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THE METABOLIC EFFECTS OF INTERMITTENT ANTIRETROVIRAL THERAPY WITH AND WITHOUT IL-2 (ACTG A5102)

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BACKGROUND: CD4-driven antiretroviral therapy is being evaluated in large trials. The metabolic effects of this strategy are largely unknown. ACTG 5102 evaluated the utility of IL-2 and pulses of ART based on CD4 cell counts as a strategy to reduce the costs and toxicity of continuous ARV.

OBJECTIVES: To evaluate the effects on lipid and glucose metabolism of IL-2 and prolonged TI.

DESIGN: Forty-seven HIV+ subjects on ART with CD4+ Tcell counts >500 cells/mm³ and HIV RNA levels <200 copies/ml were randomized to receive or not three 5-day cycles of IL-2, 4.5 million units subcutaneously twice daily every 8 weeks (*n*=23 and 24, respectively) for 18 weeks. Then they discontinued ARV until the CD4 cell count dropped below 350. The median follow-up off ARV is greater than 1 year. Twenty-six of the subjects received NNRTI-based therapy. Fasting glucose, insulin and lipid parameters were evaluated every 8 weeks initially and at weeks 2, 4, 8 and every 8 weeks after TI.

RESULTS: Three cycles of IL-2 did not affect lipid or glucose metabolism. After 48 weeks of TI there were significant decreases of triglycerides (from 172 mg/dl, -20%, *P*<0.001), total cholesterol (from 213 mg/dl, -15%, *P*<0.001) and LDL cholesterol (126 mg/dl, -12%, *P*=0.008). There were no significant changes in glucose or insulin levels or HOMA-IR. Lipid changes occurred relatively early after interruption (within the first 4 weeks).

CONCLUSIONS: Three cycles of IL-2 do not have significant metabolic effects on subjects receiving stable antiretroviral therapy. Treatment interruption is associated with immediate and sustained decreases in cholesterol levels (both LDL and HDL) and TG. The effects on glucose and insulin metabolism were limited in this cohort. A strategy of intermittent therapy can decrease the cardiovascular risk associated with ARV therapy and provide insight into which of the metabolic abnormalities observed in treated patients are HIV- or ARV-related.

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