



# 1st International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV

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## THE SALSALSA (SELF-ASCERTAINED LIPODYSTROPHY SYNDROME ASSESSMENT) COHORT: ABNORMALITIES IN CASES COMPARED TO CONTROLS

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**INTRODUCTION:** In some HIV surveys low percentages (often <10%) of patients display pronounced fat redistribution. The SALSALSA cohort focuses on HIV patients with abnormal body shape and/or metabolism and compares them to demographically matched controls. Presently the cohort includes over 430 patients from 48 clinical centres. To help establish a lipodystrophy (LD) case definition, abnormalities reported by 'cases' diagnosed by their clinicians with altered body habitus and/or metabolic pathology are compared to those reported by HIV-positive and healthy controls not diagnosed by their clinicians as cases.

**DESIGN/SUBJECTS:** Sites provide patient/physician SALSALSA questionnaires which inquire in detail about body shape and laboratory abnormalities. Frequencies of self-reported LD, fat accumulation (FA) and physician-reported laboratory abnormalities are compared by Fischer's exact test. This analysis includes the first 270 patients. Cases ( $n=210$ , 24% female) were aged 25 to 69 years, with CD4 counts of 4 to 1456 cells/mm<sup>3</sup>, 98% receiving combination antiretroviral therapy including a PI, and 51 having undetectable viral loads (VL) <500 copies/ml. HIV-positive controls ( $n=36$ , 25% female) were 30 to 69 years, with CD4 counts of 54 to 1338 cells/mm<sup>3</sup>, 86% on PI and 55% with undetectable VL. Healthy controls ( $n=24$ , 10 female) were 29 to 64 years.

**RESULTS:** Male cases ( $n=160$ ) reported significantly ( $P<0.05$ ) more belly FA (with frequencies of 76%, 66%, 42% in the cases, HIV-positive and healthy controls,

respectively) limb LD (68%, 33%, 36%), buttock LD (59%, 26%, 14%), facial LD (57%, 22%, 14%) and buffalo hump (19%, 0%, 0%). Male cases also displayed more hypertriglyceridaemia (84%, 14%, 0%), hypercholesterolaemia (53%, 15%, 0%) and hypertension (20%, 0%, 7%) than gender-matched controls. Female cases ( $n=50$ ) reported significantly ( $P<0.05$ ) more belly FA (98%, 44%, 40%), breast FA (74%, 22%, 10%), limb LD (54%, 11%, 10%), buttock LD (44%, 0%, 10%) and had more hypertriglyceridaemia (32%, 0%, 0%) and hypercholesterolaemia (29%, 0%, 0%) than gender-matched controls.

**CONCLUSIONS:** Although HIV-positive 'cases' report more abnormalities than gender-matched HIV-positive and healthy controls, controls also report abnormalities. Additional multivariate analyses and studies employing more objective measures of fat distribution (ongoing) are needed to more fully elucidate a case definition for LD syndrome(s).

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