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Effectiveness, safety and tolerability of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in HIV-1 infected adult patients in routine clinical practice – 6 months results of the BICSTaR cohort

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Background

In randomized clinical trials (RCTs), 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 infected patients, with zero resistance. BICSTaR is an ongoing, non-interventional, prospective, multicountry cohort study of B/F/TAF in clinical practice.

Methods

- Interim analysis from 18 German sites
- Outcomes
  - HIV-1 RNA <50 cp/mL; B/F/TAF discontinuation/missing = excluded (On-Treatment)
  - HIV-1 RNA <50 cp/mL; B/F/TAF discontinuation = failure, missing = excluded
  - Drug-related (DR) adverse events (AEs) and DR serious AEs (DRSAEs)
  - Treatment persistence: % patients remaining on B/F/TAF at M6
  - Treatment satisfaction using the validated HIV treatment satisfaction status (TSQs) and change (TSQc) questionnaires

Results

Study population

- A total of 223 HIV-1 infected patients (32 TN [14%], 191 TE [86%]) initiated B/F/TAF and were followed for at least 6 months at time of data cut-off.

Table 1. Baseline characteristics

	Overall	Treatment-naïve (TN)	Treatment-experienced (TE)
N (%)	223 (100)	32 (100)	191 (100)
Male gender, n (%)	208 (93)	28 (88)	180 (94)
Age, years, median (Q1-Q3)	47 (37-54)	38 (30-45)	48 (39-54)
Age ≥50 years, n (%)	86 (39)	6 (19)	80 (42)
Weight, kg, median (Q1-Q3) [n]	79 (68-90) [131]	69 (61-79) [20]	80 (70-90) [111]
Comorbidities/Coinfections; any, n (%)	158 (71)	15 (47)	143 (75)
1-2, n (%)	99 (45)	9 (28)	90 (47)
≥3, n (%)	59 (27)	6 (19)	53 (28)
Neuropsychiatric disorders, n (%)	51 (23)	5 (16)	46 (24)
Arterial hypertension, n (%)	47 (21)	3 (9)	44 (23)
Hyperlipidemia, n (%)	34 (15)	2 (6)	32 (17)
Infections and infestations, n (%)	24 (11)	4 (13)	20 (11)
Cardiovascular disorders, n (%)	23 (10)	2 (6)	21 (11)
HIV-related characteristics			
HIV-1 RNA, log_{10} cp/mL, median (Q1-Q3) [n]	1.6 (1.3-1.8) [202]	4.8 (3.9-5.2) [32]	1.6 (1.3-1.7) [170]
HIV-1 RNA <50 cp/mL, n (%)	150 (74)	0 (0)	150 (88)
HIV-1 RNA >100,000 cp/mL, n (%)	13 (6)	12 (38)	1 (1)
CD4 count, cells/µL, median (Q1-Q3) [n]	654 (432-914) [202]	479 (283-607) [30]	695 (463-930) [172]
CD4 <200 cells/µL, n (%)	16 (8)	6 (20)	10 (6)
CDC Stage C (AIDS), n (%) [n]	32 (14) [221]	2 (6) [32]	30 (16) [189]

cp/mL: copies per mL; Q: quartile; CDC: Centers for Disease Control and Prevention

Previous ART and reasons for ART initiation with or switch to B/F/TAF

Table 2a. Reasons for initiating B/F/TAF multiple responses permitted

	N	%
Early treatment acc. to guidelines	15	47
Treatment as prevention	11	34
Patient's wish	17	53
Other	1	3

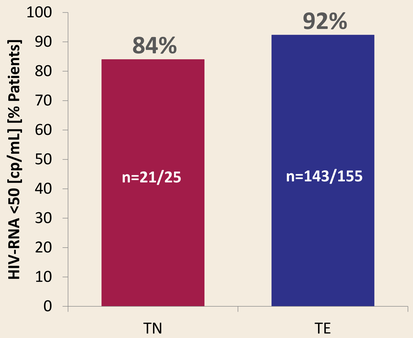
Table 2b. Reasons for switching to B/F/TAF multiple responses permitted

	N	%
Simplification of ART	120	63
Patient's preference	81	42
Side effects of current ART	41	22
Other	11	6

TE patients received a median of 2 ART regimens (Q1-Q3: 1-3) prior to switching to B/F/TAF. Prior ART included an NNRTI, a PI, or an INSTI in 18%, 9% and 71% (36% DTG, 19% EVG, 16% RAL), respectively; 61% had been on a prior TDF-based regimen. A history of viral failure was documented in 12 (6%) patients.

Effectiveness

Figure 1. HIV-1 RNA <50 cp/mL at M6; B/F/TAF discontinuation/missing* = excluded [On-Treatment])



- Similar results were obtained at M6 for the B/F/TAF discontinuation=failure, missing=excluded analysis
- HIV-1 RNA <50 cp/mL: TN: 81%, TE: 88%

*TN: n=6 with missing values
*TE: n=29 with missing values

- Of the 16 patients with HIV-1 RNA >50 cp/mL at M6 (4 TN, 12 TE), the HIV-1 RNA was <200 cp/mL in 13 patients (3 TN, 10 TE).
- Median CD4 cell count increased to 731/µL (Q1-Q3: 462-856) in TN and to 752/µL (Q1-Q3: 522-937) in TE patients.
- Persistence on B/F/TAF was high at 96% after 6 months with 8 patients (4%; 1 TN and 7 TE) discontinuing B/F/TAF prior to M6. In three of these patients, the last evaluable VL while on B/F/TAF was <50 cp/mL.
- Reasons for discontinuation:
  - DRAEs (nightmare [1], suicidal ideation [1], depression and sleep disorder [1])
  - AEs (myalgia and arthralgia [1], onychoclasis [1], blood HIV-1 RNA increased [1])
  - Investigator's discretion (1)
  - Missing reason (1)

Safety and Tolerability

- Overall, 28 DRAEs and 1 DRSAE were reported in 21 (10%) and 1 (0.4%) patients, respectively.
- Most common DRAEs are shown in Table 3.
- The one reported DRSAE was depression.
- There were no discontinuations due to renal or bone AEs.
- Of those patients with available weight data at 6 months (n=87), the median weight gain from baseline was 1.8 kg (Q1-Q3: 0-6) in TN (n=12), and 1.0 kg (Q1-Q3: 0-3) in TE (n=75).

Table 3. Most common DRAEs per System Organ Class

	N (events)	N (patients) [%]
Psychiatric disorders	9	7 [3]
depression (5), anxiety (1), nightmare (1), sleep disorder (1), suicidal ideation (1)		
Gastrointestinal disorders	6	5 [2]
abdominal pain (4), constipation (1), flatulence (1)		
Investigations	4	4 [2]
weight increased (3), blood creatinine increased (1)		

Patient Reported Outcomes: Treatment satisfaction in TE patients

Table 4. Treatment satisfaction status (TSQs) at baseline and change (TSQc) scores (only TE patients)

	TE patients
Patients completing TSQs at baseline and TSQc at M3 and M6 (n=78)	
Baseline TSQs[1], mean (SD) [n]	52.1 (11.9) [78]
Month 3 TSQc[2], adjusted mean (95% CI)	+17.8* (11.5-20.1)
Month 6 TSQc[2], adjusted mean (95% CI)	+16.4* (13.6-19.2)

SD, standard deviation; CI, confidence interval

[1] Range 0 to 60, higher total scores indicate greater satisfaction with treatment

[2] Range -30 to +30, positive total scores indicate improvement in satisfaction with study treatment

* Repeated measures ANCOVA adjusting for baseline TSQs (forced-in variable) and 'simplification of ART' as the reason for switch to B/F/TAF (further covariates ('patient preference' as reason for switch and baseline HIV-1 RNA (log_{10} cp/mL)) were removed from the model using a backward selection procedure with an α-level <0.05). P<0.0001 (for the difference from zero in TSQc score).

Patients reported a significant improvement in treatment satisfaction at 3 and 6 months after switching to B/F/TAF.

Conclusions

- This early analysis of the real world use of B/F/TAF in PLHIV with a high prevalence of comorbidities (71%) and with older age (39% ≥50yrs) demonstrated:
  - High virologic effectiveness in both TN (84%) and TE (92%) patients at M6
  - High persistence (96%) and a low number of discontinuations
  - No discontinuations due to renal or bone AEs
  - High levels of treatment satisfaction with B/F/TAF
- These data support the effectiveness, safety and tolerability of B/F/TAF in PLHIV

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