| BMI > 30    | 1.8 (1.3; 2.5)      |

Conclusion. In this cohort, early DCs occurred in 11% initiating INSTI-based therapy, however of these only 2% were treatment-related. These data support use of INSTI-based regimens as preferred options for treatment-naïve patients living with HIV due to their favorable safety and tolerability profiles.

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890. Evaluation of Association Among Integrase Inhibitors for HIV Treatment, Weight Gain, and Body Image
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Session: P-51: HIV: Treatment

Background. Integrase inhibitors (INSTIs) are preferred antiretroviral agents for people living with HIV (PLWH). Recent studies suggest that INSTIs may contribute to weight gain, potentially exacerbating the development of metabolic syndrome. A lack of clarity remains about how INSTIs affect metabolic parameters that contribute to weight gain as well as the impact of weight gain on medication adherence and body image in PLWH.

Methods. We conducted a retrospective chart review along with a real time survey of PLWH who were receiving HIV care at UConn Health. Participants who were switched to or added an INSTI to their ART regimen between 2012 - 2020 were included (n=204). Patient weight was recorded in 3-month intervals for two years prior to and two years after INSTI initiation. Lipid profile parameters and hemoglobin A1c were noted pre and post INSTI switch. A survey was administered to rate perception of weight gain, body appearance, and medication adherence on a five-point Likert scale. Statistical methods included Chi-square test and Fisher’s Exact test for categorical data, and T-test or Kruskal-Wallis test for continuous data.

Results. Patients started on or switched to any INSTI regimen experienced a mean weight gain of 5 and 7 pounds at 12 and 24 months, respectively (p < 0.001). Weight gain was greatest with raltegravir and elvitegravir (Figure 1,2). Bictegravir regimens resulted in a 4 pound weight loss at 24 months. An INSTI switch increased cholesterol by a mean of 7 mg/dL (p=0.05), with no effect on other parameters. A switch to Bictegravir increased HDL by 4 mg/dL (p=0.04) and decreased triglycerides by 35 mg/dL (p=0.04). Survey results showed that 100% of patients denied missing ART doses despite 69% mentioning weight gain due to ART. 97% of patients were satisfied with their ART regimen, with the majority disagreeing that their body image was negatively affected.

Conclusion. We demonstrate a link between INSTI use and weight gain up to two years following INSTI initiation, with the most weight gained within the first 12 months. Elvitegravir and raltegravir are associated with greater weight gain whereas bictegravir demonstrates weight loss and beneficial effects on lipid profile. Despite weight gain, most patients remained adherent and satisfied with their medication and denied negative perceptions of body image.

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891. Minimum Manufacturing Costs and National Prices for Weight Loss Treatments, as Potential Mitigation for Anti-Retroviral Related Weight Gain in HIV
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Session: P-51: HIV: Treatment

Background. Weight gain is being observed for a wide range of antiretroviral treatments. Weight gains are higher for people taking first-line integrase inhibitor based treatments, especially those including TAF/FTC. Weight gains are higher for women and people of colour. Clinical obesity increases the risks of cardiovascular disease, diabetes, adverse birth outcomes and could lower survival rates. Anti-obesity treatments are needed to supplement lifestyle interventions and counteract progressive weight gains, but are not routinely provided as part of HIV care.

Methods. Costs of production for FDA-recommended weight loss treatments and anti-diabetic medications (orlistat, naltrexone-bupropion, topiramate, phenentermine, semaglutide, liraglutide and metformin) were estimated using an established and published methodology based on costs of active pharmaceutical ingredients (API), extracted from the global shipping records database Panjiva. This was compared with national drug list price data from a range of low, medium, and high-income countries.