Outcomes on Cabotegravir + Rilpivirine in Suppressed People with HIV (PWH) in TRIO Health US Cohort

675

Paul E. Sax[1], Andrew Frick[2], Janna Radtchenko[2], Supriya Sarkar[3], Gayathri Sridhar[3], Leigh Ragone[3], Richard Elion[2], Joseph Eron[5], Steven Santiago[6], Karam Mounzer[7], Moti Ramgopal[8], Charles Walworth[9], Jean van Wyk[4], Vani Vannappagari[3]

[1]Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts; [2]Trio Health, Louisville, CO, USA; [3]ViiV Healthcare, Durham, NC, USA; [4]ViiV Healthcare, London, UK; [5]University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; [6]Care Resource, Miami, FL, USA; [7]School of Medicine at The University of Pennsylvania; Philadelphia Fight Community Health Centers, Philadelphia, PA, USA; [8]Midway Immunology & Research Center, Fort Pierce, FL, USA; [9] Monogram Biosciences (a Labcorp subsidiary), South San Francisco, USA

BACKGROUND

- Cabotegravir + Rilpivirine (CAB+RPV) is the first complete long-acting injectable antiretroviral therapy (ART) for the treatment of HIV for ART-experienced PWH with undetectable viral load (VL <50 copies/mL).
- This study examined the utilization and effectiveness of CAB+RPV in real-world settings in the US.

METHODS

- ART-experienced adults with undetectable VL at initiation who received ≥1 CAB+RPV injection between Feb 2021-Mar 2024 were identified from electronic health records in the Trio Health Cohort.
- Maintenance of viral suppression at all viral loads through 6-, 12-, and 24-months was assessed, along with suppression at last recorded viral load.
- Discontinuation of CAB+RPV was defined as 2 consecutive missed injections or an ART regimen switch, while confirmed virologic failure (CVF) was defined as 2 consecutive VLs >200 copies/mL or 1 VL >200 copies/mL with discontinuation within 4 months.
- Delayed injections were defined as occurring >7 days after target date (Q1M or Q2M). Analyses included those with at least 2 administrations of CAB+RPV. Total days delayed was defined as sum of all delays for individuals, excluding missed injections.
- ART resistance based on HIV genotype results prior to baseline and at CVF was available for a subset of PWH and analyzed using the Stanford HIVdb algorithm.

RESULTS

- Analyses included 1198 virologically suppressed PWH initiating CAB+RPV with median 12 months (IQR: 5- 19) follow-up time after the first injection.
- At the end of follow-up, 944 (79%) PWH remained on CAB+RPV, including 21 who re-initiated after discontinuing during follow-up. (Figure 1)

CROI Conference on Retroviruses and Opportunistic Infections

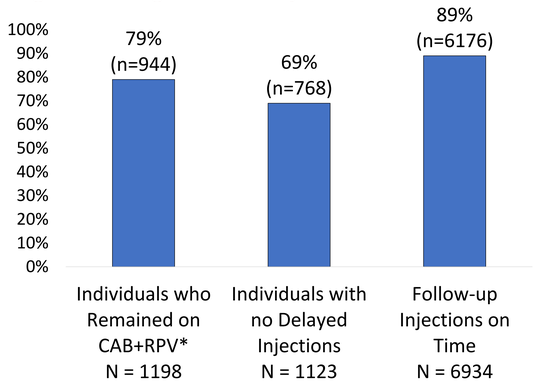
Virologic failure occurred in < 2% of 1198 PWH who initiated CAB+RPV, consistent with clinical trials. Very low emergent resistance was observed, with RPV resistance identified in 3 patients (0.25%) and CAB resistance in only 1 (< 0.1%).

Table 1: Baseline Characteristics of Study Population

	N (%) or Median (IQR)	All Initiators n=1198	With Viral Failure N=15
Follow-up	Months Follow-up in EMR	11 (5, 18)	13 (7, 18)
	>12 months Follow-up	549 (46)	8 (53)
	>24 months Follow-up	101 (8)	3 (20)
	Age at Start	43 (34, 54)	49 (36, 52)
Gender	Male	921 (77)	6 (40)
	Female	269 (22)	8 (53)
	Another or Unknown Gender	8 (1)	1 (7)
Race	White	500 (42)	4 (27)
	Black or African American	573 (48)	9 (60)
	Another or Unknown Race	125 (10)	2 (13)
	Hispanic Ethnicity	244 (20)	1 (7)
Payer	Commercial Payer	622 (52)	12 (80)
	Medicare/Medicaid Payer	330 (28)	2 (13)
	Other or Unknown Payer	246 (21)	1 (7)
	Years since HIV Diagnosis	4 (1, 8)	3 (1, 4)
BMI	Body mass index (BMI kg/m^2)	28 (24, 32)	31 (26, 37)
	Obese I (BMI 30-39)	357 (30)	5 (33)
	Obese II (BMI ≥40)	68 (6)	3 (20)
CD4	Absolute CD4 (cells/μL)	677 (488, 882)	657 (430, 833)
	Nadir CD4 (cells/μL)	437 (284, 631)	321 (194, 480)
Baseline resistance	INSTI	6/314 (2)	0/3 (0)
	CAB	2/314 (<1)	0/3 (0)
	NNRTI	61/314 (19)	0/3 (0)
	RPV	15/314 (5)	0/3 (0)
	Both CAB and RPV	1/314 (<1)	0/3 (0)

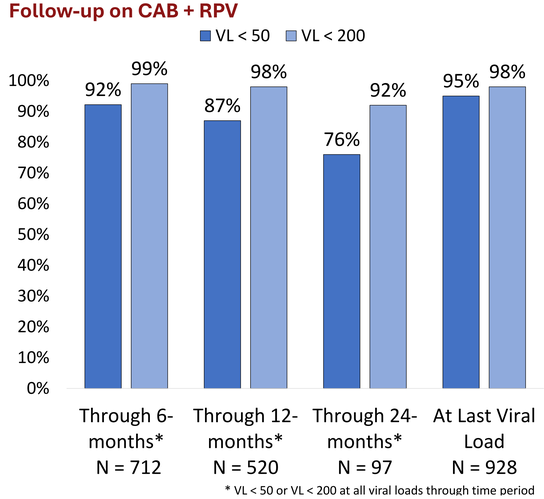
INSTI: Integrase Strand Inhibitor; NNRTI: Non-nucleoside reverse transcriptase inhibitors; CAB: Cabotegravir; RPV: Rilpivirine
Percentages may not sum to 100% due to rounding

Figure 1: Adherence to and Durability of CAB+RPV Regimen Through End of Study Period



* Includes 21 who re-initiated CAB+RPV and remained on CAB+RPV through end of follow-up

Figure 2: Maintenance of Viral Suppression During Follow-up on CAB + RPV



* VL < 50 or VL < 200 at all viral loads through time period

RESULTS (cont.)

- During study period, 89% of injections were administered without delay, with 69% of PWH receiving no delayed injections. (Figure 1)
- Of 314 PWH with HIV genotype data prior to initiation, 6 (2%) had baseline resistance to ≥1 INSTIs, and 61 (19%) had resistance to ≥1 NNRTIs.
- Among all CAB+RPV initiators, 928 (77%) individuals had ≥1 follow-up VL with 882 (95%) observed with last VL <50 copies/mL. (Figure 2)
- CVF among those with follow-up VL data was observed in 15 (1.6%) individuals with a median of 7 months from initiation (IQR: 3-12); 8 (53%) had > 2 months follow-up on a subsequent regimen, with re-suppression observed in 6 individuals (75%).
- Injection delays were observed in 4 (27%) individuals with CVF (median 5 total days delayed, mean 5.5 [range: 2-11]), compared to 31% of total population (median 9 total days delayed, mean 14, [range: 1-80]).
- HIV genotype at CVF was available for 5/15 (33%). RPV resistance was identified in 3 PWH (Y181C + G190S; K101E; Y181C), 1 of whom also had CAB resistance (S147G + N155H).

CONCLUSIONS

- High rates of viral suppression were seen among PWH initiating CAB+RPV, including those with prior NNRTI/INSTI resistance. CVF with emergent CAB resistance was rare.
- These results are consistent with previous studies reporting low rates of emergent RPV resistance and even lower rates of CAB resistance among individuals with CVF.

ACKNOWLEDGEMENTS

The study was supported by ViiV Healthcare.
The data and analyses were provided by Trio Health.

FOR MORE INFORMATION:

Contact: Richard Elion, Rick.Elion@triohealth.com or Andrew Frick, Andrew.Frick@triohealth.com