Characteristics and Treatment Outcomes of People With HIV Prescribed Fostemsavir in The Trio Cohort

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Moti Ramgopal[1], Cassidy Henegar[2], Andrew J. Frick[3], Janna Radtchenko[3], Isobel McEwen[3], Valeria Duran[3], Leigh Ragone[2], Michael Aboud[2], Steven Santiago[4], Karam Mounzer[5], Greg Huhn[6], Charles Walworth[7], Richard Elion[3], Vani Vannappagari[2]

[1]Midway Immunology & Research Center, Fort Pierce, FL, USA; [2]ViiV Healthcare, Durham, NC, USA; [3]Trio Health, Louisville, CO, USA; [4]Care Resource, Miami, FL, USA; [5]School of Medicine at The University of Pennsylvania; Philadelphia Fight Community Health Centers, Philadelphia, PA, USA; [6]Ruth M. Rothstein CORE Center, Rush University Medical Center, Chicago, IL, USA; [7]Monogram Biosciences (a Labcorp subsidiary), South San Francisco, USA

BACKGROUND

- Fostemsavir [FTR] is approved for use with other active antiretrovirals [ARVs] for treatment of heavily treatment-experienced people with HIV [PWH] and multi-drug resistance (MDR). We described characteristics and treatment outcomes among PWH prescribed FTR in a real-world setting in the US.

METHODS

- PWH initiating FTR for the first time from July 2, 2020 (FDA approval) to Aug 1, 2023 identified from electronic health records in the Trio Health HIV Cohort were followed for 12 months from baseline (first FTR Prescription).
- Outcomes included suppression (VL <50 copies/mL), virologic failure ([VF]: 2 consecutive viral loads (VL) ≥200 copies/mL or 1 VL ≥200 copies/mL + FTR discontinuation within 4 mo), change in CD4 count at 6 and 12 months, and CD4 recovery (CD4 > 350 cells/μL or +50 cells/μL per 6 months on FTR). CD4 recovery was analyzed among those with Baseline CD4 < 350 cells/μL.
- ARV class resistance (among PI, NRTI, NNRTI, and INSTI classes) was identified through most recent available HIV Genotype and defined as intermediate/high resistance to ≥ 1 ARV in a class by Stanford HIVdb algorithm, and MDR HIV as resistance to ≥ 3 ARV classes.
- Analyses were stratified by viral load at baseline (suppressed: VL <50 copies/mL; viremic: VL ≥50 copies/mL).

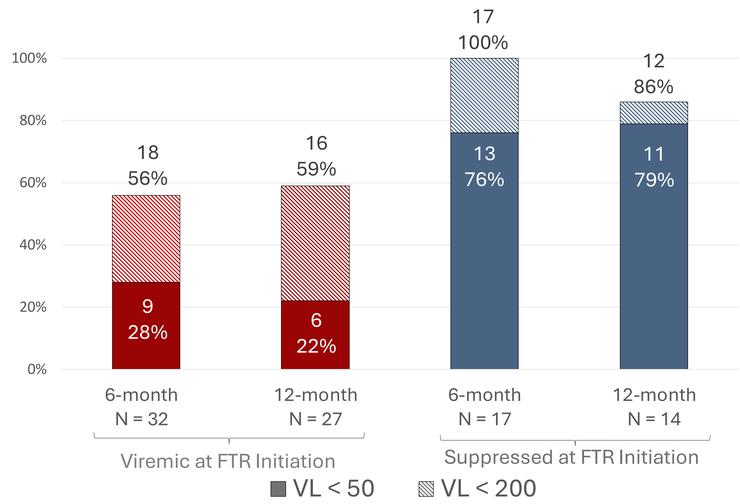
Fostemsavir was prescribed to a heterogeneous population. The majority of people with HIV suppressed at baseline remained suppressed, and over 1/3 of people with HIV with viremia at initiation achieved viral undetectability. CD4 cell counts increased through 12 months, with larger increases in suppressed PWH.

Table 1: Population Characteristics at FTR Initiation

N (%) or Median (IQR)	Baseline VL ≥ 50 copies/mL N = 46	Baseline VL < 50 copies/mL N = 31
Age < 50 years at FTR Start	22 (48%)	3 (10%)
Male Gender	32 (70%)	28 (90%)
Female Gender	12 (26%)	3 (10%)
Other Gender	2 (4%)	0 (0%)
White Race	18 (39%)	19 (61%)
Black/African American Race	25 (54%)	7 (23%)
Other Race	3 (7%)	5 (16%)
Years since Diagnosis	7 (3, 8)	5 (1, 9)
Core Agent of OBT*		
Bictegravir	8 (17%)	9 (29%)
Dolutegravir	26 (57%)	13 (42%)
Other INSTI	3 (6%)	2 (6%)
PI	9 (20%)	7 (23%)
Viral Load (log10 copies/mL)	3.3 (2.2,4.5)	N/A
Absolute CD4 (cells/μL)	156 (270, 452)	260 (189, 486)
Absolute CD4 < 350	28/45 (62%)	14/27 (52%)
Available HIV Genotype Prior to Initiation	29 (63%)	12 (39%)
INSTI Resistance	2/29 (7%)	0/12 (0%)
PI Resistance	7/29 (24%)	4/12 (33%)
NNRTI Resistance	19/29 (66%)	5/12 (42%)
NRTI Resistance	20/29 (69%)	5/12 (42%)
No Resistance	7/29 (24%)	4/12 (33%)
1 Class Resistance	5/29 (17%)	4/12 (33%)
2 Class Resistance	8/29 (28%)	2/12 (17%)
3 Class Resistance (MDR)	9/29 (31%)	2/12 (17%)

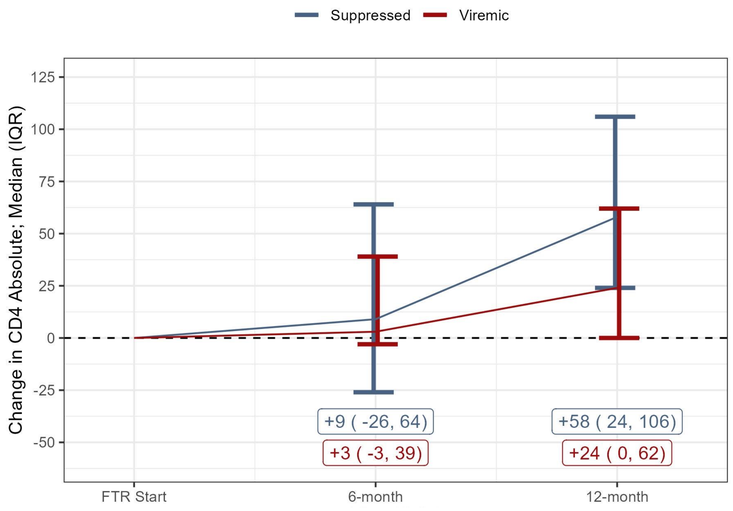
FTR: Fostemsavir; OBT: Optimized Background therapy: Prescribed ART regimen in combination with FTR; INSTI: Integrase Strand Inhibitor; NRTI: Nucleoside reverse transcriptase inhibitors; NNRTI: Non-nucleoside reverse transcriptase inhibitors; PI: Protease Inhibitors
Percentages may not sum to 100% due to rounding

Figure 1: Virologic Suppression At 6-/12-Months Follow-up on FTR



6-month viral load: nearest result to 180 days occurring between 90 and 269 days
12-month viral load: nearest result to 365 days occurring between 270 and 450 days

Figure 2: Immunologic Outcomes at 6-/12-months on FTR



6-month CD4 Cell Count: nearest result to 180 days occurring between 90 and 269 days
12-month CD4 Cell Count : nearest result to 365 days occurring between 270 and 450 days

RESULTS

- 77 PWH qualified for inclusion; 46 (60%) were viremic at initiation while 31 (40%) were suppressed (Table 1). INSTI-based OBTs were prescribed to 79% of the cohort.
- FTR was prescribed along with new OBT in majority of those viremic at initiation (54%), while those suppressed at initiation were more commonly observed with FTR added to existing regimen (70%).
- Most continued FTR therapy through 12-months follow-up (74% viremic; 71% suppressed), while others discontinued FTR (11% viremic; 23% suppressed) or were lost to follow-up (24% viremic; 6% suppressed). Those suppressed at initiation discontinued earlier than those with observed viremia (median 5 vs 9 months).
- Follow-up viral loads were available in 39 (85%) of viremic PWH and 26 (83%) of suppressed PWH. Undetectable viral load within 12 months was achieved in 36% of viremic initiators. The majority of suppressed PWH maintained suppression at all follow-up viral loads (77%). Virologic failure was observed in 3 (12%) of suppressed PWH. Virologic outcomes at 6 and 12 months are presented in Figure 1.
- Over one-third of FTR initiators with baseline CD4 < 350 cells/μL achieved CD4 recovery (36% viremic vs. 38% suppressed). Increases in CD4 were observed at 12-months in both viremic and suppressed groups. (Figure 2)

CONCLUSIONS

- Most PWH suppressed at FTR initiation maintained suppression and over one-third of viremic initiators achieved undetectable viral load.
- PWH suppressed at FTR initiation had higher gains in CD4 compared to those viremic at initiation, but similar proportions of CD4 recovery were observed among those with Baseline CD4 < 350.

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

CROI Conference on Retroviruses and Opportunistic Infections