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The Global 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

Jeremy Fraysse,[1] Bryn Jones,[2] Jennifer Kuretski,[3] Emilio Letang,[4] María Jesús Pérez Elías,[5] Gustavo Verdier,[6] Mark Lynam,[7] Qingxia Zhao,[8] Eva Fernvik,[9] Jun Yong Choi,[10] Richard Grove,[11] Chien-Yu Cheng,[12] Cynthia Firnhaber,[13,14] Arnaud Desclaux,[15] Axel Baumgarten,[16] Eleonora Zonta,[7] Julie Priest[1]

[1]ViiV Healthcare, Durham, NC, USA; [2]ViiV Healthcare, London, UK; [3]Midway Specialty Care Center, West Palm Beach, FL, USA; [4]ViiV Healthcare, Tres Cantos, Spain; [5]Hospital Universitario Ramón y Cajal, Madrid, Spain; [6]ViiV Healthcare, Montréal, Canada; [7]IQVIA, Barcelona, Spain; [8]The Sixth People's Hospital of Zhengzhou, Zhengzhou, China; [9]ViiV Healthcare, Stockholm, Sweden; [10]Yonsei University College of Medicine, Seoul, Republic of Korea; [11]GSK, London, UK; [12]Taoyuan General Hospital, Taoyuan, Taiwan; [13]Vivent Health, Denver, CO, USA; [14]University of Colorado Anschutz Medical Center, Denver, CO, USA; [15]Hôpital Pellegrin CHU Bordeaux, Bordeaux, France; [16]Zentrum für Infektiologie, Berlin, Germany

Presenting author:
Jeremy Fraysse
410 Blackwell Street
Durham, NC, USA 27701
jeremy.r.fraysse@viivhealthcare.com

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Key Takeaways

- The global REGAL study evaluates outcomes after switching to either dolutegravir/lamivudine (DTG/3TC) or bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in people aging with HIV across 7 countries
- The study cohort comprises people aged ≥50 years who are antiretroviral therapy (ART) experienced and have been living with HIV for more than a decade with diverse comorbidities and co-medications
- Only 2 virologic failures (1 in each group) occurred at 48 weeks; adjusted incidence rate differences did not yield differences across treatment groups
- Compared with BIC/FTC/TAF, DTG/3TC was equally effective and well tolerated in a population of people with HIV aged ≥50 years who were virologically suppressed

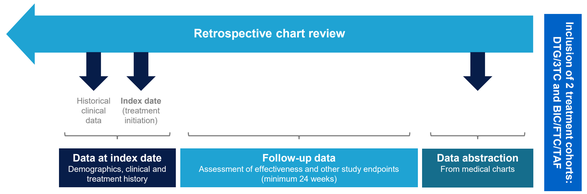
Introduction

- ART has prolonged life expectancy for people with HIV
  - People aging with HIV have more comorbidities than the overall population and a higher potential to experience polypharmacy and drug–drug interactions with ART[1]
- Modern ART has evolved from 3-drug regimens to 2-drug regimens, including guidelines recommending DTG/3TC both for initial treatment and as a switch option for those with prior ART experience[1-6]
  - Switching to a regimen with fewer drugs can potentially reduce drug–drug interactions, which may be beneficial as people age[1,6]
- Data comparing the real-world effectiveness of the 2-drug regimen DTG/3TC with the 3-drug regimen BIC/FTC/TAF are limited in people with HIV aged ≥50 years
- **Study aim:** To compare the real-world effectiveness, tolerability, and other core outcomes of switching treatment to DTG/3TC vs BIC/FTC/TAF in people with HIV aged ≥50 years

Methods

- Retrospective chart review of people with HIV aged ≥50 years who were ART-experienced and virologically suppressed at time of DTG/3TC or BIC/FTC/TAF initiation with ≥24 weeks of follow-up after switch
- The global REGAL study included people from China, France, Germany, Korea, Spain, Taiwan, and the United States
- Definitions
  - Study exposure: treatment with either DTG/3TC or BIC/FTC/TAF for at least 24 weeks
  - Index date: DTG/3TC or BIC/FTC/TAF initiation date
- Outcomes
  - Primary study outcome: virologic failure (VF) at 48 weeks, defined as 2 consecutive HIV-1 RNA values ≥200 c/mL or 1 HIV-1 RNA value ≥200 c/mL followed by core agent/regimen change within 4 months
  - Secondary endpoints: baseline demographics and clinical characteristics; difference in incidence rate of treatment switches after initial regimen switch; and difference in proportion of discontinuations between groups at 24 weeks, 48 weeks, and annually until end of follow-up
  - Exploratory endpoints: change from index date in CD4+ cell count, CD4+/CD8+ ratio, and biomarkers of hepatic function
- Demographics, clinical characteristics, and effectiveness outcomes were abstracted from clinical charts after DTG/3TC or BIC/FTC/TAF initiation and summarized using appropriate descriptive statistics
- Propensity score weighting, using inverse probability of treatment weighting, was used in analyses of all endpoints to ensure comparability of baseline characteristics between groups
- The propensity score model was derived based on clinical and demographic characteristics before or up to the index date and included age, gender, race/ethnicity, and region

Figure 1. Overall Study Design



Results

Table 1. Description of Demographic Characteristics at Index Date

Parameter	DTG/3TC (N=593)	BIC/FTC/TAF (N=551)
Age, years		
Mean (SD)	60.8 (7.4)	59.8 (6.6)
Median (IQR) [range]	59.0 (55.0, 65.0) [50.0-87.0]	59.0 (55.0, 64.0) [50.0-80.0]
Age >65 years, n (%)		
Yes	146 (24.6)	103 (18.7)
No	447 (75.4)	448 (81.3)
Sex assigned at birth, n (%)		
Female	119 (20.1)	96 (17.5)
Male	474 (79.9)	454 (82.5)
Country, n (%)		
China	110 (18.5)	111 (20.1)
France	65 (11.0)	48 (8.7)
Germany	78 (13.2)	62 (11.3)
Korea	50 (8.4)	50 (9.1)
Spain	98 (16.5)	91 (16.5)
Taiwan	27 (4.6)	28 (5.1)
United States	165 (27.8)	161 (29.2)

Demographics at Index Date

- 1144 people with HIV (593 on DTG/3TC and 551 on BIC/FTC/TAF) were enrolled in REGAL
- 24.6% and 18.7% of people on DTG/3TC and BIC/FTC/TAF were aged >65 years, respectively
- 79.9% and 82.5% of people on DTG/3TC and BIC/FTC/TAF were assigned male sex at birth, respectively

Table 2. Description of Clinical Characteristics at Index Date

Parameter	DTG/3TC (N=593)	BIC/FTC/TAF (N=551)
Time between HIV diagnosis and index date, years		
Median (IQR)	14.3 (7.7, 22.6)	15.7 (9.0, 24.4)
Not reported, n	44	43
Plasma HIV-1 RNA, n (%)[a]		
Undetectable, target not detected	382 (71.5)	329 (64.5)
Detectable but unquantifiable	113 (21.2)	101 (19.8)
Detectable and quantifiable	39 (7.3)	80 (15.7)
Not reported, n	59	41
CD4+ cell count, cells/mm^3		
Median (IQR)	642.5 (444.0, 866.0)	620.0 (393.0, 826.0)
Not reported, n	65	60
CD4+/CD8+ ratio		
Median (IQR)	0.8 (0.6, 1.3)	0.8 (0.6, 1.2)
Not reported, n	121	79
≥3 comorbidities, n/N (%)	181/550 (32.9)	172/506 (34.0)
Any non-ART co-medications, n/N (%)	413/554 (74.5)	350/502 (69.7)
Weight, kg		
Median (IQR)	74.0 (64.0, 85.5)	75.0 (65.0, 88.0)
Not reported, n	202	184
BMI category, n/N (%)		
<18.5 kg/m^2	10/374 (2.7)	12/348 (3.4)
18.5 to <25.0 kg/m^2	162/374 (43.3)	146/348 (42.0)
25.0 to <30 kg/m^2	138/374 (36.9)	125/348 (35.9)
≥30 kg/m^2	64/374 (17.1)	65/348 (18.7)
Not reported, n	219	203

BMI, body mass index. [a]Limit of detection by HIV-1 RNA viral load assay varies by site and local laboratory.

Clinical Characteristics at Index Date

- Among people on DTG/3TC and BIC/FTC/TAF, respectively
  - The most common body mass index (BMI) categories were 18.5 to <25.0 kg/m^2 (43.3% and 42.0%) and 25.0 to <30 kg/m^2 (36.9% and 35.9%)
  - Median time from HIV diagnosis to index date was 14.3 and 15.7 years
  - Median CD4+/CD8+ ratio was 0.8 in both treatment groups

Table 3. Description of Historical Characteristics Before Index Date

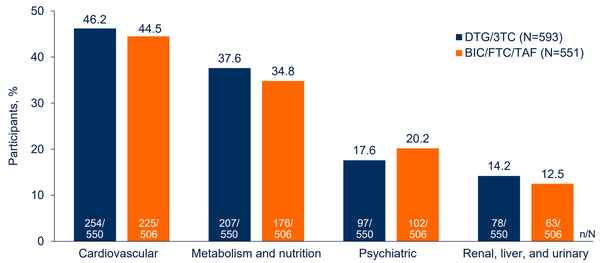
Parameter	DTG/3TC (N=593)	BIC/FTC/TAF (N=551)
Prior VF, n/N (%)[a]		
No	422/450 (93.8)	383/415 (92.3)
Yes	28/450 (6.2)	32/415 (7.7)
Not reported, n	143	136
Number of prior ART regimens		
Median (IQR)	3.0 (1.0, 5.0)	3.0 (1.0, 6.0)
Not reported, n	133	124
Duration of prior ART regimens, years[b]		
Median (IQR)	9.8 (4.9, 19.3)	12.4 (5.0, 20.7)
Not reported, n	138	122

[a]VF defined as 2 consecutive HIV-1 RNA values ≥200 c/mL or 1 HIV-1 RNA value ≥200 c/mL followed by core agent/regimen change within 4 months. [b]Summarized duration of all prior treatments.

Historical Characteristics Before Index Date

- 6.2% of people in the DTG/3TC group and 7.7% in the BIC/FTC/TAF group had experienced VF before index date
- Both groups had been exposed to a median of 3.0 prior ART regimens

Figure 2. Top 4 Comorbidities at Index Date

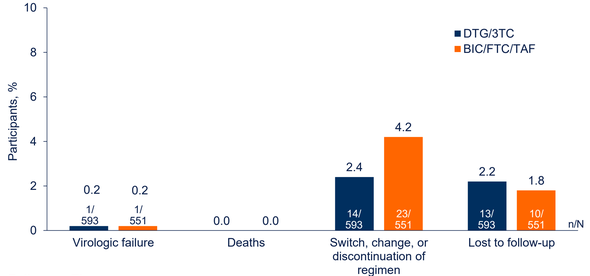


Comorbidities and Co-medications

- At the index date, 72.1% of the overall population had ≥1 comorbidity; ≥3 comorbidities were reported in 32.9% of people on DTG/3TC and 34.0% on BIC/FTC/TAF
- Concurrent use of 1 or more non-ART co-medications was reported in 74.5% of people on DTG/3TC and 69.7% on BIC/FTC/TAF

Endpoint Results

Figure 3. Cumulative Incidence of VF, Death, Switch, Change, or Discontinuation Up to 288 Weeks from Index Date



Follow-up Time

- Total study follow-up was 1463.3 and 1481.9 person-years in the DTG/3TC and BIC/FTC/TAF groups, respectively
- Overall, ~25% of people had 240 weeks of follow-up

Table 4. Study Outcomes by Follow-up Visit

	DTG/3TC				BIC/FTC/TAF			
Visit, n (%)	N	VF	Switch, change, or discontinuation of regimen	Lost to follow-up	N	VF	Switch, change, or discontinuation of regimen	Lost to follow-up
Week 24	593 (100.0)	0 (0.0)	1 (0.2)	0 (0.0)	551 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
Week 48	592 (99.8)	1 (0.2)	4 (0.7)	3 (0.5)	551 (100.0)	1 (0.2)	7 (1.3)	0 (0.0)
Week 96	539 (90.9)	0 (0.0)	4 (0.7)	5 (0.9)	515 (93.5)	0 (0.0)	8 (1.6)	2 (0.4)
Week 144	401 (67.6)	0 (0.0)	1 (0.2)	4 (1.0)	402 (73.0)	0 (0.0)	3 (0.7)	0 (0.0)
Week 192	274 (46.2)	0 (0.0)	1 (0.4)	1 (0.4)	278 (50.5)	0 (0.0)	4 (1.4)	1 (0.4)
Week 240	126 (21.2)	0 (0.0)	2 (1.6)	0 (0.0)	153 (27.8)	0 (0.0)	1 (0.7)	7 (4.6)
Week 288	35 (5.9)	0 (0.0)	1 (2.9)	0 (0.0)	49 (8.9)	0 (0.0)	0 (0.0)	0 (0.0)
Cumulative	NA	1 (0.2)	14 (2.4)	13 (2.2)	NA	1 (0.2)	23 (4.2)	10 (1.8)

NA, not applicable.

Primary and Secondary Study Outcomes

- 2 VFs were reported, 1 for each group, with no resistance reported
- Switch, change, or discontinuation of regimen was observed in 14 (2.4%) people on DTG/3TC and 23 (4.2%) on BIC/FTC/TAF through 288 weeks of follow-up
- At 48 weeks, incidence rate (IR; 95% CI) of VF per 100 person-years (primary endpoint) was 0.18 (0.00-0.42) for DTG/3TC and 0.20 (0.00-0.46) for BIC/FTC/TAF
  - No significant difference was observed between groups (IR difference, −0.02; 95% CI, −0.62, 0.57)
- At end of study, IR of VF per 100 person-years was 0.06 for DTG/3TC and 0.07 for BIC/FTC/TAF, with cumulative VF IRs of 0.16 and 0.18, respectively
- Cumulative IR difference (95% CI) for intolerability and discontinuation between DTG/3TC and BIC/FTC/TAF was −1.47 (−3.56, 0.62) and −0.84 (−3.56, 1.88) per 100 person-years, respectively

Exploratory Study Outcomes

Table 5. Change in CD4+ Cell Count and CD4+/CD8+ Ratio From Index Date

Change from index date, median (IQR) [n]	DTG/3TC	BIC/FTC/TAF
CD4+ cell count, cells/mm^3		
Week 48	14.0 (−70.0, 100.0) [355]	4.0 (−79.0, 100.0) [342]
Week 96	26.0 (−77.0, 137.0) [263]	7.0 (−83.0, 118.0) [260]
CD4+/CD8+ ratio		
Week 48	0.0 (−0.1, 0.1) [309]	0.0 (−0.1, 0.1) [312]
Week 96	0.1 (−0.1, 0.2) [241]	0.0 (−0.1, 0.2) [246]

- At the index date, median CD4+ cell count was 642.5 cells/mm^3 in the DTG/3TC group and 620.0 cells/mm^3 in the BIC/FTC/TAF group; median CD4+/CD8+ ratio was 0.8 in both groups
- Median CD4+ cell count increased slightly and CD4+/CD8+ ratio remained stable from index date through Week 96, with no significant differences between groups for both outcomes

Table 6. Change in Biomarkers of Hepatic Function From Index Date

Change from index date, median (IQR) [n]	DTG/3TC	BIC/FTC/TAF
APRI, IU/L		
Week 48	−0.0 (−0.1, 0.0) [363]	−0.0 (−0.1, 0.0) [345]
Week 96	0.0 (−0.1, 0.1) [283]	0.0 (−0.1, 0.1) [257]
FIB-4 score		
Week 48	0.0 (−0.2, 0.2) [363]	0.0 (−0.2, 0.2) [344]
Week 96	0.1 (−0.2, 0.3) [283]	0.1 (−0.1, 0.4) [257]

APRI, aspartate aminotransferase-to-platelet ratio; FIB-4, fibrosis 4 index.

- At the index date, median APRI was 0.3 IU/L and median FIB-4 score was 1.3 in both groups, indicating low risk of hepatic fibrosis
- No significant differences between groups were observed for biomarkers of hepatic function, and they remained stable through 96 weeks

Limitations

- Certain endpoints with a high number of missing values due to the retrospective nature of the study should be interpreted with caution

Conclusions

- As compared with BIC/FTC/TAF, older people with HIV (mean age, ~60 years) who had significant burden of age-related comorbidities and co-medications maintained long-term viral suppression without resistance after switching to the 2-drug regimen DTG/3TC
- Only 2 VFs were observed in the total cohort (1 in each group)
- Both DTG/3TC and BIC/FTC/TAF were well tolerated, with minimal switches, regimen changes, and discontinuations reported
- Using a 2-drug regimen such as DTG/3TC provides high effectiveness in adults with HIV aged ≥50 years while using fewer medications than 3-drug regimens

For REGAL data specific to the United States, please see Poster P-376.

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