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Impact of Early ART Initiation with BIC/FTC/TAF on HIV-1 Reservoir Decay During Primary Infection

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BACKGROUND

Viral reservoir (VR) is established early at primary HIV infection (PHI). Early antiretroviral therapy (ART) is essential to limit reservoir development.

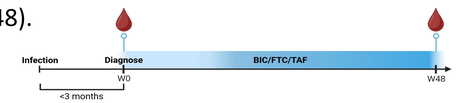
OBJECTIVE

To evaluate the impact of rapid bictegravir/emtricitabine/tenofovir alafenamide (**BIC/FTC/TAF**) treatment on intact and defective proviral HIV-1 DNA in people with **PHI**.

METHODS

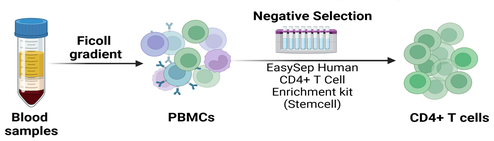
STUDY DESIGN

- Multicenter, single-arm clinical trial in confirmed 64 PHI individuals (<3 months, documented by seroconversion or incomplete confirmatory serologic tests) starting BIC/FTC/TAF.
- Blood samples were obtained at baseline (W0) and after 48 weeks of ART initiation (W48).



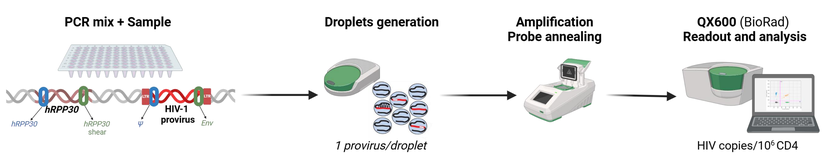
SAMPLE PROCESSING

CD4+ T cells were obtained from PBMCs through negative selection.



IPDA

HIV-1 proviral DNA (intact and defective) was measured from CD4+ T cells by IPDA.



Significant reductions in the VR size were observed for all Fiebig stages, however **intact/defective ratio was lower in Fiebig II-IV**.

Table 1: Basal virology and immunology results

Variable (n=64)	Median (IQR)
HIV Viral Load (log10 cp/mL)	5,7 (5,0 ; 6,1)
CD4 absolute (cel/µL)	406 (321,5 ; 535)
CD4 (%)	23 (18,25 ; 29)
CD8 absolute (cel/µL)	970 (612 ; 1310,5)
CD8 (%)	50 (43 ; 61)
Ratio CD4:CD8	0,5 (0,3 ; 0,7)

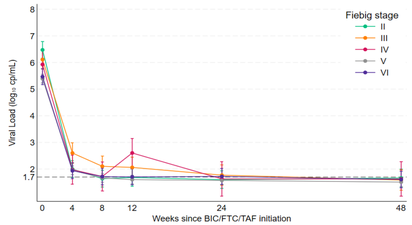


Figure 1: Viral Load decay from week 0 to week 48 from ART initiation. Values of VL classified according to Fiebig stages.

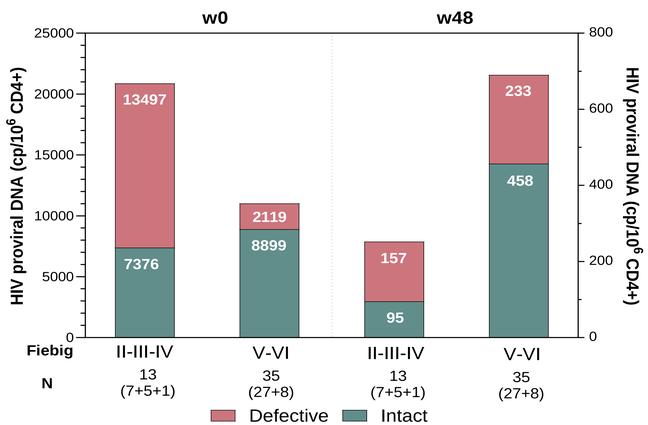


Figure 2: Intact and defective proviral HIV-1 DNA at week 0 (w0) or week 48 (w48) from ART initiation classified by seroconversion Fiebig stages (II-III-IV or V-VI). The value represented on the upper part of each bar are the medians, calculated from the intact and defective HIV-1 DNA copies per million of CD4 + T cells from each sample. Different scales were used for w0 (left axis) and w48 (right axis).

RESULTS

- Median (IQR) age was 31,5 (26 ; 41) years, 92% were males and most common HIV risk factor was MSM (88%).
- 48 individuals (75%) had baseline and 48-week samples.
- At ART initiation, 13 individuals were at Fiebig stages II-IV (27%) and 35 at V-VI (73%).
- At ART initiation, median (IQR) **VL** was 5,7 (5,0 ; 6,1) log10 cp/mL and median (IQR) **CD4 T cell count** was 406 (322 ; 535) cells/µL (**Table 1**).
- VL significantly decreased at W48 in all Fiebig stages. VL kinetics were assessed at different timepoints (**Figure 1**).
- **VR** (intact and defective) significantly (p<0,001) **decreased at W48** in Fiebig II-IV (from 7376 to 95 and from 13497 to 157 cp/10^6 CD4+ T cells respectively) and in Fiebig V-VI (from 8899 to 458 and from 2119 to 233 cp/10^6 CD4+ T cells respectively) (**Figure 2**).
- **VR** (intact and defective) **fold decrease** between W0 and W48 **was higher in Fiebig II-IV** (77,64 and 85,97 respectively) than in Fiebig V-VI (19,43 and 9,09 respectivelly).
- **Intact/defective ratio was lower in Fiebig II-IV** group than in Fiebig V-VI group both at W0 (0,54 and 4,2 respectively) and W48 (0,60 and 1,9 respectively).
- More pronounced **VR decrease was associated with higher VL** at W0 (p<0,001), **subtype B** (p=0,049) and **Fiebig stages II-IV** (p=0,002); but it was not statistically significant for intact proviral HIV-1 DNA.

CONCLUSIONS

- **Reservoir**, including intact DNA, **significantly decreases** at w48, after controlling for Fiebig stage, viral subtype or baseline VL.
- Starting ART at **Fiebig II-IV** results in a more pronounced **reservoir decay** and a **lower intact/defective ratio** at both timepoints than at Fiebig V-VI.

...and study participants!

*Equivalent merits as senior authors