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RATES OF CHANGE IN BODY COMPOSITION AMONG ANTIRETROVIRAL-NAÏVE HIV-INFECTED PATIENTS RANDOMIZED TO A DIDANOSINE/STAVUDINE VERSUS ABACAVIR/LAMIVUDINE CONTAINING REGIMEN IN THE FLEXIBLE INITIAL RETROVIRUS SUPPRESSIVE THERAPIES (FIRST) STUDY (CPCRA 058)

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OBJECTIVE: To compare rates of change in body composition from baseline in antiretroviral-naïve patients randomized to didanosine/stavudine versus abacavir/lamivudine containing regimens.

METHODS: Of 1400 patients randomized to one of three FIRST arms [protease inhibitor (PI)-containing, non-nucleoside reverse transcriptase inhibitor (NNRTI)-containing or PI and NNRTI-containing], 182 enrolled in the nucleoside reverse transcriptase inhibitor (NRTI) substudy (didanosine/stavudine versus abacavir/lamivudine). Of those enrolled in NRTI substudy, 96 enrolled in the metabolic substudy. Anthropometric measurements (skinfolds and body circumferences) were done by centrally trained personnel at baseline and every 4 months for a median follow-up of 33 months. Total body fat and body cell mass were measured with BIA. Rates of change estimated by using the slopes of regression lines for body mass index (BMI), body cell mass, total body fat, body circumferences and skinfolds were calculated.

RESULTS: Baseline characteristics: 28% females, mean age 37 years; 64% African-American, 13% Latino; 19% prior AIDS; 12% intravenous drug user; median CD4 237 cells/mm³, median logRNA 5.07 copies/ml; and BMI 24.8 kg/m² did not differ by study assignment. The rate of change* (units/month) and standard error of the body composition measurements for didanosine/stavudine (*n*=46) versus abacavir/lamivudine (*n*=50) were as follows: BMI (kg/m²): -0.03 (0.01) vs 0.04 (0.01); body cell mass (kg): 0.02 (0.01) vs 0.04 (0.01); total body fat (kg): -0.09 (0.02) vs 0.10 (0.02); body circumferences (cm): arm: -0.04 (0.01) vs 0.01 (0.01), waist: -0.04 (0.03) vs 0.01 (0.01), hip: -0.19 (0.04) vs 0.09 (0.04), thigh: -0.08 (0.02) vs 0.01 (0.01); skinfolds (mm): triceps: -0.13 (0.02) vs 0.01 (0.02), subscapular: -0.03 (0.02) vs 0.05 (0.02) (*P*<0.05), abdomen: -0.15 (0.04) vs 0.12 (0.03), thigh: -0.12 (0.03) vs -0.01 (0.03). All results were statistically significant with a *P*<0.01 unless indicated.

CONCLUSIONS: Using basic anthropometric measurements, we found a significant difference in the rate of change in BMI, body cell mass, total body fat, body circumferences and skinfolds for didanosine/stavudine versus abacavir/lamivudine. This data supports a significantly greater subcutaneous fat loss in both peripheral and central sites in the didanosine/stavudine arm compared to the abacavir/lamivudine arm among antiretroviral-naïve patients treated with their first antiretroviral regimen.

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13

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