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The LipoWatch program from Visionary Health Concepts is designed to support providers and patients with education that integrates a "real world" focus with scientific data. This month we discuss the role of human growth hormone in treating the metabolic complications of HIV-1 and antiretroviral therapy. NOTE: LipoWatch faxes are archived on the web at http://www.vhconcepts.com/edu_progs.cfm.

Human growth hormone (HGH) regulates body composition, aerobic capacity, and metabolism. Early work with HGH focused on promoting normal growth in children. The development of recombinant HGH in the mid 1980s stimulated increased research in adults. Replacement therapy in adults with growth hormone deficiency produced increases in lean body mass, reductions of fat mass, increase in total body water, increases in bone mineral density after 12-24 months of treatment, and improvements in cardiac function, psychological well-being and quality of life.⁽ⁱ⁾ Studies in adults led to exaggerated claims that HGH could "reverse the aging process." However, differentiating between normal age-related decreases in HGH levels and true growth hormone deficiency remains an open question.

HGH is administered via subcutaneous injection. Typical replacement doses are between 0.04 and 0.08 mg/kg/week. For a 200-pound adult, replacement doses would be between 3.6 mg and 7.2 mg/week. Adverse effects of therapy include weight gain, edema, joint stiffness, and carpal tunnel syndrome which resolve after dose reduction or discontinuation of therapy. Caution is advised when growth hormone is administered to patients with diabetes mellitus, because insulin dosage may need to be adjusted. Patients with diabetes or glucose intolerance

should be monitored closely during treatment.⁽ⁱⁱ⁾

In 1996, HGH was approved for treatment of AIDS wasting at daily doses of 4-6 mg. It was found to induce a significant increase in LBM; decrease body fat; increase overall body weight due to the dominant effect of LBM gain; and increase physical functioning as measured by treadmill performance.⁽ⁱⁱⁱ⁾ An in vitro study suggested that HGH increased HIV activity and should not be used by people with HIV unless they are using antiviral medications. Patients with elevated glucose levels or risk factors for glucose intolerance should be closely monitored. Although the benefits of HGH in the treatment of AIDS wasting are clear, its use remains controversial because of its cost (dosing of either Serostim[®] or Genotropin[®] brands of HGH is in excess of \$1,000 per week).

More recently, because of its lipolytic properties, HGH has been used to reduce fat accumulations associated with lipodystrophy.^(iv) Initial reports noted dramatic reductions in abdominal visceral fat and in buffalo humps. More recent reports confirmed these findings but noted rapid reversal of HGH's benefits when therapy was discontinued.^(v) Major concerns associated with long term HGH therapy include the high rate of side effects, particularly edema and carpal tunnel syndrome, and concerns that its lipolytic activity might exacerbate peripheral fat wasting. Despite these concerns, there are anecdotal reports of improvement in facial wasting during HGH therapy, possibly due to increased water content of facial tissue. Together with the product's cost, these concerns prompted interest

in studies of lower doses of HGH for treatment of fat accumulation.

Results of two studies using 4 mg daily or alternate-day doses of HGH were recently reported.^(vi/vii) These studies found that initial increases in insulin resistance may return to baseline by 24 weeks. In addition, although alternate day dosing was not as effective as daily dosing in reducing fat accumulations, it may be sufficient to help sustain losses achieved by daily dosing.

Research on HGH in the treatment of fat accumulations in lipodystrophy will continue. Whatever the results, two major issues remain: the cost of HGH, and the lack of FDA approval of HGH for this indication. Although data is accruing, the absence of a documented link between lipodystrophy's fat accumulations and increased morbidity and mortality, the FDA may view this use of HGH as purely cosmetic.

ⁱCarroll PV, Christ ER, Bengtsson BA, et al., Growth Hormone Deficiency in Adulthood and the Effects of Growth Hormone Replacement: A Review. *Journal of Clinical Endocrinology and Metabolism* 83: 382-395.

ⁱⁱAvailable on line at http://www.genotropin.com/resources/Prescribing_Information.pdf

ⁱⁱⁱSerostim product monograph, available on line at http://www.aidswasting.com/aids/serostim/html/frame_clinicians.html?monograf.html

^{iv}Wanke C, Gerrior J, Kantaros J, Coakley E, Albrecht M: Recombinant human growth hormone improves the fat redistribution syndrome (lipodystrophy) in patients with HIV. *AIDS* 1999; 13(15): 2099-103.

^vEngelson ES, Glesby M, Sheikhan J, et al. Body composition changes during and after growth hormone therapy for lipodystrophy with truncal adiposity. 13th International AIDS Conference; July 9-14, 2000; Durban. Abstract 1437.

^{vi}Moyle G, Baldwin C, Langroudi B, Gazzard B. Growth Hormone Improves Appearance and Lean Mass in Lipodystrophic Patients and These Benefits are Maintained with Alternate Day Dosing. 42nd Interscience Conference on Antimicrobial Agents and Chemotherapy, September 27 - 30, 2002, San Diego, CA, Abstract H-1935

^{vii}Kotler DP, Thompson M, Grunfeld C et al. Transient Insulin Resistance during Recombinant Human Growth Hormone (rhGH) Therapy for HIV-Associated Adipose Redistribution Syndrome (HARS). 42nd Interscience Conference on Antimicrobial Agents and Chemotherapy, September 27-30, 2002, San Diego, CA, Abstract LB-20.

Next month's LipoWatch will discuss the role of exercise in treating the metabolic complications of HIV-1 and antiretroviral therapy.

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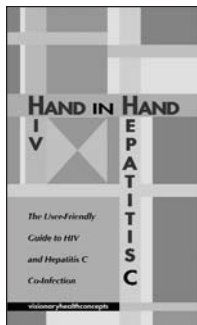
patients about—and promotes understanding of—the reasons for utilizing HIV treatment. Also includes helpful discussion about the ins and outs of effective adherence to antiviral therapy.



Vital Lines:

Clinical Insights into HIV/HCV Co-Infection©

A 2-page legal-size, double-sided direct-mail piece primarily for physicians and secondary providers designed to provide a “state-of-the-state” update on HIV/HCV co-infection.

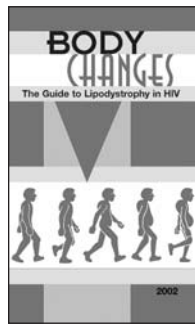


Hand in Hand:

The User-Friendly Guide to HIV and Hepatitis C Co-Infection©

Written by the author of “Double Jeopardy: The HIV/HCV Co-Infection Handbook”. This 40-page booklet gives an up-to-date overview of HIV/HCV

co-infection and its treatment. Written at a 9th grade reading level in English and Spanish to assist secondary providers and peers in translating information easily to anyone. Information on complementary therapies and harm reduction also included.

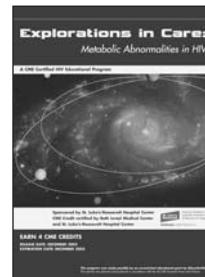


Body Changes:

The Guide to Lipodystrophy in HIV

A 32-page booklet that provides a helpful overview of

lipodystrophy as it pertains to body changes, including management tools that promote wellness for those suffering from these symptoms.



Exploration in Care: Metabolic Abnormalities in HIV©

A 32-page, CME-accredited monograph that provides up-to-date information about metabolic complications of antiretroviral treatment, with an emphasis on fat

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Dosing Matters:

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What's New?

A User-Friendly Guide to the HIV Guidelines 2003© This 32-page booklet is designed to assist people who want to understand how HIV treatment “Guidelines” fit into the overall planning and design of the best healthcare strategies for HIV-positive individuals