Ninety-six-week observational outcomes of long-acting injectable HIV therapy in people with adherence challenges, including people who use drugs

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Objective: To evaluate virological outcomes of people with HIV (PWH) and adherence challenges to oral antiretroviral therapy (ART) who initiate long-acting injectable ART.

Design: Observational cohort study.

Setting: Single-center urban HIV primary care clinic at the University of California San Diego.

Participants: All PWH who initiated long-acting injectable (LAI)-ART between November 2021 and September 2023 with documented adherence challenges to oral ART.

Main outcome measures: The primary outcomes were virologic failure (two consecutive viral loads ≥200 copies/ml, one viral load ≥1000 copies/ml, or one viral load ≥200 copies/ml with evidence of resistance mutation to LAI-ART ≥30 days after initiation of LAI-ART) or discontinuation of LAI-ART for any reason within 96 weeks of initiation.

Results: Of the 62 eligible individuals, 48 (77.4%) remained virologically suppressed on LAI-ART and 14 (22.6%) discontinued therapy by 96 weeks. Of these 14 individuals, 3 experienced virologic failure (at 28, 40, and 42 weeks) and 3 were lost to follow-up. There were similar outcomes among the 26 participants with active substance use, of whom 18 (69%) remained suppressed on LAI-ART at 96 weeks. The remaining participants discontinued LAI-ART due to preference, adverse events, insurance issues, or death.

Conclusion: High rates of viral suppression were achieved and maintained at 96 weeks, supporting the use of LAI-ART among those with adherence challenges to oral ART, including those with significant barriers to care, including substance use disorder and psychiatric comorbidities.

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Introduction

Adherence to daily oral antiretroviral therapy (ART) remains a barrier to viral suppression among people with HIV (PWH) due to structural, economic, and psychosocial barriers [1]. US Centers for Disease Control and Prevention (CDC) data suggests that only 65% of those in the United States with known HIV diagnosis were on treatment and virologically suppressed in 2022, the latest year for which CDC data are publicly available.

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Among men and women who inject drugs this falls to 51 and 60%, respectively [2]. Addressing this gap in the care cascade, namely for those with known diagnosis of HIV on ART and not virologically suppressed, is an essential component of ending the HIV epidemic [3].

Long-acting injectable ART (LAI-ART) is an alternative for people with barriers to daily oral ART, with trial data demonstrating high rates of viral suppression [4–6]. These trials also demonstrated high rates of treatment satisfaction and preference for LAI-ART. Qualitative research has indicated significant interest in and acceptance of LAI-ART, which may address concerns related to pill fatigue, loss or theft of pills, stigma or inadvertent disclosure associated with daily oral therapy [7,8].

Early studies of LAI-ART excluded PWH who had difficulties with adherence and required individuals to be virally suppressed prior to inclusion. More recently, the LATITUDE Study has provided strong evidence supporting LAI-ART among PWH with evidence of poor adherence to oral ART [9]. The trial was structured with conditional economic incentives (CEI) to achieve suppression on oral ART before randomization to either LAI-ART [cabotegravir/rilpivirine (CAB/RPV)] or continuation of oral ART. After 48 weeks, virological failure was observed in 41% of participants in the oral ART arm compared to 23% ($P = 0.002$) in the LAI-ART arm.

These findings have been further supported by real-world observational studies among PWH who have difficulty with adherence to oral ART or who are viremic at LAI-ART initiation [10–14]. While evidence supporting LAI-ART among PWH with adherence difficulties is growing, data on long-term outcomes are still limited. Our group previously published 48-week outcomes among a cohort of patients with adherence challenges initiated on LAI-ART and demonstrated that more than 85% of participants remained suppressed on LAI-ART after 48 weeks [13]. This study represents the 96-week extension of data previously published among this cohort. No published studies to date have explored outcomes in this population beyond the first year.

Methods

This was an observational cohort study of PWH with history of adherence challenges who initiated LAI-ART between November 2021 and September 2023 at the University of California, San Diego Owen Clinic (San Diego, California, USA). Adherence challenges were defined as: HIV viral load at least 200 copies/ml in the prior 12 months and either poor response to oral ART (two HIV viral loads $\geq$200 copies/ml separated by $\geq$4 weeks in the prior 18 months despite being prescribed oral ART) or lost to follow-up (no contact with an HIV provider for $\geq$6 months and nonadherence to ART for $\geq$7 days).

Primary outcomes were virologic failure (two consecutive viral load $\geq$200 copies/ml, one viral load $\geq$1000 copies/ml or one viral load $\geq$200 copies/ml with evidence of resistance mutation to LAI-ART $\geq$30 days after initiation of LAI-ART) or discontinuation of LAI-ART within 96 weeks of initiation for any reason. The definition of virologic failure was updated from the week 48 report as multiple participants were found to have viral load at least 200 copies/ml that subsequently resuppressed without a change in therapy. Many reports suggest that viral loads between 200 and 1000 copies/ml as single measures should not be considered to represent virologic failure [13,15].

All participants received care at the Owen Clinic, an HIV clinic that provides primary and HIV care for more than 3600 PWH. LAI-ART is managed by a specialized team of HIV pharmacists and pharmacy technicians who provide adherence counseling and support, as well as manage prior authorization and insurance approval. The clinic provides other supportive care including medications for addiction treatment and counseling for substance use disorders, HIV psychiatry, financial counselors, and social work support. Participants were assessed for and offered the use of LAI-ART through routine clinical care by their primary HIV provider in conjunction with the HIV pharmacist team. Eligibility for using LAI-ART was determined by evaluating various clinical factors, as well as extensive counseling and discussion with the patient regarding the risk/benefit of using LAI-ART in off-label situations, particularly in those with detectable HIV viremia. The decision to use additional ART in combination with CAB/RPV was made on a case-by-case basis at the discretion of the treating provider and clinical pharmacist, and was primarily used in situations of detectable viremia at baseline, given the limited efficacy data with the use of CAB/RPV alone in more diverse clinical scenarios than encountered in clinical trials.

Baseline characteristics, including demographic data, date of HIV diagnosis, baseline HIV viral load and $CD4^+$ T-cell count, insurance status, baseline resistance mutations, history of injection drug use (IDU), active substance use [defined as positive urine toxicology or provider documentation or indication on patient-reported outcomes (PROs) data collected as part of the CFAR Network of Integrated Clinical Systems (CNICS) in the past 12 months], and any history of psychiatric diagnosis (depression, anxiety, bipolar disorder, schizoaffective disorder, schizophrenia, based on chart review of provider notes, and diagnosis codes) were collected. We also collected data on additional ART at baseline, which included lenacapavir, tenofovir alafenamide/emtricitabine, and fostemsavir. All medications were covered by

insurance, the Ryan White HIV/AIDS Program (RWHAP), or medication assistance programs. Follow-up data collected included the date of discontinuation of LAI-CAB/RPV, reason for discontinuation, any late injections (>7 days beyond due date), and presence of resistance-associated mutations. Chart reviews of provider notes and laboratory results were performed to clarify substance use, psychiatric diagnoses, and reasons for discontinuation.

The date of failure was defined as the date LAI-ART was discontinued or the date of HIV viral load at least 200 copies/ml or HIV viral load at least 1000 copies/ml. Ninety-six-week outcomes were evaluated among participants who initiated LAI-ART at least 96 weeks before data abstraction. We performed univariate and multivariate Firth logistic regression to identify factors associated with discontinuation, including substance use in the previous year, baseline $CD4^+$ cell count, viral suppression at switch, and psychiatric comorbidities. We performed regression analysis on two outcomes: all treatment discontinuations ($n = 14$) and discontinuations because of virologic failure/loss to follow-up ($n = 6$). All analyses were performed using R.4.5.2.

This study was deemed exempt by the Institutional Review Board of the University of California San Diego.

Results

Sixty-two PWH met inclusion criteria and initiated LAI-ART at least 96 weeks prior to data abstraction. Demographics, baseline HIV variables, substance use, and psychiatric comorbidities are shown in Table 1. Among 62 participants, 26 (41.9%) had active substance use, including injection and noninjection use. Additionally, 25 participants (40.5%) actively or previously injected drugs. Thirty-five participants (56.5%) were diagnosed with psychiatric conditions. Most participants (75.8%) were insured with Medicaid. For those in whom baseline genotype data were available (61/62 participants), none had major resistance mutations to CAB or RPV.

At the time of initiation of LAI-ART, 35 participants (56.5%) had viral load 50 copies/ml or less, 15 (24.2%) had viral load at least 200 copies/ml, and 7 (11.3%) had viral load at least 10 000 copies/ml. Nine participants (14.5%) completed an oral lead-in with oral CAB/RPV for at least 4 weeks prior to initiating LAI-ART, and 95.2% began on an every 2-month injection schedule. At time of initiation of LAI-CAB/RPV, concurrent use of additional ART included TAF/FTC in three (4.8%), lenacapavir in nine (14.5%), and fostemsavir in one (1.6%) participant.

After 96 weeks, 48 participants (77.4%) remained virologically suppressed on LAI-ART, and 14 participants (22.6%) had discontinued therapy. Of these 14 individuals, 3 experienced virologic failure (at 28, 40 and 42 weeks) and 3 were lost to follow-up (Table 2). Other reasons for discontinuation included: patient preference ($n = 2$), adverse events ($n = 3$), death ($n = 1$), desire to become pregnant ($n = 1$), and insurance issues ($n = 1$). Kaplan–Meier time-to-event analysis is shown in Fig. 1. Among the three virologic failures, treatment-emergent drug resistance mutations to either RPV or both RPV and CAB were identified in all three patients (Table 3). Twenty participants (32.3%) had at least one late injection with a median of 3 days late [interquartile range (IQR) 2–10.5].

Among the 26 participants with active substance use, 18 (69.2%) remained virologically suppressed on LAI-ART after 96 weeks. Differences in outcomes between participants with active substance use versus the entire cohort were not statistically significant [odds ratio (OR) = 0.66, $P = 0.43$]. In univariate analysis, baseline methamphetamine use was significantly associated with virologic failure or loss to follow-up (OR = 11.5, $P = 0.031$) and viral load 50 or less at switch was protective against LAI-ART discontinuation for any reason (OR = 0.28, $P = 0.044$) (Table 4). Firth multivariable logistic regression did not show significant independent predictors of treatment failure, likely due to limited power (Table 4).

Discussion

Our study evaluated long-term real-world 96-week outcomes of LAI-ART among PWH with documented difficulty with adherence to oral ART. After 96 weeks, over 75% of the participants remained adherent and virally suppressed on LAI-ART. Notably, participants with active substance use also achieved high levels of viral suppression on LAI-ART. While methamphetamine use was associated with increased virologic failure or loss to follow -up, more than two-thirds remained suppressed on therapy after 96 weeks.

This study enhances the recent data published by the LATITUDE study. While LATITUDE provided supportive evidence, the CEIs used and the selective nature of clinical trials limit its generalizability to real-world populations with adherence challenges. Our study indicates that not only do PWH with adherence difficulties achieve high rates of suppression on LAI-ART, but also that the response and suppression have good durability over 96 weeks. Also, despite concerns over resistance and loss to follow-up, relatively few (6/62) were lost to follow-up or developed resistance mutations. The durable suppression achieved among this population has the potential to provide meaningful improvement in the care cascade and to reduce morbidity and onward transmission of HIV, as LAI-ART can address issues

Table 1. Participant characteristics.

N		Entire cohort (62)	Active substance use (26)
Age (median, IQR)		5	41 (38–49)
Race (*N*, %)	Asian	2 (3.2)	0
	Black	10 (16.1)	5 (19.2)
	Mixed/other	20 (32.3)	7 (26.9)
	Unknown	2 (3.2)	0
	White	28 (45.2)	14 (53.8)
Ethnicity (*N*, %)	Hispanic	22 (35.5)	8 (30.8)
	Non-Hispanic	37 (59.7)	17 (65.4)
	Unknown	3 (4.8)	1 (3.8)
Sex at birth (*N*, %)	Female	17 (27.4)	3 (11.5)
	Male	45 (72.6)	23 (88.5)
Gender identity (*N*, %)	Female	17 (27.4)	3 (11.5)
	Male	44 (71)	23 (88.5)
	Nonbinary	1 (1.6)	0
Insurance (*N*, %)	Medicaid	40 (64.5)	18 (68)
	Medicare/Medicaid	7 (11.3)	3 (11.5)
	Medicare only	5 (8.1)	2 (7.7)
	Private	9 (14.5)	3 (11.5)
	Ryan White/ADAP	1 (1.6)	0
BMI (median, IQR)		26.45 (23.9–30.6)	27 (23.9–30.8)
Years since HIV diagnosis (median, IQR)		13.3 (8.2–18.5)	13.5 (10.3–16.4)
Baseline VL (median, IQR)		37 (0–182.5)	87 (0–330.3)
VL≤50 at initiation (*N*, %)		35 (56.5)	10 (38.5)
VL≥200 at initiation (*N*, %)		15 (24.2)	8 (30.8)
VL≥10,000 at initiation (*N*, %)		7 (11.3)	5 (19.2)
Baseline $CD4^+$ cell count (median, IQR)		496.5 (292.5–738.8)	417 (244.8–576.8)
$CD4^+$ cell count <200 cells/μl at initiation (*N*, %)		9 (14.5)	6 (24)
Any prior injection drug use (*N*, %)		25 (40.3)	16 (61.5)
Substance use in prior year (*N*, %)		26 (41.9)	26 (100)
	Methamphetamine	22 (35.5)	22 (84.6)
	Cocaine	2 (3.2)	2 (7.7)
	Alcohol	7 (11.3)	7 (26.9)
	Opiate	2 (3.2)	2 (7.7)
Psychiatric disorder (*N*, %)		35 (56.5)	17 (65.4)
	Depression/anxiety	29 (46.8)	12 (46.2)
	Bipolar	4 (6.5)	3 (11.5)
	Schizoaffective disorder	2 (3.2)	2 (7.7)
Oral lead-in with oral CAB/RPV prior to initiating LAI-ART (*N*, %)		9 (14.5)	2 (7.7)
Dosing regimen	Every 2 months	59 (95.2)	26 (100)
	Every 1 month followed by every 2 months	3 (4.8)	0
Other ART at LAI-initiation (*N*, %)	TAF/FTC	3 (4.8)	1 (3.8)
	Lenacapavir (sq)	9 (14.5)	8 (30.8)
	Fostemsavir	1 (1.6)	0
Baseline resistance (*N*, %)			
	NRTI	20 (32.3)	10 (38.5)
	NNRTI	6 (9.7)	5 (19.2)
	INSTI	2 (3.2)	2 (7.7)
	PI	2 (3.2)	1 (3.8)

ADAP, AIDS Drug Assistance Program; ART, antiretroviral therapy; CAB, cabotegravir; FTC, emtricitabine; INSTI, integrase inhibitor; IQR, interquartile range; LAI, long-acting injectable; NNRTI, nonnucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; RPV, rilpivirine; sq, subcutaneous; TAF, tenofovir alafenamide.

related to stigma and difficulty in remembering to take a daily pill.

Strengths of our study include comprehensive longitudinal data and prospectively recorded data collection regarding LAI-ART administration and chart review to enable the accurate documentation of barriers to care including substance use and psychiatric comorbidities. Recognizing that provider documentation and urine toxicology may lead to underreporting of substance use, we additionally reviewed PRO surveys available through the CNICS database, which have been shown to be more likely to accurately capture substance use [16,17]. Another strength is that this study represents real-world evidence of LAI-ART in a more challenging population that is rarely captured in clinical studies and provides evidence to support other centers looking to implement LAI-ART in high-risk populations.

Table 2. Participant outcomes among the overall cohort and among those with substance use in the prior year.

	Entire cohort	Active substance use
Viral suppression on LAI-ART at 96 weeks (*N*, %)	48 (77.4)	18 (69.2)
LAI-ART discontinued by 96 weeks (*N*, %)	14 (22.6)	8 (30.8)
Time to discontinuation (weeks) (median, IQR)	34 (22.1–50.5)	21 (14.3–24.2)
Reason for discontinuation (*N*, %)		
Participant preference[a]	2 (3.2)	1 (3.8)
Virologic failure	3 (4.8)	2 (7.7)
Adverse event[b]	3 (4.8)	1 (3.8)
Lost to follow-up	3 (4.8)	3 (11.5)
Death	1 (1.6)	1 (3.8)
Other[c]	2 (3.2)	0
Any late injection (*N*, %)	20 (32.3)	8 (30.8)
Days late (median, IQR)	3 (2–10.5)	13 (2–37)

ART, antiretroviral therapy; IQR, interquartile range; LAI, long-acting injectable.
[a]Participant stated reasons for discontinuation: pain with injections ($n=1$), difficulty attending injection appointments ($n=1$).
[b]Adverse events: mood changes ($n=1$), leg pain ($n=1$), weakness ($n=1$).
[c]Other reasons: desire to become pregnant ($n=1$), insurance challenges ($n=1$).

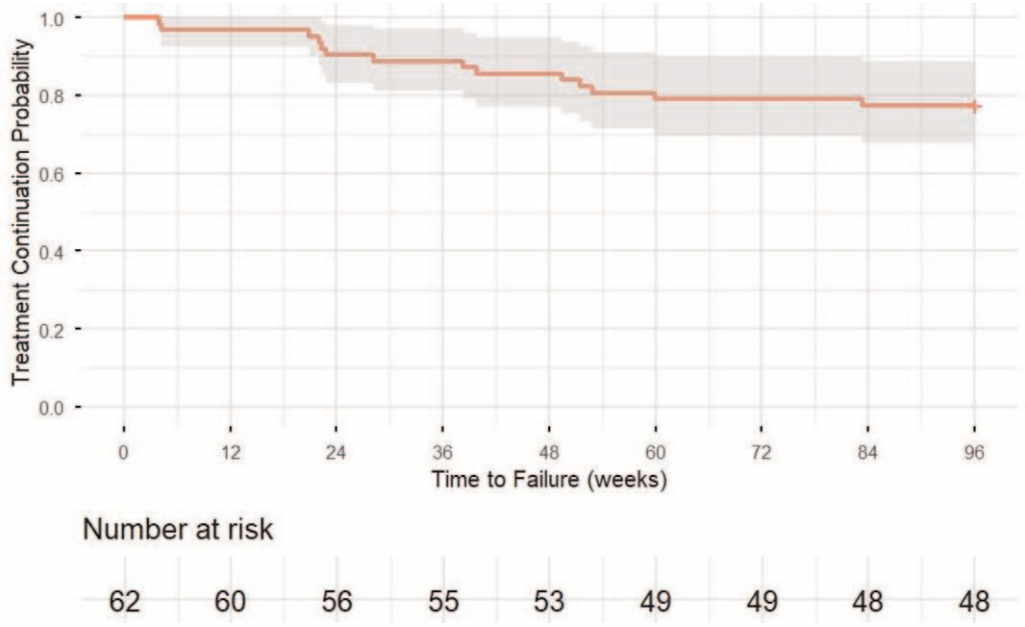

Fig. 1. Kaplan–Meier curve showing probability of survival free from long-acting injectable-antiretroviral therapy discontinuation.

Table 3. Treatment-emergent drug resistance mutations.

Participant	Baseline DRMs	Treatment-emergent DRMs
1	NNRTI: K103R, I135T, D177N INSTI: none	NNRTI: M230I; subsequently E138Q, V179I/L INSTI: none
2	NNRTI: none	NNRTI: E138K INSTI: G140C, Q148R
3	NNRTI: none INSTI: none	NNRTI: E138A, M230L INSTI: G140S, Q148H

DRM, drug resistance mutation; INSTI, integrase inhibitor; NNRTI, nonnucleoside reverse transcriptase inhibitor.

Table 4. Multivariate (Firth) regression.

	Multivariate regression			
	Treatment discontinuation		Virologic failure or LTFU	
Variable	OR (95% CI)	*P* value*	OR (95% CI)	*P* value
VL ≤50 at switch	0.35 (0.08–1.34)	0.13	0.38 (0.04–2.35)	0.31
Baseline $CD4^+$ cell count (per cell/μl)	1 (1.00–1.00)	0.61	1.00 (1.00–1.00)	0.45
Substance use in prior year	2.25 (0.62–8.73)	0.22	3.28 (0.56–33.59)	0.20
Neuropsychiatric condition	0.62 (0.17–2.20)	0.46	1.12 (0.21–7.43)	0.90

CI, confidence interval; LTFU, lost to follow-up; OR, odds ratio; VL, viral load.
*$P < 0.05$, estimates unstable due to small sample size.

This study has several limitations. First, the relatively small sample size limits statistical power and precision, meaning that strong conclusions about subpopulations cannot be made. Second, the study was conducted at a single site in Southern California and thus findings may not be generalizable to other populations, such as those without Medicaid expansion, regions with different population structures or transmission risks, areas outside the United States, or to clinic settings with less pharmacy support. Third, there is natural selection bias introduced in this observational study; however, many participants used substances in the prior year and had psychiatric comorbidities, and all had proven nonadherence to oral ART as part of the entry criteria. Additionally, several participants in our study received additional ART with CAB/RPV, which distinguishes it from the protocol of the LATITUDE study and may limit generalizability to settings where the availability of additional agents is limited. Finally, only 24.2% of participants in our study had viral load at least 200 copies/ml at initiation of LAI-ART, indicating that while this group had recent issues with adherence to oral ART, many were able to achieve virologic suppression prior to starting LAI-ART.

There were three virologic failures in our cohort of 62 (4.8%), which is higher than in registrational trials and some observational studies, though is consistent with a recent meta-analysis where virologic failure was found in 1–5% [18].

Our study demonstrates high levels of viral suppression and treatment continuation at 96 weeks among people with a history of adherence challenges, including those with substance use disorders and psychiatric comorbidities and supports the use of LAI-ART in these populations. This study highlights the need to examine outcomes in larger and more diverse cohorts.

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Conflicts of interest

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