P087

Patient-reported outcome (PRO) measures at 12 months in a real-world cohort of people living with HIV with a high prevalence of comorbidities receiving bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in Europe, Canada, and Israel

Watch a brief overview of this data from the presenting author, and access supplemental data from this presentation using your smart phone or click HERE

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Introduction

B/F/TAF is a guideline-recommended single-tablet regimen for the treatment of HIV-1 infection and is widely used in clinical practice

BICSTaR is a large, ongoing, multi-country, prospective, observational study that plans to enroll over 2,000 ARV treatment-naïve (TN) and treatment-experienced (TE) people living with HIV across Europe, Canada, Israel, Japan, Taiwan, South Korea, and Singapore

Here we report **12-month patient-reported outcome (PRO) measure data** for 1,135 people living with HIV receiving B/F/TAF in routine clinical care across Europe (France, Germany, Ireland, Italy, Netherlands, Spain, UK), Canada, and Israel

Study design

BICSTaR

Cut-off date for analysis 22 Feb 2021

N=1,135

HIV-1 infection
TN or TE
≥18 years of age

Baseline — 12 months: primary endpoint — 24 months

B/F/TAF once daily

Analysis of people living with HIV starting B/F/TAF between Jun 2018 and Sep 2020

PRO measures collected

- ✓ Adherence (VAS)
- ✓ Short Form 36 (SF-36) questionnaire
- ✓ HIV Symptom Index (HIV-SI)
- ✓ HIV Treatment Satisfaction Questionnaire (HIVTSQ)
- ✓ Healthcare utilisation (physician visits)

Methods

For PRO analyses (except physician visits), two populations were defined according to availability of completed questionnaires

Unrestricted PRO analysis population
Included PRO data from all participants who completed questionnaires at baseline and/or 12 months
PRO measures: VAS (TN only), HIVTSQ

Restricted PRO analysis population
Included PRO data only from those participants who completed questionnaires at both baseline and 12 months
PRO measures: VAS (TE only), SF-36, HIV-SI

Further details of the PRO analysis methodology and data analyses, including outcomes in the subgroup of participants with/without neuropsychiatric symptoms, can be found in the supplementary material available via the QR code

Participants: baseline characteristics (PRO analysis populations)

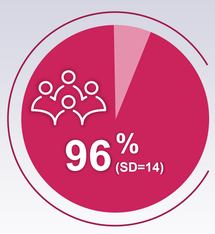
	SF-36		HIV-SI		Overall population	
	TN n=91	TE n=497	TN n=102	TE n=564	TN n=180	TE n=955
White	80%	80%	79%	80%	77%	78%
Male	88%	85%	89%	87%	88%	83%
Median age, years (Q1, Q3)	37 (30, 47)	49 (40, 56)	37 (29, 47)	49 (40, 56)	38 (30, 48)	49 (39, 56)

The PRO analysis populations were reflective of the overall analysis population (N=1,135)

Further details on baseline characteristics of the overall BICSTaR population can be found in poster number P010

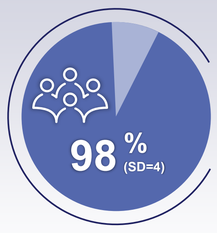
Results

Mean adherence at 12 months (VAS score, %)



of TN participants (n=95*)

(baseline: n/a)

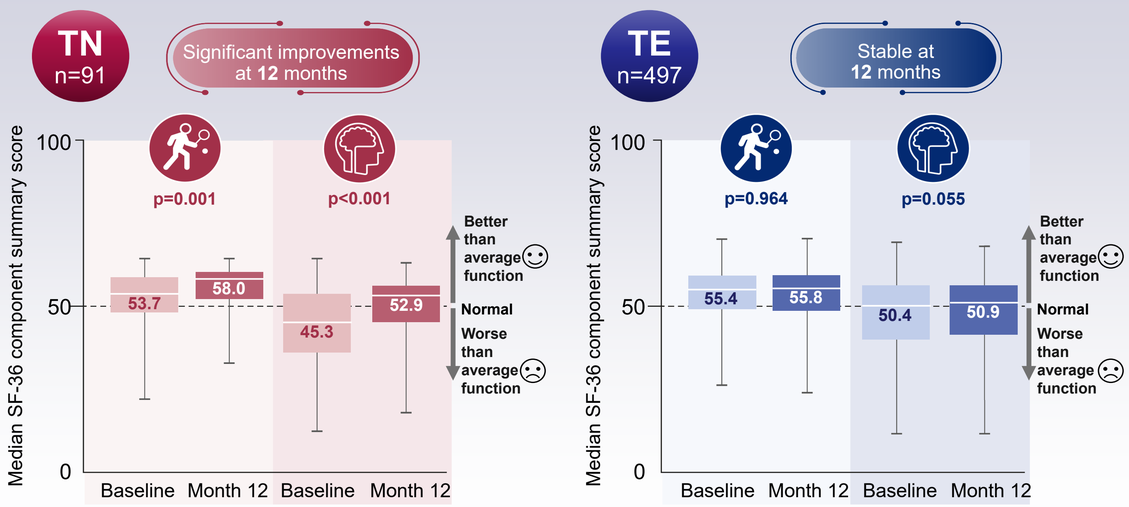


of TE participants (n=203)

(baseline: 97% [SD=11])

**All participants who completed the 12-month VAS questionnaire*

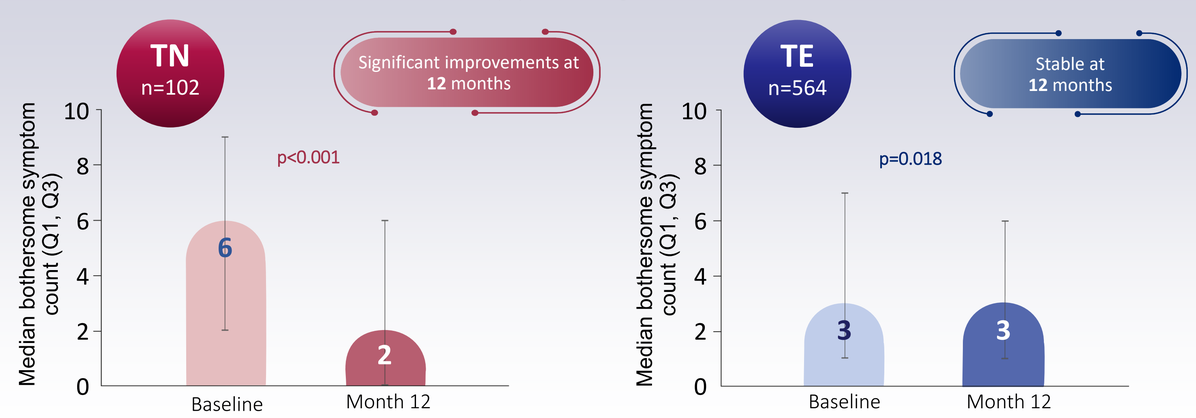
Physical and mental health (SF-36 PCS and MCS scores)



Box plot represents minimum, Q1, median, Q3, and maximum values; p-values calculated by Wilcoxon signed-rank test and Student t-test

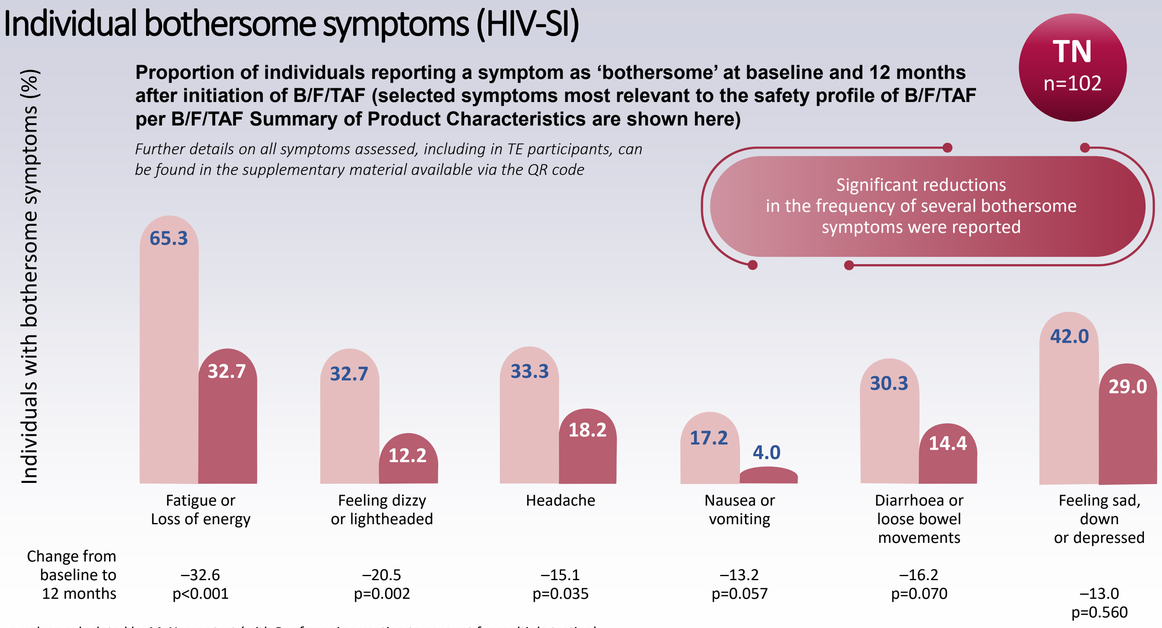
Overall number of bothersome symptoms (HIV-SI)

The overall bothersome count indicates the number of bothersome symptoms and ranges from 0 to 20



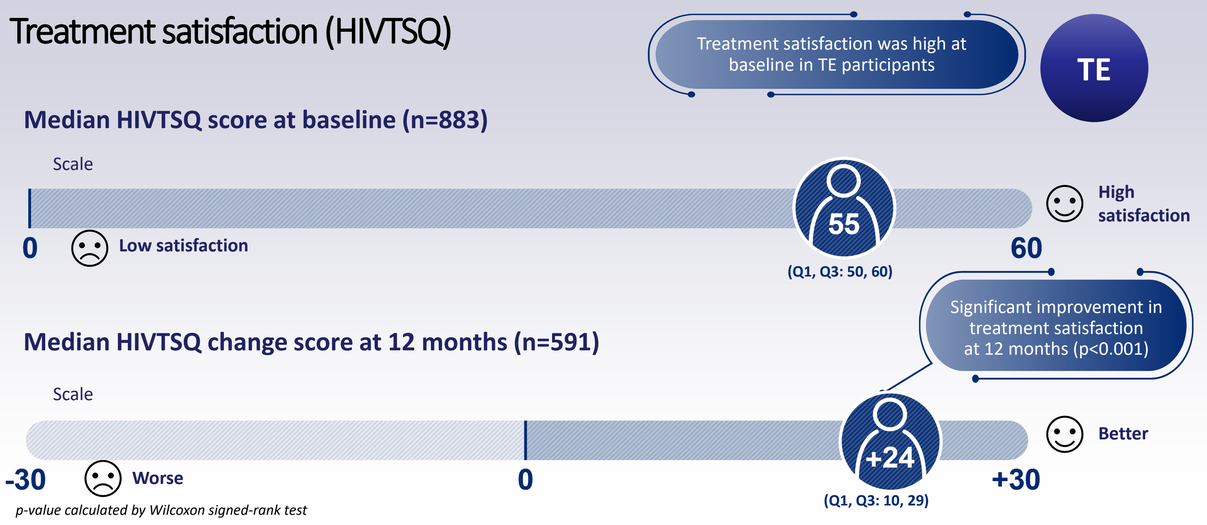
p-values calculated by Wilcoxon signed-rank test for change from baseline

Individual bothersome symptoms (HIV-SI)



p-values calculated by McNemar test (with Bonferroni correction to account for multiple testing)

Treatment satisfaction (HIVTSQ)



p-value calculated by Wilcoxon signed-rank test

Conclusions

This large, observational study of people living with HIV receiving B/F/TAF and incorporating PRO measures in a real-life clinical setting found the following:

- **Significant improvements in physical/mental health and symptom burden were observed in treatment naive people living with HIV starting B/F/TAF**
- **Overall wellbeing, treatment satisfaction, and adherence with current treatment were high at study entry in treatment experienced people living with HIV**
- **In treatment experienced people living with HIV switching to B/F/TAF, symptom burden remained low, with further improvements observed in treatment satisfaction**

Abbreviations
ART, antiretroviral treatment; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; HIV-SI, HIV Symptom Index; HIVTSQ, HIV Treatment Satisfaction Questionnaire; HIVTSQs, HIV Treatment Satisfaction Questionnaire score; MCS, mental component summary; PCS, physical component summary; PRO, patient-reported outcome; Q, quartile; SD, standard deviation; SF-36, 36-Item Short Form Health Survey; TE, treatment-experienced; TN, treatment-naïve; VAS, visual analogue scale

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