THE ROLE OF SOMATOTROPH-SPECIFIC PEPTIDES AND IGF-1 INTERMEDIATES AS AN ALTERNATIVE TO HGH INJECTIONS

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Background: *The age-reversing effects of growth hormone injections have been established in several clinical trials. Results consistently demonstrate increased muscle mass, reduction in body fat, enhanced immune function, improved healing rate of injuries, increased endurance, improved sexual function, hair regrowth, thickening of the skin, and improved mental function. Side effects include edema, carpal tunnel syndrome, allergic response, possible down-regulation of endogenous GH and promotion of cancerous tumor growth. These side effects, the high cost and inconvenience of GH injections, and the knowledge that hGH continues to be produced, but not released by pituitary somatotrophs, has led to an abundance of research on GH secretagogues, which appear to stimulate the release of GH within physiologic boundaries. This research often involves the use of injectable peptides and other sensitive materials, which are marginally effective at raising IGF-1 levels, and consequently have not generally elicited the symptomatic improvement demonstrated with GH injection therapy.*

Abstract

Thirty-six individuals with low levels of Insulin-like Growth Factor Type 1 (IGF-1 < 350 ng/ml), were evaluated clinically for changes in existing symptomatology and serum IGF-1 levels over a period of 12 weeks while being administered Symbiotropin, a combination of anterior pituitary peptides, sequenced glycoamino acid complex, pharmaceutical saccharides, a plant-derived source of L-Dopa, and botanical regulators of insulin and IGF-1. Patients experienced a 30% average increase in IGF-1. Patient self-assessments in areas of endurance and body composition, hair and skin, sexual function, healing and immunity, and mental function reflect significant improvement in all 23 areas of evaluation, with range of 21% - 74% of patients reporting improvement in these areas. Additional clinical observations reflect significant improvements in blood sugar management in diabetic patients, lowered prostate-specific antigen (PSA), improved cardiac and pulmonary function, blood pressure management, and improvement in menopausal symptoms.

Introduction

Unlike other endocrine hormones, which diminish in production with age, hGH is continuously produced by pituitary somatotrophs well into the 70's and 80's, except in the presence of certain pituitary disorders. However, in a state referred to as somatopause, circulating growth hormone levels diminish due to a variety of influences that cause hGH to remain sequestered in pituitary somatotrophs. Age-related increase in production of the hypothalamic hormone somatostatin plays a dominant role in limiting growth hormone release. Age-related decrease in the hypothalamic hormone growth hormone releasing hormone (GHRH) limits hGH release. Excessive carbohydrate intake and diminishing pancreatic function lead to decreased growth hormone release due to poor blood sugar management. Pituitary receptors have been identified that respond to specific hGH-releasing peptides. Hypothalamic receptors have been identified that respond to peptides, which inhibit somatostatin and stimulate GHRH. Management of growth hormone secretion through the use of peptides and other

compounds generally increases the amplitude and frequency of growth hormone release within physiologic boundaries.

CHARACTERISTICS OF GH DEFICIENCY

Anabolic Tone
- Reduced lean body mass and/or skeletal muscle mass
- Reduced skeletal muscle strength
- Reduced exercise performance
- Increased total body fat
- Increased abdominal and visceral fat

Lipid Effects
- Elevated LDL cholesterol
- Decreased HDL cholesterol
- Elevated apolipoprotein-B

Bone Effects
- Osteopenia (lack of bone)

Metabolic Effects
- Insulin resistance (in obese people)
- Hypoglycemia
- Possible abnormal resting metabolic rate
- Reduced T4 to T3 conversion

Protein Synthesis
- Thin skin
- Lack of collagen
- Decreased size of organs
- Decreased nail and hair growth

Dehydration
- Reduced glomerular filtration and renal plasma flow
- Reduced sweating – inability to thermoregulate
- Reduced cardiac output (potentially)
- Increased vein resistance

Mental Health
- Reduced energy
- Emotional instability
- Poor memory and concentration
- Depression
- Lack of social interaction
- Lack of purpose
- Reduced sex drive

Physiologic effects associated with growth hormone are accomplished primarily through the function of IGF-1. Circulating GH (1/2 life = 20 minutes) stimulates the liver and other tissues to release IGF-1 (1/2 life = 20 hours). Serum IGF-1 levels are more sustained, and therefore a more practical indicator of growth hormone status.

AREAS OF IGF-1 ACTIVITY
- Synthesized by Leukocytes
- Restores Lymphoid Organ Size
- Stimulates Proliferation of Leukemic Blasts and T Lymphocytes
- Increases Uptake and Degradation of LDL by Macrophages
- Estrogens Influence Formation of IGF-1 and IGF-1 BP's
- Nitrogen Retention/Sodium Excretion
- Parathyroid-Vitamin D Axis
- Increased Circulating Osteocalcin
- Increased Urinary Hydroxyproline Secretion
- IGF-1 Levels Do Not Exhibit Diurnal Variations
- IGF-1 Measurements Reflect Integrated GH Secretion and Bioactivity
- Average 1/2 Life of IGF: 20 Hours

There are several known factors that affect GH release and IGF-1 response, including insulin regulation, somatotroph receptors, GHRH, somatostatin, hepatic function, and IGF-1 receptor sites. Pharmacologically correlating these factors with the action of anterior pituitary peptides, a sequenced glycoamino acid complex, a plant-derived source of L-Dopa, and botanical regulators of insulin and IGF-1 has led to the development of Symbiotropin, a promoter of GH release and IGF-1 formation. Clinically, the efficacy of Symbiotropin has been evaluated through IGF-1 measurement and patient self-assessment.

Method

36 patients, 18 women and 18 men, were selected for this study based on IGF-1 measurements that indicate GH deficiency. Initial IGF-1 measurements ranged from 21 to 276. Patients were instructed to take two

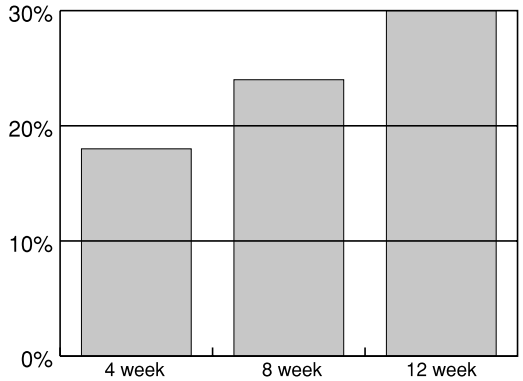
Symbiotropin effervescent tablets dissolved in water four hours after the last meal and prior to retiring. This schedule was maintained in five-day cycles, with two days separating each cycle for a term of twelve weeks.

IGF-1 levels were measured before the onset of Symbiotropin therapy and then at four week intervals. Patient self-assessments were performed every four weeks throughout the twelve week term. Additional clinical observations were made during routine office visits.

Results

The results of patient self-assessments indicate symptomatic response to Symbiotropin within the first four weeks in all patients, with continued improvement between the fourth and twelfth week. Improved energy, endurance, and body composition were among the most frequently reported improvements within the first four weeks. New hair growth, restoration of hair color, thickening of skin, and disappearance of skin discoloration generally occurred between the eighth and twelfth weeks, with continued improvement beyond the twelve week term. It should be noted that the results of this patient self-assessment are not adjusted for areas that did not apply to each individual.

Average increase in IGF1 throught first 12-week cycle of Symbiotropin



No side effects were observed that could be attributed to Symbiotropin. One female patient was removed from the study due to a citric acid allergy that was aggravated by Symbiotropin.

Patients % Reported Improvement with Symbiotropin

Area of Assessment	Month Three
Endurance & Body Composition	
Muscle Strength	58%
Muscle Size	42%
Fat Reduction	68%
Overall Energy	74%
Exercise Tolerance	58%
Exercise Endurance	68%
Hair & Skin	
Skin Texture	47%
Skin Thickness	32%
Skin Elasticity	26%
Wrinkle Disappearance	37%
New Hair Growth	47%
Healing & Immunity	
Healing of old injuries	26%
Healing of other injuries	21%
Healing Capacity	21%
Back & Joint Flexibility	37%
Resistance to Common Illness	47%
Sexual Function	
Sexual Potency/Frequency	32%
Duration of Penile Erection	44%
Frequency of Nighttime Urination	66%
Mental Function	
Mental Energy & Clarity	53%
Emotional Stability	42%
Attitude Toward Life	37%
Memory	47%

IGF-1 measurements indicate continued increases in IGF-1 throughout the twelve week term. Measurements taken during the first four weeks indicate increases of over 200% and averaging over 18%. Eight week measurements indicate increases of over 100% and averaging 24%. Twelve week measurements indicate a 30% average increase in IGF-1. Rate of symptomatic response occurred independent of the rate of IGF-1 increase.

Conclusion

Symbiotropin appears to offer benefits that are similar to those found with hGH injections. Symptomatic improvements generally occur more rapidly and with fewer side effects. Cost is approximately 1/10 of hGH injections, while the convenience of a drink allows for greater compliance.

Symptomatic improvements with Symbiotropin, which were not included in the patient self-assessment indicate that its therapeutic potential may exceed that of hGH injections. Consistent and significant improvement in diabetes, BPH, hypertension, cardiomyopathy, pulmonary disorders, rheumatism, Crohn's disease, obesity, and chronic fatigue syndrome, all warrant further investigation into Symbiotropin's therapeutic potential.

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