

## 2nd International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV



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### LIPODYSTROPHY AND METABOLIC ABNORMALITIES IN A CROSS-SECTIONAL STUDY OF PARTICIPANTS IN RANDOMIZED CONTROLLED STUDIES OF COMBINATION ANTIRETROVIRAL THERAPY

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**BACKGROUND:** Observational studies of lipodystrophy compromise complex antiretroviral therapy (ARV) histories. Randomized, controlled studies provide patient cohorts with well-defined treatment experience in which treatment related outcomes can be assessed.

**OBJECTIVES:** To summarize measures of lipodystrophy and metabolism in patients from two randomized, controlled studies of combination ARV.

**DESIGN:** Patients randomized to receive zidovudine plus lamivudine versus stavudine plus lamivudine versus stavudine plus didanosine in Ozcombo I (each with indinavir) and Ozcombo II (each with nevirapine) were examined cross-sectionally for HIV history/demographics, ARV history, patient and clinician-diagnosed lipodystrophy, dual X-ray absorptiometry (DEXA), abdominal (L4) CT scans and a battery of laboratory markers. Data were summarized on the basis of originally assigned treatment group and both nucleoside components, and nevirapine versus indinavir were compared.

**RESULTS:** Of 178 eligible patients, 84 (47%) participated comprising 21 recipients of zidovudine plus lamivudine, 35 recipients of stavudine plus lamivudine and 28 recipients of stavudine plus didanosine. Patient characteristics were well matched across treatment groups. Treatment histories were consistent with the random assignments. Physician and patient reported peripheral lipodystrophy was significantly ( $P<0.05$ ) more frequent in

recipients of stavudine plus didanosine relative to stavudine plus lamivudine relative to zidovudine plus lamivudine and for the comparison between indinavir with nevirapine recipients. Differences ( $P<0.001$ ) in central fat change were only apparent for the comparison of indinavir with nevirapine. These observations were broadly confirmed by imaging studies. In Ozcombo I participants, serum lactate levels were significantly ( $P<0.05$ ) higher in recipients of stavudine plus didanosine than recipients of either stavudine plus lamivudine or zidovudine plus lamivudine.

**CONCLUSIONS:** While the results need careful interpretation, they suggest that stavudine plus didanosine-containing regimens result in more frequent peripheral fat changes and elevations in serum lactate.

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