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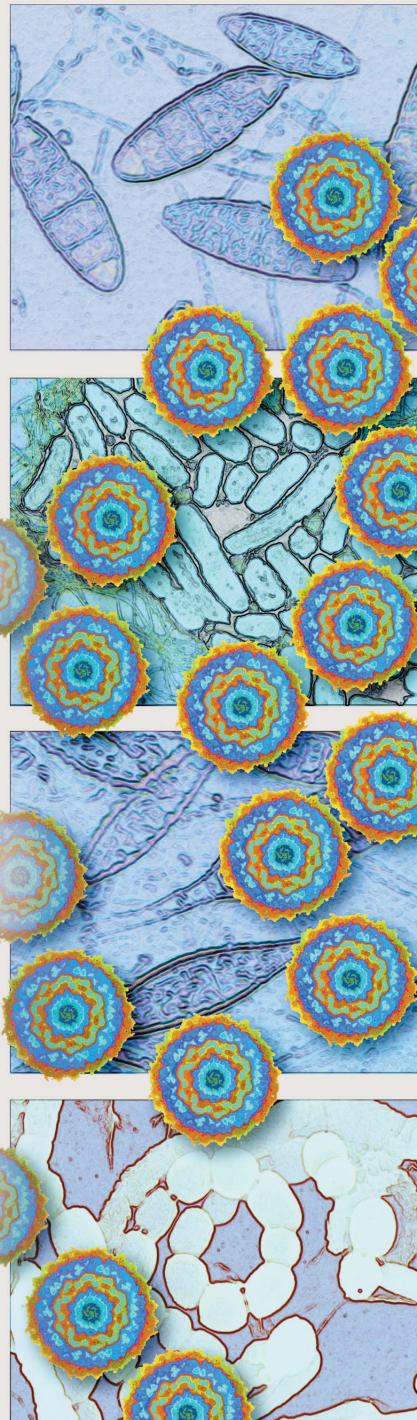
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P-019. IMPACT OF SWITCHING FROM DUAL TO TRIPLE THERAPY ON INFLAMMATION AT 48 WEEKS: INSTINCT STUDY

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Introduction: Because inflammation is associated with morbidity and mortality and has been linked to HIV transcription in lymphoid tissues during ART, it is necessary to address the impact of switching ART regimens with different numbers of antiretroviral on inflammation.

Methods: In this interim analysis of the randomized, open-label, multicenter INSTINCT trial (clinicaltrial.gov: NCT04076423), we evaluated the effect of switching from DTG/3TC to BIC/FTC/TAF vs. remaining on DTG/3TC on systemic inflammation up to 48 weeks. We included 117 participants. Participants were adults with confirmed, virologically suppressed HIV, on stable ART with DTG/3TC for a minimum of 48 weeks. Exclusion criteria included previous virological failure, drug resistance, and autoimmune conditions. IL-6 levels (Kit Human IL-6 HS Bio-techne) measured in triplicate were carefully analysed located on plates to avoid batch-effects. We focused on this inflammatory biomarker changes from baseline to week 48 using high-sensitivity ELISA. Statistical analysis: Mann-Whitney and linear regression.

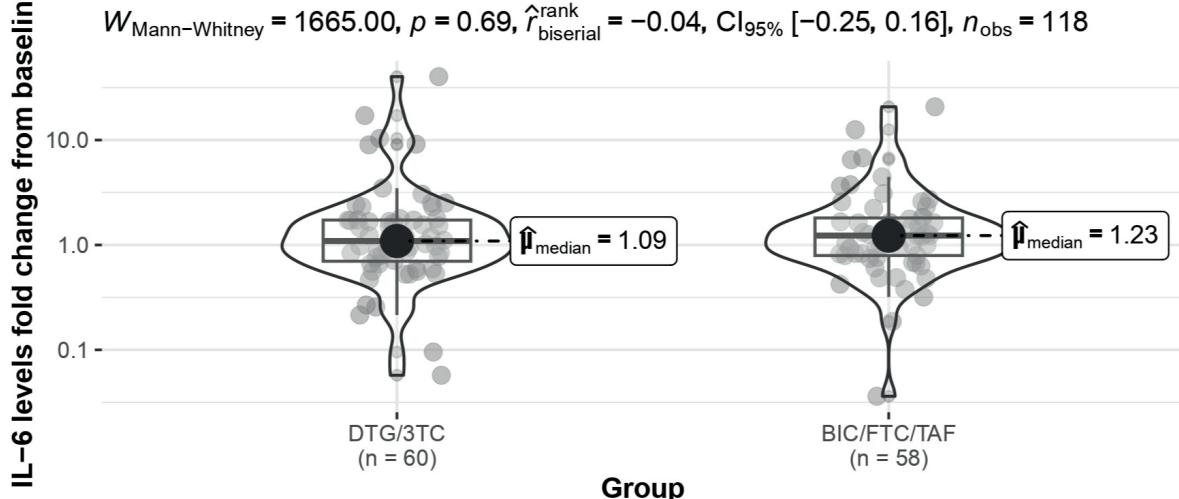
Results: A total of 117 participants completed the 48-week follow-up; 17% women, mean age 44 ± 11 years, 79% white, 62% MSM, 9% with past AIDS diagnosis, median nadir CD4 338 cells/uL, baseline CD4 counts 776/uL, median duration of HIV suppression 5.2 years. Median IL6 levels in all study participants 0.96 pg/mL, IQR 0.53-1.44 (within normal ranges). No differences were observed in the general characteristics between groups. No significant differences in IL-6 changes were observed between groups from week 0 to 48 (median fold change for DTG/3TC, 1.1 [0.7-1.7]; for BIC/FTC/TAF, 1.2 [0.8-1.8], Mann Whitney, $p = 0.688$; group effect in linear regression analysis: Coef -0.07, $p = 0.931$) (Fig.).

Conclusions: This analysis revealed no significant impact on IL-6 levels when switching from DTG/3TC to BIC/FTC/TAF in the first 48

Figura P-019.

Changes in IL-6 plasma concentrations after 48 weeks

$$W_{\text{Mann-Whitney}} = 1665.00, p = 0.69, r_{\text{biserial}}^{\text{rank}} = -0.04, \text{CI}_{95\%} [-0.25, 0.16], n_{\text{obs}} = 118$$



weeks. These preliminary findings suggest a neutral inflammatory effect for the ART switch, warranting further study to elucidate the longer-term influence on inflammation.