#### HIV-Associated Lipodystrophy

Douglas G. Fish, MD
Albany Medical College
Albany, New York, USA
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Cali, Colombia

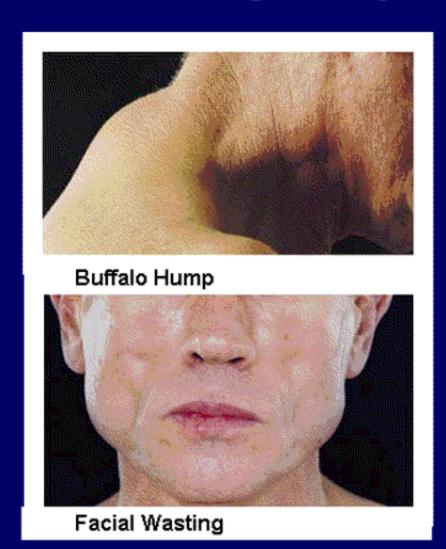
#### Metabolic Complications

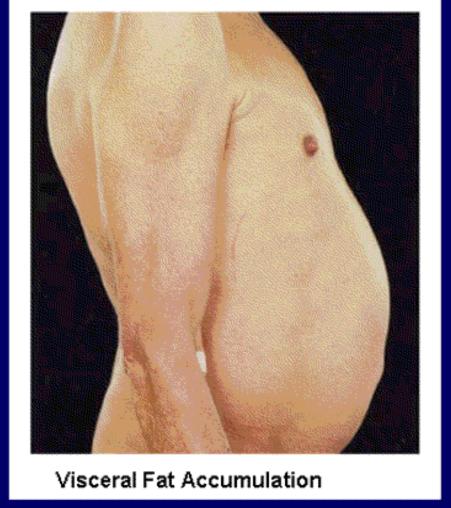
- Lipodystrophy
- Hyperlipidemia
- Insulin resistance
- Lactic acidosis
- Peripheral neuropathy

#### Lipodystrophy

- Fat accumulation (redistribution)
  - Abdomen, neck, occiput
- Lipoatrophy
  - Face, limbs, buttocks

#### HIV-Associated Body Composition Changes





Aboulafia DM, et al. N Engl J Med, 1998; Carry A, et el. N Engl J Med, 1998.

# A Randomized, Double-blind, Placebo-controlled Study of Rosiglitazone for Patients with HIV Lipodystropy.

C. Hadigan, S Yawetz, A Thomas, et al.

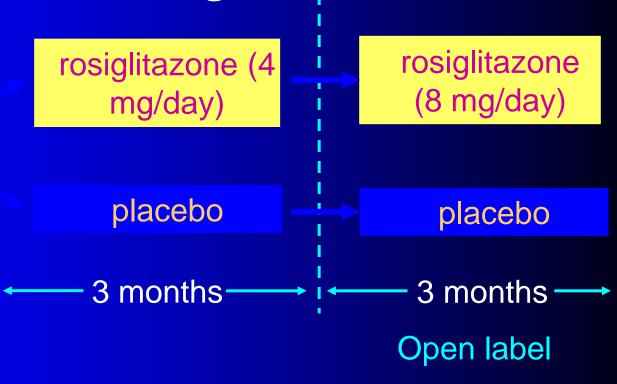
## Study of Rosiglitazone for Patients with HIV Lipodystropy

 ARV therapy often leads to loss of subcutaneous fat and metabolic abnormalities including insulin

resistance.

HIV-infected patients with hyperinsulinemia and lipoatrophy

Double-blind randomization n = 28



## Study of Rosiglitazone for Patients with HIV Lipodystropy

#### At 6 months:

Insulin sensitivity remained improved SAT from baseline \$\frac{15\%}{}

## Study of Rosiglitazone for Patients with HIV Lipodystropy

- Positive effects of rosiglitazone on insulin sensitivity and fat in HIV-infected patients
- Study powered to look at insulin resistance, but not body shape changes
- Body shape changes small
- Larger studies are required to:
  - Identify optimal dose, duration of treatment, subpopulations most likely to benefit, and choice of specific thiazolidinedione

## Recombinant Human Growth Hormone in HIV Wasting

- 757 pts, with 646 completing 12 wks of Rx
- Double-blind, randomized, placebocontrolled
  - 1:1:1 6mg/d r-hGH: 6mg r-hGH qod: placebo
- Assessment by DEXA or bioelectrical impedance spectroscopy
- Body wt and lean body mass increased significantly compared to placebo
- Greater impact on truncal fat compared to limb fat
  - Moyle G et al. 2<sup>nd</sup> IAS, Abs.719; July, 2003

## Recombinant Human Growth Hormone in HIV Wasting

- LBM increased by 3.44kg in daily group, and by 2.62kg (both P<0.0001 vs placebo)
- Total and trunk fat mass decreased by 1.4kg & 1.1 kg, respectively, in QD group, and by 1.2kg & 1.1 kg in qod group (both p<0.0001 vs placebo)
- Net weight gain occurred in both Rx arms