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Background

- CAB+RPV LA is the first and only complete LA ART regimen approved (January 2021) for the treatment of HIV in the US
 - Injections monthly or every two months (Q2M)
 - Indicated for ART-experienced individuals with VL <50 copies/mL
- ~10% of individuals who initiated CAB+RPV LA in the OPERA Cohort had viremia (VL ≥50 c/mL)
- A substantial proportion of individuals initiating CAB+RPV LA have a BMI ≥30 kg/m²
 - Longer needle lengths may be required for patients with higher BMI

Objective

To assess clinical outcomes in individuals in the OPERA Cohort who initiated CAB+RPV LA with viremia (VL ≥50 copies/mL) stratified by BMI at initiation

Methods

Study Population: OPERA Cohort

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

Inclusion Criteria

- Treatment-experienced adults
- Switched to CAB+RPV LA between 21JAN2021 and 31DEC2024
- Initiated with HIV viremia (VL ≥50 copies/mL)

Stratification

- Non-obese BMI: <30 kg/m²
- High BMI: ≥30 to <40 kg/m²
- Very high BMI: ≥40 kg/m²

Abbreviations

AIDS, Acquired immunodeficiency syndrome; **ART**, antiretroviral therapy; **BMI**, body mass index; **CAB+RPV**, cabotegravir + rilpivirine; **CVF**, confirmed virologic failure; **FTR**, Fostemsavir; **HIV**, human immunodeficiency virus; **INSTI**, integrase strand transfer inhibitor; **IQR**, interquartile range; **LA**, long-acting; **LEN**, Lenacapavir; **(c)/mL**, (copies per) milliliter; **μL**, microliter; **NNRTI**, non-nucleoside reverse transcriptase inhibitor; **PI**, protease inhibitors; **US**, United States; **VL**, viral load.

Results

Table 1. Demographic and clinical characteristics of viremic individuals switching to CAB+RPV LA, by BMI (kg/m²) at initiation

	BMI <30 N=387	BMI ≥30 to <40 N=133	BMI ≥40 N=36
Age, median years (IQR)	39 (32, 51)	41 (34, 50)	39 (33, 50)
Age ≥50 years old, n (%)	105 (27)	34 (26)	10 (28)
Female sex, n (%)	78 (20)	46 (35)	21 (58)
Black race, n (%)	186 (48)	87 (65)	27 (75)
Hispanic ethnicity, n (%)	88 (23)	24 (18)	6 (17)
Care in Southern US, n (%)	210 (54)	83 (62)	29 (81)
History of AIDS-defined events, n (%)	148 (38)	46 (35)	10 (28)
BMI, median (IQR)	25 (22, 27)	33 (31, 36)	45 (42, 51)
CD4 <500 cells/μL, n (%)	177 (46)	57 (43)	15 (42)
Time since HIV diagnosis, median years (IQR)	8 (2, 16)	8 (3, 17)	10 (3, 17)
VL at CAB+RPV LA initiation, median c/mL (IQR) ^a	130 (60, 2550)	117 (62, 460)	180 (69, 1835)
VL ≥50 to <200, n (%)	227 (59)	90 (68)	18 (50)
VL ≥200 to <1000, n (%)	46 (12)	13 (10)	7 (19)
VL ≥1000 to <10,000, n (%)	31 (8)	12 (9)	≤5
VL ≥10,000 to <100,000, n (%)	61 (16)	13 (10)	≤5
VL ≥100,000, n (%)	22 (6)	≤5	≤5

Table 2. Persistence among viremic individuals with complete initiation of CAB+RPV LA, by BMI at initiation

	BMI <30 N=387	BMI ≥30 to <40 N=133	BMI ≥40 N=36
Completed initiation, n (%)	349 (90)	123 (92)	32 (89)
Alive and active in care ^a at study end, n (%)	339 (97)	122 (99)	30 (94)
Months on CAB+RPV LA, median (IQR) ^b	15 (8, 27)	15 (8, 27)	11 (7, 19)
On CAB+RPV LA on 28FEB2025, regardless of previous discontinuation(s), n (%)	259 (76)	87 (71)	22 (73)

^a Last contact date on or within 24 months of study end

^b Time until first censoring; addition of FTR or LEN did not stop CAB+RPV regimen (n=20)

Table 3. Dosing schedule at first & last injection, by BMI at initiation

	BMI <30 N=387	BMI ≥30 to <40 N=133	BMI ≥40 N=36
Completed initiation, n (%)	349 (90)	123 (92)	32 (89)
Q2M 600/900 mg at initiation, n (%)	298 (85)	106 (86)	26 (81)
Q2M 600/900 mg at last injection, n (%)	327 (94)	117 (95)	28 (87)

Discussion

Summary of findings

- Among 582 individuals initiating CAB+RPV LA with viremia (≥50 c/mL), 387 (66%) had non-obese BMI, 133 (25%) had high BMI (≥30 to <40 kg/m²) and 36 (6%) had very high BMI (≥40) at initiation (**Fig 1**)
 - Nearly all individuals (89-92%) completed initiation
 - Most (75-89%) received maintenance injections
 - Over half (54-67%) received all injection on-time, the very high BMI group had the best adherence
- Characteristics of individuals at initiation varied markedly across the groups (**Table 1**)
 - The very high BMI group was more likely to be female, Black, and receive care in the Southern US
 - The non-obese BMI group was more likely to be Hispanic and have a history of AIDS
- Approximately three-quarters of individuals were still on CAB+RPV LA at end of analysis period (76%, 71%, and 73%, respectively, among BMI groups; **Table 2**)

- Every two months dosing was more common at initiation and at last injections (**Table 3**)
 - The very high BMI group was most likely to use monthly dosing schedule
- All groups were similarly likely to achieve virologic suppression (88%, 88%, 85%) and remain suppressed at study end (79%, 81%, 81%; **Fig 2**)
 - CVF was rare across all BMI subgroups (**Fig 2**)

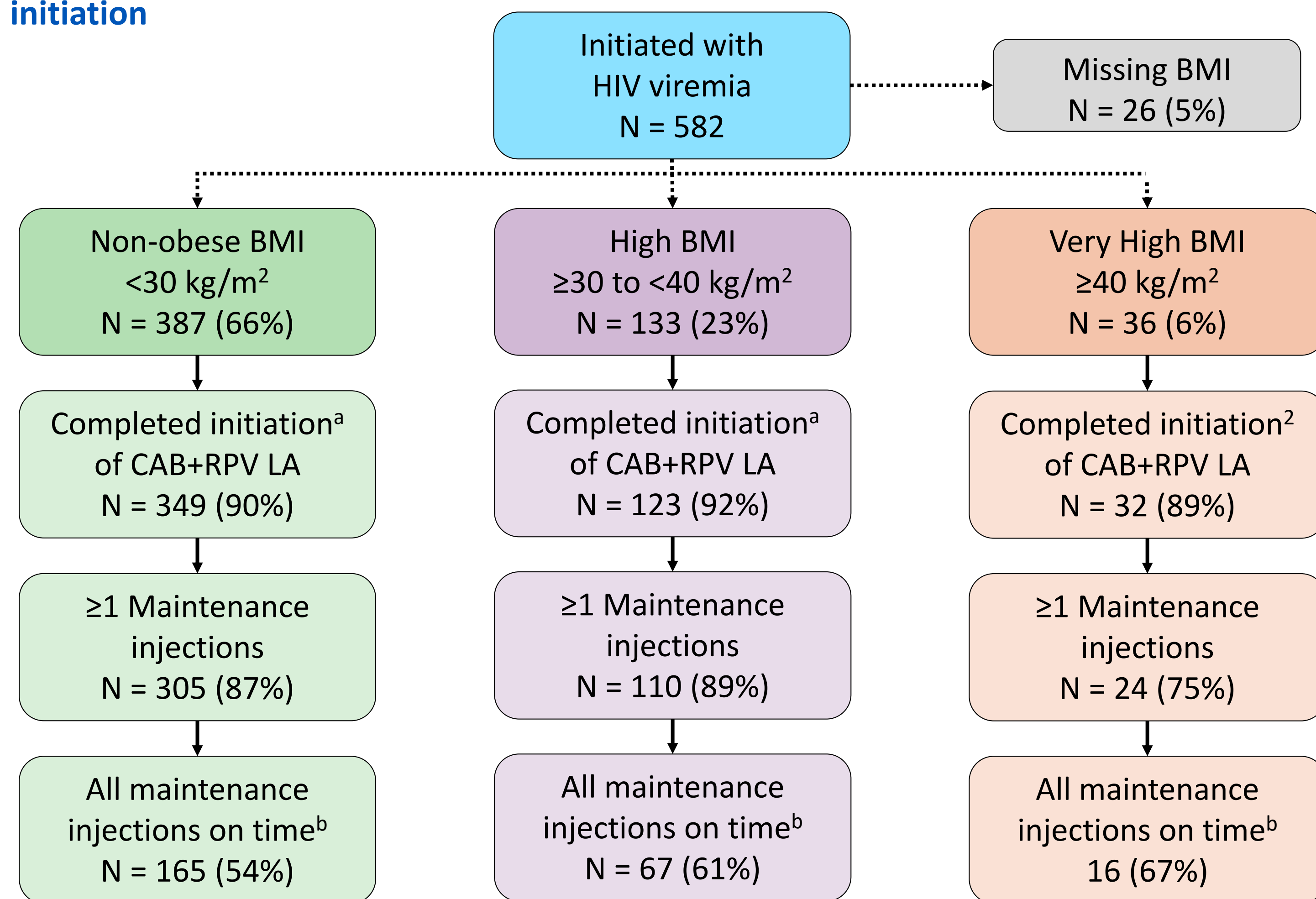
Strengths

- Real-world experience with CAB+RPV LA in individuals with viremia
 - Large population with variety of body sizes
 - All injections were observed in the clinic

Limitations

- Electronic health records data quality may vary quality practices and providers; measurement error is possible
- Oral bridging is not well documented; this may result in underestimation of CAB+RPV LA adherence
- The number of individuals in the BMI subgroups, especially the very high BMI subgroup, was small

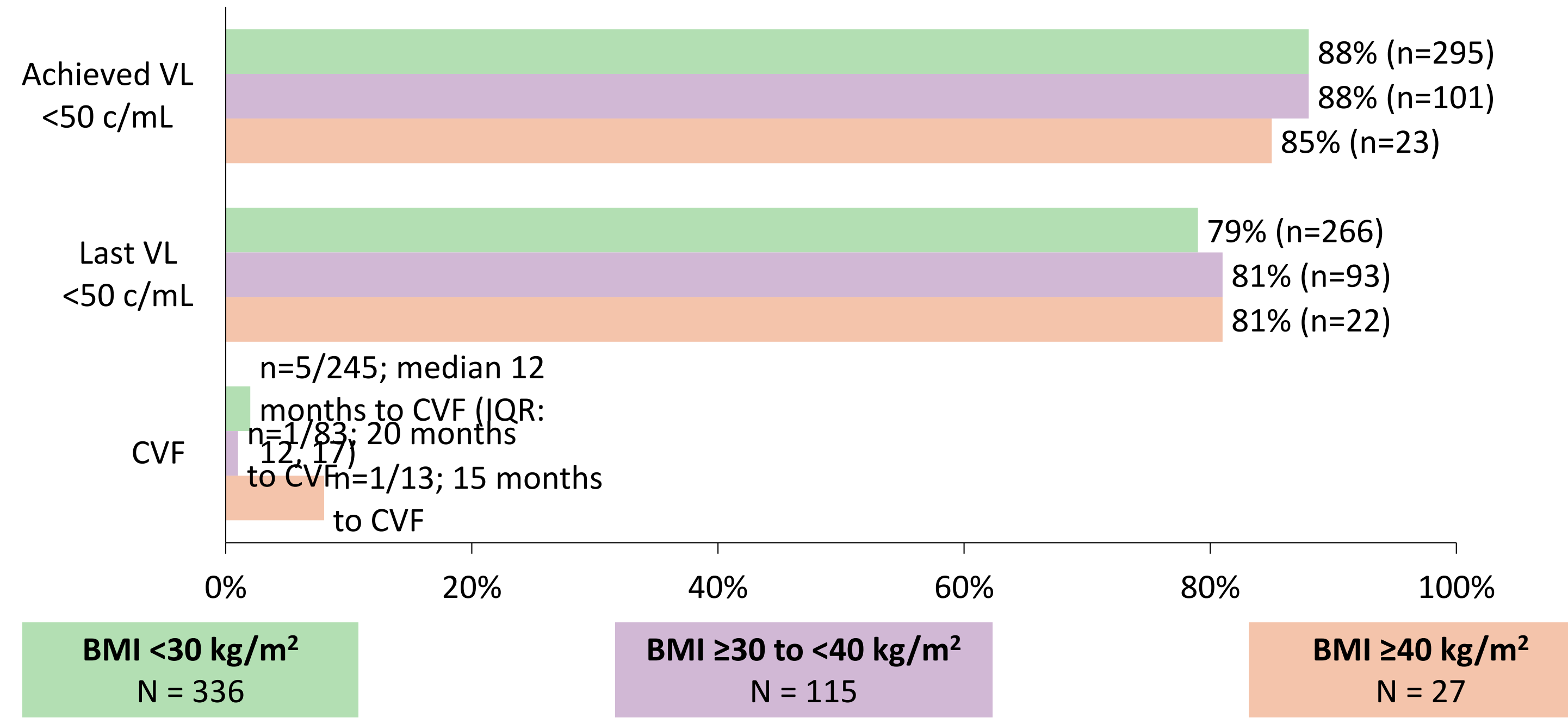
Figure 1. Adherence in individuals who initiated CAB+RPV LA with viremia, by BMI at initiation



^a Received initiation injections ≤67 days apart

^b On time was defined as within ±7 days of injection target

Figure 2. Virologic effectiveness among viremic individuals with complete initiation of CAB+RPV LA and ≥1 VL over follow-up, by BMI at initiation



Key Findings

- In this large, real-world analysis of 582 viremic individuals initiating CAB+RPV LA, the majority achieved virologic suppression to <50 copies/mL; CVF was rare across BMI categories
- These results support CAB+RPV LA as an effective treatment option for individuals who are viremic, including those with very high BMI, and may experience adherence or tolerability challenges with daily oral regimens

Acknowledgements

This research would not be possible without the generosity of people living with HIV and their OPERA caregivers. Additionally, we are grateful for the following individuals: Kelly Oh (SAS programming), Bill Johnson (QA), poster design (Rachel Palmieri Weber & Michael Osterman), Bernie Stooks (data management), Lisa Lutzi & Nicole Shaw (data management/quality), and Judy Johnson (clinical data classification).

Support

This research was supported by ViiV Healthcare.



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