Virologic Outcomes by ART Initiation Timing: Sub-Analysis of the REVIVE Study (DTG/3TC & BIC/F/TAF)

Kuretski, J.[1], Bolivar, H. [1], Ha, B.[2], Patel, P.[2], Patarroyo, J. [2], Harper, G. [3], Naylor, R. [3], Taylor-Whiteley, T. [3] & Ramgopal, M. [1]

[1]*Midway Specialty Care Center,* [2]*ViiV Healthcare,* [3]*Adelphi Real World, Bollington, UK*

Key Takeaways:

- High virologic suppression was achieved across ART initiation timeframes, including among PWH initiating ART within 0–7 days of diagnosis.
- Virologic outcomes were durable through 48 weeks, with suppression rates of 91.5% for DTG/3TC and 89.7% for BIC/F/TAF.
- Both regimens were well tolerated, with no treatment discontinuations through 48 weeks, supporting real-world use of simplified ART across different initiation timeframes.

BACKGROUND

- Rapid ART initiation enhances HIV outcomes, but limited real-world data exists on how timing affects results across contemporary regimens.
- We evaluated virologic outcomes by initiation timing among people with HIV (PWH) receiving dolutegravir/lamivudine (DTG/3TC) or bictegravir/emtricitabine/tenofovir alafenamide (BIC/F/TAF).

METHODS

- We conducted a retrospective cohort study of PWH initiating or switching to DTG/3TC or BIC/F/TAF between May 1, 2019, and January 28, 2023, at 12 infectious disease clinics in the Southeastern United States.
- Data from 146 patients, naïve to HIV treatment, were analyzed, stratified by regimen and time from HIV diagnosis to index ART initiation (0–7, 8–30, >30 days).
- Descriptive statistics were used to describe study outcomes.
- Analyses were exploratory and intended to characterize trends across populations.

SAMPLE POPULATION

	Total N = 146	DTG/3TC N = 59	BIC/F/TAF N = 87
Age, median (range)	38 (19 - 72)	43 (21 - 68)	37 (19 - 72)
Gender Identity, n (%)			
• Cisgender Female	36 (24.7 %)	17 (28.8%)	19 (21.8%)
• Cisgender Male	108 (74.0%)	41 (69.5%)	67 (77.0%)
• Transgender Male	0 (0.0%)	0 (0.0%)	0 (0.0%)
• Transgender Female	2 (1.4%)	1 (1.7%)	1 (1.1%)
Days from Diagnosis of HIV to Baseline, median (range)	12 (0 – 6,753)	7 (0 – 4,179)	15 (0 – 6,753)
• 0 – 7 days, n (%)	65 (44.5%)	30 (50.8%)	35 (41.0%)
• 8 – 30 days, n (%)	36 (24.7%)	7 (11.9%)	29 (33.0%)
• > 30 days, n (%)	45 (30.8%)	22 (37.3%)	23 (26.4%)
Race, n (%)			
• Asian	0 (0.0%)	0 (0.0%)	0 (0.0%)
• American Indian or Alaska Native	1 (0.7%)	0 (0.0%)	1 (1.1%)
• Black	67 (45.9%)	30 (50.8%)	37 (42.5%)
• White	57 (39.0%)	22 (37.3%)	35 (40.2%)
• Mixed	2 (1.4%)	0 (0.0%)	2 (2.3%)
• Another Race Not Mentioned	8 (5.5%)	2 (3.4%)	6 (6.9%)
• Unknown	11 (7.5%)	5 (8.5%)	6 (6.9%)
Ethnicity, n (%)			
• Hispanic/Latinx	27 (18.5%)	11 (18.6%)	16 (18.4%)
• Not Hispanic/Latinx	107 (73.3%)	44 (74.6%)	63 (72.4%)
• Unknown	12 (8.2%)	4 (6.8%)	8 (9.2%)
Number of Social Determinants of Health at Baseline, n (%)			
• 1	16 (11.0%)	7 (12.0%)	9 (10.3%)
• 2	18 (12.3%)	4 (7.0%)	14 (16.1%)
• More than 2	23 (15.8%)	12 (20.0%)	11 (12.6%)
• Unknown	89 (61.0%)	36 (61.0%)	53 (60.9%)
HIV-1 RNA level at Baseline (log), median (range)	4.7 (1.3 – 7.0)	4.7 (1.3 – 6.8)	4.6 (1.3 – 7.0)
HIV-1 RNA level at Baseline, n (%)			
• < 100,000 copies/mL	91 (62.3%)	37 (62.7%)	54 (62.1%)
• 100,000 – 500,000 copies/mL	27 (18.5%)	14 (23.7%)	13 (14.9%)
• > 500,000 copies/mL	28 (19.2%)	8 (13.6%)	20 (23.0%)
CD4 Count at Baseline (cells/mm^3), median (range)	378 (13 - 1554)	337 (13 – 1554)	403 (19 – 1464)
BMI at Baseline, n (%)			
• Underweight	4 (2.7%)	1 (1.7%)	3 (3.5%)
• Normal	49 (33.6%)	22 (37.3%)	27 (31.0%)
• Overweight	30 (20.6%)	10 (16.9%)	20 (23.0%)
• Obese	33 (22.6%)	15 (25.4%)	18 (20.7%)
• Unknown	30 (20.6%)	11 (18.6%)	19 (21.8%)
Genotypic Resistance Documented at Baseline, n (%)			
• No	61 (41.8%)	32 (54.2%)	29 (33.3%)
• Yes	9 (6.2%)	4 (6.7%)	5 (5.8%)
• Unknown	76 (52.1%)	23 (39.0%)	53 (60.9%)

OBJECTIVES

- Describe viral suppression rates, HIV-1 RNA < 50 copies/mL, at 24- and 48-weeks
- Describe proportion of participants who experienced > 5% weight gain over 48 weeks
- Describe the change in absolute CD4 over 48 weeks
- Describe incidence of adverse events and treatment discontinuations

RESULTS

- At 24 weeks, 91.5% on DTG/3TC and 71.3% on BIC/F/TAF had virologic suppression (<50 copies/mL).
- By 48 weeks, suppression rates were similar (DTG/3TC 91.5%; BIC/F/TAF 89.7%). High rates of virologic suppression were also observed across ART initiation timing subgroups, including those initiating within 0-7 days, although some regimen-specific subgroup sizes were small.
- Drug-related AEs occurred in 11.6% of PWH (DTG/3TC 8.5%; BIC/F/TAF 13.8%), with no treatment discontinuations through 48 weeks. Weight gain ≥5% at 48 weeks was observed in 57.7% overall (DTG/3TC 63.3%; BIC/F/TAF 56.1%).
- Median CD4 count increases at 48 weeks were +172 cells/mm^3 (DTG/3TC) and +202 cells/mm^3 (BIC/F/TAF).

	Total N = 146	DTG/3TC N = 59			BIC/F/TAF N = 87			
		Total	0-7 days	8-30 days	>30 days	Total	0-7 days	8-30 days	>30 days
HIV-1 RNA level, 24 Weeks, n (%)									
• < 50 copies/mL	116 (79.5%)	54 (91.5%)	26 (86.7%)	6 (85.7%)	22 (100%)	62 (71.3%)	24 (68.6%)	21 (72.4%)	17 (73.9%)
• ≥ 50 copies/mL	30 (20.6%)	5 (8.5%)	4 (13.3%)	1 (14.3%)	0 (0.0%)	25 (28.8%)	11 (31.4%)	8 (27.6%)	6 (26.1%)
HIV-1 RNA level, 48 Weeks, n (%)									
• < 50 copies/mL	132 (90.4%)	54 (91.5%)	27 (90.0%)	6 (85.7%)	21 (95.5%)	78 (89.7%)	32 (91.4%)	26 (89.7%)	20 (87.0%)
• ≥ 50 copies/mL	14 (9.6%)	5 (8.5%)	3 (10.0%)	1 (14.3%)	1 (4.5%)	9 (10.3%)	3 (8.6%)	3 (10.3%)	3 (13.0%)

RESULTS

	Total N = 146	DTG/3TC N = 59				BIC/F/TAF N = 87			
		Total	0-7 days	8-30 days	>30 days	Total	0-7 days	8-30 days	>30 days
At Least one drug related adverse reaction through 48 week follow up, n (%)	17 (11.6%)	5 (8.5%)	4 (13.3%)	0 (0.0%)	1 (4.6%)	12 (13.8%)	5 (14.3%)	5 (17.2%)	3 (13.0%)
Weight gain from baseline – 24 week follow up, n (%) ≥ 5% weight gain	49 (46.7%)	13 (46.4%)	8 (57.1%)	1 (33.3%)	4 (36.4%)	31 (48.4%)	11 (42.3%)	10 (50.0%)	10 (55.6%)
Weight gain from baseline – 48 week follow up, n (%) ≥ 5% weight gain	56 (57.7%)	19 (63.3%)	6 (54.6%)	4 (100.0%)	9 (60.0%)	32 (56.1%)	8 (36.4%)	14 (73.7%)	10 (62.5%)
Change in CD4 Count from Baseline at 24 week follow up (cells/mm^3), median (range)	126.5 (-643–805)	138 (-230–805)	139 (-230–500)	239 (5-805)	82 (-54–309)	109.5 (-643–763)	136 (-210-396)	86.5 (-268–763)	100.5 (-643-323)
Change in CD4 Count from Baseline at 48 week follow up (cells/mm^3), median (range)	190.5 (-846–1007)	172 (-260–700)	172.5 (-230–700)	206 (75-629)	131 (-260–593)	202 (-846–1007)	264.5 (-84-900)	202 (-151–1007)	152 (-846-535)

CONCLUSION

- In this descriptive analysis, DTG/3TC and BIC/F/TAF were associated with high rates of virologic suppression across initiation timeframes, with durable outcomes through 48 weeks.
- Similar rates of weight gain were reported at 48 weeks.
- Both regimens were well tolerated, and no treatment discontinuations occurred due to drug-related AEs
- These findings contribute to real-world evidence supporting the use of simplified ART regimens across a range of clinical scenarios.

Corresponding author: Jenn Kuretski – jkuretski@midwaycare.org

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