Real-World Virological Effectiveness Outcomes With Long-Acting Cabotegravir Plus Rilpivirine in Women: A Systematic Literature Review

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Key Takeaways

- This systematic literature review identified 494 publications reporting long-acting cabotegravir plus rilpivirine (CAB+RPV LA) use in diverse real-world settings, of which 25 reported outcomes on 2837 cisgender and transgender women, supporting high effectiveness in a global population
- 83% to 100% of women across publications had a suppressed viral load at follow-up, including women with a suppressed viral load or viremia at initiation, while 0% to 4% experienced virologic failure, with resistance-associated mutations reported in only 1 publication, in 2 of 64 women
- Most women remained on CAB+RPV LA during follow-up, while adherence findings varied according to the definitions used across publications
- Virologic outcomes in pregnant women were reported in 2 publications, with 75% to 100% of women having a viral load <20 copies/mL and no cases of perinatal HIV transmission

Plain Language Summary

- This review looked at data from routine clinic visits around the world to study how well long-acting cabotegravir plus rilpivirine, an HIV treatment given as injections 6 or 12 times a year, works for women
- Researchers found 25 studies in medical databases and conferences, collecting results on 2837 cisgender and transgender women across North America, Europe, and Asia
- The medicine kept HIV levels under control in 83% to 100% of women, while 0% to 4% of women had an increase in HIV levels that was considered treatment failure
- Studies measured whether women received their injections as scheduled in different ways and the results varied. Most women continued their treatment with long-acting cabotegravir plus rilpivirine
- 2 studies looked at women using long-acting cabotegravir plus rilpivirine during pregnancy; HIV was under control in 75% to 100%, with no reported cases of babies born with HIV

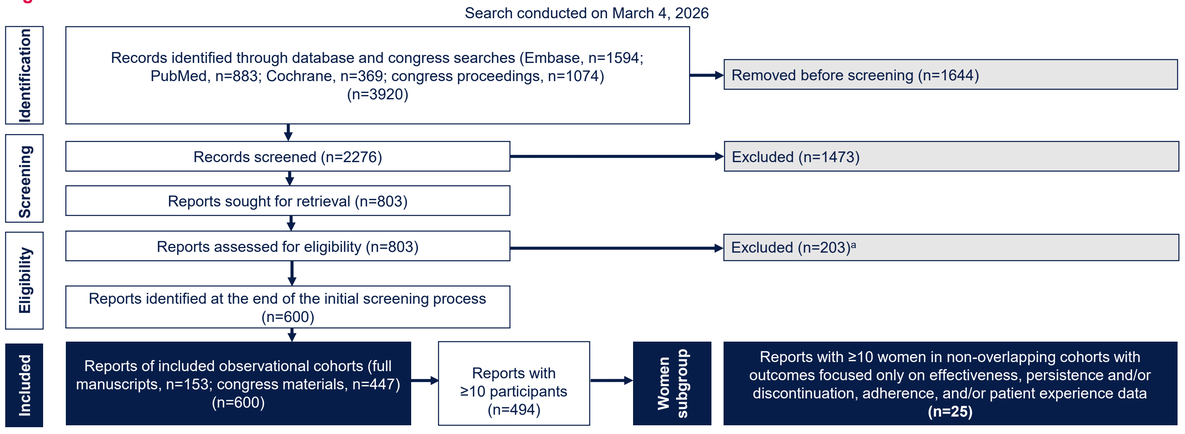
Introduction

- Women account for 53% of people with HIV-1 globally[1] and may have distinct clinical and treatment considerations across different life stages, including potential drug-drug interactions with oral contraceptives,[2] altered pharmacokinetics during pregnancy,[3] and considerations related to menopause and menopausal hormone therapy[4]
  - Caregiving responsibilities and other competing demands may also create adherence challenges, highlighting the need for treatment options that can accommodate women's varied circumstances[3,5]
- Cabotegravir (CAB) + rilpivirine (RPV) is the first and only complete long-acting (LA) injectable regimen approved for people with HIV-1 who have suppressed viral loads[6,7]
- CAB+RPV LA has demonstrated high virologic suppression and good tolerability in phase 3/3b trials[8,9] and real-world evidence (RWE),[10,11] with comparable outcomes reported in women and men
- However, women have historically been underrepresented in clinical research, and real-world outcomes with CAB+RPV LA in this population have not been systematically characterized[12]
- Therefore, we conducted a systematic literature review (SLR) to evaluate RWE, persistence, adherence, and patient experience outcomes of CAB+RPV LA use in women across diverse settings

Methods

- An SLR of RWE was conducted following Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines
- Literature searches were conducted in Embase®, PubMed®, and Cochrane Library databases, supplemented by manual searches of major international HIV congresses to capture both journal articles and congress proceedings from January 2020 to March 2026 (Figure 1)
- Eligible RWE studies reported outcomes in ≥10 women in routine clinical practice or non-interventional settings
- Publications, defined here as peer-reviewed manuscripts and congress proceedings, were assessed for overlapping cohorts to avoid double-counting
- Clinical endpoints were synthesized and presented descriptively

Figure 1. SLR PRISMA Flowchart



[a]Reasons for exclusion: intervention, n=50; study design, n=33; publication type, n=55; outcomes, n=36; lack of sufficient information for individuals using CAB+RPV LA, n=20; presentation was withdrawn or presumed to have been withdrawn from congress, n=4; full text was not available or encore included instead, n=2; abstract or final presentation with incomplete data, n=1; unclear if the study included individuals using CAB+RPV LA, n=1; individual in the study died from other complications soon after starting CAB+RPV LA, n=1.

Results

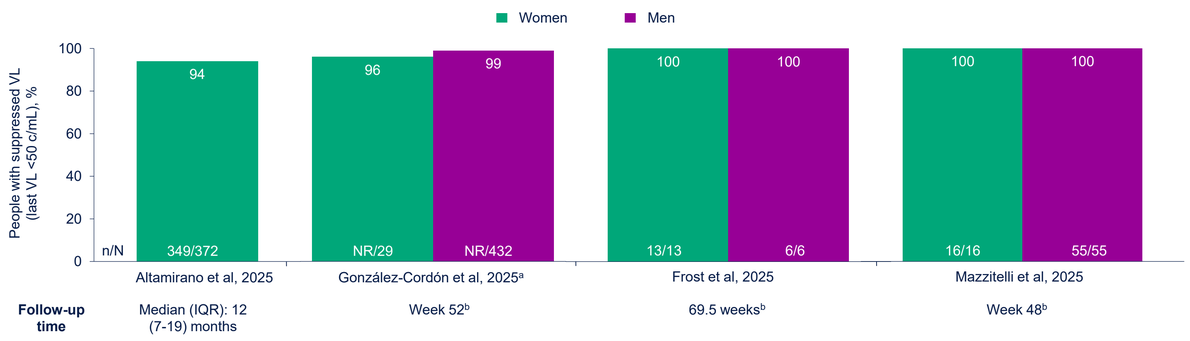
Overview of Included RWE

- The SLR identified 494 publications reporting CAB+RPV LA in ≥10 women, representing 364 studies, 133 cohorts, and 45,596 people with HIV-1
- Of these, 25 non-overlapping cohorts reporting outcomes data for 2837 cisgender and transgender women with HIV-1 were included in this analysis,[13-37] with 2 describing virologic and neonatal outcomes in women using CAB+RPV LA during pregnancy[22,37]
- 5 of these publications[19,20,28,35,36] included a total of 81 transgender women
- The included cohorts represented routine clinical practice, comprising 13 cohorts from the United States,[13,15,20-22,29-33,35-37] 4 from France,[14,18,23,25] 2 each from Italy[17,34] and Spain,[26,27] and 1 each from the United Kingdom[19] and Taiwan,[24] as well as 2 multi-country European cohorts[16,28]

Effectiveness

- 17 publications reported effectiveness outcomes in 1976 non-pregnant women,[14-17,19,20,24-27,29-31,33-36] with 4 reporting virologic suppression[20,27,30,34] and 15 reporting virologic failure[14-17,19,20,24-27,29,31,33,35,36] in 501 and 1947 women, respectively
- High effectiveness was reported across 4 publications, with 83% to 100% of women having a suppressed viral load at follow-up, including those with a suppressed viral load or viremia at initiation (Figure 2)[20,27,30,34]
- 3 publications demonstrated similar virologic suppression rates between men and women[27,30,34]
- Virologic failure was uncommon, occurring in 27 women, with rates ranging from 0% to 4% across publications[14-17,19,24-27,29,31,33,35,36]; 7 publications, including 272 women, reported no virologic failure events (Table 1)[15,24,27,29,31,35,36]
  - 1 publication including 415 women reported ≤5 virologic failure events, corresponding to a rate of ≤1% (exact values were not disclosed in accordance with Health Insurance Portability and Accountability Act regulations)[20]
- Findings from formal analyses of virologic failure by sex were mixed
  - 1 publication (456 women) identifying female sex as a factor associated with virologic failure in a univariate Cox regression analysis (hazard ratio [95% CI] 2.30 [1.23-4.33]; *P*=0.01),[25] whereas another (477 women) found no statistically significant difference in virologic failure between women and men (odds ratio [95% CI] 1.71 [0.56-4.43]; *P*=0.266)[26]
- 5 publications, including 227 women, reported resistance outcomes following virologic failure,[14,16,17,19,33] with resistance-associated mutations (RAMs) reported in only 1 publication, in both women who experienced virologic failure and 2 of 64 women overall (3%; Table 1)[33]
- 4 publications reported regimens used after virologic failure, comprising bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in 2 women and protease inhibitor–based regimens in the other 2 women; all 4 women re-suppressed (Table 1)[14,16,17,19]

Figure 2. Virologic Suppression in Women and Men Using CAB+RPV LA



IQR, interquartile range; ITT, intention-to-treat; mITT, modified intention-to-treat; NR, not reported; OT, on treatment; VL, viral load. [a]83% (NR/29) women and 92% (NR/432) men in the ITT population, while 83% (NR/29) women and 89% (NR/432) men in the mITT population had suppressed VL at last assessment. [b]Follow-up time reported for the overall cohort, including women.

Table 1. Virologic Failure and Related Outcomes in Women Using CAB+RPV LA

Publication	Women/ Overall cohort, n/N (%)	Follow-up time	Virologic failure definition	Virologic failure, n/N (%)	RAMs at virologic failure, n/N (%), details/no/NR	Historic RAMs among virologic failure, yes, n/N (%), details/no/NR	Post–virologic failure regimen, n/N (%)	Re-suppression post–virologic failure, n/N (%)
Ferre et al, 2023[14]	33/126 (26)	Median (IQR): 12.7 (8.5-26.7) months[a]	2 consecutive VLs >200 c/mL or 1 VL >50 c/mL and CAB+RPV LA D/C	1/33 (3)	0/33 (0)	No, 0/1 (0)	TDF/FTC+ DRV/r: 1/1 (100)	1/1 (100)
Maguire et al, 2024[15]	94/374 (25)	Median (IQR): 255 (147-362) days[a,b]	2 consecutive VLs >200 c/mL	0/94 (0)	NA	NA	NA	NA
Pozniak et al, 2024[16]	53/472 (11)	Median (IQR): 3.0 (2.8-7.1) months[a,b]	2 consecutive VLs ≥200 c/mL or 1 VL ≥200 c/mL followed by D/C	1/53 (2)	0/472 (0)	No, 0/1 (0)	ABC/3TC + DRV/r: 1/1 (100)	1/1 (100)
Antonucci et al, 2024[17]	24/79 (30)	Median (IQR): 55 (24-63) weeks[a]	NR	1/24 (4)	0/24 (0)	NR	BIC/FTC/TAF: 1/1 (100)	1/1 (100)
Ring et al, 2024[19]	153/518 (30)	Median (IQR): 7.5 (3.7-11.3) months[a,b]	NR	1/153 (<1)	0/153 (0)	NR	BIC/FTC/TAF: 1/1 (100)	1/1 (100)
Altamirano et al, 2025[20]	415/415 (100)	Median (IQR): 12 (7-19) months	2 consecutive VLs ≥200 c/mL or 1 VL ≥200 c/mL followed by D/C within 4 months	≤5/415 (≤1)[c]	NR	NR	NR	NR
Cheng et al, 2025[24]	10/229 (4)	13 months[a]	2 consecutive VLs >200 c/mL, with an interval of ≥1 month between the tests	0/10 (0)	NA	NA	NA	NA
Deschanvres et al, 2025[25]	456/2196 (21)	Median (IQR): 13 (7-19) months[a,b]	1 VL >200 c/mL or 2 consecutive VLs >50 c/mL	15/456 (3)	NR	NR	NR	NR
Galindo Puerto et al, 2025[26]	477/3203 (15)	Median (IQR): 13.1 (7.5-18.5) months	NR	6/477 (1)	NR	NR	NR	NR
González-Cordón et al, 2025[28]	57/741 (8)	52 weeks[a]	NR	0/57 (0)	NA	NA	NA	NA
Bhayani et al, 2025[29]	19/100 (19)	24 months[a,b]	NR	0/19 (0)	NA	NA	NA	NA
Hockney et al, 2025[31]	29/201 (14)	Median (IQR): 380 (206-729) days[a,b]	≥2 consecutive VLs ≥200 c/mL necessitating a change in therapy	0/29 (0)	NA	NA	NA	NA
Faggiano et al, 2025[33]	64/438 (15)	Median (IQR): 612 (355-848) days[a,b]	NR	2/64 (3)	2/64 (3) NNRTI: 2 INSTI: 2	Yes, 1/2 (50): NNRTI: 1	NR	NR
O'Connor et al, 2025[35]	35/98 (36)	Median (IQR): 5 (2-10) months[a]	2 consecutive VLs >1000 c/mL	0/35 (0)	NA	NA	NA	NA
Dieterich et al, 2026[36]	82/162 (51)	≥10 months[a]	2 consecutive VLs ≥200 c/mL	0/28 (0)[d]	NA	NA	NA	NA

ABC, abacavir; c, cobicistat; D/C, discontinuation; DRV, darunavir; HIPAA, Health Insurance Portability and Accountability Act; INSTI, integrase strand transfer inhibitor; IQR, interquartile range; NA, not applicable; NNRTI, non-nucleoside reverse transcriptase inhibitor; NR, not reported; VL, viral load; r, ritonavir; 3TC, lamivudine; TDF, tenofovir disoproxil fumarate. [a]Follow-up time reported for the overall cohort, including women. [b]Reflects time on CAB+RPV LA. [c]Exact values were not disclosed because HIPAA regulations require masking values of 1 to 5 individuals. [d]Virologic failure data only available in 28 women (MORE cohort).

Treatment Persistence and/or Discontinuation

- 4 publications reported treatment persistence and/or discontinuation in 1024 women[18,20,26,32]
- Across 3 publications (609 women), 8% to 20% of women discontinued CAB+RPV LA over follow-up periods ranging from approximately 5 to 18 months, depending on the publication (Table 2)[18,26,32]
  - 1 publication (477 women) reported local injection reactions and systemic adverse events as reasons for discontinuation, each occurring in 2% of women[26]
- Treatment persistence was reported in 1 publication, with 78% (297/381) of women remaining on CAB+RPV LA over a median follow-up of 12 months[20]

Table 2. CAB+RPV LA Discontinuation

Publication	Women/Overall cohort, n/N (%)	Follow-up time	Discontinuation rate, n/N (%)	Other persistence/discontinuation-related outcomes
Gerbe et al, 2024[18]	83/218 (38)	Median (IQR): 152 (77-478) days[a,b]	17/83 (20)	NR
Galindo Puerto et al, 2025[26]	477/3203 (15)	Median (IQR): 13 (8-19) months	39/477 (8)	• Definitive discontinuations were low but statistically significant between women and men (39/477 [8%] vs 127/2698 [5%]; OR [95% CI] 1.8 [1.21-2.64], *P*=0.003) • Discontinuation reasons (including ISRs, systemic AEs and virologic failure[c]) did not significantly differ between women and men
Christopoulos et al, 2025[32]	49/438 (11)	Median (IQR): 18 (8-27) months[a,b]	6/49 (12)	NR

AE, adverse event; IQR, interquartile range; ISR, injection site reaction; NR, not reported; OR, odds ratio. [a]Follow-up time reported for the overall cohort, including women. [b]Reflects time on CAB+RPV LA. [c]ISRs OR (95% CI) 1.68 (0.73-3.5), *P*=0.198; systemic AEs OR (95% CI) 2.86 (1.13-6.76), *P*=0.014; virologic failure OR (95% CI) 1.71 (0.56-4.43), *P*=0.266.

Adherence

- 5 publications reported adherence outcomes in 998 women, with findings varying according to the definitions used, including injections received on time, missed or delayed injections, and proportion of days covered ≥90% (Table 3)[13,20,21,27,28]

Table 3. CAB+RPV LA Adherence in Women Using CAB+RPV LA

Publication	Women/Overall cohort, n/N (%)	Follow-up time	Outcomes
Garris et al, 2023[13]	218/947 (23)	Median: 9.3 months[a]	77% (167/218) of women maintained a proportion of days covered[b] ≥90%
Altamirano et al, 2025[20]	415/415 (100)	Median (IQR): 12 (7-19) months	• 44% (148/340)[c] of women received all maintenance injections on time (±7-day window) • 37% (125/340)[c,d] of women received ≥1 delayed injection • 12% (42/340)[c,d] of women missed ≥1 injection
Do et al, 2025[21]	279/1226 (23)	6 months after first injection[a]	• 66% (185/279) of women followed their injection schedule, including planned oral bridging therapy every 2 months or once monthly • 26% (73/279) missed their scheduled injections post-initiation • 8% (21/279) of women dropped out before completing the first 2 initiation injections
González-Cordón et al, 2025[27]	57/741 (8)	52 weeks[a]	96% (NR/57) of women received injections on time
Peters et al, 2025[28]	29/142 (20)	Median (IQR): 323 (204-466) days[a]	0% (0/29) of women missed any injections

IQR, interquartile range; NR, not reported. [a]Follow-up time reported for the overall cohort, including women. [b]Proportion of days covered over a 6-month period after index was calculated as *Days from the first claim to the latest claim plus days of supply* divided by *the length of the follow-up period*. [c]Denominator is women with known dosing schedules and ≥1 maintenance injection. [d]Responses not mutually exclusive.

Patient Experience

- 1 publication explored reasons for switching to CAB+RPV LA among 102 women[23]
  - The most commonly reported reasons were the inconvenience of carrying oral medication (58%), better fit of long-acting treatment with daily life (53%), and not having to think about taking pills (51%)
  - Reasons were generally similar between women and men, although more women reported no longer having the strength to take pills (10% vs 2%; *P*=0.007)

Virologic and Neonatal Outcomes in Pregnancy

- 2 publications reported virologic, perinatal, and neonatal outcomes in 46 women using CAB+RPV LA during pregnancy[22,37]
  - The proportion of individuals with viral load <20 copies/mL ranged from 75% to 100% at the initial visit and 81% to 100% at delivery[22,37]; only 1 publication reported virologic failure data, with no cases of virologic failure among 15 women[37]
  - The rate of vaginal delivery was 52% to 86%. Median gestational age at delivery was 37 weeks, median birth weight ranged from 2330 to 2750 grams, and no cases of perinatal HIV transmission were reported[22,37]
- 1 publication (31 women) compared outcomes between women who conceived while using CAB+RPV LA versus those who initiated it during pregnancy,[22] and another included 15 pregnant women using CAB+RPV LA every other month[37]
  - 23 women conceived while using CAB+RPV LA and 8 initiated during pregnancy; 7 women transitioned from CAB+RPV LA to BIC/FTC/TAF during pregnancy[22]

Conclusions

- This SLR identified 494 publications representing 45,596 people with HIV-1 using CAB+RPV LA, including 25 non-overlapping cohorts reporting outcomes in 2837 cisgender and transgender women across diverse real-world settings
- RWE supports high effectiveness in women using CAB+RPV LA, with high virologic suppression rates and uncommon virologic failure. Most women remained on treatment during follow-up, while adherence findings varied according to the definitions used across publications
- Importantly, virologic outcomes in women were generally consistent with those reported in men and in phase 3/3b clinical trials,[8,9] supporting the effectiveness of CAB+RPV LA irrespective of sex
- RWE in women is growing, but women remain underrepresented, despite accounting for half of the HIV-1 cases worldwide.[1] Further research is particularly needed during pregnancy, for which outcomes were reported in only 2 publications

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