HIV-1 RNA DECAY IN SEMEN AND RECTUM AFTER INITIATING THERAPY WITH DTG PLUS 3TC

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BACKGROUND

- The assessment of HIV decay kinetics in genital fluids and rectum may assist in predicting the potential risk of sexual transmission after initiating antiretroviral therapy (ART).
- We observed similar HIV-1 RNA decay patterns in seminal plasma (SP) and rectal fluid (RF) with DTG+3TC and BIC/FTC/TAF (Imaz et al., CROI 2022, #495).
- This study aims to evaluate differences in HIV-1 RNA decay in SP, RF, and blood plasma (BP) with the dual antiretroviral combination DTG+3TC.

METHODS

- ❑ Design: Sub-study of open-label, randomized, multicenter, pilot clinical trial (Imaz et al., CROI 2022, #495).
- ❑ Inclusion criteria: ART–naive cisgender males with plasma HIV-1 RNA <500,000 copies/mL, CD4 cell count >200/µL, negative for HBV and absence of mutations associated with resistance to the study treatments at screening. Individuals with acute HIV infection were not eligible.
- ❑ Participants were randomized 2:1 to initiate first-line ART with DTG 50 mg plus 3TC 300 mg OD or BIC/F/TAF 50/200/25 mg OD, respectively, and randomization was stratified by plasma HIV-1 RNA below or above 100,000 copies/mL and CD4 count below or above 350 cells/µL.
- ❑ HIV-1 RNA was measured in BP, SP and RF at baseline (BL), days 3, 7, 14 and 28, and weeks 12 and 24 (Alinity m HIV-1 AMP assay, Abbott Molecular; limit of quantification, 20 copies per mL or per swab in case of RF).
- ❑ This analysis is focused on the DTG+3TC group.

Statistical Methods

- The categorical variables were described as number of cases and percentage. Continuous variables that followed a normal distribution were described with the mean and standard deviation. Continuous variables that did not follow a normal distribution were described with the median and range or interquartile range
- HIV-1 RNA (log10) decline from BL at each time point was described using the median and interquartile range (IQR).
- The paired T test and Friedman test were used for comparisons between compartments.
- Linear mixed effects models were used to assess factors related with HIV-1 RNA decline.
- Interval-censoring Kaplan-Meier survival analysis was used to assess the time to achieve HIV-1 RNA <20 copies/mL and the asymptotic log-rank test was used for comparisons between compartments.

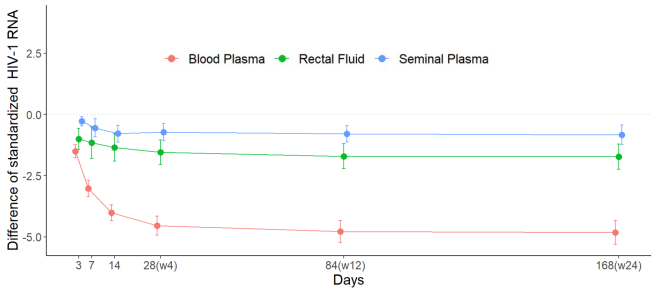
RESULTS

Table 1. Baseline Characteristics

Characteristic	DTG/3TC N = 16
Age (years), median (range)	31 (22-60)
CD4 count, cells/µL, median (range)	392 (331-463)
Blood plasma HIV-1 RNA, log_{10} copies/mL, Median [IQR]	4.56 [4.22;4.86]
Seminal plasma HIV-1 RNA, log_{10} copies/mL, Median [IQR]	2.38 [1.30;2.95]
Rectal fluid HIV-1 RNA, log_{10} copies/swab, Median [IQR]	2.92 [2.36;3.73]

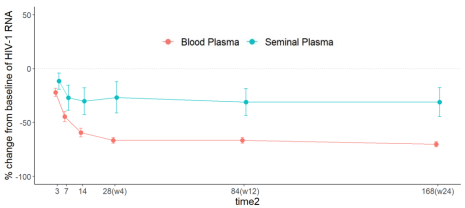
HIV-1 RNA Decline Through Week 24

Figure 1. Median [Q1;Q3] Difference of standardized HIV-1 RNA by study time

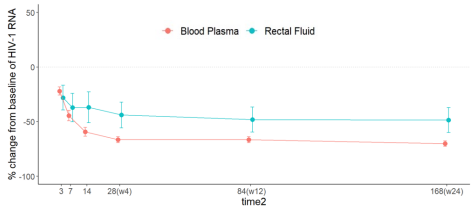


The linear mixed effects models showed a significant interaction between the compartment and the magnitude of HIV-1 RNA decline when seminal plasma and rectal fluid were compared to blood plasma.

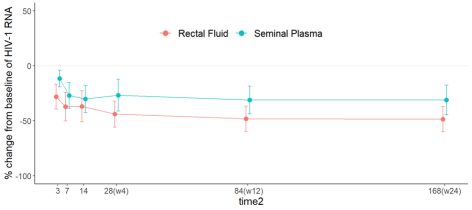
Figure 2. Mean and IC95% Difference % change from baseline HIV-1 RNA by study time point



Statistically significant differences were observed between seminal plasma and blood plasma in the mean percentage of change of HIV-1 RNA from BL at all time points.



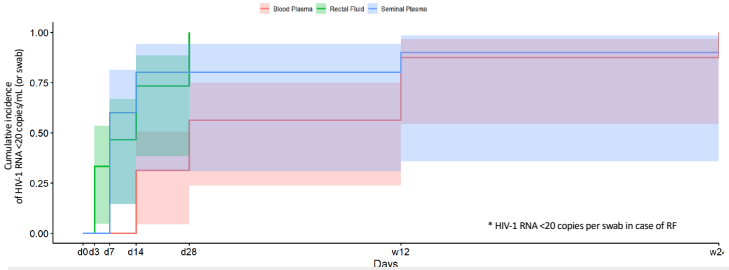
Statistically significant differences were observed between rectal fluid and blood plasma in the mean percentage of change of HIV-1 RNA from BL at all time points except at day 3.



Statistically significant differences were observed between seminal plasma and rectal fluid in the mean percentage of change of HIV-1 RNA from BL at all time points except at days 7 and 14.

HIV-1 RNA below 20 copies/mL (or swab) Through Week 24

Figure 3. Cumulative incidence of HIV-1 RNA <20 copies/mL (or swab)*



The median time to achieve HIV-1 RNA <20 copies/mL (or swab) was shorter in SP (7 days [0;8.75]) and in RF (10 days [3;17.5]) than in BP (28 days [14;84]) (p<0.001).
In 1 individual HIV-1 RNA <20c/mL was not achieved in SP at W24 (32 c/mL) despite suppression in BP and RF

CONCLUSIONS

- **Different HIV-1 RNA decay patterns were observed in seminal plasma and rectal fluid compared to blood plasma in ART-naïve PLWH treated with DTG+3TC.**
- **Despite a more pronounced decline in blood plasma, a rapid HIV-1 RNA suppression was observed in seminal plasma and rectal fluid. This might be explained in part by a lower viral load in these compartments at baseline.**

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