

Comparison of At-Home Versus In-Clinic Receipt of Long-Acting Injectable Cabotegravir/Rilpivirine

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Background. The need for frequent travel to a clinic could impair access to injectable antiretroviral therapy for persons with human immunodeficiency virus type 1 (HIV-1) infection. We hypothesized that allowing persons receiving treatment with long-acting injectable cabotegravir plus rilpivirine (LA CAB/RPV) to receive and store the medication in their own refrigerator prior to in-home administration by a healthcare provider would be as safe and effective as receiving treatment in a clinic.

Methods. Persons prescribed LA CAB/RPV in the Infectious Diseases clinic at the Medical University of South Carolina were offered enrollment in this non-randomized, observational study between August 2021 and December 2022. After in-clinic receipt of the initial LA CAB/RPV injection, participants chose to receive each subsequent injection over the following 12-months either in clinic or at home.

Results. The 33 enrolled participants were primarily Black (64%), male (73%), and had a median age of 46. Three participants stopped LA CAB/RPV and transitioned to oral antiretroviral therapy due to allergy ($n = 1$), loss of virologic suppression ($n = 1$), and visit adherence ($n = 1$) concerns. A comparable number of participants received treatment primarily in clinic ($n = 18$) relative to at home ($n = 15$). Injection site pain/soreness was common (52% of injections) but did not differ between groups. There were no differences in safety or efficacy between groups and both groups reported high treatment satisfaction. All participants were virologically suppressed and retained in care at the end of the study.

Conclusions. At-home administration of LA CAB/RPV by a healthcare provider was comparably safe, effective, and associated with high participant satisfaction relative to in-clinic administration.

Keywords. HIV; long acting injectable antiretrovirals; cabotegravir/rilpivirine long-acting; home health; observational research study.

Treatment of human immunodeficiency virus (HIV) infection with injectable antiretroviral therapy (ART) has potential to decrease pill fatigue, increase medication adherence, and improve patient satisfaction, particularly in the southern United States, which is disproportionately affected by the HIV epidemic and where stigma can impair oral ART adherence [1–6]. Long-acting injectable cabotegravir plus rilpivirine (LA CAB/RPV) is approved by the Food and Drug Administration (FDA) for intramuscular administration every 1 or 2 months for treatment of human immunodeficiency virus type 1 (HIV-1)

and can reduce the burden of taking HIV medication from 365 days/year to 6–12 days/year [7, 8]. Logistical barriers or stigma related to the need to present to a clinical venue to receive LA CAB/RPV could challenge the desirability and capacity of some persons to receive LA CAB/RPV and thus limit access [9, 10]. Developing novel LA CAB/RPV administration approaches could help destigmatize HIV treatment and improve access to care and health outcomes [9, 11–14]. Recent work identified that some patients may prefer receiving LA CAB/RPV at home rather than at a clinical venue [9, 15]. To evaluate this concept, we designed and conducted a non-randomized observational study to examine whether receiving LA CAB/RPV at home with a healthcare provider would be safe, effective, and associated with patient satisfaction relative to in-clinic treatment. The RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework [16] was used to guide the systematic evaluation of programmatic outcomes.

METHODS

Persons prescribed LA CAB/RPV in the Infectious Diseases Clinic at Medical University of South Carolina (MUSC), who accessed LA CAB/RPV via prescription insurance benefits

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(medication was not provided by the study), and who resided in Charleston, Dorchester, or Berkeley Counties were offered enrollment between August 2021 and December 2022. Clinical eligibility criteria and the decision to use LA CAB/RPV for HIV treatment were jointly determined by participants and their primary HIV provider and were not protocol driven. Utilization of oral lead-in therapy prior to LA CAB/RPV initiation and the needle length used for injections were determined by providers referencing standard of care guidelines and were not specified or recorded by the study. For all patients receiving LA CAB/RPV, the clinic followed product information guidance and individual provider discretion for management of unavoidable, unplanned missed injections not given within the recommended timeframe (ie, out of window injections). All staff who administered LA CAB/RPV were clinical personnel who received standard of care training. All participants received LA CAB/RPV through a single specialty pharmacy throughout the study, allowing for efficient communication between the study team and a single point person at the pharmacy through use of instant messaging, telephone calls, and email.

After receiving initial LA CAB/RPV injections in the clinic, participants chose to receive subsequent injections over the 12-month intervention at home or in clinic, with the option to change the location of receipt with each treatment. There was no predefined sample size calculation for the 2 groups as the decision for where to receive treatment, the primary outcome of the study, was determined by participant preference and was not protocol driven. Study participation began at the time participants provided written informed consent and continued for 12 months; participants were not followed after completion of the 12 months, and all decisions regarding use of LA CAB/RPV both during and after completion of the study were at the discretion of each participant and their primary HIV provider.

For at-home injections, LA CAB/RPV was shipped to participants' homes in temperature-controlled packaging and stored in the participants' own refrigerator, with verbal instruction for how to properly store the medication provided by the study team, until preparation and administration by the home health provider. Medication shipments for at-home participants were scheduled to assure medication receipt prior to scheduled injection visits while minimizing excessive durations of self-storage to decrease the odds of refrigerator outages (ie, hurricane, appliance failure).

For in-clinic injections, LA CAB/RPV was shipped to the clinic and stored in the clinic's medication refrigerator until the injection visit. For participants known to want solely in-clinic injections, the specialty pharmacy used scheduled injection dates along with earliest insurance fill dates to allow for batched shipments to the clinic to decrease packaging waste and administrative staff time. A single home health licensed practical nurse (LPN) performed at-home injections in the 3 counties that comprise 3163 square miles, representing 10% of South

Carolina's total area, and where 73% of the MUSC HIV clinic cohort reside. At-home participants could elect to have an epinephrine pen available in case of an unanticipated allergic reaction. The study team, participants, specialty pharmacy, and home health LPN coordinated medication shipment logistics. The specific days of availability of the LPN to conduct home injection visits varied on a week-by-week basis based on their other professional responsibilities, but for any given week a minimum of 2 days (Monday–Friday, 8 AM to 5 PM) were offered for participants to schedule visits. In-clinic injections were offered between 8:00 AM and 4:30 PM Monday–Friday during regular clinic hours. The cost of administering LA CAB/RPV in both locations was covered by the study (ie, reimbursement for the LPN visit at home or the medication administration fee in clinic). Injections administered at home were recorded in the electronic health record (EPIC) as scanned, faxed documentation from the LPN. In-clinic administrations were documented in real-time in the EPIC medication administration record.

The study was initiated when LA CAB/RPV was approved as a monthly treatment; participants could transition to receipt every 2 months once this injection interval received regulatory approval by the FDA. Satisfaction surveys were completed by study participants using REDCap after each injection visit and at the end of the 12-month intervention (specific questions reported in this study are noted in [Table 1](#)). For each participant, treatment satisfaction scores from all completed surveys during the 12 months were averaged to derive an overall score per participant. For post-intervention surveys, data from the 26 participants who completed the surveys were analyzed. For analysis, participants were categorized into “at-home” versus “in-clinic” groups based on the predominant location where treatment was received (>50% of all injections). This study was approved by the Medical University of South Carolina (MUSC) Institutional Review Board and all participants signed written informed consent prior to any study activities.

Outcomes pertaining to the RE-AIM framework [16] were assessed as follows: (1) Reach: the number of participants electing to receive LA CAB/RPV primarily at home versus in clinic; (2) Effectiveness: virologic suppression (HIV viral load <200 copies/mL) throughout and at the end of study, retention in care at the end of study, reversion to oral HIV therapy by end of study, adherence (in vs out of window injections), side effects, and participant satisfaction (as measured by the specific questions noted in the Table); (3) Adoption: not measured (implemented with only one clinical team and one LPN); (4) Implementation: medication delivery and days in refrigerated storage; and (5) Maintenance: intent to remain on LA CAB/RPV and to continue to receive LA CAB/RPV at the same location at the end of study.

Statistical analyses were performed by *t* test or χ^2 test using GraphPad Prism software (v10.2.2) using non-parametric assumptions as the data were not assumed or observed to have normal distribution. The categorical demographic characteristics of

Table 1. Demographic Characteristics and Implementation Outcomes for At-Home and In-Clinic LA CAB/RPV Groups

	At Home	In Clinic	P Value
Reach			
Number of participants choosing at-home versus in-clinic administration (%)	15 (45%)	18 (55%)	.60 ^a
Cohort demographics			
Age: median (IQR)	48 (31–51)	41 (37–56)	.57 ^b
Sex: number male/female (%)	9/6 (60/40)	15/3 (87/13)	.14 ^a
Race: number Black/White (%)	8/7 (53/47)	13/5 (72/28)	.26 ^a
Miles to clinic from residence: median (IQR)	22 (9–22)	15 (12–24)	.13 ^b
Effectiveness			
Virologic suppression at end of study	15/15	18/18	1.0 ^a
Virologic suppression throughout study	15/15	17/18	.31 ^a
Retention in care at end of study	15/15	18/18	1.0 ^a
Out of window injections: number/total injections	0/83	3/135	.17 ^a
Reversion to oral ART by end of study	1 ^c	2 ^d	.66 ^a
Participant satisfaction: ^e mean $\pm$ SD	5.9 $\pm$ 0.2	5.9 $\pm$ 0.2	.83 ^b
Injection site reactions: number/total injections (%)	40/74 (54%)	85/166 (51%)	.68 ^a
Implementation			
Days medication kept in refrigerated storage: median (IQR)	8.5 (3–15)	15 (8–22)	<.0001 ^b
Post-intervention surveys (n = 26)			
Number of participants who completed survey	13	13	
Maintenance			
Participant intends to remain on LA CAB/RPV moving forward ^f	12/12	12/12	1.0 ^b
Participant prefers to continue LA CAB/RPV at the same location ^f	10/12	12/12	.14 ^a
Driving factor is convenience:	7	10	.13 ^a
Driving factor is privacy:	4	1	
Co-resident(s) are aware of the participant's HIV status	10/13	10/13	1.0 ^a
Participant rating of overall health: ^g mean $\pm$ SD	2.1 $\pm$ 1.0	1.9 $\pm$ 1.0	.83 ^b
Main benefits to LA CAB/RPV:^h			
No more pills	10/13	13/13	.07 ^a
More convenient	7/13	9/13	.42 ^a
Takes <30 min to get to clinic	5/13	9/13	.12 ^a
Lives in a rural area	5/13	2/13	.18 ^a
Works either full or part time	4/13	9/13	.049 ^a

Abbreviations: ART, antiretroviral therapy; HIV, human immunodeficiency virus; IQR, interquartile range; LA CAB/RPV, long-acting injectable cabotegravir plus rilpivirine; SD, standard deviation.

^a χ^2 test.

^bMann-Whitney unpaired *t* test.

^cDue to possible allergic reaction.

^dDue to loss of virologic suppression (n = 1) and provider decision (n = 1).

^eAverage participant score during the 12-month intervention with injection visits "How satisfied are you with your current treatment?" where 0 = very dissatisfied and 6 = very satisfied.

^fn = 2 no longer on LA CAB/RPV so excluded.

^gHow would you rate your overall health? 1 = excellent, 2 = very good, 3 = good, 4 = fair.

^hWhat benefits did you experience in switching to injectable HIV treatment? Response choices: a: no more pills, b: more convenient, c: fewer side effects, d: don't have to remember to take pills every day, e: don't have to hide my medications, f: no stigma from daily pills, g: no more difficulty with swallowing daily pills, h: no need to pick up monthly refills from the pharmacy.

the sample were summarized using frequency and percentages (%), whereas continuous demographic characteristics were summarized using the median and interquartile range (IQR) or the mean and standard deviation (SD).

RESULTS

Participant demographic characteristics (n = 33) are shown in Table 1. Regarding Reach, a comparable number of participants elected to primarily receive treatment at home (n = 15) relative to in clinic (n = 18), and there were no significant differences between groups in age, sex, race, or distance from their place of residence to the clinic (Table 1). Switching the primary location

of treatment receipt during the study was infrequent (n = 1 transitioned from at home to in clinic, n = 1 transitioned from in clinic to at home, and n = 1 transitioned from at home to an infusion center due to incompatibility with the LPN's schedule).

Regarding effectiveness, all participants were virologically suppressed (viral load [VL] <200 IU/mL) and retained in care at the end of study, and thirty participants remained on LA CAB/RPV throughout the 12-month intervention (Table 1). No significant differences in days between injections (not shown) or out of window injections (Table 1) were observed between groups. Treatment satisfaction was high and comparable between groups (Table 1). Consistent with reported clinical experience, the most common side effect was injection site pain/

soreness (52% of all injections); however, this did not differ between groups. No at-home participants reported an allergic reaction, use of an epinephrine pen, or any other untoward events associated with at-home administration.

Three participants stopped LA CAB/RPV and transitioned to oral therapy due to hypersensitivity reaction ($n = 1$, etiology LA CAB/RPV vs metformin, which were started concurrently), loss of virologic suppression ($n = 1$), and provider decision due to inconsistent injection visit adherence ($n = 1$). The participant who experienced treatment failure was in the in-clinic group, was heavily treatment-experienced with prior adherence concerns, had been virologically suppressed on bictegravir/tenofovir alafenamide/emtricitabine prior to oral CAB/RPV lead-in, and had a remote HIV-1 genotype showing K103N and A71T mutations. Genosure archive testing performed after virologic rebound revealed NRTI (K65R, M184V), NNRTI (L100I, K103N, Q207E), PI (A71T, E35D) and INSTI (E138A, G140S, Q148H, N155H) resistance mutations (the HIV viral load was too low for standard genotype testing). Virologic suppression was regained on a regimen of oral darunavir/cobicistat, fostemsavir, and doravirine.

The participant for whom LA CAB/RPV was discontinued secondary to poor visit adherence had visit attendance and communication concerns prior to initiation of LA CAB/RPV and was in the in-clinic group. During receipt of LA CAB/RPV, several injection visits were given outside of the recommended timeframe due to visit non-adherence. Through shared medical decision making, the participant and clinical team reverted to oral ART. LA CAB/RPV prescribing guidance was followed regarding the management of delayed dosing and virologic suppression was maintained throughout the study while on LA CAB/RPV and oral ART.

Regarding Implementation, the time LA CAB/RPV was kept in refrigerated storage was shorter for the at-home cohort (Table 1). This difference was attributed to pharmacy and clinic staff preferences who timed medication shipments for at-home participants with the intent to limit the need for medication replacements, such as the potential for at-home refrigerator malfunctions, for participants to misplace LA CAB/RPV, or the potential for desire to change their desired location of treatment. Given favored, planned earlier shipments to in-clinic versus at-home participants (see Methods), the significant difference of medication time in storage highlights successful implementation of different workflows based on location of treatment receipt.

Regarding Maintenance, in post-intervention surveys ($n = 26$), all participants still receiving LA CAB/RPV intended to continue this treatment. Most endorsed a preference to continue treatment at the same location, and convenience rather than privacy or stigma concerns was the primary factor driving this preference (Table 1). Notably, continued at-home receipt of LA CAB/RPV was not offered by our clinic after study completion, and at-home participants returned to receiving treatment in clinic (no at-home participants reverted to oral ART at end of study). Distance from clinic and residing in a rural area did not significantly

associate with preference for where to receive therapy; however, in equal sized samples twice as many patients living 30 minutes or more from clinic chose to receive at-home injections (Table 1). Patients who reported they were not employed, either part- or full-time, were more likely to prefer receipt of LA CAB/RPV at home (Table 1).

DISCUSSION

To our knowledge, this is the first report to describe at-home administration by a healthcare provider of a complete long-acting injectable antiretroviral regimen for treatment of HIV infection. This study provided the infrastructure to allow participants to choose how and where to receive LA CAB/RPV. We found that receipt of LA CAB/RPV at home was safe, effective, and associated with high participant satisfaction. Although the sample size of the 2 groups was relatively small, which could limit the ability to identify statistically meaningful differences between the groups, we were intrigued to find that the preference for receiving treatment both at home and in clinic was primarily related to convenience and did not correlate with any measured demographic or geographic variables, including travel time to clinic and perceptions of overall health (Table 1). These results highlight the utility and clinical benefit of offering access to LA CAB/RPV in diverse settings outside of traditional clinical venues [17]. This approach of enabling LA CAB/RPV administration at home allows participants to experience convenience that has some similarities to self-administered injections, which is not an approved approach for LA CAB/RPV administration, while also giving providers the confirmation of receipt of on-time and appropriately administered doses. Directly observed therapy and administration documentation remain desired attributes for prescribers with LA CAB/RPV; therefore, despite inquiries from some participants whether healthcare professional friends or family members could administer LA CAB/RPV at home, this was not allowed during the study.

In addition to quantified measures, the study team observed subjective benefits of home-receipt of LA CAB/RPV that were not formally quantified as part of study measures. As the study used a single home health LPN, at-home participants became familiar with, and anecdotally endorsed satisfaction with, having a consistent provider; injection/documentation training was completed efficiently; and no out-of-window injection instances occurred in this cohort (Table 1). Clinic staff turnover necessitated injection protocol education for new staff members and may have provided a less consistent provider interaction for in-clinic participants. As the clinic utilizes medical case managers to assist with transportation, use of home health obviated the need for transportation assistance and had the potential to free up case manager time, although this was not quantified during the study. Future studies will be necessary to compare relative home health

costs versus clinic transportation costs when considering the feasibility of implementing at-home treatment programs.

We also identified practical limitations of at-home LA CAB/RPV administration. Implementation of a LA CAB/RPV program already requires significant effort for insurance approvals, patient education, coordinating and tracking visit dates, and nursing documentation education [11–14]. Therefore, adding an at-home option for patients to receive LA CAB/RPV added increased complexity and time commitment for clinical staff, although the amount of added effort was not formally quantified during the study. If this program were to be continued, efforts to further streamline data sharing and communication with the external pharmacy would be necessary to continue to ensure medication is delivered on time, while limiting additional effort to coordinate care by clinical staff. Although no such instances occurred during the study, at-home administration could also confound access to immediate colleague confirmation if product is damaged or there is any uncertainty if product seems unusable. This study did not allow at-home lab collection or other services that could typically be provided during clinic visits (eg, contraception injections or immunizations) as this was outside of the scope of the study design. As such, separate visits and additional time investment of at-home participants were required to receive these services. As home receipt of LA CAB/RPV is not currently covered by insurance payers unless a patient is homebound, this treatment option is not likely to be financially viable for most clinics. Additionally, this study used a single home health LPN, and as such, home injections were not feasible to offer every day. Some patients may prefer injections off-hours or over weekends to accommodate working schedules, which could help explain why the at-home group was less likely to be employed (Table 1), an observation that requires further analysis in future studies. Finally, the study's relatively small sample size was an additional limitation, which may have limited our ability to detect significant differences across groups. Larger studies evaluating implementation of home-based injectable HIV therapy are warranted.

In conclusion, at-home receipt of LA CAB/RPV was safe, effective, and associated with high participant satisfaction. Although many participants valued and wanted to continue at-home LA CAB/RPV, real world limitations and lack of insurance coverage to cover the cost for at-home receipt of treatment made continuation of this effort impractical after study completion. Benefits of the effort were somewhat offset by the extensive time and coordination efforts from clinical team members needed to support at-home LA CAB/RPV, which may be difficult to reproduce, sustain, afford, and implement in clinical practice. Nonetheless, this work serves as a proof of concept in support of continued efforts to make LA CAB/RPV accessible in non-clinical settings.

Notes

Author Contributions. Study design (S. E. K., V. F., E. G. M.); Study implementation (S. E. K., C. Y., H. B., J. W., E. G. M.); Analysis of study results

(S. E. K., R. H., A. M., M. G., E. G. M.); Composition of manuscript (S. E. K., E. G. M.); Critical review and editing of manuscript (S. E. K., C. Y., H. B., R. H., A. M., V. F., M. G., J. W., E. G. M.) Interim results from this study were presented at IDWeek 2023.

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