Dr. Steven Santiago received his BS from City College of New York and his MD from the State University of New York at Stony Brook Medical School. He completed his residency in family practice at the University of Medicine and Dentistry of New Jersey/Robert Wood Johnson Medical School in New Brunswick, NJ. Dr. Santiago is board certified in family practice and is a fellow of the American Academy of Family Physicians. He is currently chief medical officer at Care Resource, South Florida's largest nonprofit AIDS service organization. He directed the research program at Care Resource and has functioned as principal investigator for numerous HIV-related clinical trials. An active member of the HIV education community, Dr. Santiago speaks frequently to patient groups as well as to physicians and allied health professionals.

Clinical Conversations in HIV-Associated Wasting

A brief discussion with Steven Santiago, MD

INDICATIONS AND USAGE

Serostim® (somatropin) for injection is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Acute Critical Illness: Serostim® should not be initiated in patients with acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure.

Active Malignancy: Somatropin is contraindicated in the presence of active malignancy. Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with somatropin. Discontinue somatropin if there is evidence of recurrent activity.

Hypersensitivity: Serostim® is contraindicated in patients with a known hypersensitivity to somatropin or any of its excipients. Systemic hypersensitivity reactions have been reported.

Diabetic Retinopathy: Somatropin is contraindicated in patients with active proliferative or severe non-proliferative diabetic retinopathy.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Serostim®
(somatropin) for injection

A brief discussion with Steven Santiago, MD

Q: Can you tell us about a patient you've treated for HIV-associated wasting?

A: I've been caring for a 50-year-old Hispanic male who is originally from Latin America. He was diagnosed with advanced AIDS shortly after arriving in the United States in the early 2000s. When he came to us for care in 2004, he only mentioned a five-pound weight loss. Since it was only five pounds and the patient was about to start on antiretrovirals, this was not concerning to me at the time. He was always pretty active, especially due to his valet parking job, which kept him running around.

He went almost a year without being seen, but he continued to take his medication. When I did see him, his weight had dropped again, and he had a BMI of 19.2—this was eye-opening. When I questioned him about the weight loss, he blamed it on having increased stress caused by his partner and some financial problems. He also complained of fatigue, which was not unusual for him. He typically complained of fatigue, decreased endurance, and trouble concentrating, which can be attributed to depression, anxiety, anhedonia, and just generally being overworked from his valet job. In addition, he had low self-esteem associated with his weight loss, as well as poor appetite.

Q: Were you concerned about his weight loss and fatigue?

A: We were both concerned, but decided together to continue to observe the symptoms and rule out other contributing factors before looking into further treatments.

Q: Did you see any improvement?

A: Over the next couple of visits, we noticed an increase in his weight, which I attributed to the interventions to increase his weight and caloric intake. However, he was still below his baseline and continued to experience poor self-esteem due to the weight loss, as well as decreased strength and endurance.

His wasting got worse, even though we were addressing the underlying issues. In 2012, he was in the 160s, and 2015 he dropped to 138, so in my mind, there was no question that he was wasting.

Q: When did you decide to prescribe Serostim® (somatropin) for injection to this patient?

A: Ideally, I would have started this patient on Serostim® when he first expressed the weight loss. Instead, I waited and treated him with other modalities.

Q: What did you take away from this experience?

A: We oftentimes forget about HIV-wasting manifestations, because most of our patients are viralogically controlled. If I had tried to get him on Serostim® earlier, I believe it would have improved his weight, energy, and decreased his fatigue. His HIV-associated wasting was not actively addressed for many years post diagnosis. He came to see us complaining of fatigue, weight loss and, and lack of endurance, but we attributed it to the fact that he was working 16 hours a day. It distracted me from the possibility that it was really HIV-related. Looking back, had I been more aggressive or thought about HIV-associated wasting, I could have prescribed Serostim® at that time, but I didn't think of it and decided to wait instead.

Q: How did this affect your strategy for treating HIV-associated wasting moving forward?

A: HIV-associated wasting is something I now look for earlier on, and I am much more aggressive about treating. Nowadays, we have electronic medical records, which make it much easier to track a patient's symptoms, such as weight loss and fatigue, with all the information we need in one place. This helps us to facilitate proactive discussions about weight and energy, and greatly improves quality of care.

If I had a patient today in a similar situation with unintentional weight loss, I would be much more aggressive with ruling out other possible factors, and then prescribing Serostim® as soon as they met the criteria, instead of waiting to see if I could resolve the problems with other means. I would immediately start an evaluation to rule out other causes to determine if Serostim® is an appropriate treatment.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Acute Critical Illness: Increased mortality (42% vs 19% in somatropin compared to placebo treated) in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic amounts of somatropin.

Patient Case

Clinician's observation: "We oftentimes forget about HIV-associated wasting manifestations because most of our patients are virologically controlled."

PATIENT PROFILE

50-year-old male diagnosed with HIV/AIDS in 2003. Shortly after diagnosis, patient experienced a nominal weight loss. For approximately 12 years, his viral load remained stable. In 2015, he experienced weight loss and a decrease in BMI. In addition to weight loss, the patient reported fatigue and low self-esteem due to his physical appearance. Initial interventions to increase his weight resulted in minimal weight gain. Serostim® (somatropin) for injection was prescribed to further address his weight loss and associated persistent fatigue.

RELEVANT MEDICAL HISTORY

- HIV+; AIDS (2003)
- Depression/anxiety disorder
- HSV-2

SOCIAL HISTORY

- Employed as a valet
- In a committed relationship

WEIGHT HISTORY

- Height: 5'11"
- Premorbid weight: 175 lb
- Premorbid BMI: 24.4
- Weight at HIV-associated wasting diagnosis: 138 lb
- BMI at HIV-associated wasting diagnosis: 19.2

OVERVIEW OF SYMPTOMS AT TIME OF HIV-ASSOCIATED WASTING DIAGNOSIS

- Weight loss
- Constant fatigue
- Decreased energy
- Depression; anxiety
- Anhedonia
- Low self-esteem associated with weight loss
- Poor appetite

SCREENING

- Anal PAP: Abnormal (low-grade squamous intraepithelial lesion)
- Sleep study: Organic circadian rhythm sleep disorder; insomnia due to anxiety disorder
- Gonorrhea and chlamydia throat/rectal culture: Not detected
- Hepatitis: Negative

LABORATORY RESULTS

- CD4-cell count: 214 cells/mm^3
- Viral load: Undetectable
- Testosterone levels: Below normal range
- Stool studies: Normal
- TSH: Within normal limits
- LDH: Within normal limits

ULTRASOUND IMAGING

- Testicular ultrasound: Benign mass in right testis
- Prostate: Enlarged; negative for masses

TREATMENT HISTORY

- Testosterone replacement therapy
- Appetite stimulants

This case study represents a real patient of Dr. Santiago, however, it may not be a complete representation of the individual's entire medical case or include his full experience with Serostim®. Certain details such as concomitant medications, dose adjustments, and adverse reactions may not be reflected. For more information obtained from clinical trials and unsolicited post-marketing reporting of adverse experiences, refer to the Important Risk Information throughout and see enclosed Full Prescribing Information.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Concomitant Antiretroviral Therapy: Somatropin has been shown to potentiate HIV replication in vitro, and there was no increase in virus production when antiretroviral agents were added to the culture medium. No significant somatropin-associated increase in viral burden was observed. All patients received antiretroviral therapy for the duration of treatment during Serostim® clinical trials.

Neoplasms: Patients with preexisting tumors should be monitored for progression or reoccurrence. Monitor patients on somatropin therapy carefully for preexisting nevi.

Please see additional Important Safety Information continued on the back and click here for full Prescribing Information.

Patients' Perceptions

Patients' perceptions of the impact of 12 weeks of treatment on their wasting symptoms as assessed by the Bristol-Meyers Anorexia/Cachexia Recovery Instrument improved with both doses of Serostim® (somatropin) for injection in Clinical Trial 2.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Impaired Glucose Tolerance/Diabetes: Patients with other risk factors for glucose intolerance should be monitored closely during Serostim® therapy. Cases of new onset impaired glucose tolerance, new onset type 2 diabetes, and exacerbation of preexisting diabetes have been reported in patients receiving Serostim®. Some patients developed diabetic ketoacidosis and diabetic coma and, in some, improved when Serostim® was discontinued and in others persisted. Some of these patients required initiation or adjustment of antidiabetic treatment.

Intracranial Hypertension: Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported usually within the first 8 weeks of somatropin therapy and rapidly resolved after stopping or reducing the somatropin dose. Funduscopic examination should be performed prior to initiating treatment with somatropin and periodically during treatment. If papilledema is observed, treatment should be stopped and restarted at a lower dose after IH-associated symptoms have resolved.

Severe Hypersensitivity: Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with postmarketing use of somatropin products. Patients and caregivers should be informed that such reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs.

Fluid Retention/Carpal Tunnel Syndrome: Increased tissue turgor (swelling, particularly in the hands and feet) and musculoskeletal discomfort (pain, swelling and/or stiffness) may occur during treatment with Serostim®, but may resolve spontaneously, with analgesic therapy, or after reducing the frequency of dosing. Carpal tunnel syndrome may occur and if the symptoms of carpal tunnel do not resolve by decreasing the weekly number of doses, it is recommended that Serostim® treatment be discontinued.

Skin Atrophy: Rotate the injection site to avoid tissue atrophy.

Pancreatitis: Cases of pancreatitis have been reported rarely. Consider pancreatitis in patients who develop persistent severe abdominal pain.

ADVERSE REACTIONS

In clinical trials in HIV-associated wasting or cachexia the most common adverse reactions (incidence >5%) were arthralgia, myalgia, peripheral edema, arthrosis, nausea, paresthesia, generalized edema, gynecomastia, hypoesthesia and fatigue.

SPECIAL POPULATIONS:

Somatropin should be used during pregnancy only if clearly needed and with caution in nursing mothers because it is not known whether somatropin is excreted in human milk. The safety and effectiveness of somatropin in pediatric patients with HIV have not been established. Clinical studies did not include sufficient numbers of subjects > 65 to determine a response different from that of younger patients. Studies have not been conducted in patients with hepatic or renal impairment. Gender-based analysis is not available.

Please click here for full Prescribing Information.

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