Early Implementation and Clinical Outcomes of Long-Acting Injectable Cabotegravir and Rilpivirine in a Safety-Net Clinic

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Background

- Registrational trials of long-acting cabotegravir-rilpivirine (CAB/RPV-LA) required viral suppression (VS) on oral antiretrovirals, but CAB/RPV-LA may benefit people living with HIV (PLWH) unable to attain VS due to adherence challenges.
- We assessed the early clinical outcomes of a CAB/RPV-LA demonstration project in PLWH with and without detectable viremia.

Study Setting

- Ward 86 in San Francisco serves ~2400 publically insured PLWH. Patients without VS have high rates of substance use, marginal housing, and mental illness. In 2019, the clinic developed "POP-UP," a multidisciplinary drop-in primary care model for chronically virally unsuppressed PLWH with marginal housing, which improved VS up to 55%.

Program Description

- Informed by the capability-opportunity-motivation behavior (COM-B model), we developed a program to support patients and providers to initiate CAB/RPV-LA and promote patient adherence to injections.
- Patients with and without VS were allowed to enter the program. Other considerations were willingness to receive 2 gluteal injections every 28 days, to resume oral ART if CAB/RPV-LA was interrupted, and to provide a reliable form of communication with an additional method of contact. Pre-existing rilpivirine-associated mutations and drug-drug interactions precluded CAB/RPV-LA use.
- Providers received education, feedback on early outcomes, and training on a structural referral process to the clinic pharmacy team for counseling, insurance authorization, and initiation.
- The program favors a direct-to-inject approach for patients with and without viral suppression to remove the barrier of adhering to oral ART for an additional month for those with adherence challenges as well as any obstacles to taking oral RPV with food or without gastric acid reducing medications.
- Patients without VS have individualized plans, including identification of community-based supports, e.g. case managers, home/street-based nursing services, community-based injection sites, and small financial incentives for visits or blood draws.
- All referred and active patients are reviewed in a biweekly multidisciplinary (i.e., physician, nursing, pharmacy) case conference, with additional discussion of POP-UP patients in a weekly POP-UP case conference.

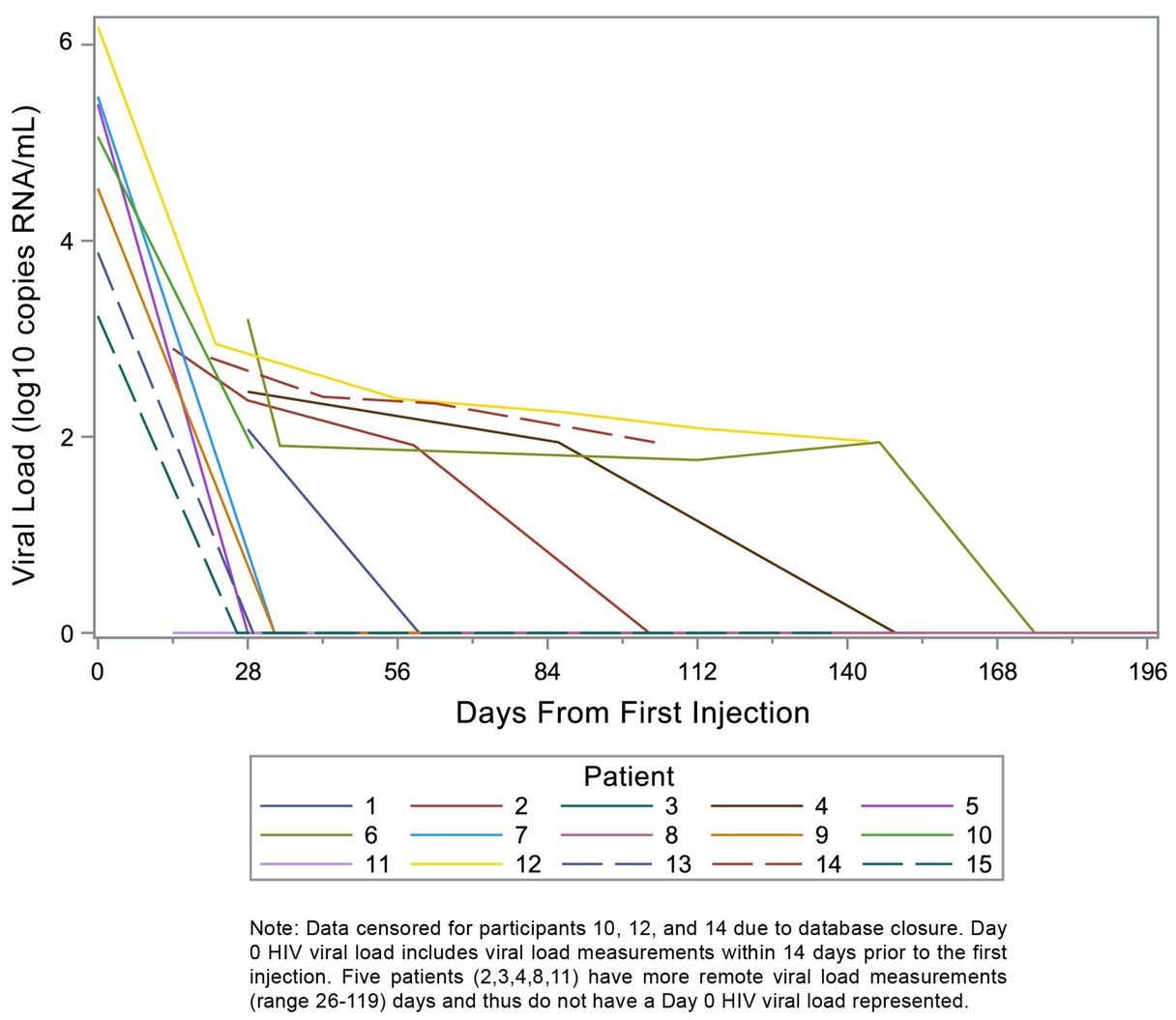
Data Collection and Analysis

- Data were extracted from pharmacy logs and the medical record. Descriptive statistics characterize those initiating CAB/RPV-LA by 2/10/22 and thus were expected to have at least 2 follow-up injections by database closure (4/15/22).
- We present median and range number of injections and VS outcomes, stratified by VS status at baseline. VS was defined as HIV RNA <30 copies/mL. For those without VS at baseline, we display HIV RNA levels over time.
- On-time injections were defined as 28 days +/- 7 days from last injection.

Results

- As of July 1, 2022, 67 patients were on injections.
- Between 2/1/2021-4/15/2022, providers referred 132 patients, of whom 51 were started on injections.
- Of 51 patients receiving injections between 6/1/2022-4/15/2022, 39 had at least 2 follow-up injections. Median age was 46; there were 3 cisgender and one transgender women and 24 (61%) had non-White race/ethnicity, 16 (41%) were experiencing unstable housing or homelessness, and 20 (54%) endorsed current stimulant use.
- Of 24 patients initiating CAB/RPV-LA with VS (median CD4 cell count 706 cells/mm^3), 19 (79%) direct-to-inject, with median 6 injections (range 2-8), 100% maintained VS after starting injections.
- Of 15 patients starting with detectable viremia, (median CD4 cell count 99 cells/mm^3, mean log10 viral load 4.67 SD 1.16), all direct-to-inject, with median 6 injections (range 3-11), 12 (80%) have achieved and maintained VS. For the 3 patients who have not yet achieved viral suppression, all had a 2-log decline by a median of 22 days (Figure 1).
- 34 patients (87%) had on-time injection attendance, with one patient late for one injection and two patients late for two injections each. Two episodes of lateness required re-induction dosing. All patients had VS after the delayed visits.

Figure 1. HIV Viral Loads Over Time for Patients Initiating



Note: Data censored for participants 10, 12, and 14 due to database closure. Day 0 HIV viral load includes viral load measurements within 14 days prior to the first injection. Five patients (2,3,4,8,11) have more remote viral load measurements (range 26-119) days and thus do not have a Day 0 HIV viral load represented.

Discussion

- We describe to our knowledge the first demonstration project to use CAB/RPV-LA in PLWH with challenges adhering to oral ART.
- We demonstrate preliminary success in using CAB-RPV-LA in achieving VS in those with detectable viremia and in keeping those with VS suppressed.
- A longer period of follow-up and a larger cohort, along with other demonstration projects examining the use of CAB/RPV-LA in hard-to-reach populations and qualitative assessments of acceptability, are needed.

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