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DEXA OUTCOMES IN ANTIRETROVIRAL-NAÏVE SUBJECTS RECEIVING NELFINAVIR OR EFAVIRENZ OR BOTH PLUS DUAL NUCLEOSIDES: LONG-TERM AS-TREATED RESULTS FROM A5005s

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BACKGROUND: Long-term regional body fat outcomes have not been well-described in randomized antiretroviral drug trials. We previously reported more favorable limb fat changes over 64 weeks with ZDV+3TC versus ddI+d4T, and efavirenz versus nelfinavir.

METHODS: DEXA scans were performed every 16 weeks on a subset of 157 antiretroviral-naïve subjects who were randomized to receive nelfinavir, efavirenz, or both, combined with ZDV+3TC or ddI+d4T in a multicenter trial. Subjects with any available data after baseline up to week 144 contributed to this as-treated analysis. Data were censored 28 days after a regimen change.

RESULTS: Limb fat increased similarly in all treatment arms during the first 32 weeks. Sixty-five subjects had week 144 DEXA. Among 13 subjects who continued to receive ddI+d4T at week 144, the median change from baseline in limb fat was -32.5% (P=0.04 from baseline) and among 19 subjects on ZDV+3TC, the median change was +1.4% (P=1.0 from baseline). After week 32, limb fat changed by -1.7%/year for ZDV+3TC and -19.0%/year for ddI+d4T (MMANOVA P<0.0001). Among 7 subjects receiving nelfinavir without efavirenz at week 144, the median change from baseline limb fat was -23.8%; among 14 receiving both nelfinavir+efavirenz -21.4% (P=0.05 from baseline for pooled data from all nelfinavir recipients), and among 11 subjects on efavirenz without nelfinavir, the median change was +2.4% (P=0.90 from baseline). Focusing on subjects receiving ZDV+3TC, after week 32 limb fat changed by +2.7%/year with efavirenz and -7.9%/year for the combined nelfinavir and nelfinavir+efavirenz group (MMANOVA

P=0.03). Trunk fat increased similarly in all treatment arms during the first 32 weeks, tending to remain above baseline over time. There were marginal differences between NRTIs after week 32 (MMANOVA *P*=0.05), with trunk fat changes +7.0%/year for ZDV+3TC and -3.4%/year for ddI+d4T. Among those subjects receiving ZDV+3TC, after week 32 trunk fat changed by +18.9%/year with efavirenz and -3.5%/year for the combined nelfinavir and nelfinavir+efavirenz group (MMANOVA *P*<0.0001).

CONCLUSIONS: Over 144 weeks, ZDV+3TC continued to be superior to ddI+d4T with regards to limb fat loss. The combination of ZDV+3TC+efavirenz had greater trunk fat increases, but showed no overall pattern suggesting limb fat loss over time and was significantly superior to the pooled ZDV+3TC+nelfinavir (with and without efavirenz) arms.

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