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Baseline and early on-treatment predictors of lipoatrophy at 64 weeks in a randomized trial of initial antiretroviral therapy: a secondary analysis of A5005s, a substudy of ACTG 384

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BACKGROUND: Observational studies have reported many non-drug risk factors for lipoatrophy. We sought to identify baseline characteristics and early on-treatment metabolic changes predictive of lipoatrophy.

METHODS: Antiretroviral-naïve subjects were randomized to nelfinavir, efavirenz or both with ZDV+3TC or ddI+d4T. DEXA was available at entry and week 64 for 102 subjects; 95 subjects had baseline lipids and 77 also had week 8 lipids available. One-third had lipoatrophy, defined as >20% decrease in limb fat from baseline. Individual variables were screened using standard tests (Wilcoxon Rank Sum; Fisher's Exact test); logistic regression was used for multivariate analyses.

RESULTS: In univariate analyses, higher baseline (pre-ART) CD4, body mass index (BMI), triglycerides (TGs) and cholesterol and assignment to ddI+d4T were associated with an increased risk of lipoatrophy at week 64 (each $P=0.2$). At week 8, larger increases in TGs and cholesterol were associated with an increased risk of lipoatrophy, but changes in fasting C-peptide, HOMA-IR, and HDL-C were not. In multivariate models, the odds ratio for developing lipoatrophy was 3.27 (95% CI: 1.40–7.63) for a 100 mg/dl increase in TGs at week 8 and was 3.19 (0.99–10.22) for assignment to ddI+d4T; baseline BMI, CD4 and RNA were not significant predictors after adjustment for these factors. The association between TG increase and lipoatrophy however appeared to be largely due to the effect of ddI+d4T assignment, where the median week 8 increase in

TGs was 103 mg/dl in those with lipoatrophy ($n=19$) and 28 mg/dl without ($n=24$); with ZDV+3TC, for those with lipoatrophy ($n=6$) TGs increased by median 24 mg/dl, for those without ($n=28$) 26 mg/dl.

CONCLUSIONS: Nucleoside assignment, greater baseline CD4 and BMI, but not age, sex or white race were associated with lipoatrophy in univariate analyses. Baseline TGs and cholesterol (and their early changes), but not measures of glucose metabolism, were associated with lipoatrophy. In multivariate models, increases in TGs and ddI+d4T treatment were associated with lipoatrophy. We did not find evidence of an association between lower nadir CD4+ cell counts and white race with lipoatrophy.



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