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Jessica Altamirano¹, Brooke Levis², Cindy Markarian³, Quateka Cochran⁴, Courtney Sherman⁵, Mona-Gekanju Toeque³, Laura Armas⁶, Gayathri Sridhar⁷, Vani Vannappagari⁷, Kimberley Brown⁷, Jennifer S. Fusco²

¹ CAN Community Health, Miami, FL, USA; ² Epividian, Inc., Raleigh, NC, USA; ³ AIDS Healthcare Foundation, Los Angeles, CA, USA; ⁴ AIDS Healthcare Foundation, Fort Lauderdale, FL, USA; ⁵ CAN Community Health, Arlington, TX, USA; ⁶ Human Centered Consulting & Care, McKinney, TX, USA; ⁷ ViiV Healthcare, Durham, NC, USA

OPERA[®]
The Longitudinal Cohort



Background

- LA ART**
- Convenience with potential for improved adherence
 - Reduced daily reminders of HIV, stigma, and fear of disclosure
 - Minimized pill burden and gastrointestinal issues
 - May be a good option for women, who represent > 50% of people with HIV worldwide (~20% of people with HIV in the US)

- CAB+RPV LA**
- The first and currently only complete LA ART regimen
 - Injections once a month or every 2 months
 - Indicated for ART-experienced individuals with VL < 50 copies/mL
 - In US cohorts, 9-35% of CAB+RPV LA users initiated the regimen with viremia (VL ≥ 30¹ or ≥ 50²⁻⁴ copies/mL)
 - Among women in the OPERA Cohort, 20% initiated with VL ≥ 50 copies/mL⁵

Objective

To assess clinical outcomes among women initiating CAB+RPV LA with VL > 50 copies/mL over the first 3 years of regimen availability

Methods

- OPERA Cohort**
- Prospectively captured, routine clinical data from electronic health records in the US (101 clinics, 23 US states/territories), representing ~14% of PWH in the US (~11% of women with HIV in the US)

- Inclusion Criteria**
- Cisgender and transgender women living with HIV
 - Aged ≥ 18 years
 - ART-experienced
 - Received ≥ 1 CAB+RPV LA injection from 21JAN2021-31AUG2023
 - VL ≥ 50 copies/mL at first injection

- Censoring Criteria**
- Regimen discontinuation
 - Lost to follow-up (12 months after last clinical contact)
 - Death
 - End of analysis period (29FEB2024)

Abbreviations
ADAP, AIDS Drug Assistance Program; AIDS, Acquired immunodeficiency syndrome; ART, antiretroviral; BMI, body mass index; CAB+RPV, cabotegravir + rilpivirine; CVF, confirmed virologic failure; HIPAA, Health Insurance Portability and Accountability Act; HIV, human immunodeficiency virus; INSTI, integrase inhibitor; IQR, interquartile range; kg, kilograms; LA, long-acting; mL, milliliter; µL, microliter; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; Q1M, monthly dosing schedule; Q2M, every 2 months dosing schedule; US, United States; VACS, Veterans Aging Cohort Study; VL, viral load

- Outcomes**
- Complete initiation:** First 2 sets of injections within 67 days
 - Adherence of initiation/maintenance injections:**

	Days after last injection	
	2 nd initiation or Q1M maintenance injections	Q2M maintenance injections
On-time	23-37	53-67
Late	38-67	68-127
Delayed	38-52	68-112
Missed	53-67	113-127
Discontinued	> 67	> 127

- Persistence:** On regimen at time of analysis; cumulative months of exposure among those on regimen at time of analysis
- Virologic suppression:** Achievement of VL < 50 copies/mL at any time during follow-up, during the 1st 6 months, and at last follow-up
- CVF:** VL suppression < 50 copies/mL followed by 2 consecutive VLs ≥ 200 copies/mL or 1 VL ≥ 200 copies/mL and discontinuation

Results

Table 1. Demographic and clinical characteristics at CAB+RPV LA initiation (N = 105)

	Women with ≥ 1 injection
Age, median years (IQR)	43 (35, 52)
≥ 50 years old, n (%)	37 (35%)
Transgender, n (%)	8 (8%)
Black race, n (%)	83 (79%)
Hispanic ethnicity, n (%) ^a	9 (9%)
Married or domestic partner, n (%) ^a	15 (14%)
Injection drug use, n (%)	≤ 5 ^b
Care in Southern US, n (%)	85 (81%)
Payer, n (%) ^c	
Medicare	28 (27%)
Medicaid	54 (51%)
Commercial Insurance	67 (64%)
Ryan White/ADAP	17 (16%)
Cash	≤ 5 ^b
Years since HIV diagnosis, median (IQR)	13 (4, 22)
History of AIDS-defining illnesses, n (%)	40 (38%)
BMI ≥ 30 kg/m ² , n (%) ^a	46 (44%)
VACS Index, median (IQR) ^a	28 (17, 47)
≥ 1 comorbidity, n (%) ^d	90 (86%)
Co-infections (ever), n (%)	
Hepatitis B	≤ 5 ^b
Hepatitis C	10 (10%)
Syphilis	21 (20%)
Viral load, median copies/mL (IQR)	1090 (89, 24700)
CD4 cell count, median cells/µL (IQR) ^a	438 (253, 686)
Prior core agent class, n (%) ^a	
INSTI	61 (58%)
PI	14 (13%)
NNRTI	12 (11%)
≥ 2 core agents	14 (13%)
Other or missing	≤ 5 ^b
Duration of prior regimen, median months (IQR)	17 (8, 34)

^a N missing: ethnicity = 1, marital status = 7, BMI = 4, VACS index = 4, CD4 cell count = 1
^b HIPAA regulations require masking cells with 1 to 5 individuals
^c Payer categories are not mutually exclusive
^d At least one of the following comorbidities (ever): autoimmune disease, cardiovascular disease, invasive cancer, endocrine disorder, mental health disorder, liver disease, bone disorder, peripheral neuropathy, renal disease, hypertension, or substance use disorder

Figure 1. CAB+RPV LA dosing at initiation and at time of analysis among complete initiators (N = 95)

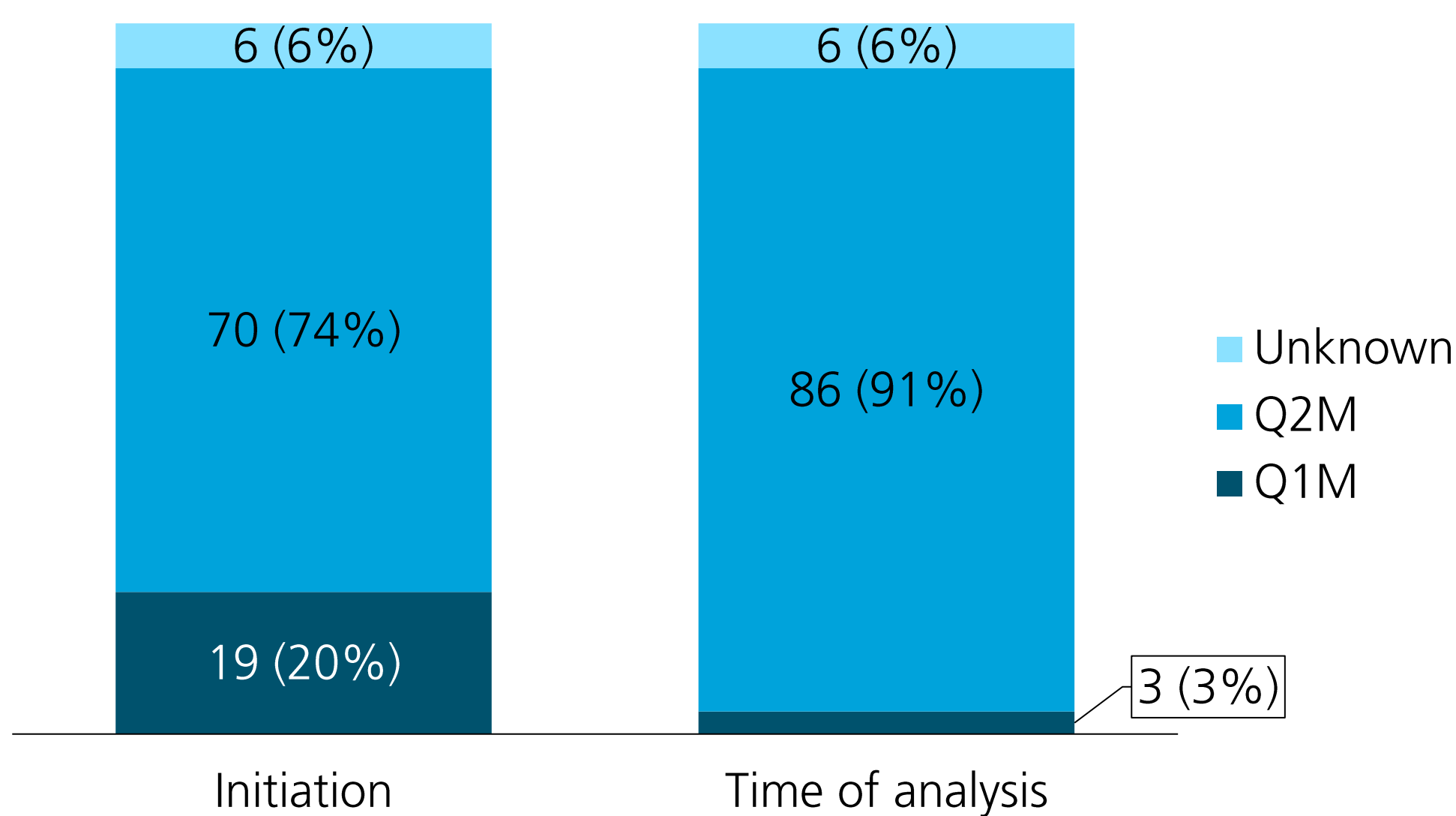


Figure 3. Adherence of maintenance injections among women with known dosing schedules and ≥ 1 maintenance injection (N = 82)

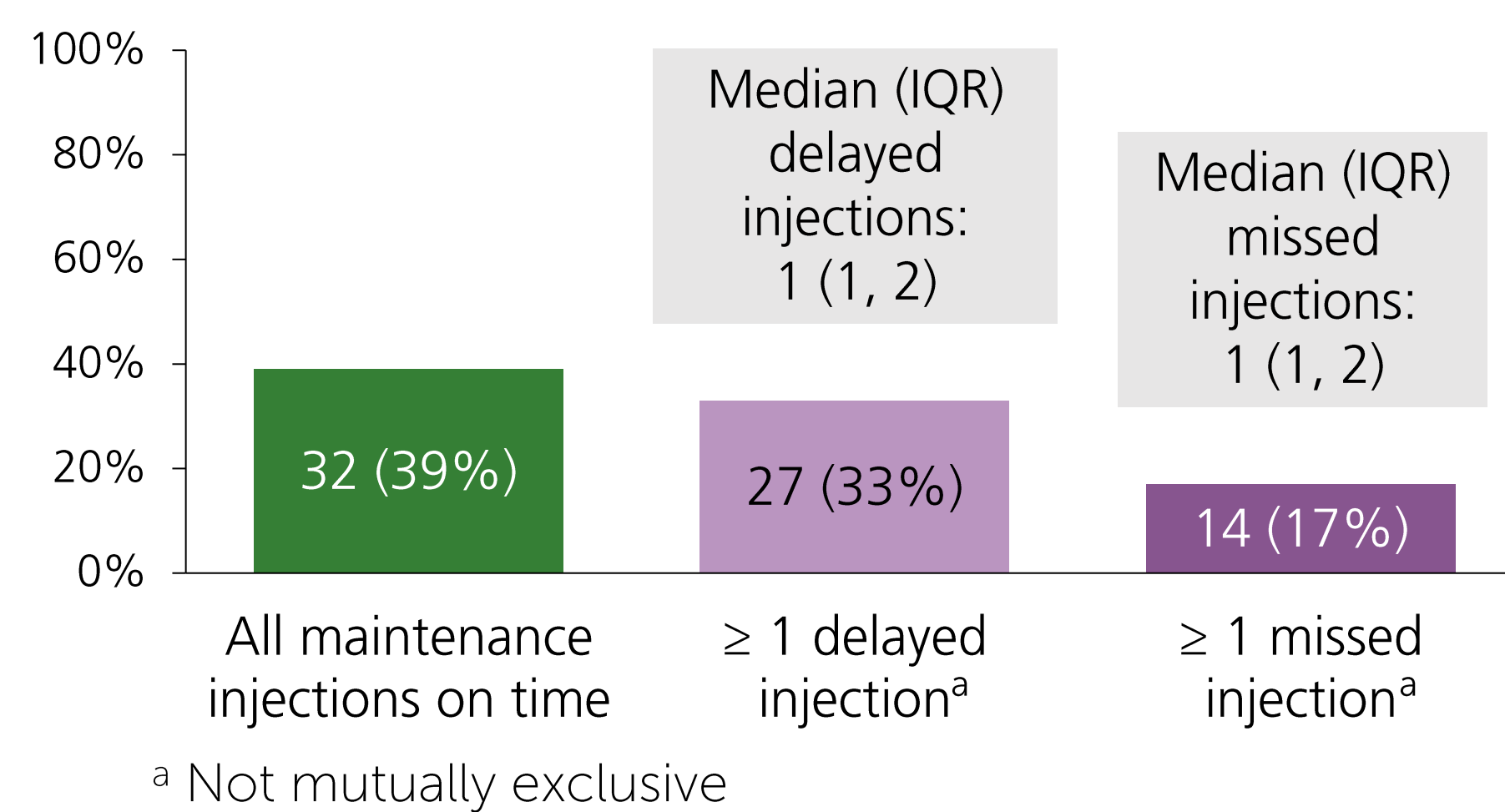


Figure 2. Persistence on all CAB+RPV LA exposures, among complete initiators (N = 95)

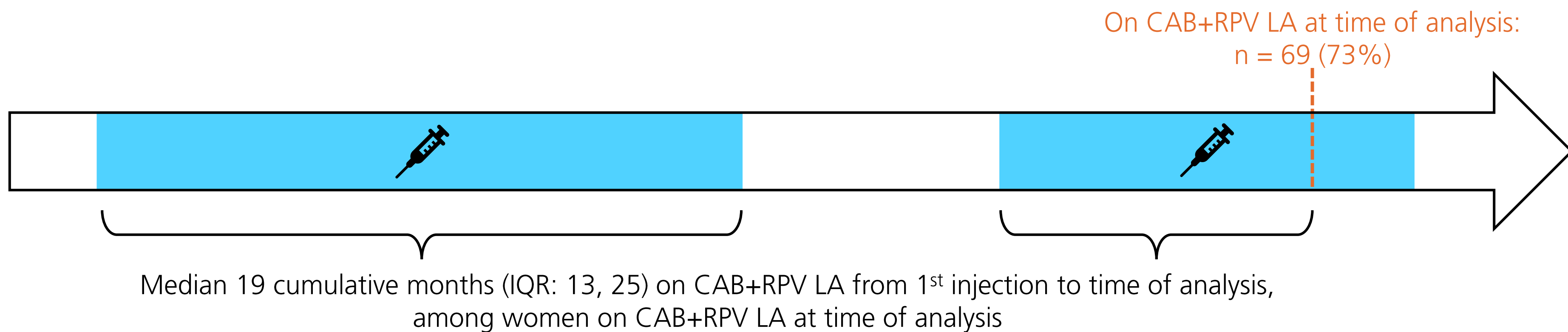


Figure 4. Virologic suppression to VL < 50 copies/mL among women with ≥ 1 VL over follow-up (N = 91)

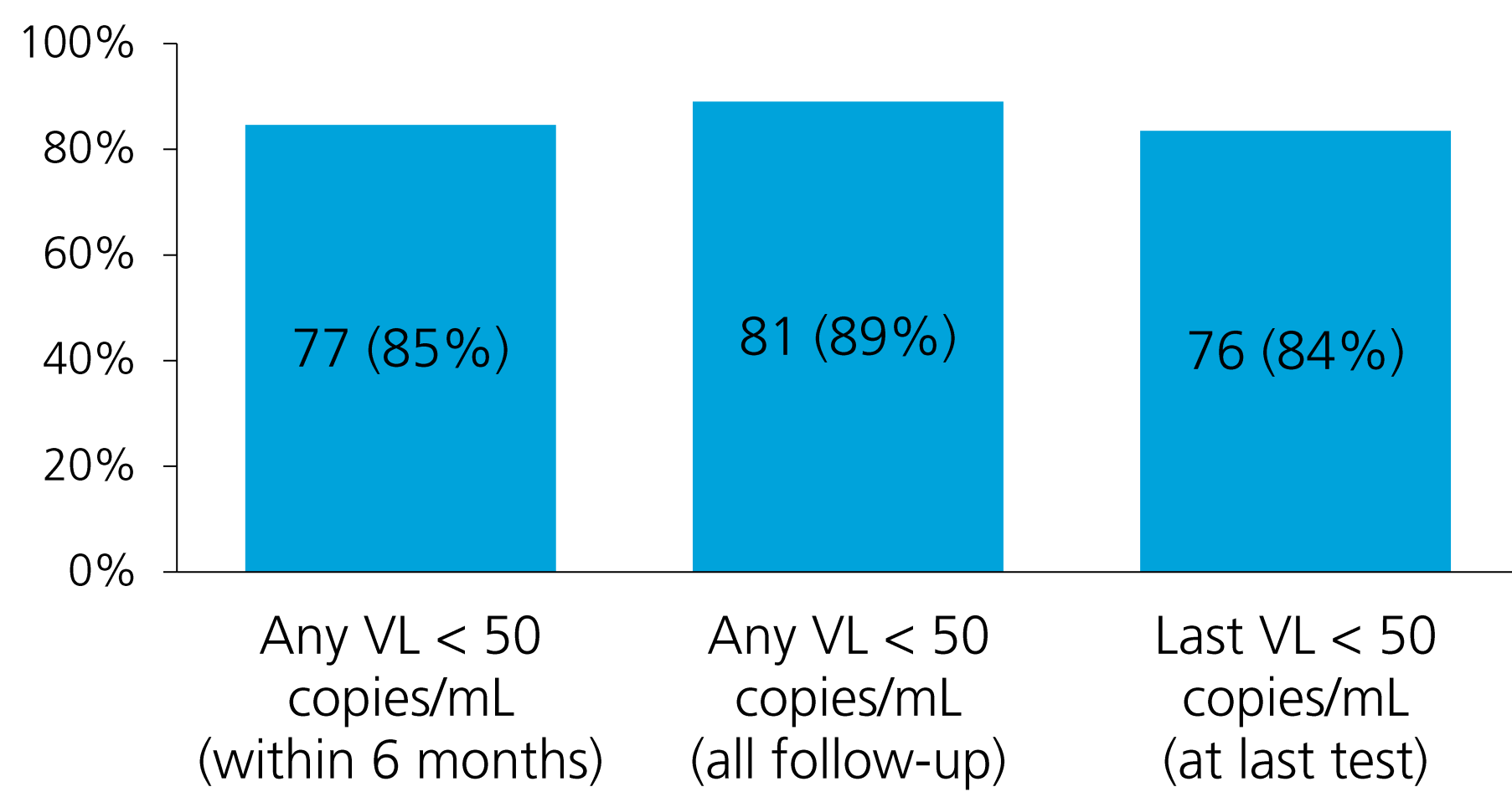
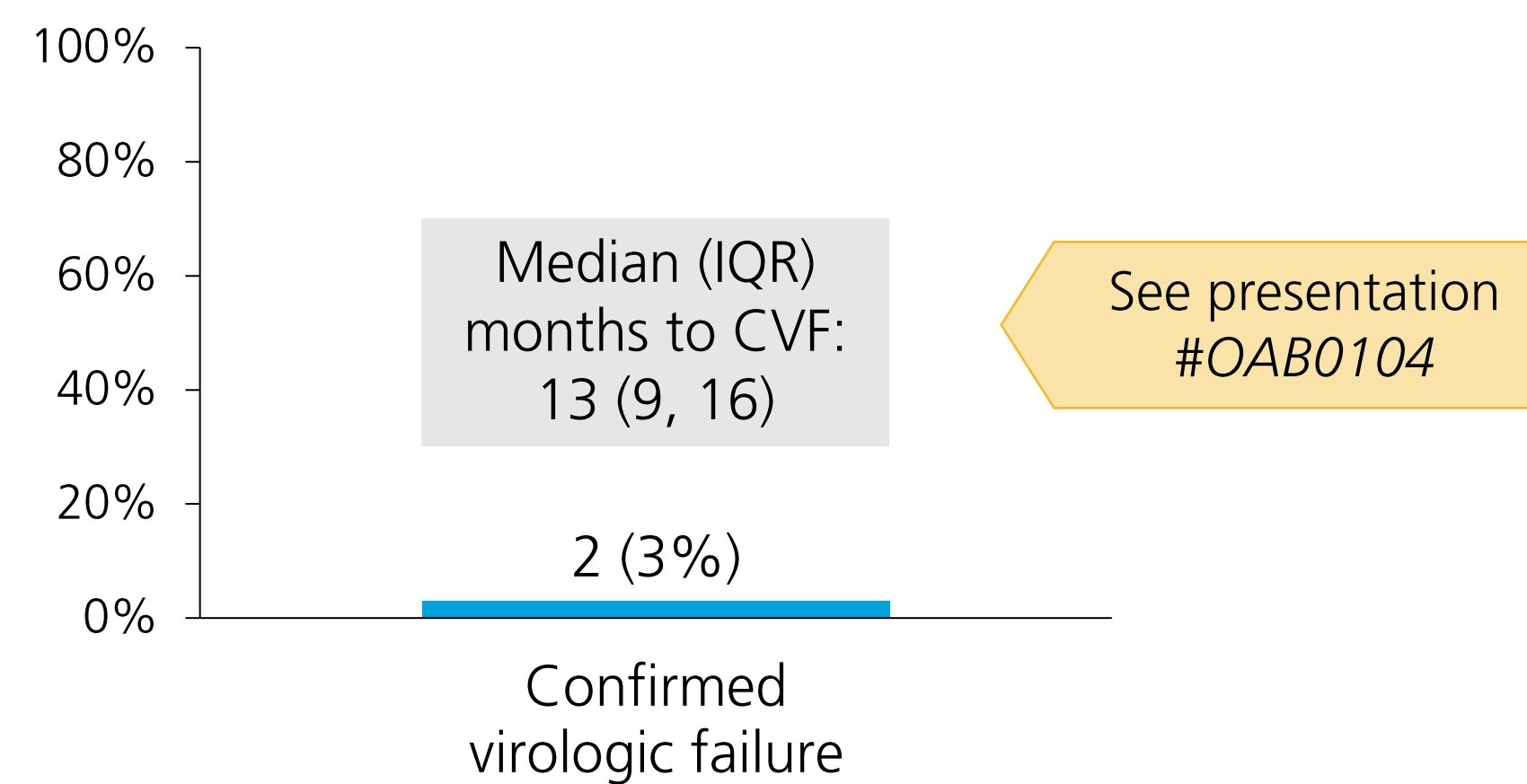


Figure 5. CVF among women with ≥ 1 VL available after suppression to VL < 50 copies/mL (N = 64)



Discussion

Summary of Findings

- Of 532 women in OPERA initiating CAB+RPV LA during the study period, 105 (20%) had VL ≥ 50 copies/mL at initiation
 - Median age was 43, 79% were Black, and 44% had a BMI ≥ 30 kg/m²
 - Most had longstanding HIV, ≥ 1 comorbidity, commercial insurance and/or Medicaid, and switched from an INSTI-containing regimen (**Table 1**)
 - Median VL was 1090 copies/mL (IQR: 89, 24700).
- Most women (90%) completed initiation (**Figure 1**)
 - Most were on Q2M schedules (**Figure 1**)
 - Almost three-quarters were on regimen at time of analysis, with a median follow-up of 19 months (**Figure 2**)
- 61% of women were late for ≥ 1 maintenance injection and/or discontinued (**Figure 3**)
 - Median of 1 delayed injection/woman with delay(s)
 - Median of 1 missed injection/woman with missed injection(s)
- Most women achieved virologic suppression (**Figure 4**)
 - 85% suppressed within 6 months
 - 11% never suppressed throughout follow-up
- Only 2 women (3%) experienced CVF, after a median of 13 months (**Figure 5**)

Strengths

- This was one of the first studies to examine CAB+RPV LA use and outcomes among women (exclusively) who initiated CAB+RPV LA with VL ≥ 50 copies/mL and included > 100 women
- This study was conducted using data from the OPERA cohort database, which includes > 155,000 PWH (~20% women) from clinics across the US, representing approximately 11% of women with HIV in the US

Limitations

- Possible misclassification of non-persistence due to:
 - Incomplete documentation of oral bridging in EHR
 - Loss to care (e.g., care interruption, transfer to a non-OPERA clinic)

Key Findings

- In this diverse cohort of 105 women in routine clinical care in the US who initiated CAB+RPV LA regimen with VL ≥ 50 copies/mL
 - Most suppressed to VL < 50 copies/mL within 6 months
 - Confirmed virologic failure was rare
- CAB+RPV LA may have a role for women with VL ≥ 50 copies/mL who may be struggling with adherence or tolerability of oral therapy

References

¹ Spinelli, et al. *JAMA*. 2025;333(16):1451-1453; ² Sension, et al. *Infect Dis Ther*. 2023;12:2807-2817; ³ Elion, et al. Abstract 1592. IDWeek 2023; ⁴ Hickey, et al. *Clin Infect Dis*. 2025;80(4):864-870; ⁵ Altamirano, et al. P-559. IDWeek 2024

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