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BACKGROUND

The use of bicitgravir/emtricitabine/tenofovir alafenamide (BIK) is mainly based on robust pivotal clinical trials [1,2]. However, data in real life are not widely available. In HIV Unit of Hospital Clínic in Barcelona we have a large cohort of BIK-treated patients.

METHODS

This was an observational, retrospective, single-centre study. All antiretroviral-naïve (TN) and -experienced (TE) adult patients and starting BIK from 07/06/2018 to 04/06/2020 were included. We describe the demographic and HIV-related characteristics of the population. Effectiveness (HIV-RNA <50 copies/ml, on-treatment (OT) (discontinuation/missing=excluded), modified intention-to-treat (mITT) (discontinuation=failure, missing=excluded) and ITT), tolerability and safety (drug-related (DR) adverse events (DRAEs) and DR serious AEs (DRSAEs)) were assessed during 6 and 12 months of follow-up.

RESULTS

- A total of 984 HIV-1 infected patients (157 TN [16%], 827 TE [84%]) were included. Median follow-up was 7.4 (4–10.5) months, with 67% and 17% patients reaching 6 and 12 months, respectively.

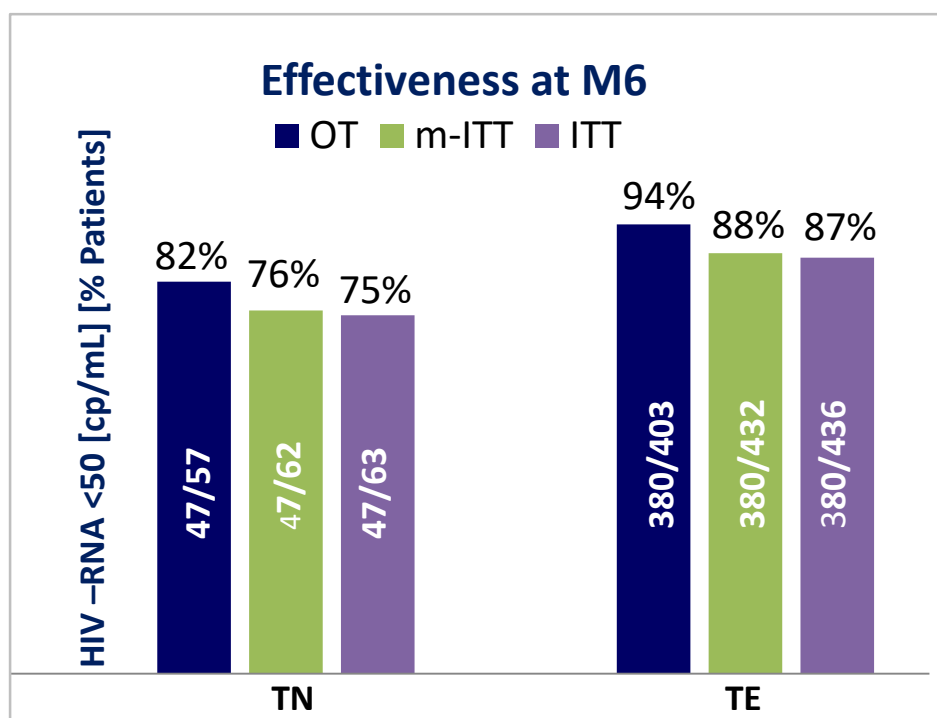
Baseline characteristics	Overall	TN	TE
N (%)	984 (100)	157 (100)	827 (100)
Male gender, n (%)	852 (87)	144 (92)	708 (86)
Age, years, median (IQR)	42 (34 ; 51)	36 (30 ; 42)	44 (35 ; 52)
Age ≥50 years, n (%)	300 (30)	16 (10)	284 (34)
HIV-related characteristics			
Time since HIV diagnosis, median years (IQR) [n]	9 (3 ; 16) [945]	0 (0 ; 3) [148]	10 (5 ; 17) [797]
HIV-RNA, VL cp./mL, median (IQR) [n]	49 (49 ; 85) [921]	61500 (14100 ; 232000) [149]	49 (49 ; 49) [772]
HIV-1 RNA <50 cp/mL, n (%)	669 (73)	0 (0)	669 (87)
HIV-1 RNA >100,000 cp/mL, n (%)	81 (9)	64 (43)	17 (2)
CD4 count, cells/μL, median (IQR) [n]	581 (373 ; 811) [793]	293 (172 ; 510) [149]	635.5 (446 ; 853.5) [644]
CD4 <200 cells/μL, n (%)	77 (10)	45 (30)	32 (5)
CD4 >500 cells/μL, n (%)	484 (61)	41 (28)	443 (69)
HCV Seropositive ¹ , n (%)	123 (13)	6 (4)	117 (14)
eGFR _{CG} , median mL/min (IQR) [n]	90 (81 ; 90) [926]	90 (90 ; 90) [143]	90 (79 ; 90) [783]

1. HCV antibody

Causes of switch to BIK

Causes of switch to BIK	N (%)
Simplification	344 (42)
Side effects of ART	118 (14)
Patient's preference	22 (3)
Interactions	273 (33)
Virologic failure	18 (2)
Other	52 (6)
Previous ARV treatment (%)	
INSTI (DTG, ELV, RAL)	69 (10, 52, 7)
PI	10
NNRTI	22

- 19% of TE patients had been on a prior TDF-based regimen and 67% had been on a prior TAF-based regimen.



- Of the 33 patients with HIV-1 RNA>50cp/mL at M6 (10 TN, 23 TE), the HIV-1 RNA was <200cp/mL in 21 patients (7 TN, 14 TE).
- Median CD4 cell count increased from 293 to 502/μL (Q1–Q3: 295–764) in TN and from 635 to 694/μL (Q1–Q3: 539–926) in TE patients at Month 6.
- 616 (94%) patients persisted with BIK after 6 months; 5 (0.8%) were lost to follow-up and 34 (5.2%; 5 TN and 29 TE) discontinuing BIK prior to Month 6 due to:
 - DRAEs 24 (3.6%) [neuropsychiatric 11 (1.7%), gastrointestinal 8 (1.2%) none DRSAEs]
 - Other AEs 4 (0.6%)
 - Virological failures 3 (0.4%) (no treatment emerging resistance)
 - Interactions 2 (0.3%)
 - Simplification 1 (0.1%).

CONCLUSIONS

This observational cohort supports the high effectiveness (only 0.4% virological failure), tolerability and safety of BIK in clinical practice and demonstrates high persistence through 6 months.

References

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