Introduction

No single parameter reliably predicts post-treatment control (PTC) among HIV-infected patients. However, both total HIV-1 DNA (tDNA) and cell-associated RNA (caRNA) have been individually associated to delayed viral rebound after ATI. We evaluated the predictive value of the combination of low DNA and caRNA in the identification of PTC.

Methods

The study is a two-step single arm multicentric non-randomized prospective trial (NCT02590354). Major inclusion criteria in step 1 were: nadir CD4+ T-cell count >350cells/µL and plasma viral load (pVL) <50 cp/mL since ≥2 years. The size of the HIV reservoir was determined by droplet digital PCR measurement of tDNA and caRNA in peripheral blood mononuclear cells (PBMCs). In step 2, consenting participants with reservoir parameters below the detection limit (tDNA <66 cps/10^5 PBLs and caRNA <10 cps/10^5 PBLs) underwent a leucapheresis prior to ATI.

cART was re-initiated whenever pVL measured every other week, was >1,000 cps/ml at two consecutive measurements or at pVL >10,000 cps/ml. tDNA and caRNA were measured at every visit during ATI as well as 4 and 12 weeks after cART re-initiation. Quantitative viral outgrowth assays (qVOA), viral release assays (VRA) and ultra-sensitive pVL were performed on pre-ATI samples. Associations between clinical, virological or immunological parameters and viral rebound dynamics were assessed with Kaplan-Meier estimates and Cox proportional hazard models.

Results

Of the 114 participants, 37 (32.5%) met the viral reservoir criteria for ATI. Of them, 16 (14.0%) consented and underwent ATI. No serious adverse events have been reported. The three episodes of adverse events related to the intervention were one episode of fatigue, one influenza-like illness and one episode of oropharyngeal pain.

Viral dynamics after treatment interruption and upon treatment resumption

All participants experienced rapid viral rebound two to eight weeks after ATI. All participants suppressed viremia to levels below the limit of detection within 12 weeks of cART re-initiation. tDNA and caRNA returned to baseline levels within the 12 weeks after cART re-initiation.

Acknowledgement: We are grateful to the participants who made this study possible. We also thank all the staff involved in the various clinical trial sites and research laboratories.

Funding for this study was provided by Research Foundation -Flanders (FWO) through a TBM grant (application 140189).

1. 1. Institute of Tropical Medicine, Antwerp, Belgium. 2. HIV Cure Research Center, Ghent University, Ghent, Belgium. 3. Saint-Pierre University Hospital, Brussels, Belgium. 4. Vrije Universiteit Brussel, Brussels, Belgium. 5. Ghent University, Ghent, Belgium. 6. Antwerp University Hospital, Antwerp, Belgium.