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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

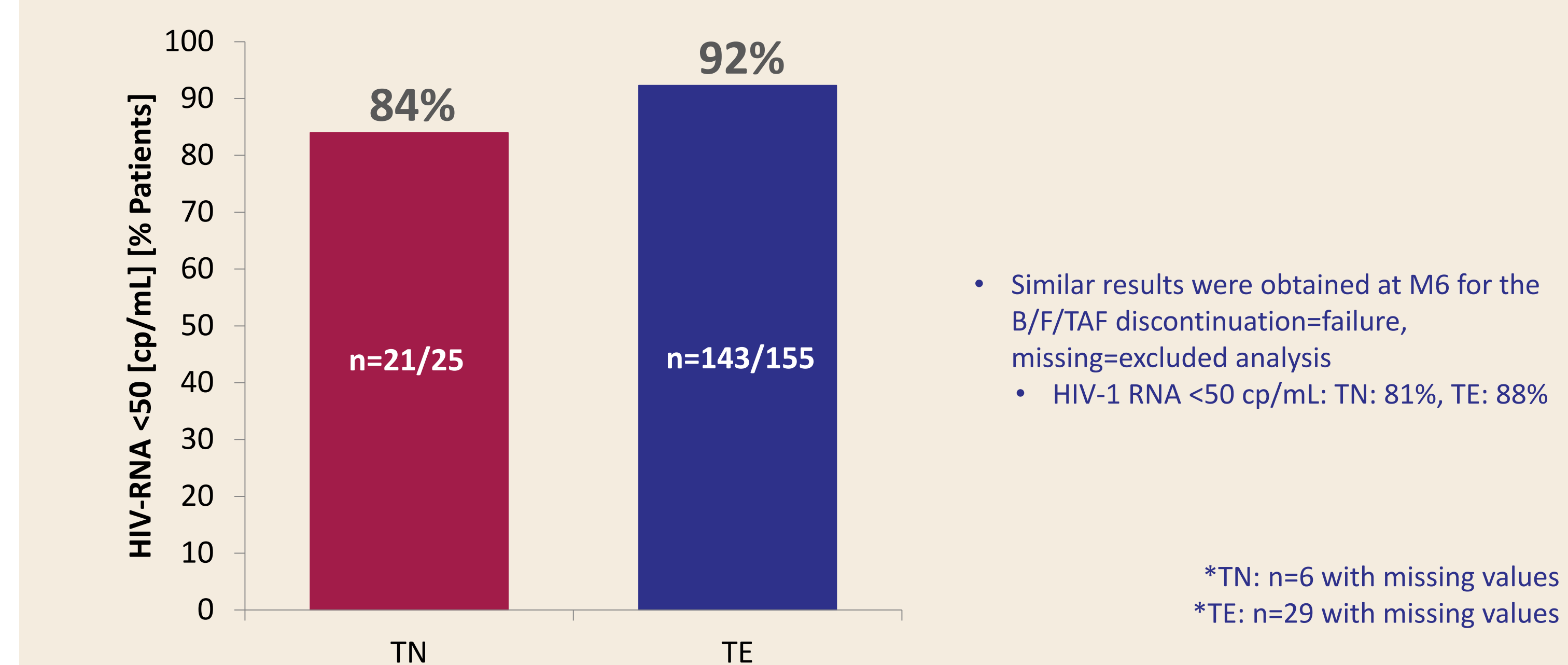
Previous ART and reasons for ART initiation with or switch to B/F/TAF

| Table 2a. Reasons for initiating B/F/TAF multiple responses permitted | N | % | Table 2b. Reasons for switching to B/F/TAF multiple responses permitted | N | % |
|---|----|----|---|-----|----|
| Early treatment acc. to guidelines | 15 | 47 | Simplification of ART | 120 | 63 |
| Treatment as prevention | 11 | 34 | Patient's preference | 81 | 42 |
| Patient's wish | 17 | 53 | Side effects of current ART | 41 | 22 |
| Other | 1 | 3 | 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]



- 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], onychoclasia [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 (log₁₀ 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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