

LONG-TERM PERSISTENCE, EFFECTIVENESS, SAFETY, AND METABOLIC IMPACT OF BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE FIXED-DOSE COMBINATION IN TREATMENT-NAÏVE AND EXPERIENCED PEOPLE LIVING WITH HIV IN A LARGE LATIN AMERICAN COHORT

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BACKGROUND

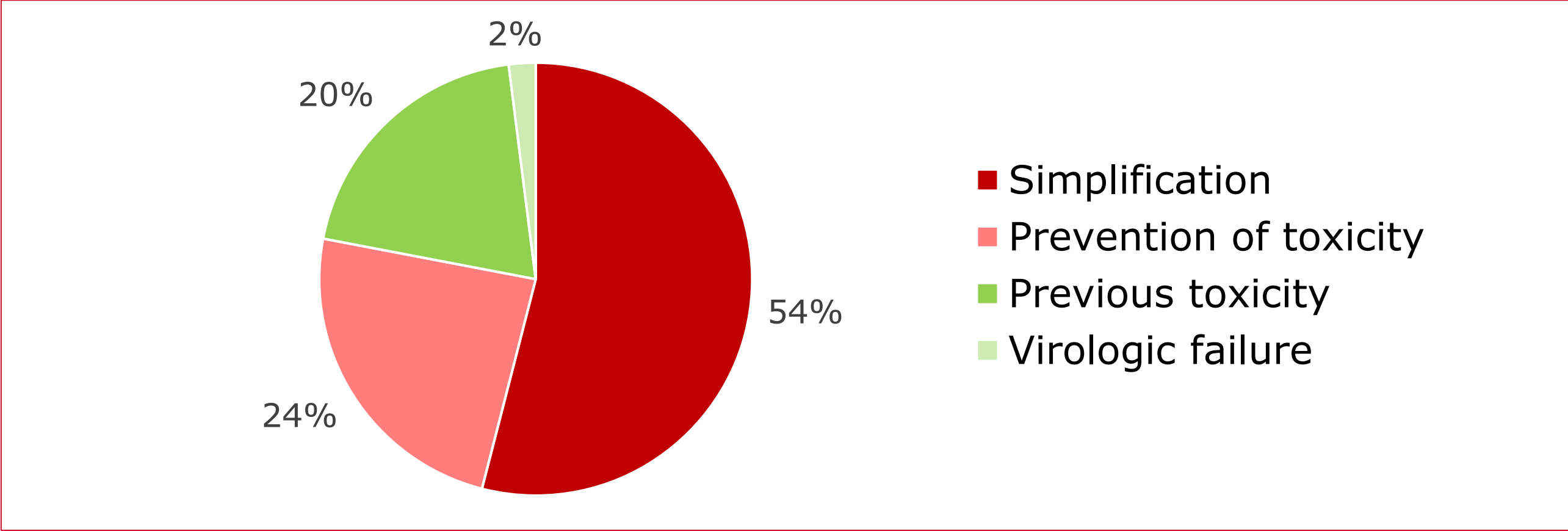
Real-world data for bictegrovir/emtricitabine/tenofovir alafenamide (B/F/TAF) fixed-dose combination (FDC) emerges mainly from cohorts from high-income settings, with scarce data on long-term effectiveness and safety for Latin American population. We describe 48-month outcomes of people living with HIV (PLWH) prescribed B/F/TAF in clinical practice in Argentina.

RESULTS

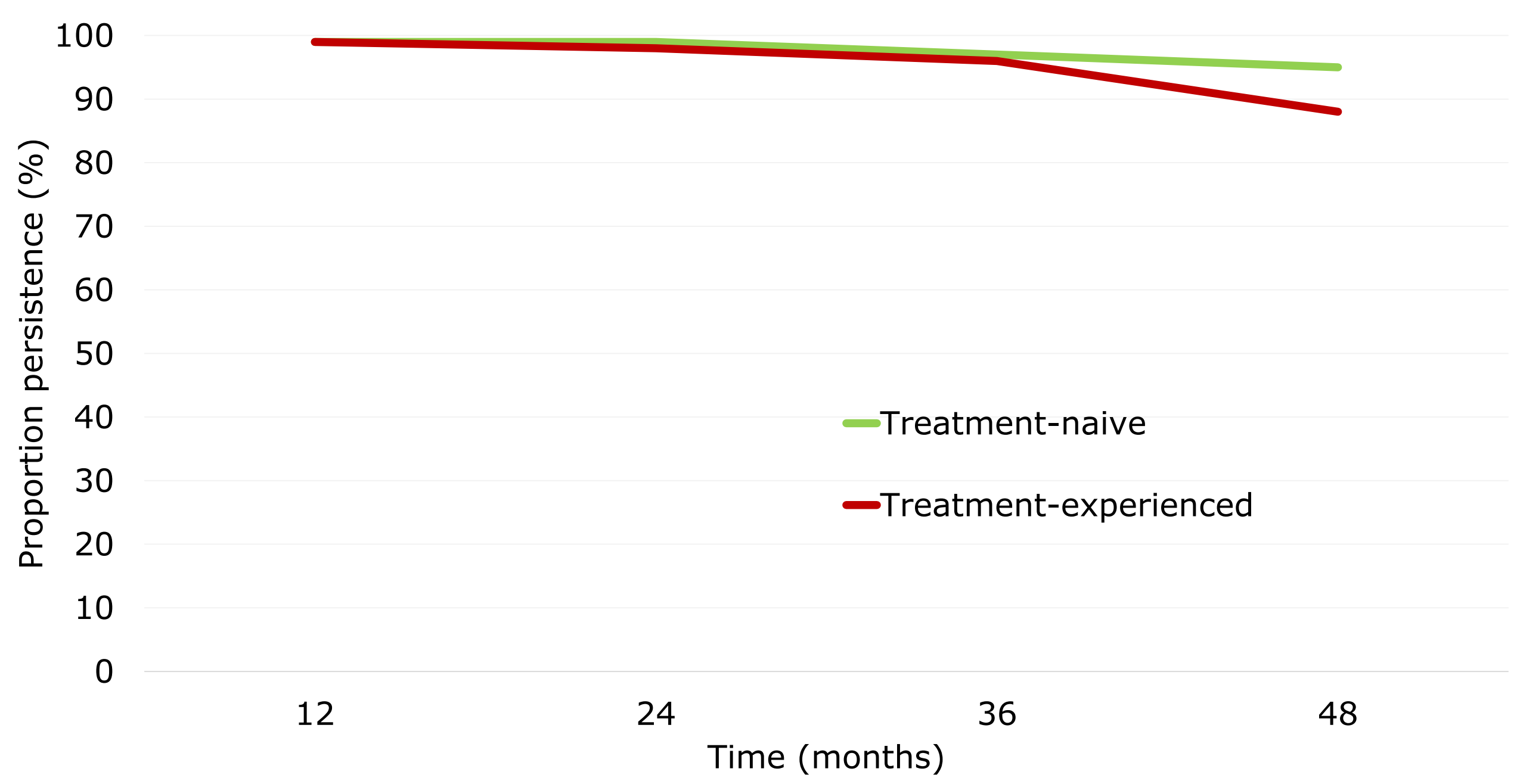
- We included 3057 PLWH: 425 TN (14%) and 2632 TE (86%). Baseline characteristics are presented in **Table 1**.
- In the TE group, 89% had VS when switched to B/F/TAF, while in the TN group, the median baseline viral load was 47,300 c/mL.
- TE subjects were switched mainly for simplification (54%) from boosted-PI (36%) and first-generation NNRTI (34%) regimens. Other reasons for switching are shown in **Figure 1**.
- Persistence and VS were assessed over 48 months (**Figures 2 and 3**).
- No adverse events were reported in treatment-naïve PLWH. In TE, AE rates were 0.4%, 0.1%, and 0% at 24, 36, and 48 months, respectively.
- No virological failure occurred.
- Metabolic parameters are shown in **Tables 2 and 3** for naïve and treatment-experienced groups.

**Table 1.** Baseline characteristics of treatment-naïve and treatment-experienced PLWH who initiated B/F/TAF in Argentina between October 2019 and December 2022.

Baseline characteristics	Treatment-naïve (n=425)	Treatment-experienced (n=2632)
Age, years (IQR)	36 (30-46)	46 (37-53)
Male sex (%)	81	72
Hispanic/latin ethnicity (%)	99,6	99,6
Comorbidities (%)	21	49
CD4 (cells/mm³), median (IQR)	318 (147-508)	624 (438-845)



**Figure 1.** Reasons for switching to B/F/TAF among treatment-experienced PLWH in Argentina between October 2019 and December 2022

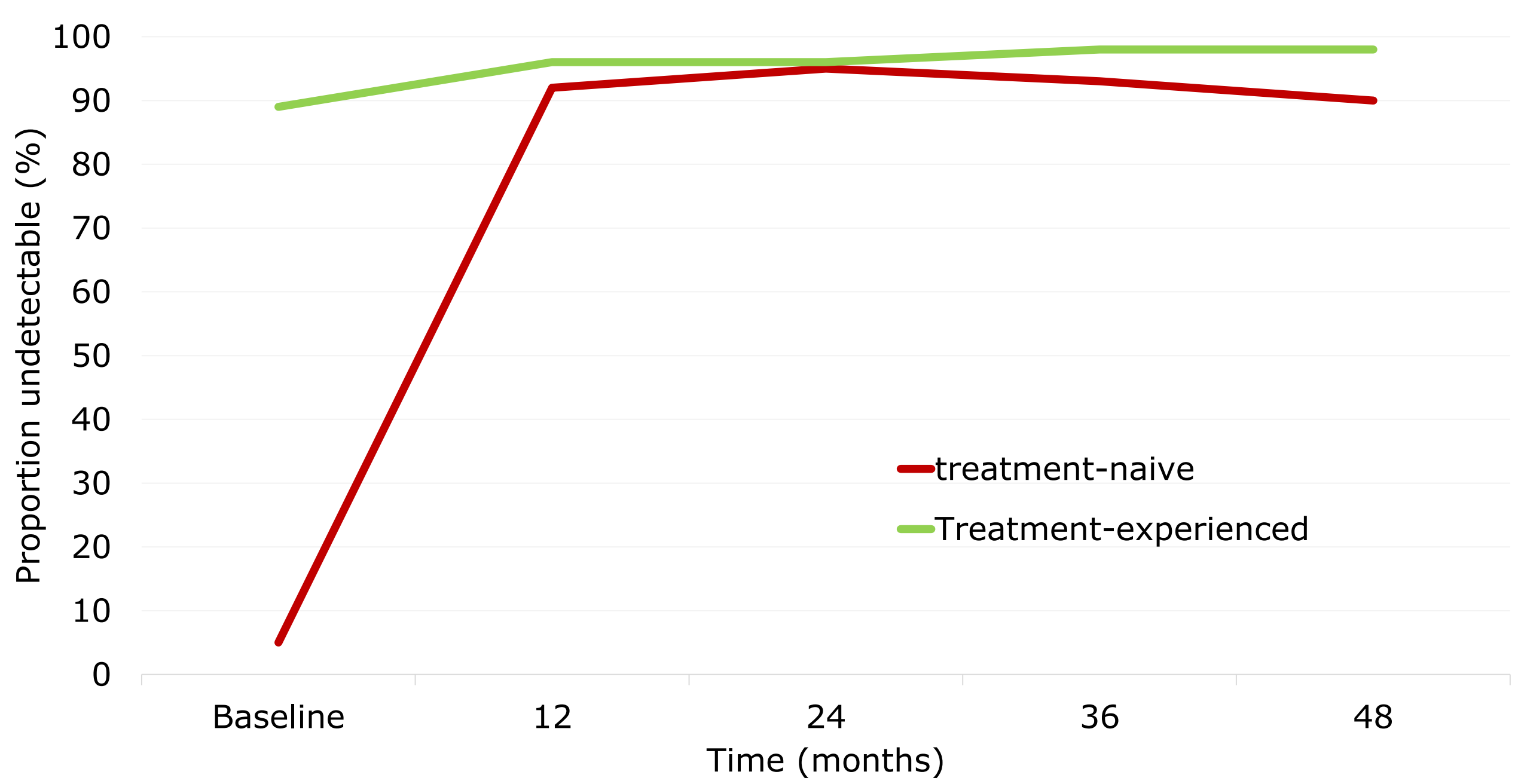


	12 months	24 months	36 months	48 months
Treatment-naïve	346/349 (99%)	226/229 (99%)	118/122 (97%)	35/37 (95%)
Treatment-experienced	2,255/2269 (99%)	1,625/1656 (98%)	812/84 (96%)	214/244 (88%)

**Figure 2.** Persistence on B/F/TAF treatment among treatment-naïve and treatment-experienced PLWH in Argentina (48-month follow-up)

METHODS

Observational, retrospective open cohort study of treatment-naïve (TN) and experienced (TE) PLWH initiating B/F/TAF between 10/2019-12/2022. We evaluated persistence and virologic suppression (VS, <50 copies/mL), occurrence of adverse events (AE), and metabolic parameters (fasting glucose, cholesterol and triglycerides) at 24, 36 and 48-month time points.



	Baseline	12 months	24 months	36 months	48 months
Treatment-naïve	18/388 (5%)	227/247 (92%)	121/128 (95%)	57/61 (93%)	19/21 (90%)
Treatment-experienced	2,101/2,362 (89%)	1,798/1,870 (96%)	1,227/1,278 (96%)	549/561 (98%)	127/130 (98%)

**Figure 3.** Virologic suppression over time under B/F/TAF in treatment-naïve and treatment-experienced PLWH in Argentina (48-month follow-up)

**Table 2.** Evolution of metabolic parameters over time in treatment-naïve PLHIV who initiated B/F/TAF in Argentina between October 2019 and December 2022.

Variable	Baseline (n=230)	24 months (n=59)	36 months (n=23)	48 months (n=4)	p-value
Fasting glucose (mg/dL)	89 [82-95]	92 [86-102]	91 [85-100]	97 [95-97]	0,2
Total cholesterol (mg/dL)	159 [138-188]	173 [163-205]	195 [165-216]	221 [198-254]	<0,001
Triglycerides (mg/dL)	119 [89-170]	112 [84-190]	152 [91-250]	275 [201-333]	0,14
HDL (mg/dL)	38 [31-47]	43 [38-50]	43 [35-56]	55 [42-114]	<0,001
LDL (mg/dL)	95 [76-120]	110 [95-126]	119 [89-156]	132 [117-146]	<0,001

**Table 3.** Evolution of metabolic parameters over time in treatment-experienced PLHIV who initiated B/F/TAF in Argentina between October 2019 and December 2022.

Variable	Baseline (n=230)	24 months (n=59)	36 months (n=23)	48 months (n=4)	p-value
Fasting glucose (mg/dL)	92 [86-99]	92 [86-99]	92 [85-99]	94 [87-101]	0,9
Total cholesterol (mg/dL)	187 [161-220]	184 [161-209]	180 [156-206]	187 [156-210]	0,005
Triglycerides (mg/dL)	132 [92-194]	127 [88-178]	128 [87-176]	123 [99-181]	<0,001
HDL (mg/dL)	45 [37-54]	45 [38-53]	45 [38-52]	45 [38-55]	0,7
LDL (mg/dL)	114 [91-139]	112 [93-135]	109 [91-130]	116 [97-138]	0,4

CONCLUSIONS

In TN and TE PLWH from Argentina, B/F/TAF demonstrated high persistence and sustained VS, with low AE rates over 48 months. To our knowledge, these findings represent the first long-term real-world evidence from Latin America, supporting B/F/TAF in guidelines as an effective and well tolerated treatment option.