

Visceral Fat (Hard Belly) and HIV: Improving Patients' Lives

By Gary S. Wolfe, RN, CCM

State of HIV Disease

HIV and AIDS have been part of the world's consciousness for more than 40 years now. In 1981, the first cases of HIV/AIDS were reported. At the end of 2018, it was estimated that 1.2 million people in the United States were living with HIV infection and that about 14% of those individuals didn't know they were infected.¹ HIV disease is reasonably controlled in the United States. For individuals who receive an early diagnosis and can be treated, the news is mostly good. Half of those living with HIV infection are over 50 years old, and the number of individuals over 50 years who are living with HIV infection will continue to increase. Life expectancy for HIV-positive individuals over 50 years is nearly as long as for those in the general population. HIV-positive patients who were acutely ill once had limited treatment options and were given a death sentence, but today HIV disease is managed as a chronic disease. The focus of treatment is on controlling the viral load and treating the comorbidities that impact HIV disease progression and quality of life.

The most significant advance in the medical management of HIV disease was the introduction of antiretroviral therapy in 1995. The number of deaths due to HIV infection peaked in 1995, declined thereafter, and have continued to decline.² The cause of death in HIV-positive patients has shifted from AIDS to non-AIDS-related malignancies and other causes such as liver disease, cardiovascular events, non-AIDS-defining infections, suicide, and unexplained sudden death. The health of HIV-positive individuals is affected by health problems commonly associated with aging.³ These conditions include:

- Cardiovascular events
- Renal impairment
- Fractures/osteoporosis
- Hypertension
- Diabetes
- Obesity
- Hyperlipidemia
- Cognitive decline

There are significantly higher age-associated noncommunicable comorbidities among HIV-positive than HIV-negative individuals over 50 years old.

HIV infection is better suppressed in patients today than in the past, and life expectancy for HIV-positive patients has dramatically increased because of medication and therapy; thus, the focus and challenge for many HIV-positive patients is to manage the side effects of HIV infection and treatment as well as other comorbidities associated with aging.

Managing HIV infection

Goals for HIV-positive patients are multifaceted, focusing on adherence to a treatment plan as well as prevention and management of long-term and chronic conditions. These conditions may include:

- High cholesterol
- Diabetes
- Heart disease
- Renal disease
- Depression
- Lipodystrophy

These conditions are not isolated; a patient may have several of these conditions simultaneously.

The first focus on treatment of HIV-positive patients is on viral suppression. Is the HIV viral load suppressed and undetectable? If not, why? Is the patient taking the right antiretroviral therapy? Does the treatment need to be changed? Is the patient adherent to the medication? Is the patient taking the medications as prescribed? This is a critical factor. If the patient is not taking the medications as prescribed, why not? Factors in nonadherence include cost, availability, convenience, and side effects. These causes must be addressed. One important consideration in patient adherence is side effects, and lipodystrophy is one of the important side effects of treatment for HIV infection.

Lipodystrophy

Lipodystrophy is defined as a change in body fat. There are three types of changes in fat associated with HIV infection.⁴

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Lipodystrophy is one of the important side effects of treatment for HIV infection.

- Lipatrophy—peripheral fat loss such as in the arms and legs
- Lipohypertrophy—localized fat accumulation
 - Usually seen as:
 - Dorsocervical area—fat pad between the shoulders commonly referred to a buffalo hump
 - Breast enlargement
 - Lipomas—benign fat tissue deposits just under the skin
 - Intra-abdominal compartment or visceral fat
- Mixed lipodystrophy: Lipatrophy and lipohypertrophy

The exact mechanism of HIV-associated lipodystrophy is not fully understood. It is believed that adipose tissue may be a reservoir for HIV, altering the local tissue environment and promoting tissue inflammation.⁵ There is some evidence that HIV-associated lipodystrophy can be caused by antiretroviral therapy (ART),⁶⁻⁸ but the role of ART in fat gain remains uncertain.⁴

There is a difference between hard belly fat (visceral fat) and subcutaneous adipose tissue (obesity). Visceral fat is deep in the visceral tissue of the abdomen, surrounding internal organs. Subcutaneous adipose tissue is fat that is beneath the skin but outside the abdominal wall. Visceral fat can be evaluated by a computed tomography scan, by waist circumference, by hip circumference, and by the waist-to-hip ratio (waist circumference/hip circumference). Subcutaneous adipose tissue is usually evaluated using a body mass index of ≥ 30 kg/m².

Excess visceral fat in HIV-positive patients has been linked to dyslipidemia, insulin resistance, nonalcoholic fatty liver, cardiovascular disease, and impaired cognition.⁵ Visceral fat impacts HIV-positive patients physically and psychologically (Table 1).

Table 1. IMPACT OF EXCESS VISCERAL FAT IN HIV-POSITIVE PATIENTS	
Physical effects	Psychological effects
Bloating	Impaired physical functioning
Difficulty bending	Decline in physical health-related quality of life
Feel like there is a soccer ball in my stomach	Reduced ability to perform some activities of daily living
Difficulty breathing	Less satisfaction with body image
Sleep apnea	<ul style="list-style-type: none"> • Increased stigmatization • Increased anxiety and depression

Although the exact causes of excess belly fat in HIV-positive patients are not yet known, some evidence suggests that the following are contributing factors:⁹

- HIV itself
 - High viral load and low CD4 count
 - Length of HIV infection
- Chronic inflammation
- Antiretroviral therapy
 - Length of use
- Endocrine alterations
 - Local cortisol production
 - Relative growth hormone deficiency/growth hormone resistance

Other contributing factors to excess belly fat include age, gender (female), genetics, and high body mass index.¹⁰ The number of HIV-positive patients with excess body fat is difficult to determine but is estimated to be between 10% to 30% of those infected.

Visceral fat is linked to inflammation, which contributes to high cholesterol, diabetes, liver disease, heart disease, and impaired cognition. Visceral fat can affect life expectancy, and those living with visceral fat may have an increased risk of death.¹¹ Visceral fat is associated with a higher risk of cancer, cardiovascular disease, and liver disease. It is also linked to increased inflammation in the body, which can cause other health conditions.

Patient Assessment

The patient may be the first to notice any change in their body fat and may present with any of the following complaints:

- My fat feels hard and it’s difficult to pinch it
- I have trouble bending over to put on my socks
- I have no energy
- I get short of breath going up and down steps
- My belly fat doesn’t feel normal
- My waist has gotten wider over time
- The change in the size and shape of my belly has affected the way my clothing fits
- I cannot get rid of my excess belly fat with diet and exercise alone

The provider’s assessment should include a medical history, a physical examination, manual palpation of skin fold thickness, measurement of waist and hip circumference, and calculation of the waist-to-hip ratio.

Visceral fat is linked to inflammation, which contributes to high cholesterol, diabetes, liver disease, heart disease, and impaired cognition. Visceral fat can affect life expectancy, and those living with visceral fat may have an increased risk of death.

Treatment

After assessment and discussion with the patient, the provider should offer treatment options for lipodystrophy. Options include changing the patient's HIV (ART) medication, recommending a change to the patient's diet and exercise regimen, or drug therapy. Changing patients' HIV (ART) medication and/or changing their diet and exercise regimens have shown inconsistent results for treating lipodystrophy.¹¹ *EGRIFTA SV*[®] is the only medication approved by the U.S. Food and Drug Administration for HIV-positive patients with lipodystrophy.

EGRIFTA SV[®] (tesamorelin for subcutaneous injection)

EGRIFTA SV[®] is a growth hormone-releasing factor analog indicated for the reduction of excess abdominal fat in HIV-positive adult patients with lipodystrophy. *EGRIFTA SV*[®] is self-administered as a subcutaneous injection once a day. *EGRIFTA SV*[®] may help reduce excess visceral fat by helping the body to naturally release its own growth hormone.¹²

EGRIFTA SV[®] is contraindicated in patients:

- Who have pituitary gland tumor, pituitary gland surgery, or other problems related to the pituitary gland
- Who have active cancer
- Who are allergic to tesamorelin or any of the ingredients in *EGRIFTA SV*[®]
- Who are pregnant

Warnings and precautions include:

Neoplasms: Preexisting malignancy should be inactive and its treatment should be complete before starting *EGRIFTA SV*[®].

Elevated insulin-like growth factor 1: Monitor regularly in all patients. Consider discontinuation in patients with persistent elevations.

Fluid retention: May include edema, arthralgia, and carpal tunnel syndrome

Glucose intolerance: May develop with *EGRIFTA SV*[®] treatment. Evaluate glucose status before and during therapy with *EGRIFTA SV*[®].

Hypersensitivity reactions: Advise patients to seek immediate medical attention if suspected.

Injection site reaction: Advise patient to rotate sites.

Acute critical illness: *EGRIFTA SV*[®] has not been studied in

patients with acute critical illness. Increased mortality in critically ill patients has been reported in patients treated with pharmacological doses of growth hormone. Since *EGRIFTA SV*[®] stimulates the production of growth hormone, consider discontinuation in critically ill patients.

There are considerations for use of *EGRIFTA SV*[®] in specific populations.

For nursing mothers: Because of both the potential for transmission of HIV-1 infection and serious adverse reactions in nursing infants, mothers receiving *EGRIFTA SV*[®] should be instructed not to breastfeed.

For pediatric use: The safety and effectiveness in pediatric patients have not been established.

For renal and hepatic impairment: Use in patients with renal and hepatic impairment have not been studied.

For geriatric use: There is no information on use in geriatric patients >64 years of age.

The most commonly reported adverse reactions to *EGRIFTA SV*[®] include hypersensitivity reactions, arthralgia, injection site erythema, injection site pruritus, pain in extremity, peripheral edema, and myalgia.

The safety and efficacy of *EGRIFTA SV*[®] has been demonstrated in two studies. In Study 1, 412 HIV-positive patients with lipodystrophy and excess abdominal fat were randomized to receive either a 2-mg dose of *EGRIFTA SV*[®] or placebo. In Study 2, 404 HIV-positive patients with lipodystrophy and excess abnormal fat were randomized to receive either a 2-mg dose of *EGRIFTA SV*[®] or placebo. Study 1 and Study 2 consisted of a 26-week main phase and a 26-week extension phase, respectively. *EGRIFTA SV*[®] reduced HIV-related excess visceral fat at 6 and 12 months. In Study 1, visceral adiposity was reduced 18% and 14% at 6 and 12 months, respectively. In Study 2, visceral adiposity was reduced 17% and 18% at 6 and 12 months, respectively. Many patients taking *EGRIFTA SV*[®] daily saw reductions in their visceral fat by 13 weeks. Although some patients may not see a significant reduction in their visceral fat after 1 year, patients who stopped taking *EGRIFTA SV*[®] after 6 months had their HIV-related excess belly fat return. During Study 1 and 2, patients reported less distress associated with their belly appearance.¹³

Complete product information including full prescribing information, patient information, and patient instructions for use of *EGRIFTA SV*® is available at egriftasv.com.¹²

Case Management

According to the Case Management Society of America's Standards of Practice for Case Management, the foundation of case management is based on the fact that when a patient reaches the optimum level of wellness and function, everyone benefits: patients, support systems, health care delivery systems, and reimbursement sources.¹⁴ Case management focuses on advocacy, communication, education, identification of resources and services, and evaluation. Steps in the case management process include assessment/problem identification, development of a plan, implementation and coordination, and evaluation. The case manager educates the client and support system and advocates for positive outcomes.

The case manager role and function for HIV-positive patients with visceral fat is important for positive patient outcomes. The case manager facilitates communication between the patient, support system, and providers, helping to ensure that the patient receives the most efficient and effective care to achieve the desired outcomes.

The first step in the case management process is assessment. Assessment is a continuous process throughout the continuum of disease. If you are managing a relatively newly diagnosed patient with HIV infection, the assessment should include baseline information so that over time you can evaluate change. The initial assessment should include a medical history including viral load and CD4 cell count and a medication history including adherence to the medication regimen. The patient's appearance, weight, waist circumference, hip circumference, waist-to-hip ratio, social history, and mental health status should also be assessed.

The next step is the development of the case management plan in consultation with the patient and provider. If it is early in the patient's HIV-infection diagnosis, the plan may be to monitor for visceral fat. Education is an important component of the plan. This is the time the case manager can start educating the patient about visceral fat. Remember that patients may be the first to recognize changes in their body. Educating patients early reduces apprehension and anxiety and encourages early treatment without affecting quality of life. Education should include a definition of visceral fat as well as the pathophysiology, signs, symptoms, and treatment of visceral fat. One of the best tools the patient can use in monitoring signs and symptoms of visceral fat is the waist-to-hip ratio. The case manager should teach their patient how to measure this ratio. The patient should wrap the tape measure

around his/her waist at the belly button so that it is parallel to the floor. The hip measurement should be taken at the widest part of the hip—the greatest protrusion of the buttocks. The ratio is calculated by the waist circumference divided by the hip circumference.

The waist-to-hip ratio is abnormal if:

- For men: >.94
- For women: >.88

The case manager can provide a log for the patient to document the waist-to-hip ratio. By monitoring the log over time, it will be easy to recognize the development of visceral fat.

As the case management plan is implemented, the case manager continually monitors the patient's progress. The case manager works with the provider and patient to achieve the mutually agreed patient outcomes. Part of the education process is to also educate the provider. The provider may not be familiar or knowledgeable about visceral fat and the treatment. This is an excellent time for the case manager to educate the provider.

As the signs and symptoms of visceral fat appear, the case manager advocates for the patient. The case manager ensures that relevant data has been reported to the provider. The patient should take the chart of waist-to-hip ratio to each provider visit.

If the provider prescribes *EGRIFTA SV*®, the case manager works with the patient's pharmacist to ensure that the patient is taught how to administer the medication. Although *EGRIFTA SV*® is a simple daily injection, some patients may have barriers to overcome. Barriers may include fear of self-injection, fear of needles, drug availability, drug storage, disposal of the syringe, knowing how to administer the medication, and knowing how to prepare the medication for injection. For the patient to be successful, all barriers must be overcome. The barriers can be overcome with education and talking through the barriers. A Step-By-Step Administration Guide as well as other patient education resources are available on the [EGRIFTA SV](http://egriftasv.com)® website. The case manager provides support and education with regard to the administration of *EGRIFTA SV*® to ensure patient adherence.

The recognition, diagnosis, and treatment of visceral fat in HIV-positive patients is important in improving lives. Empowering HIV-positive patients to stay healthy as they age is best accomplished when the patient adheres to the ART regimen and when the case manager is supportive in managing the patient's comorbidities and side effects. The case manager plays an important role in advocating and educating the patient, their support system, and their providers. Working together, mutual goals can be achieved.

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Questions

- At the end of 2018 in the United States, how many people were estimated to be living with HIV infection?**
 - 1 million
 - 1.1 million
 - 1.2 million
 - 1.5 million
- The health of HIV-positive individuals is affected by which of the following health problems commonly associated with aging?**
 - Obesity
 - Hyperlipidemia
 - Cardiovascular events
 - All of the above
- The primary focus on the treatment of HIV-positive patients is on viral suppression.**
 - True
 - False
- Treatment goals for HIV-positive patients focus on prevention and management of which of the following chronic conditions?**
 - Lipodystrophy
 - Heart disease
 - Depression
 - All of the above
- Lipodystrophy is defined as a change in body fat.**
 - True
 - False
- Lipohypertrophy is usually seen as which of the following?**
 - Fat pad between the shoulders
 - Breast enlargement
 - Visceral fat
 - All of the above
- There is no difference between visceral fat and subcutaneous adipose tissue.**
 - True
 - False
- Excess visceral fat has been linked to which of the following?**
 - Insulin resistance
 - Impaired cognition
 - Cardiovascular disease
 - All of the above
- Evidence suggests that the following are contributing factors to excess visceral fat in HIV-positive patients:**
 - HIV itself
 - Chronic inflammation
 - Antiretroviral therapy
 - All of the above
- What percentage of HIV-positive patients is estimated to have excess visceral fat?**
 - 5%–10%
 - 10%–20%
 - 10%–30%
 - 15%–30%
- Treatment options for excess visceral fat include which of the following?**
 - Change in HIV medication
 - Change in patient's diet and exercise regimen
 - Drug therapy
 - All of the above
- EGRIFTA SV[®] is the only growth hormone-releasing factor analog indicated for the reduction of excess visceral abdominal fat in HIV-positive patients that is approved by the U.S. Food and Drug Administration.**
 - True
 - False
- One of the best tools a patient can use in monitoring signs and symptoms of visceral fat is the waist-to-hip ratio.**
 - True
 - False

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Objectives

November 2020

- a. Define lipodystrophy.
- b. State 4 factors that contribute to excess visceral fat in HIV-positive patients.
- c. State 3 treatments for lipodystrophy in HIV-positive patients.

Answers

Please indicate your answer by filling in the letter:

1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8. _____ 9. _____ 10. _____ 11. _____ 12. _____ 13. _____

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