Interim demographic, clinical characteristics, and effectiveness in the REGAL cohort: a REtrospective real-world study of the effectiveness and tolerability of the antiretroviral treatment reGimens DTG/3TC compAred to BIC/FTC/TAF in older persons Living with HIV

Julie Priest,[1] Emilio Letang,[2] Richard Grove,[3] Gustavo Verdier,[4] Eva Fernvik,[5] Andres Maldonado,[6] Cassidy Henegar,[1] Bryn Jones,[7] Ángel Baltasar,[8] Carly Rodriguez,[9] Emilio Sanchez,[8] Jeremy Fraysse,[1] Gregory Huhn[1]*

[1]ViiV Healthcare, Durham, NC, USA; [2]ViiV Healthcare, Tres Cantos, Madrid, Spain; [3]GSK, London, UK; [4]ViiV Healthcare, Montréal, Canada; [5]ViiV Healthcare, Stockholm, Sweden; [6]ViiV Healthcare, Wavre, Belgium; [7]ViiV Healthcare, London, UK; [8]IQVIA, Barcelona, Spain; [9]IQVIA, Durham, NC, USA

**Presenting on behalf of the authors.*

Key Takeaways

- **The REGAL study evaluates dolutegravir/lamivudine (DTG/3TC) and bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in aging persons living with HIV in 7 countries across North America, Europe, and Asia**
- **The study cohort comprises antiretroviral therapy (ART)-experienced people with HIV aged 50 years or greater who have been living with HIV for decades with diverse comorbidities and comedications**
- **Common reasons for initiation of DTG/3TC or BIC/FTC/TAF were drug-drug interactions with comedications, concern about long-term ART exposure, participant's decision, and comorbidities**
- **Both DTG/3TC and BIC/FTC/TAF were highly effective in a population of older, virologically suppressed people with HIV**
- **Using DTG/3TC allows for treatment with fewer medications**

Introduction

- The United Nations Programme on human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (UNAIDS) estimated that the proportion of people with HIV aged ≥50 years in 2020 was 21% and is projected to rise to 73% by 2030[1]
- The proportion of people with HIV with multiple comorbidities increases with age, and there are additional concerns about the cumulative effects of long-term ART[2]
- Increased awareness among healthcare providers and older adults on the additional needs of treating older people with HIV is needed,[3] including consideration of the management of age-related comorbidities and the increased likelihood of polypharmacy and drug-drug interactions
- Modern ART has evolved from multiple or 3-drug regimens to 2-drug regimens, which includes DTG/3TC recommended for initial treatment for most treatment-naive people and as a switch option for virologically suppressed people
- Data comparing the real-world effectiveness of the 2-drug regimen DTG/3TC and 3-drug regimen BIC/FTC/TAF are limited in older people with HIV. This interim analysis of 241 people will be followed by a full study target sample of 1,100 people

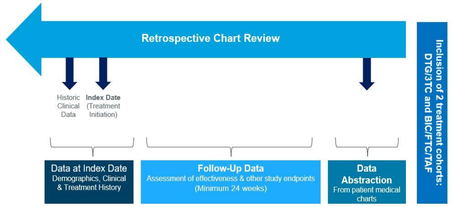
Study Aim: To assess the demographics and clinical characteristics, and compare the real-world effectiveness, tolerability, and other core outcomes of switching treatment to DTG/3TC versus BIC/FTC/TAF in older people with HIV

Methods

Study Design

- Retrospective chart review of ART-experienced, virologically suppressed people with HIV aged ≥50 years at time of DTG/3TC or BIC/FTC/TAF initiation, who have at least 24 weeks of follow-up (Figure 1)
- People from 7 countries (14 sites) including China (1 site), France (1 site), Germany (3 sites), Korea (2 sites), Spain (1 site), Taiwan (2 sites), and the United States of America (USA; 4 sites)
- Study exposure was defined as treatment for HIV-1 with either DTG/3TC or BIC/FTC/TAF for at least 24 weeks and the index date was defined as DTG/3TC or BIC/FTC/TAF initiation date
- Study outcome:
  - Virologic failure: defined as 2 consecutive HIV-1 RNA viral loads of ≥200 copies/mL or 1 HIV RNA viral load of ≥200 copies/mL followed by core agent/regimen change within 4 months of the viral load of ≥200 copies/mL

Figure 1. Overall Study Design



- Demographics, clinical characteristics, and effectiveness outcomes were abstracted from clinical charts for up to 48 weeks of follow-up after DTG/3TC or BIC/FTC/TAF initiation and summarized using appropriate descriptive statistics

Results (Interim Analyses)

Table 1. Description of Demographic Characteristics at Index Date

	DTG/3TC (N=128)	BIC/FTC/TAF (N=113)
Age (years)		
Mean (SD)	59.1 (6.43)	59.4 (6.16)
Median [Q1, Q3]	58.0 [54.0, 62.5]	58.0 [55.0, 63.0]
(Range)	(50.0, 82.0)	(50.0, 80.0)
Age >65 years		
Yes	22 (17.2%)	17 (15.0%)
No	106 (82.8%)	96 (85.0%)
Sex assigned at birth		
Male	117 (91.4%)	92 (81.4%)
Female	11 (8.6%)	21 (18.6%)
Gender identity at index		
Male	117 (91.4%)	93 (82.3%)
Female	11 (8.6%)	20 (17.7%)
Country		
Germany	51 (39.8%)	31 (27.4%)
Spain	3 (2.3%)	3 (2.7%)
France	1 (0.8%)	1 (0.9%)
China	0 (0.0%)	1 (0.9%)
Korea	1 (0.8%)	3 (2.7%)
Taiwan	4 (3.1%)	10 (8.8%)
USA	68 (53.1%)	64 (56.6%)

Demographics at Index Date

- 241 people (128 on DTG/3TC and 113 on BIC/FTC/TAF) were enrolled as of 02 July 2024
- 17.2% on DTG/3TC and 15.0% on BIC/FTC/TAF were aged >65 years
- 91.4% on DTG/3TC and 81.4% on BIC/FTC/TAF were assigned male sex at birth

Table 2. Description of Clinical Characteristics at Index Date

	DTG/3TC (N=128)	BIC/FTC/TAF (N=113)
Reason for initiation		
Drug-drug interaction with comedications	11 (10.4%)	20 (22.2%)
Concern about long-term ART exposure	21 (19.8%)	9 (10.0%)
Participant's decision	13 (12.3%)	12 (13.3%)
Comorbidities	12 (11.3%)	7 (7.8%)
Adverse event	9 (8.5%)	7 (7.8%)
Financial/Costs concerns	4 (3.8%)	3 (3.3%)
Resistance	1 (0.9%)	1 (1.1%)
Low adherence	1 (0.9%)	0 (0.0%)
Other	34 (32.1%)	31 (34.4%)
Missing	22	23
Time between HIV diagnosis and index date (years)		
n	113	98
Median [Q1, Q3]	16.6 [11.2, 22.4]	17.0 [10.3, 24.7]
Missing	15	15
Plasma HIV-1 viral load		
Undetectable - target not detected	79 (72.5%)	57 (57.6%)
Detectable but unquantifiable	20 (18.3%)	24 (24.2%)
Detectable and quantifiable	10 (9.2%)	18 (18.2%)
Missing	19	14
CD4+ cell count (cells/mm^3)		
n	95	75
Median [Q1, Q3]	688.0 [534.0, 924.0]	659.0 [428.0, 979.0]
Missing	33	38

*Limit of detection varies by site and local laboratory.

Clinical Characteristics at Index Date

- Mean time from HIV diagnosis to index date was 17.6 and 17.7 years in the DTG/3TC and BIC/FTC/TAF groups, respectively
- Median (Q1, Q3) CD4+ cell count was 688 (534, 924) and 659 (428, 979) cells/mm^3 in the DTG/3TC and BIC/FTC/TAF groups, respectively
- The most common reasons for initiation of DTG/3TC or BIC/FTC/TAF were drug-drug interactions between prior ART regimens and comedications, concern about long-term ART exposure on prior regimens, participant's decision, and comorbidities

Table 3. Description of Historical Characteristics Prior to Index Date

	DTG/3TC (N=128)	BIC/FTC/TAF (N=113)
Virologic failure		
No	78 (96.3%)	69 (88.5%)
Yes	3 (3.7%)	9 (11.5%)
Unknown	47	35
Number of prior ART regimens		
n	80	74
Median [Q1, Q3]	3.0 [2.0, 5.0]	3.5 [2.0, 5.0]
Missing	48	39
Duration of prior ART regimens (years)		
n	74	71
Median [Q1, Q3]	10.3 [6.9, 15.9]	12.1 [7.2, 21.5]
Missing	54	42

Historical Characteristics Prior to Index Date

- Prior to the index date, 3 (3.7%) people on DTG/3TC and 9 (11.5%) on BIC/FTC/TAF had a history of virologic failure
- People had a mean of 3.6 and 3.9 prior ART regimens in the DTG/3TC and BIC/FTC/TAF groups, respectively

Figure 2. Number of Different Comorbidities at Index Date

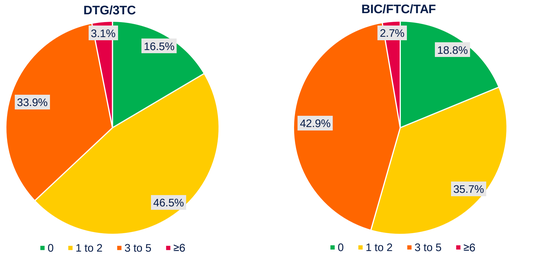
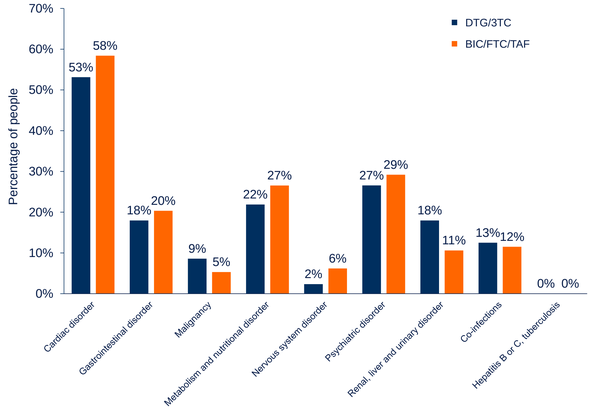


Figure 3. Comorbidities of Interest at Index Date



Comorbidities and Comedications

- At the index date, approximately 85% of people in both treatment groups had >1 comorbidity; ≥3 comorbidities were reported in 37.0% of people on DTG/3TC and 45.5% on BIC/FTC/TAF
- The most common comorbidities were cardiac disorders, psychiatric disorders, and metabolism and nutritional disorders
- One or more non-ART comedications were reported in 85.8% of people on DTG/3TC and 82.1% on BIC/FTC/TAF

Baseline Resistance Testing at Index Date

- DTG/3TC group: 10 (7.8%) had a resistance testing result available, 4 (3.1%) had resistance identified
  - Mutations included:
    - M184V/I n=1
    - Other NRTI mutation n=2
    - Any NNRTI mutations n=2
- BIC/FTC/TAF group: 5 (4.4%) completed resistance testing, 0 (0.0%) had resistance identified

Table 4. Clinical Outcomes of Participants at Each Follow-up Visit

	DTG/3TC (N=128)	BIC/FTC/TAF (N=113)
24-week follow-up		
Virologic failure	0 (0.0%)	0 (0.0%)
Censored	3 (2.3%)	3 (2.7%)
Reason for censoring		
Switch, change, or discontinuation of regimen	0 (0.0%)	1 (0.8%)
Study period ended	3 (2.3%)	2 (1.8%)
48-week follow-up		
Total	125 (100.0%)	110 (100.0%)
Virologic failure	0 (0.0%)	0 (0.0%)
Censored	7 (5.6%)	6 (5.5%)
Reason for censoring		
Switch, change, or discontinuation of regimen	2 (1.6%)	1 (0.9%)
Study period ended	5 (4.0%)	5 (4.5%)

Follow-up and Virologic Failure

- No virologic failures were observed at 24 or 48 weeks in either treatment group
- Few discontinuations occurred through 48 weeks of follow-up

Conclusions

- At the time of the interim analysis, no people in either treatment group experienced virologic failure at 24 weeks or 48 weeks
- In a population of older, virologically suppressed people with HIV with age-related comorbidities and comedications, DTG/3TC and BIC/FTC/TAF demonstrated similar high levels of effectiveness
- Using a 2-drug regimen such as DTG/3TC provides high effectiveness in older adults while using fewer medications than 3-drug regimens
- Further analyses on a target sample of 1,100 will be conducted when data collection is complete to assess outcomes and control for potential differences between treatment groups

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References: 1. Smit et al. *Lancet Infect Dis*. 2015;15:810-818. **2.** Young et al. *Open Forum Infect Dis*. 2017;4(suppl 1):S431-S432. **3.** Courlet et al. *Open Forum Infect Dis*. 2019;6:ofz531.

Presenting author: Gregory Huhn; gregory.d.huhn@viivhealthcare.com