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3-NRTI HAART SIMPLIFICATION IN CHILDREN IS EFFECTIVE IN MAINTAINING VIROLOGICAL AND IMMUNOLOGICAL CONTROL AFTER 108 WEEKS

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BACKGROUND: The shift to a simplified 3-nucleoside reverse transcriptase inhibitor (NRTI) regimen in children previously treated with a protease inhibitor (PI)-based HAART was studied to evaluate virological, immunological, and clinical outcome after a long-term follow-up.

METHODS: A total of 20 HIV-vertically infected children with at least 24 months of undetectable viral load during 2-NRTI + 1-PI treatment were shifted to a 3-NRTI regimen (zidovudine/stavudine + lamivudine + abacavir [AZT/d4T+3TC+ABC]). Clinical, immunological, and virological evaluation were done every 12 weeks.

RESULTS: Children's mean age at the shift was 104 months and mean length of previous HAART was 52 months. Of 20 patients, 7 were treated since the first months of age; 8 were symptomatic (CDC class B=6, C=3) and 6 presented severe immune deficit when they started HAART. At study entry all children had undetectable viral load (<50 copies/mL)—since a mean period of 36 months—and normal CD4+ cell count (mean 34.5±7%), good clinical condition, and normal growth percentiles. After a mean period of 108 (60 to 129) weeks of a simplified ART all but 1 children maintained undetectable viral load, normal CD4 (mean 35.5±5.4%), and good clinical and growth parameters. One virological failure was observed in an adolescent who stopped treatment for personal reasons. After a median period of 60 weeks, 8 patients (40%) experienced blips (viral load >50 and <1000 copies/mL), but returned to undetectable levels at the following controls. Total cholesterol decreased from a mean of 187±52 to 147±32 mg/dL, LDL from 113±37 to 81±22 mg/dL, and triglycerides from 91.8±53 to 74±37 mg/dL. Quantification of proviral DNA-load was performed in 12 (60%) children. In these the mean proviral DNA-load remained stable at 2.4 log₁₀ copies/10⁶ peripheral blood

mononuclear cells (PBMC) between baseline and 48 weeks. CD4 proliferative response to HIV-specific antigens was present in 8 of 15. Anti-HIV-specific CD8 response, assessed by intracellular cytokine staining, showed a significantly increased over time of T-cells releasing IFN- γ (T0: 0.06% \pm 0.11; T12: 0.11% \pm 0.09; T24: 0.22 \pm 0.17; T48: 0.22 \pm 0.2; all p <0.05 vs T0). The number of children presenting a high frequency of CD8/IFN- γ HIV-specific T cells was 8% at entry, 44% at 24 week (p =0.04 vs T0) and 46% at 48 weeks (p =0.02 vs T0).

CONCLUSIONS: HAART simplification after an induction therapy allows to maintain a complete and long-term immunological and virological control with significant improvement of dyslipidemia. The progressive increase of specific cytotoxic T lymphocyte response observed in some patients can be related to an enhanced viral replication in lymph nodes or an increased frequency of blips.

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