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Effectiveness and safety of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in people living with HIV; the BICSTaR Canadian cohort

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Background

- In randomized clinical trials, B/F/TAF is highly efficacious and well tolerated in both antiretroviral treatment (ART) naïve (TN)[1,2] and ART-experienced (TE)[3,4] HIV-1 positive individuals, with zero resistance.
- Study sites in Canada, Europe and Asia are participating in BICSTaR, a global study that aims to assess the performance of B/F/TAF in routine clinical practice.

Methods

- BICSTaR Canada is an ongoing, non-interventional, prospective, multi-center, cohort study with 200 adult participants, from six clinics across Canada, starting B/F/TAF as initial ART or as switch therapy. The effectiveness, safety and tolerability of B/F/TAF in routine clinical practice is being evaluated.
- Data were analysed for patients reaching the 6 month benchmark by the data analysis cut off date (n=123/200) and included the following outcomes where data was available/collected:
  - HIV-1 RNA <50 cp/mL*
  - Drug-related (DR) adverse events (AEs) and DR serious AEs (DRSAEs)
  - Treatment persistence: % patients remaining on B/F/TAF
  - Weight change
  - Treatment satisfaction using the validated HIV treatment satisfaction status (TSQs) and change (TSQc) questionnaires

*B/F/TAF or study discontinuation or missing = excluded from analysis

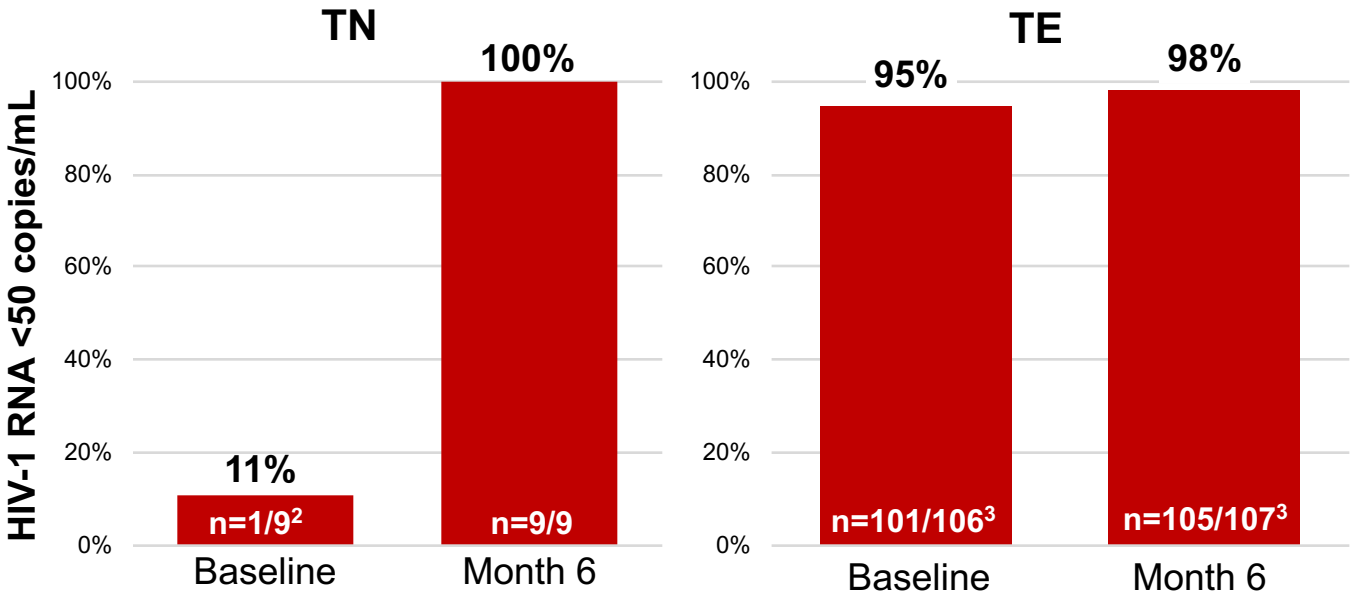
[1]Stellbrink HJ, Arribas JR, Stephens JL, et al. Lancet HIV. 2019 Jun;6(6):e364-e372.
[2]Wohl DA, Yazdanpanah Y, Baumgarten A, et al. Lancet HIV. 2019 Jun;6(6):e355-e363.
[3]Daar ES, DeJesus E, Ruane P, et al. Lancet HIV. 2018 Jul;5(7):e347-e356.
[4]Molina JM, Ward D, Brar I, et al. Lancet HIV. 2018 Jul;5(7):e357-e365

Results

Table 1. Participant baseline characteristics

Baseline characteristics	TN, n=9	TE, n=114
Male gender, *n (%)*	8 (89)	100 (88)
Age, years, *median (Q1-Q3)* • Age >50 years, *n (%)*	38 (30-45) 3 (33)	48 (39-54) 61 (54)
White ethnicity, *n (%)*	3 (33)	87 (76)
Baseline Regimen • INSTI/ NNRTI / PI, % • DTG / RAL / EVG, % • TDF, %		 71 / 22 / 6 40 / 16 / 16 25
HIV-related characteristics	**TN, n=9**	**TE, n=114**
HIV-1 RNA, log_{10} c/mL, *median (Q1-Q3) [n]* • HIV-1 RNA < 50 c/mL, *n (%)* • HIV-1 RNA > 100,000 c/mL, *n (%)*	4.83 (1.59-5.16) [9] 1 (11) 3 (33)	1.59 (1.59-1.59) [106] 101 (95) 0
CD4 count, cells/uL, *median (Q1-Q3) [n]* • CD4<200 cells/uL, *n (%)*	356 (220-460) [9] 2 (22)	574 (409-791) [114] 3 (3)
Prevalence of comorbidities at B/F/TAF start	**TN, n=9**	**TE, n=112**
• Any, *n (%)* • None, *n (%)* • 1-2, *n (%)* • ≥3, *n (%)*	7 (78) 2 (22) 1 (11) 6 (67)	105 (94) 7 (6) 26 (23) 79 (70)
Neuropsychiatric disorder, *n (%)*	2 (22)	34 (30)
Hyperlipidemia, *n (%)*	2 (22)	32 (29)
Hypertension, *n (%)*	1 (11)	25 (22)
Osteopathic disorder, *n (%)*	0 (0)	14 (13)
Cardiovascular disorders, *n (%)*	1 (11)	13 (12)

Figure 1. Effectiveness of B/F/TAF in TN and TE participants[1]



- Median CD4 cell counts increased from 356 to 590 in TN participants and remained above normal cell counts for TE participants (574 to 554 cells/μL).
- Persistence with B/F/TAF was high (98% on treatment) with 3 TE (2%) participants discontinuing B/F/TAF (2/3 due to DRAEs; 1/3 participant decision).

[1]B/F/TAF/study discontinuation or Missing=Excluded Analysis
[2]One treatment naïve participant had HIV-1 RNA <50 copies/mL at baseline
[3]Missing VL data for 8 participants at baseline and 7 participants at Month 6

Table 2. Reasons for starting B/F/TAF for TN and TE participants†

	TN, n=9
Early treatment according to guidelines, *n (%)*	5 (56)
Patient's wish, *n (%)*	3 (33)
Treatment as prevention, *n (%)*	2 (22)
Other*, *n (%)*	1 (11)

- B/F/TAF was initiated within a median of 23 days (Q1-Q3, 7-79 days) from HIV diagnosis (n=6)

	TE, n=114
Simplification, *n (%)*	77 (68)
Patient's wish, *n (%)*	54 (47)
Side effects of current ART, *n (%)*	43 (38)
Other, *n (%)*	35 (31)
• Prevent/reduce CVD Risk	16 (14)
• Prevent/reduce renal Risk	6 (5)
• Prevent/reduce bone loss	2 (2)

Comorbidity-Related [23 (20)]

†Reasons were not mutually exclusive
*Participant's CD4 count was 109 cells/uL with unknown time of HIV exposure

All Drug Related Adverse Events (DRAE)

- Overall, DRAEs were reported in 6 (5%) TE participants and none in TN participants
- No serious DRAEs were reported
- DRAEs were mild (n=2) or moderate (n=4) in severity and included each of the following:
  - Abnormal dreams (n=1)
  - Anxiety (n=1)
  - Major depression (n=1)
  - Gastroesophageal reflux (n=1)
  - Herpes simplex (n=1)
  - Headache (n=1)
- No discontinuations due to renal or bone AEs

Figure 2. Median weight change at month 6 for each participant

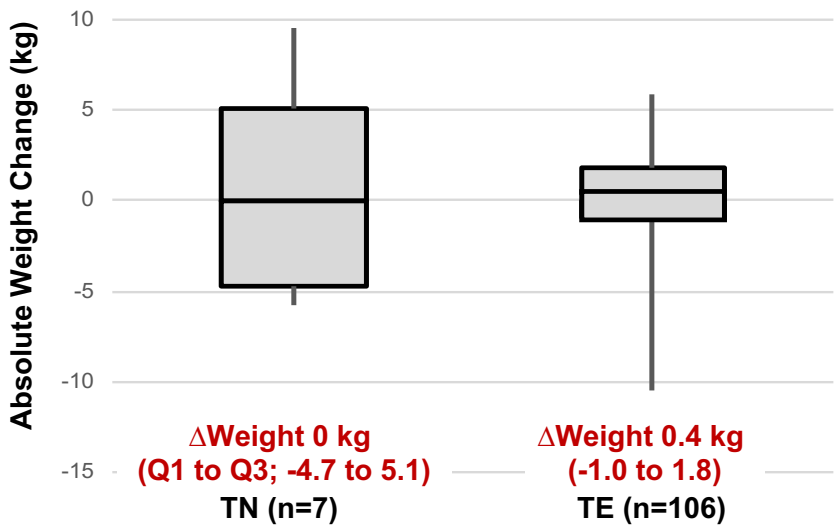


Figure 3. HIV Treatment satisfaction status at baseline and change scores for TE participants

	TE (n=76)
Baseline[1], mean (SD)	49.7 (12.9)
Month 3[2], mean (SD)	+22.9 (8.0)
Month 6[2], mean (SD)	+21.8 (9.0)

[1] Range 0 to 60, higher score indicate greater treatment satisfaction; HIVTSQs Treatment Satisfaction Total Score questionnaire used at baseline
[2] Range -30 to 30, positive total scores indicate improvement in satisfaction with B/F/TAF; HIVTSQc Treatment Satisfaction change questionnaire used at months 3 and 6.

Conclusions

This early analysis of the real world use of B/F/TAF in Canadian PLHIV with a high prevalence of comorbidities (97%) and with older age (52% ≥50yrs) demonstrated:

- High virologic effectiveness in both TN (100%) and TE (98%) patients at month 6
- High persistence (98%) and a low number of discontinuations
- No discontinuations due to renal or bone AEs
- No clear evidence of weight change
- High levels of treatment satisfaction with switching to B/F/TAF

Limitations

- Low sample size in treatment-naïve individuals
- Observational nature of the study (bias and missing data)