Real-World Use of Long-Acting Cabotegravir + Rilpivirine in People with HIV with Detectable Viral Loads at Initiation: Findings from the OPERA® Cohort

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Disclosures

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Background

Cabotegravir + rilpivirine long-acting (CAB+RPV LA)

First complete long-acting injectable antiretroviral regimen

Approved by the FDA in January 2021

Indicated for ART-experienced people with HIV (PWH) with a **VL <50 copies/mL**

Background

Demonstration project at Ward 86 in San Francisco[1]

- Study population: VL ≥30 copies/mL at initiation & numerous barriers to adherence to oral medications.
- Findings: High rates of virologic suppression (97.5% with VL <30 copies/mL at 26 weeks) with CAB+RPV LA

HIV simulation model of long-term benefits[2]

- Predicted significant improvements in survival with CAB+RPV LA over standard of care oral regimens

[1]Gandhi, *et al.* (2023) Demonstration project of long-acting antiretroviral therapy in a diverse population of people with HIV. *Annals of Internal Medicine.*
[2]Chen, *et al.* (2023) Projected Benefits of Long-Acting Antiretroviral Therapy in Nonsuppressed People With Human Immunodeficiency Virus Experiencing Adherence Barriers. *OFID.*

Study Objectives

Among individuals with VL ≥50 copies/mL at 1st CAB+RPV LA injections:

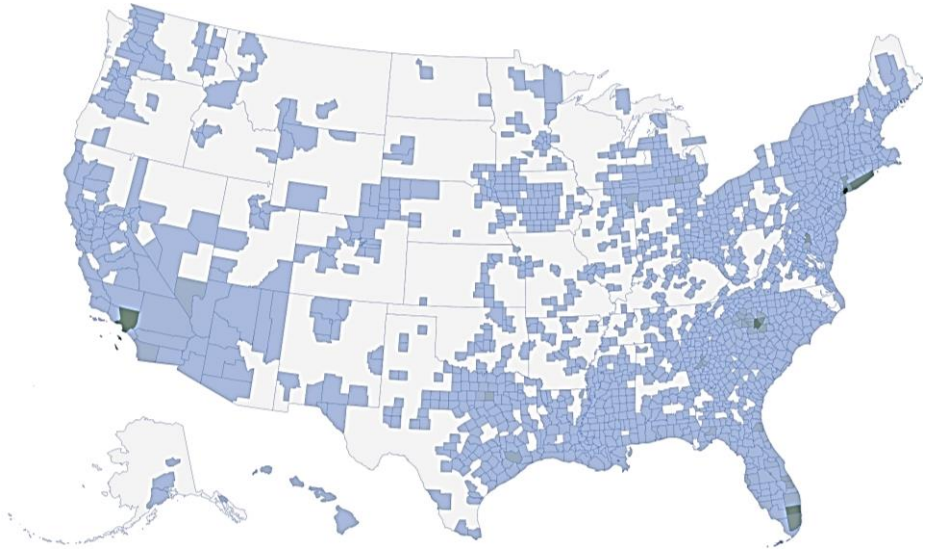
1. To describe CAB+RPV LA real-world utilization over the first 2 years of availability in the US

2. To describe CAB+RPV LA effectiveness

Methods

OPERA®

The Longitudinal Cohort



Observational **P**harmaco-
Epidemiology **R**esearch & **A**nalysis

>155K people with HIV in OPERA

~14% of people with HIV in the US

Study Design

Inclusion Criteria

- ≥18 years old
- ART-experienced
- VL ≥ 50 copies/mL at 1st injections
- 1st CAB+RPV LA injections between 21JAN2021-28FEB2023
- Did not participate in CAB+RPV LA clinical trials

Censoring Criteria

- Regimen discontinuation
- Lost to follow-up
- Death
- Analysis end (25MAR2023)

Outcomes

Achievement of virologic suppression

- Any VL <200 or <50 copies/mL
- Last VL <200 or <50 copies/mL

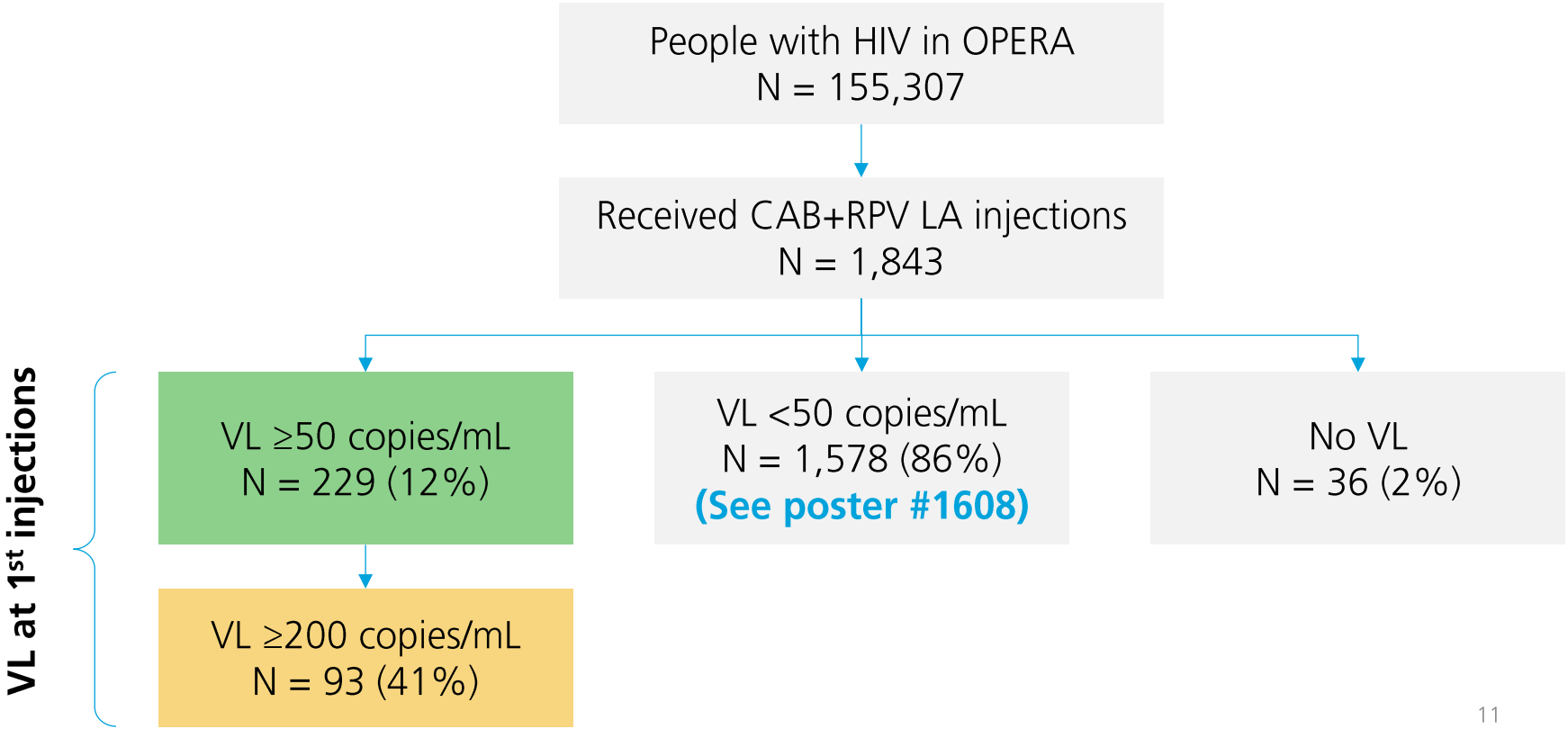
Confirmed virologic failure

Among those with a VL ≥50 to <200 at start or who achieved a VL<200 during follow-up:

- 2 consecutive VLs ≥200
  or
- VL ≥200 + discontinuation (regimen change or 2 missed injections)

Results

Study Population at Regimen Initiation



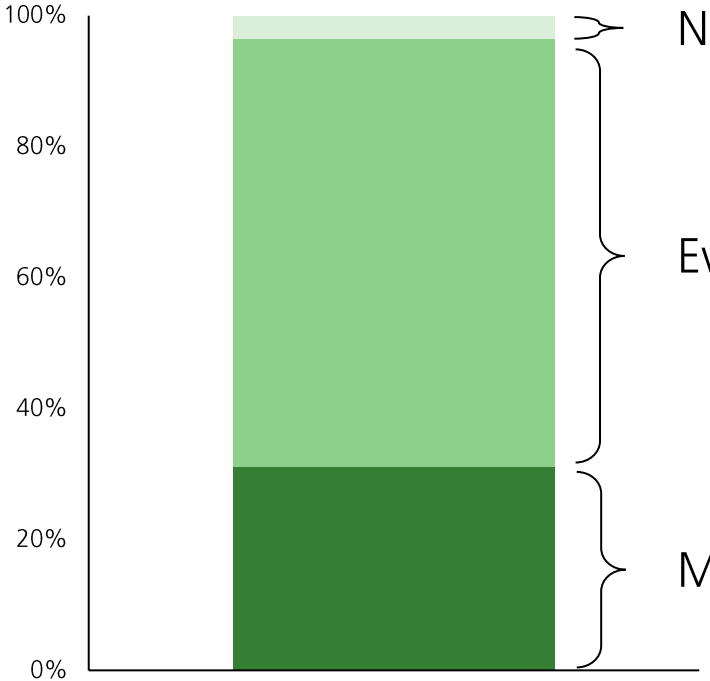
Demographic Characteristics at 1st Injections

	VL ≥50 copies/mL (N=229)	VL ≥200 copies/mL (N=93)
Age, median (IQR)	41 (33, 52)	40 (32, 48)
Female sex, n (%)	71 (31)	44 (47)
Black race, n (%)	130 (57)	65 (70)
Hispanic ethnicity, n (%)	40 (17)	8 (9)

Clinical Characteristics at 1st Injections

	VL ≥50 copies/mL (N=229)	VL ≥200 copies/mL (N=93)
BMI, median kg/m^2 (IQR)	27 (24, 31)	27 (22, 31)
Time from HIV diagnosis, median years (IQR)	9 (4, 17)	9 (4, 16)
VL, median log copies/mL (IQR)	2.1 (1.8, 3.8)	4.2 (3.2, 4.7)
CD4 count, median cells/uL (IQR)	579 (350, 759)	401 (228, 664)
VACS Mortality Index, median (IQR)	17 (6, 30)	29 (17, 46)

Initial Dosing Schedule
VL ≥50 copies/mL at 1st Injections



No dose information, 3% (n = 8)

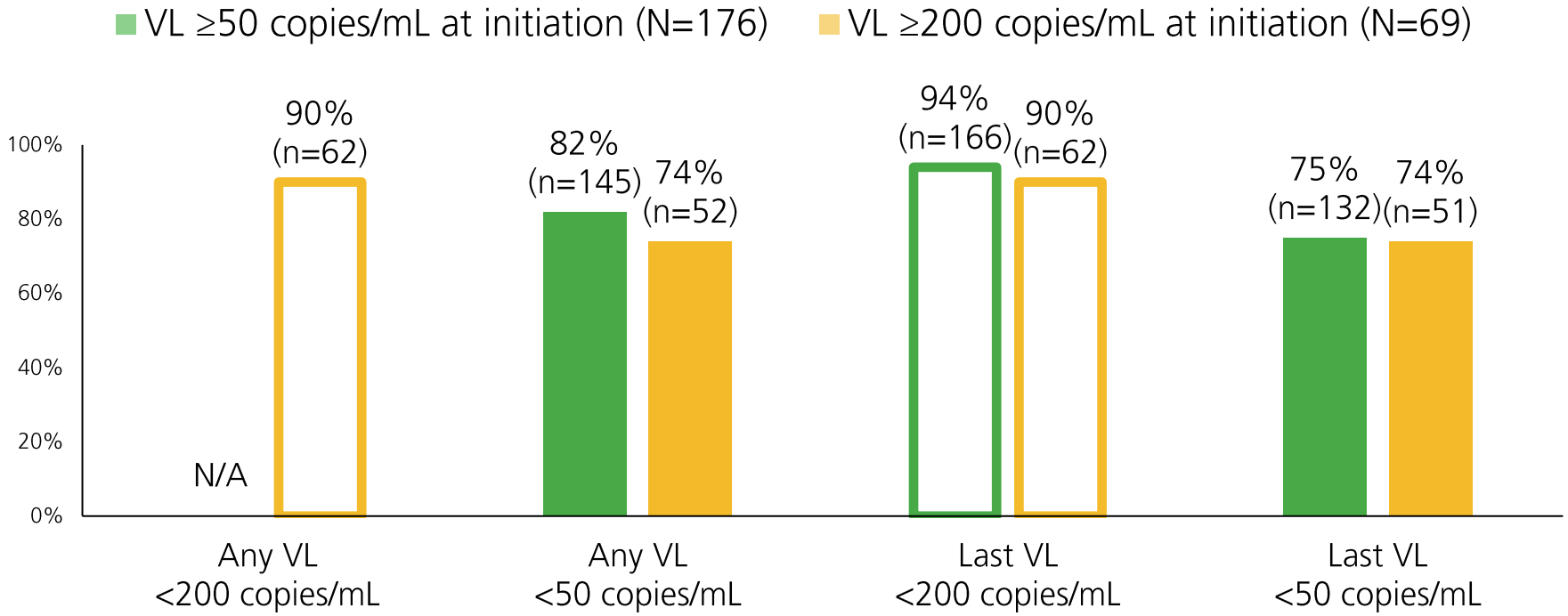
Every 2 months injections, 65% (n = 150)

Monthly injections, 31% (n = 71)

Follow-up

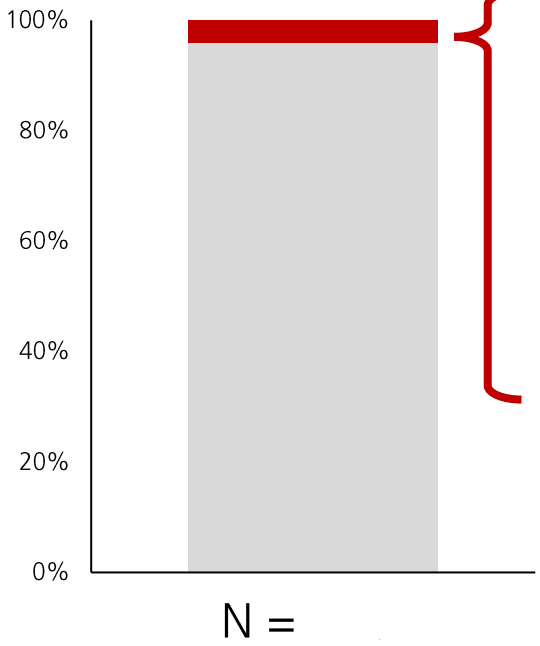
VL ≥50 at 1st injections: N = 229	VL ≥200 at 1st injections: N = 93
Median follow-up: 6 months (IQR: 4, 10)	Median follow-up: 8 months (IQR: 4, 11)
≥1 follow-up viral load: N = 176 (77%)	≥1 follow-up viral load: N = 69 (74%)

Achievement of Virologic Suppression During Follow-Up



Confirmed Virologic Failure During Follow-Up

Among Those with a Follow-Up Viral Load



Confirmed virologic failure: n = 7 (4%)

- 2 had 2 VL ≥200 and remained on CAB+RPV LA
- 3 had 2 VL ≥200 then switched regimen
- 1 had 1 VL ≥200 + discontinuation, then switched regimen
- 1 had 1 VL ≥200 + discontinuation, then reinitiated CAB+RPV LA

Discussion

Key Findings

- 12% of 1st injection CAB+RPV LA users had a VL ≥50 copies/mL, even though CAB+RPV LA is not FDA indicated for such use
- Most (82%) were able to suppress their viremia (VL <50 copies/mL) on CAB+RPV LA
- Long-acting injectables may have a role for individuals with a VL ≥50 copies/mL who may be struggling with adherence or tolerability of oral therapy

Strengths

- Large population of new users of CAB+RPV LA
- Real-world data captured through electronic health records
- Vast majority of HIV healthcare treaters are primary healthcare providers
- Regionally diverse representation of people with HIV in the US

Limitations

- Oral lead in and oral bridging were not well documented in electronic health records
- Reasons for administering long-acting injectable ART to those with a VL ≥50 copies/mL were not documented
- More follow-up needed as only a quarter of individuals had ≥10 months of CAB+RPV LA exposure
- Assessing the reasons for discontinuation and individual outcomes after switch will be important next steps

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