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Contents

I COMPLICATIONS AND SIDE EFFECTS

A. HIV-related neurocognitive problems in the time of HAART

The United States National Institutes of Mental Health and Neurological Diseases commissioned a large study to assess HIV-related neurologic problems, including the severity and risk factors associated with them. This study is called CHARTER (the CNS HIV Antiretroviral Therapy Effects Research). Scientists with CHARTER have recently published their neuromedical, psychiatric and neuropsychological examinations of over 1,500 HIV-positive people from several university-based clinics across the United States. Their findings suggest that severe HIV-associated neurocognitive impairment (dementia) was rare. This should not be surprising, as potent anti-HIV therapy, commonly called ART or HAART, can greatly suppress production of HIV. However, milder forms of neurocognitive impairment (NCI) were common even among people without other co-existing health conditions (diabetes, heart attack, hepatitis C virus infection).

Study details

Researchers recruited 1,555 HIV-positive people from the following academic medical centres in the following cities:

- Baltimore, Maryland
- Galveston, Texas
- New York City, New York
- San Diego, California
- Seattle, Washington

Participants were extensively interviewed and underwent many tests and medical examinations. Blood was drawn and 1,205 participants consented

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to have spinal taps to assess their cerebrospinal fluid (CSF).

The basic profile of CHARTER participants was as follows:

- 23% females, 77% males
- age – 43 years
- 28% were injection drug users, 58% were men who had sex with men and 31% were heterosexual (numbers do not total 100% because some categories overlap)
- 63% had AIDS in the past
- nadir (lowest-ever) CD4+ count – 174 cells
- current CD4+ cell count – 420 cells
- currently taking HAART – 71%
- proportion with detectable HIV in blood – 59%
- proportion with detectable HIV in CSF – 34%

Results—The good news

Researchers found that a substantially lower rate of neurocognitive impairment was seen (30% vs. 47%) in HAART users with an undetectable viral load in the blood and whose CD4+ count had never fallen below the 200-cell mark in the past.

HIV-related dementia was rare in the CHARTER study, with only about 2% of participants having this problem. This finding arose because of the benefit of HAART; in the pre-HAART era, rates of HIV-related dementia ranged between 10% and 15% in several studies.

Results—Other findings

Despite this good news, researchers found that about 44% of participants in CHARTER who did not have dementia or serious co-morbidities had milder forms of HIV-related neurocognitive impairment.

Persistence

Researchers are not sure why neurocognitive impairment persisted despite the use of HAART. However, they do provide several possible explanations, as follows:

- Active viral replication
  About 44% of participants who were taking HAART had a viral load in the blood greater than 50 copies/ml. Researchers stated that "extended survival with incomplete viral suppression" likely allows inflammation triggered by HIV infection to adversely affect the brain. Perhaps continued inflammation slowly degrades the brain.
- Weakened immune systems
  Participants with a history of severe immunosuppression—that is, having less than 200 CD4+ cells at some point in the past—appear to confer an increased risk for neurocognitive impairment. Furthermore, this problem persisted even after CD4+ counts rose above the 200-cell mark when HAART was initiated. In CHARTER, volunteers whose CD4+ counts never fell below the 200-cell mark and who did not have significant co-existing health complications and whose viral load in the blood fell below the 50-copy/ml mark had "much lower rates of [neurocognitive] impairment."

What's next?

The CHARTER study assessed a huge number of HIV-positive people only at one point in time. Such studies have a cross-sectional design and can find associations that need to be further explored in clinical trials of a more robust statistical design.

Scientists affiliated with CHARTER suggest that randomized clinical trials are needed in order to find the best combination of anti-HIV drugs that can help the brain cope with HIV infection. Such trials should investigate the impact of reducing HIV levels in the blood and brain and reducing inflammation. They should also investigate the impact of treating co-existing health conditions so that the overall health and quality of life of HIV-positive people can be improved.

These trials will need to last for several years and, in addition to the well-validated neuropsychological tests employed in CHARTER, newer non-invasive assessments such as functional magnetic resonance imaging need to be considered.

The results of CHARTER underscore the need to prevent and treat co-existing health conditions—including cardiovascular disease, diabetes, hepatitis C virus infection, substance use—because they can also degrade a person's neurocognitive abilities.

RESOURCES:

Further reports on understanding how HIV infection can affect the brain and potential ways of maintaining brain health are explored in several recent *CATIE News* bulletins available at: www.catie.ca/catienews.nsf/CATIE-NEWS

The Winter 2010 issue of *Positive Side* magazine features a first-person article by activist Maggie Atkinson on the topic of neurocognitive problems in HIV. You can read about her experience and what she learned about protecting her brain below:
www.positiveside.ca/e/V11I2/Mind_e.htm

REFERENCES:

1. Heaton RK, Clifford DB, Franklin DR Jr., et al. HIV-associated neurocognitive disorders persist in the era of potent antiretroviral therapy: CHARTER Study. *Neurology*. 2010 Dec 7;75(23):2087-96.

2. Cohen RA, Gongvatana A. The persistence of HIV-associated neurocognitive dysfunction and the effects of comorbidities. *Neurology*. 2010 Dec 7;75(23):25202-3.

B. Is HIV associated with accelerated aging of organs?

As the body ages, it naturally degrades. In the setting of HIV infection there are concerns that HIV somehow speeds up the decline of several organ systems. Researchers at the University of Modena and elsewhere in Italy have conducted a study comparing the health status of several thousand HIV-positive people with that of HIV-negative people of similar age, sex and ethnicity. Their review suggests that HIV infection appears to be associated with accelerated aging and that higher-than-normal blood pressure may be a common factor that plays a role in this problem.

Study details

Researchers recruited volunteers between 2002 and 2009:

- 2,854 HIV-positive people taking anti-HIV therapy
- 8,562 HIV-negative people of similar age, sex, ethnicity and geographic location

Each HIV-positive person's medical history was matched to the medical histories of several similar HIV-negative persons whose data were used for purposes of comparison. In total, data from 11,416 people were used for this analysis.

The research team focused on the following non-infectious co-morbidities:

- cardiovascular disease
- type 2 diabetes
- higher-than-normal blood pressure
- kidney disease
- bone fractures

The approximate profile of HIV-positive people enrolled in this study was as follows:

- 37% females, 63% males
- age – 46 years
- time since diagnosis of HIV – 16 years
- nadir (lowest-ever) CD4+ count – 170 cells
- current CD4+ count – 544 cells
- proportion of participants with a viral load less than 50 copies/ml – 71%

Results

Striking differences emerged between HIV-positive and HIV-negative people when researchers assessed rates of co-morbidities. For instance, co-morbidities were generally more common in HIV-positive people of a given age range than in HIV-negative people of a similar age range. Using one age range as an example, among people aged 40 years and under, cases of cardiovascular disease (heart attack, stroke), bone fractures and kidney damage were evident among some HIV-positive people but relatively absent among HIV-negative people. For all age ranges, HIV-positive people tended to have more instances of co-morbidities than HIV-negative people:

Furthermore, the risk of having two or more of the specific co-morbidities studied (referred to as polypathology by the Italian researchers) seemed to be greater in HIV-positive people than in HIV-negative people. The net effect of HIV infection was as if participants had aged by at least 10 years. For instance, the rate of two or more co-morbidities in HIV-positive people aged 41 to 50 years was equivalent to the rate seen in HIV-negative people who were aged 51 to 60 years.

Risk factors

The Italian team focused on the presence of higher-than-normal blood pressure as a key factor that seemed to link, at least in its analysis, the five major co-morbidities studied. They also found that the following factors increased the relative risk for having co-morbidities:

- being older
- being male
- having a nadir CD4+ count below 200 cells

Another finding was that, in general, the longer that people took anti-HIV medicines, the greater their risk of developing co-morbidities. However, this interpretation of the researchers' data must be taken with extreme caution because this study had a retrospective, cross-sectional design.

Such studies are prone to confounding and inadvertent bias when interpreting their results. However, conclusions from retrospective studies can be used as a guide when designing future studies with more robust statistical underpinning.

Also, because it was cross-sectional in nature, the present study used only data taken at one point in time. Thus the researchers could not assess the impact that safer, more modern anti-HIV therapies might have had compared to older therapy. Also, HIV infection causes inflammation that is only partially reduced despite the use of ART. Prolonged inflammation likely played a role in the development of some of the co-morbidities studied. Unfortunately, given the nature of the study, researchers were unable to take into account the issue of chronic inflammation.

Retrospective and cross-sectional studies are cheaper and sometimes easier to conduct than randomized, prospective and long-term studies. Thus, cost and other factors can influence study design.

The present study, despite its weaknesses, adds to the accumulating research that suggests that HIV infection and, possibly, immune deficiency appear to accelerate the aging of major organ-systems. The Italian researchers recommend that doctors caring for HIV-positive people conduct regular assessments to screen their patients for organ health so that they might prevent and treat these complications.

Future research is needed with more robust study designs to confirm and extend the present study's findings and assess the role of severe immune deficiency.

REFERENCE:

Guaraldi G. CD4+ nadir and antiretroviral exposure predict premature polypathology onset. In: Program and abstracts of the *12th International Workshop on Adverse Drug Reactions and Comorbidities in HIV*, 4–6 November 2010, London, UK. Abstract 11.

C. Changes in body fat and muscle with lopinavir-ritonavir

In the late 1990s, when potent anti-HIV therapy (commonly called ART or HAART) became available, doctors and their HIV-positive patients reported the emergence of a strange syndrome of changes in body shape—sunken cheeks, temples and limbs, and bulging bellies and breasts (in women). Some people also developed increased fat pads on the back of the neck and shoulders. These changes in body shape were accompanied by unfavourable alterations in levels of lipids (cholesterol and triglycerides), sugar and insulin in the blood. Together, these physical and biochemical changes are called the HIV lipodystrophy syndrome.

The loss of the fatty layer just under the skin (subcutaneous fat) is called lipoatrophy, and the accumulation of fat in the breasts and belly is called lipohypertrophy. In clinical trials, objective assessments of body composition (fat, bone, muscle) are generally done using low-dose X-ray scans called DEXA (dual-energy X-ray absorptiometry) or MRI (magnetic resonance imaging). Because researchers don't want to expose the brain to needless radiation or other energies, instead of scanning the face for fat loss, DEXA and MRI scans of the limbs are used, as a lot of the fat in the limbs is subcutaneous fat.

Now, many years later, though some progress has been made, the triggering event for lipodystrophy is still not known. What is known is that exposure to two older drugs—d4T (stavudine, Zerit) and, to a lesser extent, AZT (zidouvine, Retrovir; and in Combivir and Trizivir)—can cause lipoatrophy. Note that the simplified chemical names for these drugs (d4T and AZT) both have the letter T, which represents the molecule thymidine. Both of these drugs are called thymidine analogues.

Today the use of d4T is generally shunned in high-income countries. Instead, commonly used nuke combinations are as follows:

- Kivexa (abacavir + 3TC)
- Truvada (tenofovir + FTC)

In several clinical trials, the use of Kaletra (lopinavir + ritonavir) has been associated with a limited degree of fat wasting and, in some cases, even an increase in subcutaneous fat. So there is interest in understanding the impact of lopinavir and/or ritonavir on fat, both in lab experiments and in HIV-positive people

Researchers in France, Italy, Poland and Spain recruited HIV-positive people for the Monark study. The purpose of Monark was to assess the safety and efficacy of Kaletra monotherapy. In this clinical trial, participants were randomly assigned to receive one of the following regimens:

- monotherapy with lopinavir-ritonavir
- ART (lopinavir-ritonavir + AZT + 3TC)

The results of Monark suggest that participants who received monotherapy with lopinavir-ritonavir had significantly less fat and muscle loss than people who received ART. Monark also found that, in general, lopinavir-ritonavir was not able to consistently suppress HIV levels in most participants, as only 47% had HIV that was less

than 50 copies/ml after two years of monotherapy. However, other strategies, such as induction maintenance, where initially ART is used for between six and 12 months and then participants whose viral loads are less than 50 copies/ml are switched to monotherapy (with either lopinavir-ritonavir or darunavir (Prezista)-ritonavir), have been done or are planned or underway. Such trials in very highly adherent participants who do not harbour HIV that is resistant to therapy may prove to have greater efficacy than seen in Monark. For now, monotherapy with lopinavir or darunavir is considered experimental.

Study details

A total of 136 people who had never previously received anti-HIV therapy were enrolled in Monark. A subset of participants had their body composition assessed using DEXA scans both at the start and 48 and 96 weeks into the study. The sub-study focused on the following participants:

- lopinavir-ritonavir – 41 volunteers
- ART – 22 volunteers

The approximate profile of sub-study participants was as follows:

- 33% females, 67% males
- age – 35 years
- weight – 70 kg (154 lbs)
- CD4+ count – 235 cells
- viral load – 16,000 copies/ml

Results—After 48 weeks

Participants who received lopinavir-ritonavir lost 63 grams of limb fat, while those on ART lost 700 grams (1.5 pounds) of limb fat.

Another way to represent changes in limb fat would be to express it as the proportion of limb fat lost or gained. Using this metric, participants on lopinavir-ritonavir lost about 1% of their limb fat, while those on ART lost 12%.

Lipoatrophy

The study team defined lipoatrophy (fat loss) as the loss of 20% or more of limb fat. Using this definition, the following participants experienced lipoatrophy during the study:

- lopinavir-ritonavir – 5% of participants
- ART – 27% of participants

After 48 weeks, participants who took lopinavir-ritonavir monotherapy lost 93 grams of arm muscle compared to a loss of 308 grams of arm muscle in volunteers who took ART.

All of these differences in fat and muscle were statistically significant.

Lipohypertrophy

The study team defined lipohypertrophy as a 20% increase in trunk fat (chest and belly). There were no significant differences between the two study groups in the appearance of lipohypertrophy, with 20% of participants taking lopinavir-ritonavir developing this condition vs. 14% of those who took ART.

Week 96

There was not sufficient data from the sub-study for meaningful conclusions to be drawn about changes in body shape.

Factors affecting fat loss

In a statistical analysis encompassing many factors that could have played a role in the loss of limb fat, only the type of treatment used was found to be important.

Side effects

The following proportions of participants developed serious complications, none of which were due to the anti-HIV treatments used:

- lopinavir-ritonavir – 12%
- ART – 7%

Less severe side effects were roughly evenly distributed between the two study groups. Participants who took lopinavir-ritonavir reported less general side effects than participants who took ART. The most common side effects seen in the study were diarrhea and higher-than-normal levels of liver enzymes in the blood.

This analysis of the Monark sub-study, taken together with other studies assessing the impact of lopinavir and/or ritonavir on body composition, suggests that lopinavir and/or ritonavir may have a protective effect on subcutaneous fat. The study team suggests that trials be done with other protease inhibitors to also assess their impact on subcutaneous fat.

REFERENCE:

Kolta S, Flandre P, Van PN, et al. Fat tissue distribution changes in HIV-infected patients treated with lopinavir. *Current HIV Research.* 2011; *in press.*

D. Tesamorelin—overview

In adults, growth hormone helps to maintain muscle mass and reduce the buildup of fatty tissues. Growth hormone is available by prescription but is very expensive and governments do not often subsidize the cost of this drug. HIV infection tends to reduce the body's production of growth hormone, and some people have difficulty building up and maintaining muscle and they also develop fat deposited deep in the belly around organs. This type of fat is called visceral fat.

Background on an emerging therapy

Tesamorelin (Egrifta) is an analogue similar to the body's growth-hormone-releasing factor; it causes the body to release growth hormone. Tesamorelin has been approved in the United States for the treatment of visceral fat accumulation in HIV-positive people. In Canada and other countries, regulatory approval for tesamorelin is awaiting approval.

In placebo-controlled studies with more than 800 HIV-positive volunteers that lasted six months, daily injections (2 mg) of tesamorelin resulted in decreased visceral fat, reduced belly size and sometimes reduced levels of triglycerides in the blood. Next, we summarize the data used to seek approval for tesamorelin.

Tesamorelin—General side effects

Based on data from placebo-controlled phase III studies, some of the side effects reported are headache, joint pain and injection-site reactions. The distribution of some of these side effects was as follows:

Injection-site redness
- tesamorelin – 9%
- placebo – 3%

Joint stiffness and pain
- tesamorelin – 13%
- placebo – 11%

Muscle pain
- tesamorelin – 6%
- placebo – 2%

In general, the distribution of side effects did not differ because of age or gender.

Side effects related to injection-site reactions were most common; these included itchy rash, particularly on the abdomen where the drug was injected. Sometimes the rash occurred on other parts of the body.

A hypersensitivity reaction (HSR) occurred in 28 people (seven females and 21 males). In 41% of these 28 participants, researchers described the HSRs as "extended skin reactions" that affected other parts of the body. In these people with systemic HSRs, some or all of the following symptoms appeared:

- nausea
- rapid heart beats
- feeling dizzy or light-headed
- unexpected sweating
- unexpected shortness of breath
- headache

All symptoms resolved when participants were treated (with antihistamines and creams containing corticosteroids) and discontinued tesamorelin. Importantly, none of the HSRs became life threatening.

Cancer risk

In theory, there is a risk that use of tesamorelin—because it stimulates the release of growth hormone, which can drive the growth of cancer cells—may increase the risk for cancer. However, rates of cancer were low and similar among recipients of tesamorelin and placebo. Moreover, there was only one case of cancer among tesamorelin users where doctors suspected that this drug may have contributed to the growth of cancer (Hodgkin's disease). A similar case of cancer also occurred in a person who received placebo.

Blood sugar

Some users of growth hormone have developed problems controlling their blood sugar levels. Tesamorelin has been tested in volunteers with diabetes and the drug did not make this condition worse.

In a small study with HIV-negative people without diabetes, there was a slight increase in the proportion of people whose average blood sugar levels over three months were slightly abnormal—2% among tesamorelin users vs. less than 1% among those taking placebo. But this difference, while statistically significant, was not clinically meaningful.

REFERENCE:

Theratechnologies. Tesamorelin (Egrifta). *Briefing document*. NDA 22-505. Endocrinologic and Metabolic Drugs. Food and Drug Administration Advisory Committee Meeting. May 27, 2010.

E. Tesamorelin helps reduce belly fat

In this study, HIV-positive participants on stable ART were randomly assigned in a 2 to 1 ratio to receive either tesamorelin (2 mg injected daily) or placebo. In total, 211 participants completed 26 weeks on tesamorelin and 115 others on placebo.

At the time they entered the study, the approximate profile of participants was as follows:

- 13% females, 87% males
- most were over their ideal body weight with a body mass index (BMI) of 29
- 68% of participants had a viral load less than 50 copies/ml
- CD4+ count – 600 cells

Results

After 26 weeks, participants who received tesamorelin had 15% less visceral fat compared to an increase of 5% visceral fat in participants who received placebo. This difference was statistically significant; that is, not likely due to chance alone.

Researchers also assessed some blood proteins that are suggestive of inflammation. Levels of these proteins fell among participants who received tesamorelin. This suggests that reducing visceral fat likely also reduces inflammation.

Long-term concerns

An important point that needs to be made about this drug is that while it is generally effective, the benefits from its use disappeared within a few months after participants stopped taking it. This might mean that tesamorelin has to be taken for very long periods of time. It is not clear if potential patients are prepared to regularly inject themselves every day with this drug for years.

Theratechnologies, the developer of this drug, has collected health information from volunteers in placebo-controlled and observational studies. Most data collected has been from people who used the drug for between six and 12 months. If tesamorelin is going to be used for longer periods, as seems likely, then long-term monitoring will be essential so that doctors and patients can be certain about its safety.

Another concern is about the cost, which at press time is not yet available. The cost of tesamorelin will be a major factor affecting whether provincial, territorial and other government formularies are prepared to pay for it.

Tesamorelin will likely be approved by Health Canada in the next year.

REFERENCE:

Falutz J. Tesamorelin, a growth hormone releasing-factor analogue improves inflammatory markers in HIV-infected patients with excess abdominal fat: relationships between changes in inflammatory markers and visceral adipose tissue (VAT). In: Program and abstracts of the *12th International Workshop on Adverse Drug Reactions and Comorbidities in HIV*, 4–6 November 2010, London, UK. Abstract 006.

F. Predicting and preventing depression in people co-infected with hepatitis C virus

Hepatitis C virus (HCV) can be spread in ways similar to HIV, particularly through sharing or receiving:

- equipment for substance use
- tattooing needles
- contaminated blood or blood products

HCV infects the liver and can cause inflammation and liver damage. Over a period of many years, liver damage builds up and this organ becomes increasingly dysfunctional. Complications ensue, and in some cases liver cancer occurs. HIV co-infection appears to accelerate the course of HCV-related disease.

For the past two decades, HCV infection has mostly affected people who share needles to inject street drugs or who received contaminated blood products, such as clotting factors, before routine testing for HCV was available. However, in high-income countries today, transmission of HCV occurs mostly through sharing equipment for substance use and needles for tattooing.

Among HIV-positive men, unprotected anal sex has emerged as another route of HCV transmission. Presumably HCV can also be transmitted to women via unprotected anal sex.

HCV treatment

A long-lasting form of interferon, called peginterferon, is the mainstay of treatment for HCV. Unfortunately, peginterferon can cause side effects, including irritability, anxiety and the development of depression or worsening of pre-existing depression. Injection drug users (IDU) often have high rates of pre-existing psychiatric health issues, and so researchers continue to find better ways to uncover depression or prevent and treat it in people who receive therapy for HCV.

Researchers in Australia, as part of the Australian Trial in Acute Hepatitis C (ATAHC), have completed a study of very recent or acute HCV infection. Part of the purpose of that study was to explore the issue of depressive illness—anxiety and depression.

The study recruited participants from 16 sites across Australia and offered treatment in cases of acute HCV infection. In cases where participants were infected with HCV only, they received peginterferon once weekly for 24 weeks. In cases where they were co-infected with HCV and HIV, they received peginterferon once weekly and ribavirin twice daily, both drugs for 24 weeks.

Participants were extensively surveyed about mental health and their medical records were available for analysis.

Of the 163 participants enrolled, 50 were co-infected and 113 were HCV mono-infected. The basic profile of the co-infected group was as follows:

- all males
- older (41 years vs. 31 years in HCV mono-infected group)
- employed full time
- more likely to have college or university education
- less likely to engage in injecting street drugs

According to the research team, most cases of HCV in men who were co-infected were sexually transmitted.

Rates of depression

Before therapy for HCV infection was initiated, rates of depression in participants were as follows:

- HCV mono-infection – 20% had symptoms of depression
- HCV co-infection – 6% had symptoms of depression

Despite this lack of depression-related symptoms, researchers found that similar proportions of people were using antidepressants, as follows:

- HCV mono-infection – 21% used antidepressants
- HCV co-infection – 22% used antidepressants

However, there was a difference between groups when it came to the use of anti-psychotics (for schizophrenia and bipolar illness) and anti-anxiety medicines as follows:

- HCV mono-infection – 10% used anti-psychotics
- HCV co-infection – 0% used anti-psychotics
- HCV mono-infection – 8% used anti-anxiety medicines
- HCV co-infection – 16% used anti-anxiety medicines

Taking many factors into account, the study team found that the issues associated with having depression prior to HCV therapy were as follows:

- recent (in the past 30 days) episode(s) of injecting drugs
- not being employed

Depression after initiating HCV therapy

The study team also assessed new cases of depression that occurred after participants began HCV therapy and found that rates were similar between the two infection groups as follows:

- HCV mono-infection – 33% experienced a new episode of depression
- HCV co-infection – 38% experienced a new episode of depression

The study team also found a pattern to depression that occurred after the initiation of HCV therapy. New cases of depression tended to peak at about the 12th week of therapy and then begin to decline, resolving 48 weeks after therapy began. Furthermore, the researchers found that having depression in their study did not appear to affect the benefit of HCV treatment.

Based on their findings, the researchers said that "concerns regarding depression in people at risk for this complication should not prevent the use of HCV treatment but should involve frequent screening for depression both before and during HCV therapy."

REFERENCE:

Matthews G. Depression prior to and during treatment for recent hepatitis C virus (HCV) infection among HCV and HCV/HIV participants in the ATHAC study. In: Program and abstracts of the *12th International Workshop on Adverse Drug Reactions and Comorbidities in HIV*, 4–6 November 2010, London, UK. Abstract 26.

Disclaimer

Decisions about particular medical treatments should *always* be made in consultation with a qualified medical practitioner knowledgeable about HIV-related illness and the treatments in question.

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