



Universidad de Chile
Facultad de Medicina

Real World Evidence of B/F/TAF in Chile: Effectiveness and Safety from the BIKUCH Cohort

Alejandro Afani¹; Alba Rivas¹; Camila Maulen¹; Pedro Zitko²

1. HIV Centre, Service of Immunology, Clinical Hospital of University of Chile

2. School of Public Health, University of Chile

Background

Chile is one of the countries with the highest incidence of HIV in Latin America. Access to ART is guaranteed to all PLHIV. B/F/TAF is available in the country since 2020. Our aim was to study the effectiveness, safety, tolerability and adherence of B/F/TAF in a real-world evidence (RWE) cohort of patients living with HIV (PLHIV) in Chile.

Table 1. Baseline description of the BIKUCH cohort (n=464).

	Total (464)	Naïve (174; 37.5%)	Switch (290; 62.5%)
	N(%) / Mean(min-max)	N(%) / Mean(min-max)	N(%) / Mean(min-max)
Sex (men): N(%)	441 (98.0)	168 (98.2)	273 (97.8)
Age (years): Mean (min-max)	37.2 (18.0-70.8)	35.4 (18.0-62.8)	38.4 (18.9-70.8)
Age (categories): N(%)			
<30 years	119 (25.6)	52 (29.9)	67 (23.1)
30 - 50	291 (62.7)	108 (62.1)	183 (63.1)
>50 years	54 (11.6)	14 (8)	40 (13.8)
Inmigrant: N(%)	77 (17.1)	41 (24)	36 (12.9)
MSM: N(%)	358 (79.6)	133 (77.8)	225 (80.6)
basal CD4 (cel/ul): Mean (min-max)	480.8 (4.3-1731)	328.9 (4.3-1383)	570.4 (35-1731)
basal CD4 (categories): N(%)			
< 200 cel/ul	77 (16.7)	55 (32.2)	22 (7.6)
200 - 349 cel/ul	88 (19.1)	45 (26.3)	43 (14.8)
> 349 cel/ul	296 (64.2)	71 (41.5)	225 (77.6)
Viral load (copies/ul): Mean (min-max)	130554 (0-4630000)	347635 (0-4630000)	3299 (0-502000)
Viral load (categories): N(%)			
TND	19 (4.1)	1 (0.6)	18 (6.2)
< 50 copies/ml	255 (55.4)	5 (2.9)	250 (86.2)
< 200 copies/ml	279 (60.7)	7 (4.1)	272 (93.8)
> 100.000 copies/ml	63 (13.7)	61 (35.9)	2 (0.7)
LDL cholesterol (mg/dL): Mean (min-max)	109.2 (23-214)	101.5 (37-197)	113.4 (23-214)
Triglycerides (mg/dL): Mean (min-max)	157.6 (37-669)	137.6 (37-466)	168.3 (46-669)
Total cholesterol (mg/dL): Mean (min-max)	182.2 (95-294)	166 (95-269)	190.7 (102-294)
Creatinine (mg/dL): Mean (min-max)	0.9 (0.5-1.7)	0.8 (0.5-1.4)	0.9 (0.6-1.7)

Results

This cohort included 464 PLHIV (TN: 37.5% and TE: 62.5%). 441 (98%) male, mean age 37.2 years (18-70.8). In TN, before starting B/F/TAF, the mean of VL was 347.635 (0-4.630.000), 35.9% presented VL>100.000 copies/ul, and CD4 cell count was 328.9 (4.3-1.383). Likewise in TE, the mean of VL was 3.299 (0-502.000), and CD4 cell count was 570.4 (35-1.731). Simplification was the main reason of switch in TE (96.8%) from other INSTI use (EVG: 63.8%; RAL: 14.3%; DTG: 10.4%). The most frequent comorbidities were dyslipidaemia (11.4%), hypertension (6.2%), and mental health disorders (4.7%); see Table 1.

At week 60, 90% (95%CI 85.5%-94.5%) of TN and 92.7% (95%CI 89.7%-95.7%) of TE maintained virologic suppression (VL< 50 copies/ul). CD4 cell count improved in 187.2 cells/ul (95%CI 135.7-239.6) in TN and 70.1 cells/ul (95%CI 24.6-115.3) in TE. No discontinuations due to serious adverse events were registered. Good tolerability was reported by 87.2% (TN: 96.5%. TE: 81.7%). Adherence was 83.3% (TN: 86%. TE: 81.7%). No significant changes were observed in laboratory profiles.

Methods

The cohort was conformed with PLHIV in care at the Clinical Hospital, University of Chile (BIKUCH). All PLHIV aged >18 years with B/F/TAF were invited during 2023. Both, treatment naïve (TN) and treatment experienced (TE) PLHIV were included and followed at 12, 36 and 60 weeks. Viral load (VL), CD4 cell count, other laboratory tests, and safety, adherence and tolerability outcomes were evaluated. Institutional Ethical Committee approved the protocol. Multilevel modelling was implemented.

Figure 1. Virological suppression (%) in Treatment Naïve (TN; panel A) and treatment experienced (TE; panel B) at the baseline, 12, 30 and 60 weeks* of follow up. BIKUCH Cohort (n=464)

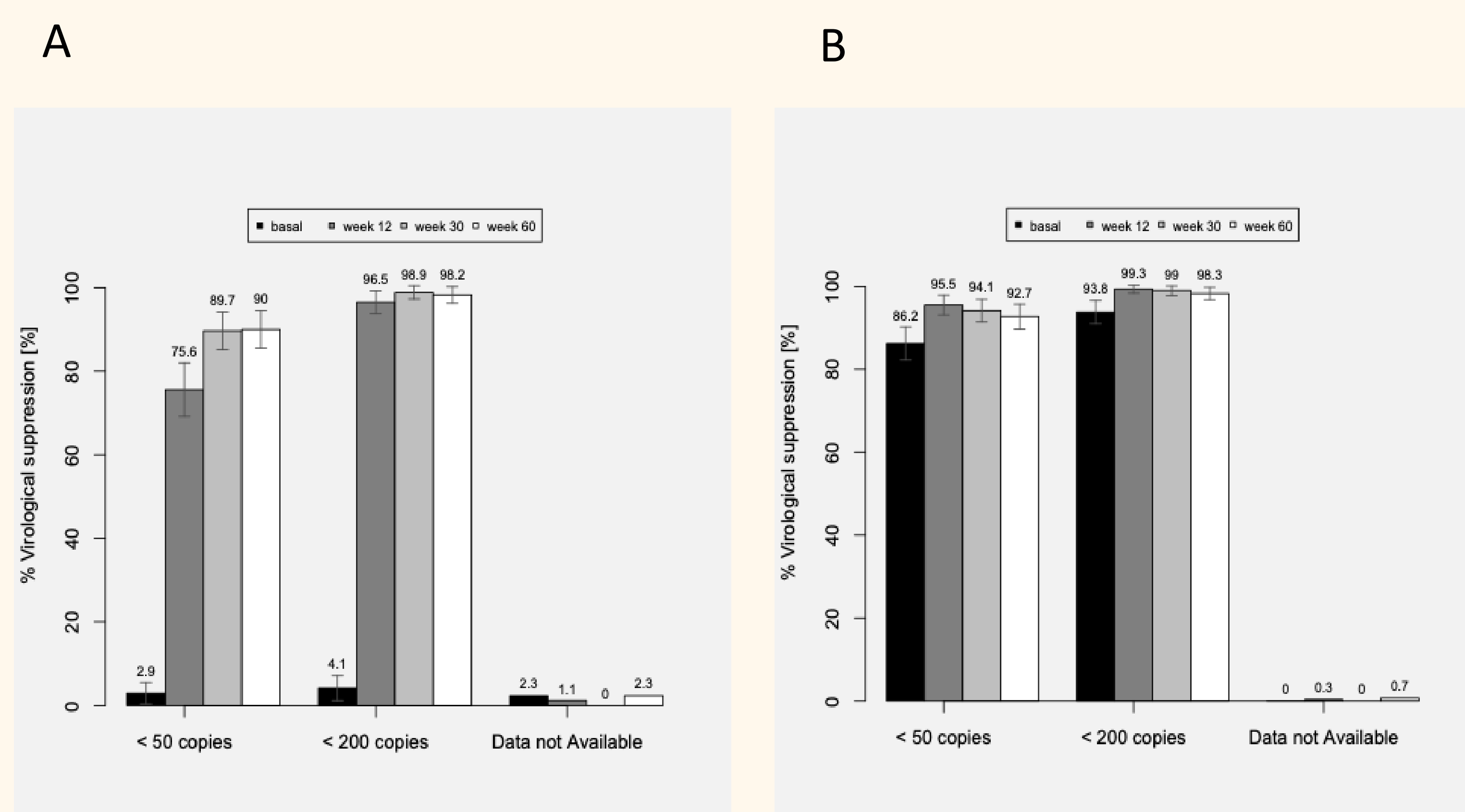
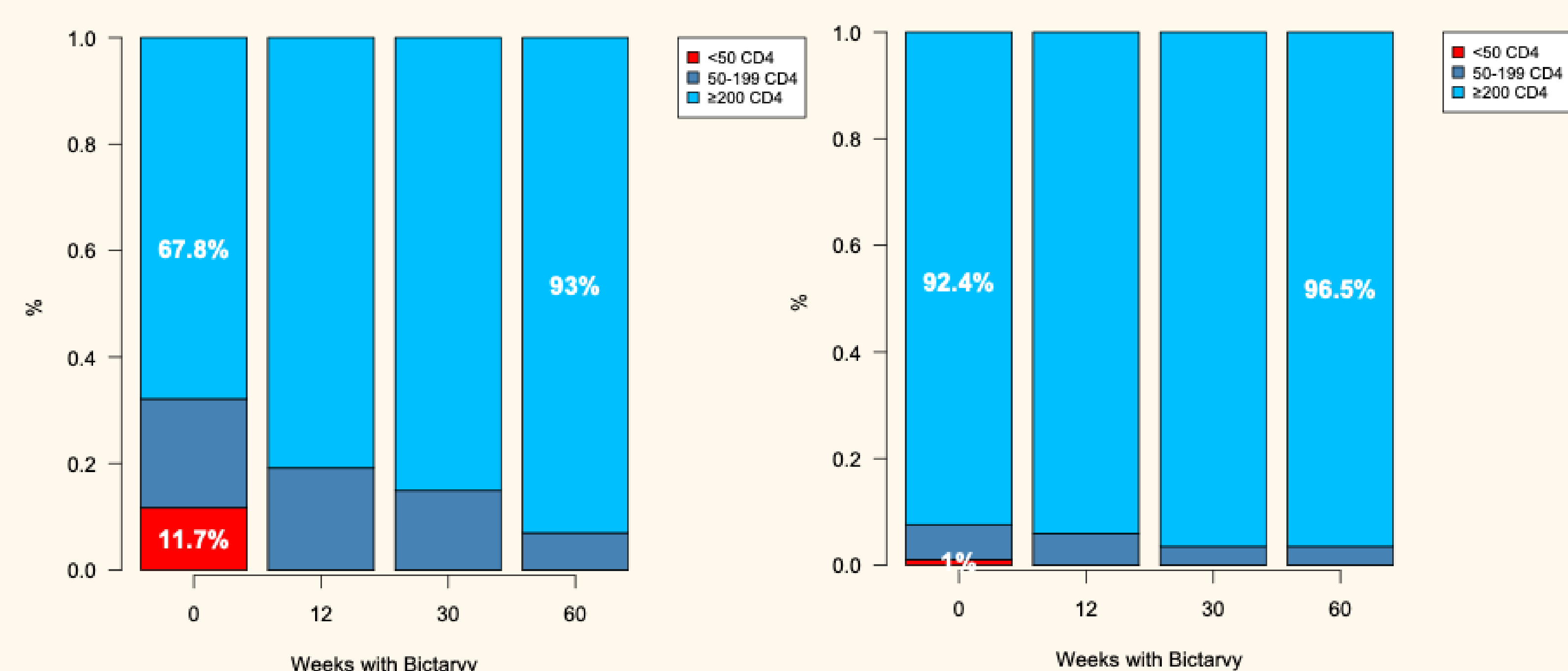


Figure 2. CD4 count categories (%) in Treatment Naïve (TN; panel A) and treatment experienced (TE; panel B) at the baseline, 12, 30 and 60 weeks* of follow up. BIKUCH Cohort (n=464)



* weeks 12, 30, 60 weeks are approximations

Conclusions

BIKUCH is the first RWE of B/F/TAF in Chile. Our results show the high effectiveness and immune recovery over time. both in TN and TE PLHIV. This cohort reinforces a B/F/TAF as an effective and safe option for ART. Our results are comparable to other RWE studies of B/F/TAF.

Funding: The conceptualization of the project. collection of data and data analysis were made without specific funding. Grant from **Gilead** funded the final statistical analysis and congress presentation.